

European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition—summary document

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Breast cancer is a major cause of suffering and death and is of significant concern to many women. Early detection of breast cancer by systematic mammography screening can find lesions for which treatment is more effective and generally more favourable for quality of life. The potential harm caused by mammography includes the creation of unnecessary anxiety and morbidity, inappropriate economic cost and the use of ionising radiation. It is for this reason that the strongest possible emphasis on quality control and quality assurance is required. Development of the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis* has been an initiative within the Europe Against Cancer Programme. The fourth edition of the multidisciplinary guidelines was published in 2006 and comprises ~400 pages divided into 12 chapters prepared by >200 authors and contributors. The multidisciplinary editorial board has prepared a summary document to provide an overview of the fundamental points and principles that should support any quality screening or diagnostic service. This document includes a summary table of key performance indicators and is presented here in order to make these principles and standards known to a wider scientific community.

Key words: best practice, breast cancer screening, certification, multidisciplinary diagnosis, quality assurance guidelines, specialist breast units

summary document

Breast cancer is currently the most frequent cancer and the most frequent cause of cancer-induced deaths in women in Europe [1]. Demographic trends indicate a continuing increase in this substantial public health problem. Systematic early detection through screening, effective diagnostic pathways and optimal treatment have the ability to substantially lower current breast cancer mortality rates and reduce the burden of this disease in the population.

In order that these benefits may be obtained, high-quality services are essential. These may be achieved through the underlying basic principles of training, specialisation, volume levels, multidisciplinary team working, the use of set targets and performance indicators and audit. Ethically these principles should be regarded as applying equally to symptomatic diagnostic services and screening.

The fourth edition of the *European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis* [2] maintains the focus on screening for breast cancer of the previous editions while at the same time supporting the provision of highly effective diagnostic services and the setting up of specialist breast units for treatment of women, irrespective of whether a breast lesion has been diagnosed within a screening programme or not. This approach also supports the resolutions of the European Parliament in June 2003 and October 2006, calling on the European Union (EU) member states to make the fight against breast cancer a health policy priority and to develop and implement effective strategies for improved health care encompassing screening, diagnosis and treatment throughout Europe [3, 4].

The primary aim of a breast screening programme is to reduce mortality from breast cancer through early detection. Unnecessary workup of lesions which show clearly benign features should be avoided in order to minimise anxiety and maintain a streamlined cost-effective service. Women attending a symptomatic breast service have different needs and anxieties

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and therefore mixing of screening and symptomatic women in clinics should be avoided.

The incorporation of additional text and sections on diagnostic activity has resulted in an expanded fourth edition. The present summary document provides an overview and underlines what the editors feel to be the key principles that should support any quality screening or diagnostic service. The choice of content, however, is to some extent arbitrary and cannot in any way be regarded as an alternative to the requirement for reading each chapter as a whole, within the context of the complete guidelines.

fundamental points and principles

- In June 2003, the European Parliament [3] called for establishment of a programme by 2008 which should lead to a future 25% reduction in breast cancer mortality rates in the EU and also a reduction to 5% in the disparity in the survival rates between member states. The importance of continuing these efforts in the expanded EU was emphasised in a second resolution of the European Parliament [4] in October 2006.
- Implementation of population-based breast screening programmes, prioritisation of quality assurance activities such as training and audit, together with the setting up of specialist breast units for management of breast lesions detected inside or outside screening programmes are regarded as essential for achieving these aims.
- Results of randomised trials lead to the implementation of regional and national population-based screening programmes for breast cancer in at least 22 countries worldwide by the mid-1990s (Shapiro et al. [5]). In the European Cancer Network in which the former EU screening networks have been integrated, 23 European countries have already implemented or are currently establishing nationwide breast screening programmes on the basis of mammography.
- An International Agency for Research on Cancer [6] expert working group has reviewed the evidence and confirmed that service screening should be offered as a public health policy directed to women age 50–69 employing two-yearly mammography. This is consistent with the Recommendation of the Council of the EU [7] of 2 December 2003 on Cancer Screening.
- Breast cancer screening is a complex multidisciplinary undertaking, the objective of which is to reduce mortality and morbidity from the disease without adversely affecting the health status of participants. It requires trained and experienced professionals using up-to-date and specialised equipment.
- Screening usually involves a healthy and asymptomatic population which requires adequate information presented in an appropriate and unbiased manner in order to allow a fully informed choice as to whether to attend or not.
- Mammography remains the cornerstone of population-based breast cancer screening. Due attention must be paid to the requisite quality required for its performance and interpretation, in order to optimise benefits, lower mortality and provide an adequate balance of sensitivity and specificity.
- All units carrying out screening, diagnosis or assessment must work to agreed protocols forming part of a local quality assurance (QA) manual, based on national or European documents containing accepted clinical standards and published values. They should work within a specialist framework, adhering to set performance indicators and targets. Variations of practices and health care environments throughout the member states must not interfere with the achievement of these.
- A robust and reliable system of accreditation is required for screening and symptomatic units, so that women, purchasers and planners of health care services, can identify those breast clinics and units which are operating to a satisfactory standard. Any accreditation system should only recognise centres that employ sufficiently skilled and trained personnel.
- All staff in a screening programme should:
 - Hold professional qualifications as required in each member state.
 - Undertake specialist training.
 - Participate in continuing medical education and updates.
 - Take part in any recognised external quality assessment schemes.
 - Hold any necessary certificate of competence.
- All units involved in screening, diagnostic or therapeutic activities must ensure the formation of proper multidisciplinary teamwork involving a full range of specially trained professionals including a radiologist, radiographer, pathologist, surgeon, nurse counsellor and medical oncologist/radiotherapist.
- All women requiring breast surgery or other treatment should have their clinical, imaging and pathology findings discussed and documented in regular preoperative and postoperative meetings of the full multidisciplinary team.
- Quality assurance programmes should be mandatory in order for breast cancer services to qualify for funding from health care providers.
- Each screening unit should have a nominated lead professional in charge of overall performance, with the authority to suspend elements of the service if necessary in order to maintain standards and outcomes.

training

- All clinical staff involved in a screening programme must have knowledge of the principles of breast cancer diagnosis, management and screening. They should attend a course having academic and clinical components, at an approved training centre.
- To reflect the importance of a multidisciplinary approach, training packages should be offered in both unidisciplinary and multidisciplinary settings, recognising the importance of effective communication between the various professionals involved.
- Participation in training courses should be carefully documented and a certificate of attendance should be issued on the basis of level of skills and performance.
- Records of training activities must be kept by each unit and should be part of any certification review process.

epidemiology

- Epidemiology is a fundamental guiding and unifying discipline throughout the entire process of a screening programme from its organisational and administrative aspects to the evaluation and assessment of impact.
- Success of screening is judged not only by the outcome of the programme and its impact on public health but also by the organisation, implementation, execution and acceptability of the programme.
- Organisation requires the availability and accuracy of necessary epidemiological and demographic data, the availability of quality assured services, the need for informational campaigns to encourage participation and the maintenance of population and screening registers.
- Implementation requires the complete and accurate recording of individual data pertaining to the target population, the screening test, its result, decisions made and the eventual outcome in terms of diagnosis and treatment. Quality of such data is essential.
- Performance parameters may be used as measures of programme quality initially but long-term effectiveness evaluation requires continuous follow-up of the target population over an extended period of time.
- Follow-up of the target population and ascertainment of interval cancers are of prime importance. This will require links with population-based cancer registries, data on follow-up, review and classification of interval cancers as well as the relationship of breast cancers in the target population to tumour size and stage at diagnosis. Classification of interval cancers by size and lymph node involvement and observation of the interval cancer rate over time since the previous negative screening episode must be available.
- The protection of individual data is a basic right of every citizen in the EU—however, if appropriate precautions are taken, personal data may be used for promotion of public health.
- Cost-effectiveness is an essential requirement for population-based screening programmes and computer simulation packages are available for analysis of this.

breast screening communication

- The woman is central to the screening process. Any communication with her must take into account the need to avoid direct or indirect harm and the requirement to balance benefits against risks.
- Information provided must be balanced, honest, adequate, evidence based, accessible, respectful and tailored to individual needs where possible.
- It is important to educate, train and motivate general practitioners and referring clinicians to play an appropriate role in enabling women to make informed decisions.
- All health professionals need to be sensitive to the educational, linguistic and religious differences of women and recognise the potential impact of race, ethnicity, class and culture.
- Adequate attention must be given to the level of literacy skills in the population, poverty, ethnicity and age. Multicultural and multilingual populations require an understanding of

ethnocultural values, beliefs, health practices and communication styles.

- The invitation and accompanying leaflet should include information as to the purpose of screening, the population to be targeted, the screening interval, the benefits and disadvantages of screening, whether the test is free or not, how to make or change the appointment, how to obtain the results and interpret them, the possibility and nature of any necessary further investigation and how women can access further information.

physico-technical

- Mammography should only be carried out using modern dedicated X-ray equipment and appropriate image receptors.
- Images must have the best possible diagnostic information available when the appropriate radiographic technique is employed and should at least contain the defined acceptable level of information necessary to detect smaller lesions.
- Quality control (QC) must ascertain that the equipment used performs at a constant high-quality level, providing sufficient diagnostic information to be able to detect breast cancer using as low a radiation dose as is reasonably achievable. Routine performance of basic test procedures and dose measurements is essential for assuring high-quality mammography and comparison between centres.
- QC starts with the specification and purchase of appropriate equipment meeting accepted standards of performance. Before any system is put into clinical use it must undergo acceptance testing to ensure that its performance meets required standards. This applies to mammography X-ray equipment, image receptors, film processors and QC test equipment itself.
- Regular QC measurements should follow a written protocol adapted to the specific requirements of a local or national QA programme. Several measurements can be carried out by local staff but more elaborate measurements should be undertaken by medical physicists who are trained and experienced in diagnostic radiology and specifically trained in mammography QC.
- Evaluation of dose levels and performance in digital mammography requires different techniques, methodologies, quality standards and test procedures to those employed for screen-film systems.
- Systems used for digital mammography screening should incorporate an automatic exposure control.
- Viewing conditions for digital mammography are important as the maximum intensity on a monitor is much lower than that of a standard viewing box and the amount of ambient light present in the room must be strictly limited. This applies to the radiographer's acquisition monitor as well as the radiologist's reporting monitor.

radiography

- The role of the radiographer is central to producing high-quality mammograms which, in turn, are crucial for the early diagnosis of breast cancer.

- Radiographers are usually the only health professionals women meet in a breast screening programme. They therefore play a key role in optimising the woman's experience and satisfaction, which are essential to her continued acceptance and uptake of the service.
- To ensure full involvement, the radiographer must participate in equipment classification and selection, commissioning and acceptance tests, in-service consistency testing and image quality assessment—reporting any breach in quality to the radiologist in charge.
- The radiographer must ensure that the breast is properly compressed, but no more than is necessary to achieve good image quality. Compression reduces the radiation dose, scattered radiation, movement blur and the thickness of the breast which reduces overlapping of tissue shadows.
- Correct positioning of the breast on the standard lateral oblique and craniocaudal views is necessary to allow maximum visualisation of the breast tissue, reduce recalls for technical inadequacies and maximise the cancer detection rate.
- Radiographers should participate in assessment clinics and be familiar with all investigative procedures carried out at that time.
- The radiographer is a vital part of the multidisciplinary team and should participate in team meetings.
- In order to maintain breast screening skills, the minimum requirement with regard to participation for radiographers in the screening programme is 2 days per week. In a similar manner, radiographers participating only in symptomatic breast services should carry out a minimum of 20 mammographic examinations per week.
- The radiologist must be resolute in refusing to accept mammograms not meeting sufficient criteria for adequate diagnosis. These films should be repeated and the number of all repeated examinations should be recorded.
- In a decentralised screening programme, it is the responsibility of the lead programme radiologist/Clinical Director to suspend unsatisfactory clinics or offices where image quality in terms of radiographic positioning or adequate penetration of breast tissue is persistently unsatisfactory.
- Double reading in screening is recommended as it increases the sensitivity of the screening test by 5%–15% according to the methodology used and the skill of the radiologists involved. The process of double reading should be carried out independently. In cases of discordant opinions between two radiologists, either consensus or preferably arbitration using a third expert screening radiologist should be carried out.
- Double reading is recommended in centralised screening programmes at least until the performance of the radiologists can be fully assessed and is mandatory in decentralised programmes where second reading should be carried out at a centralised level by radiologists reading a minimum of 5000 mammograms per year.
- Radiological protocols must be in place for satisfactory and complete assessment of women with screen-detected abnormalities.
- For quality loop purposes, the radiologist performing the screen reading should also be involved at assessment of screen-detected abnormalities.
- The review of interval cancers by radiologists is mandatory and should be regarded as an excellent feedback and educational mechanism.

radiology

- Each screening radiologist should be medically qualified and registered to practice, have had specific training, participate in continuing medical education and any relevant external quality assessment scheme, be fully experienced in all assessment techniques including the ability to perform ultrasound, tissue sampling and read a minimum of 5000 screening cases per year in centralised programmes.
- Radiologists take prime responsibility for mammographic image quality and diagnostic interpretation. They must understand the risks and benefits of breast cancer screening and the dangers of inadequately trained staff and suboptimal equipment.
- The lead programme radiologist must encourage the formation of a skilled multidisciplinary professional team and wherever possible should act as Clinical Director for the screening programme.
- Radiological performance levels must be sufficient to achieve the goals of the programme by lowering mortality from breast cancer while minimising the adverse effect of screening. To ensure this, radiologists must comply with set target standards and performance indicators and take part in internal and external audit procedures with remedial action being undertaken where parameters are consistently breached.

imaging procedures

- Mammography and ultrasound are the primary diagnostic breast imaging modalities. Under the age of 35, mammography is rarely justified. Mammography remains the recommended imaging method for screening.
- Two views of each breast should be carried out in a screening programme as this has been demonstrated scientifically to increase the number of screen-detected cancers and reduce the number of women recalled for assessment, benefits applying equally to the prevalent and incident rounds.
- Ultrasound should be carried out in the presence of a discrete clinical mass even if negative on mammography.
- Further investigation of microcalcification should include magnification in orthogonal views to establish whether core or vacuum-assisted biopsy is indicated.
- Early recall for repeat mammography either in screening or diagnostic settings is not recommended and should never be used as a substitute for inexperienced or inadequate assessment.
- Full-field digital mammography can achieve high image quality and is likely to become established due to multiple advantages such as image manipulation and transmission, data display and future technological developments.
- Magnetic resonance imaging (MRI) is not yet part of initial workup or routine follow-up. Its role is under evaluation

although it has an established place in the investigation of implant dysfunction, recurrent or multifocal malignancy. Its place in screening of women belonging to high-risk groups is being investigated. It is best carried out in units with a large throughput having expertise and equipment to proceed to MRI guided biopsy if necessary.

levels of breast unit categorisation

Three levels of units in terms of expertise and facilities are described. These range from (i) the basic Diagnostic Breast Imaging Unit to (ii) the Diagnostic Breast Assessment Unit, both referred to in the Certification Protocol (Chapter 11 of the fourth guideline edition) and (iii) the more comprehensive Specialist Breast Unit for diagnosis and management of breast disease referred to in Chapter 10.

diagnostic breast imaging unit

- Such a unit will only offer diagnostic mammography and/or breast ultrasound and must perform mammographic examinations on at least 1000 women annually in order to be eligible for certification. Despite this relatively low volume, minimum standards must still be achieved.
- Protocols should be in place for referral of women requiring further workup to a diagnostic breast assessment unit or a specialist breast unit.
- Mammographic equipment must produce low-dose, high-quality examinations and be subject to regular radiographic and physicist quality-controlled tests which satisfy published criteria.
- Ultrasound of the breast should only be carried out by specially trained and experienced personnel, ideally a radiologist specialising in breast imaging.
- Mammograms must be carried out by trained and experienced staff, ideally a radiographer, holding all necessary working professional requirements such as a certificate of competence.
- Radiologists should be trained and experienced in breast imaging and all those factors required for good image quality. They should ideally also participate in any local breast screening programme.
- Radiologists or specially trained film readers should read mammograms on dedicated film viewers with control of background lighting. Inadequate film quality must be reported to the radiographer and the image repeated if necessary for satisfactory diagnostic purposes.

diagnostic breast assessment unit

- A highly specialised unit which is required for workup of substantial clinical or imaging findings. Such a unit should perform at least 2000 mammograms per annum, employ a trained radiologist reporting at least 1000 mammograms a year, have specialist cytological and histopathological support services, organise regular multidisciplinary review meetings, monitor data and feedback results and also keep formal records of assessment processes and outcomes.

- Its specialist multidisciplinary team will have access to more sophisticated imaging equipment and nonoperative diagnostic techniques than are available in a diagnostic breast imaging unit.
- Sampling techniques may include fine needle aspirate cytology, core biopsy or vacuum-assisted biopsy. If image-guided sampling is carried out, a representative image showing accuracy of needle placement must be obtained.

specialist breast unit

- A specialist multidisciplinary breast unit should be on the basis of populations of at least 250 000 and should be subject to mandatory quality assurance programmes.
- Units must record basic data on diagnosis, pathology, primary treatment and clinical outcomes. Regular minuted audit meetings should take place and a nominated person held responsible for production of annual performance and audit figures.
- The unit must have written and agreed protocols for the diagnosis and management of cancer at all stages.
- Population breast screening programmes should ideally be based within or closely associated with a specialised breast unit and share the services of trained expert personnel.
- A unit should have >150 newly diagnosed cases of primary breast cancer each year. A minimum size for a breast unit is necessary from the point of view of expertise of specialist staff, arrangement of frequent clinics, provision of equipment and cost-effectiveness.
- The breast unit must have an identified clinical director of breast services and each member of the core team must have a specialist training in breast cancer.
- Two or more nominated breast surgeons must be available, each personally carrying out primary surgery on at least 50 newly diagnosed cancers per year and attending at least one diagnostic clinic per week.
- There must be at least two nominated, fully trained and experienced radiologists able to carry out all aspects of breast imaging, tissue sampling and localisation procedures under image control. They should fulfil volume requirements, reading a minimum of 1000 mammograms per year or 5000 for those participating in screening programmes, and should participate in any national or regional quality assurance schemes available.
- Radiographers must fulfil all training and working practice recommendations and mammograms should not be carried out by any other personnel without such specialist training.
- There should be a lead pathologist, specialised in breast disease and adhering to European performance quality standards and guidelines, also taking part in any available quality assurance schemes.
- Clinical/medical oncologists should carry out radiation therapy and prescribe chemotherapy as appropriate. They should be members of the core team and participate in case management and audit meetings.
- Patient support must be provided by specialist breast care nurses or appropriately psychologically, professionally trained persons with expertise in breast cancer. At least two such

persons are needed per unit. They must be available to counsel, offer practical advice and emotional support.

- The unit must possess suitable and up-to-date imaging and therapeutic equipment.
- Adjuvant therapies such as radiotherapy or cytotoxic therapy may be given at separate clinics or hospitals to the breast unit but such treatment must be supervised by the main breast unit and all decisions made by the unit's multidisciplinary team.
- Facilities for palliative care/pain control should be available.
- Women should have access to a family history/genetic service, preferably in the setting of a multidisciplinary clinic with a clinical geneticist present.
- Clear written or oral information must be available to women from the unit, which should also provide written information concerning local outpatient support groups and advocacy organisations.
- All work of the breast unit should be carried out or directly supervised by specialists specifically trained in breast disease. This is more efficient and cost-effective than allowing unsupervised management by junior or nonspecifically trained staff.

surgical aspects

- The surgeon is a member of the multidisciplinary team and should always personally assess and examine a woman before accepting her for surgery. The lead surgeon should ensure that important activities and decisions are not delegated to unsupervised trainees.
- The surgeon must have access to all support services including radiology and cytology/histopathology, which conform to established quality assurance guidelines.
- Management of cases coming to surgery from screening programmes should be carried out only by surgeons with specialist knowledge and expertise, having undergone specific formal multidisciplinary programme training which include courses in communication and counselling.
- Specified target figures must be observed for successful removal of mammographic abnormalities and definitive surgical treatment of those cases following a clear malignant diagnosis at the first operation. Unnecessary surgical excision and benign biopsy rate should be minimised.
- Accurate marking procedures must be available to the surgeon in order to improve postoperative cosmesis for those women having an impalpable lesions. Its aim is to allow full excision of the tumour with uniform margins. A full report of the localisation procedure and relevant images must be provided by the radiologist for the surgeon in the operating theatre.
- Specimen radiography is essential for lesions such as microcalcification visible on X-ray to confirm excision in theatre, before skin closure. Such images must also be available to the pathology department.
- Frozen sectioning is generally inappropriate in the assessment of clinically impalpable lesions.
- The surgeon must ensure that women receive information on treatment options and be aware that breast-conserving

surgery is the treatment of choice for the majority of small screen-detected cancers. Where appropriate, patients should be offered a choice of treatment including immediate or delayed breast reconstruction should mastectomy be required.

- Surgeons undertaking axillary sentinel node procedures should receive specific training and validation.
- Mastectomy should be carried out in patients who do not satisfy criteria eligibility for breast-conserving treatment or in those patients who express a preference for it. Patients with high risk factors for local recurrence should be offered adjuvant chest wall radiation treatment.
- Preoperative (neo-adjuvant) chemotherapy must be offered if appropriate in order to downstage large tumours to allow breast-conserving treatment.
- Patients with locally advanced breast cancer should be offered combined modality treatment to ensure lasting locoregional control.
- Follow-up after treatment for breast cancer is mandatory for the measurement of outcomes, assessment of recurrences and screening for second primaries.

pathology

- The pathologist is a key member of the multidisciplinary team and must participate fully in pre- and postoperative case discussions.
- Operative and nonoperative specimens provide pathologists with particular problems that frequently arise with impalpable and complex lesions which are encountered in disproportionate frequency in screening programmes.
- Accurate pathological diagnosis and the provision of prognostically important information are vital to ensure appropriate patient management as well as accurate programme monitoring and evaluation.
- All pathology laboratories should be accredited according to national standards.
- A screening programme may in part be judged by the quality of its nonoperative diagnostic procedures which attempt to provide a definitive diagnosis of breast disease, allowing rapid referral for treatment, ideally in one procedure. Definitive nonoperative diagnosis of benign conditions also allows the avoidance of surgery and rapid return to routine recall.
- The choice of nonoperative sampling lies between fine needle aspiration cytology (FNAC), needle core biopsy (NCB) or vacuum-assisted needle core biopsy (VANCB). Each one has specific and relative indications for use and written local protocols should be available clearly defining these indications.
- A standard reporting form should be used by pathologists for NCB/VANCB samples containing patient and unit data. Details of the lesion and its radiological appearance, the localisation technique, specimen type, the presence or absence of histological calcification and the opinion of the pathologist should be expressed into one of the five main categories ranging from B1 (normal tissue) to B5 (malignant). Similar forms should be used for FNAC.
- The technique chosen for pathological examination of surgical excision specimens requires knowledge of the

surgical method used and the anatomical boundaries of the resection. Lesions should be resected according to a defined protocol, any variation of which should be clearly indicated on the request form to the pathologist.

- In order to allow the use of predictive factors, fresh frozen tumour tissue will be increasingly used and the specimen should therefore be sent immediately to the pathology laboratory unfixed. Once received in the laboratory, the entire surface of the specimen should be inked so that the lines of excision can be easily determined.
- Pathological examinations should be carried out on all lymph nodes received and the report should state the total number and the number containing metastases.
- Protocols for sentinel lymph node examination and specimen handling should be clearly agreed between the surgeon and pathologist.
- Standard histopathology reporting forms should be used and should record recognised prognostic data such as tumour size, disease extent, grade, type, lymph node status, vascular invasion, marginal status and receptor status.
- Pathology laboratories must be involved in relevant QA schemes for both laboratory techniques and diagnostic accuracy. External quality assurance schemes should be used in countries where screening is established.

anxiety and delays

- Minimal delays must exist between taking a mammogram, film reading and the availability of the report, the provision of an assessment appointment for women with screen-detected abnormalities or a clinic appointment for women with substantial breast symptoms
- Women should be fully assessed in three visits or less.
- Women with symptoms and signs suggestive of breast cancer must be offered an appointment within 2 weeks.
- Communication of the diagnosis of likely breast cancer must never be given by post or over the telephone, but only verbally to the woman in the presence of a nurse counsellor.
- The provision of rapid diagnostic clinics where skilled multidisciplinary advice and investigation can be provided is advantageous for women with substantial breast problems in order to avoid unnecessary delay in outline of management planning or to permit immediate discharge of women with normal/benign disease.

data collection and monitoring

- Audit should be the responsibility of the multidisciplinary breast unit as a whole and the basis for self-assessment and participation in voluntary accreditation/certification programmes.
- Clinicians and programmes should value data monitoring as an opportunity for permanent education and improvement and to demonstrate excellence.
- Indicators should be derived from up-to-date and evidence-based guidelines or reflect clear consensus by professional experts and the public.

- Duplication of effort should be avoided as far as possible by including quality assurance criteria in routine reporting. Quality measures should be reproducible and clearly specified, and monitoring costs should be acceptable and results must be accessible to patients and advocacy organisations.
- Standard data reporting forms should be used in everyday practice. They should include essential items and appropriate coding.
- Computerised audit systems capable of calculating the great majority of recommended quality indicators have been developed within projects sponsored by the Europe against Cancer Programme of the European Commission.
- SEED—the European Screening Evaluation Database (www.cpo.it/seed). This prototype web database and audit system on the basis of individual records are capable of calculating at a local or regional level a number of process and early impact indicators of breast cancer screening. It can support multicentre projects aimed at comparing performance parameters of screening programmes in Europe (see also appd. 1). SEED should contribute to the standardisation of screening evaluation in Europe by facilitating joint data collection and multicentre comparisons and by helping individual programmes to evaluate their own performance in a standard way.
- QT—audit system on Quality of breast cancer diagnosis and Treatment. This is a Microsoft Access individual records database and is available in five languages. A web version is under construction. QT is kept updated with guidelines and allows recording of data on all women recalled for assessment in a screening programme or assessed for clinical suspicion. QT has been designed for and is being used by clinical breast units for monitoring diagnosis and treatment of breast lesions in symptomatic as well as asymptomatic women. Furthermore, it can assist cancer registries for high-resolution population studies.
- One individual, i.e. a physician, breast care nurse or data manager, should be made responsible for the co-ordination of data collection and reporting in any screening or diagnostic unit.

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appendix 1

key performance indicators

For ease of reference, Table 1 has been included in the European Guidelines (4th edition) [2]. Please note that the numbering of the indicators is not indicative of importance. For more complete information regarding definition and

Table 1. Summary table of key performance indicators

Performance indicator	Acceptable level	Desirable level
1. Target OD (2AT4.1)	1.4–1.9 OD	1.4–1.9 OD
2. Spatial resolution (2AT4.1)	>12 lp/mm	>15 lp/mm
3. Glandular dose—PMMA thickness at 4.5 cm (2AT4.1)	<2.5 mGy	<2.0 mGy
4. Threshold contrast visibility (2AT4.1)	<1.5%	<1.5%
5. Proportion of women invited that attend for screening (1T32)	>70%	>75%
6. Proportion of eligible women reinvited within the specified screening interval (1T32)	>95%	100%
7. Proportion of eligible women reinvited within the specified screening interval + 6 months (1T32)	>98%	100%
8. Proportion of women with a radiographically acceptable screening examination 3.8, (5.4.3.1)	97%	<97%
9. Proportion of women informed of procedure and timescale of receiving results (3.8, 5.4.3.1)	100%	100%
10. Proportion of women undergoing a technical repeat screening examination (1T32, 3.8, 4T2, 5.4.3.1)	<3%	<1%
11. Proportion of women undergoing additional imaging at the time of the screening examination in order to further clarify the mammographic appearances (1T32)	<5%	<1%
12. Proportion of women recalled for further assessment (1T32, 4T2)		
Initial screening examinations	<7%	<5%
Subsequent screening examinations	<5%	<3%
13. Proportion of screened women subjected to early recall following diagnostic assessment (4T2)	<1%	0%
14. Breast cancer detection rate, expressed as a multiple of the underlying, expected, breast cancer IR in the absence of screening (1T33, 4T1)		
Initial screening examinations	3 × IR	>3 × IR
Subsequent-regular screening examinations	1.5 × IR	>1.5 × IR
15. Interval cancer rate as a proportion of the underlying, expected, breast cancer IR in the absence of screening (1T33)		
Within the first year (0–11 months)	30%	<30%
Within the second year (12–23 months)	50%	<50%
16. Proportion of screen-detected cancers that are invasive (1T33, 4T1)	90%	80%–90%
17. Proportion of screen-detected cancers that are stage II+ (1T33)		
Initial screening examinations	NA	<30%
Subsequent-regular screening examinations	25%	<25%
18. Proportion of invasive screen-detected cancers that are node negative (1T33)		
Initial screening examinations	NA	>70%
Subsequent-regular screening examinations	75%	>75%
19. Proportion of invasive screen-detected cancers that are ≤10 mm in size (1T33, 4T1)		
Initial screening examinations	NA	≥25%
Subsequent-regular screening examinations	≥25%	≥30%
20. Proportion of invasive screen-detected cancers that are <15 mm in size (7A.2)	50%	>50%
21. Proportion of invasive screen-detected cancers <10 mm in size for which there was no frozen section (5.8.2, 9T1)	95%	>95%
22. Absolute sensitivity of FNAC 5.5.3, 6A A1.3	>60%	>70%
23. Complete sensitivity of FNAC (5.5.3, 6A A1.3)	>80%	>90%
24. Specificity of FNAC (5.5.3, 6A A1.3)	>55%	>65%
25. Absolute sensitivity of core biopsy (5.5.3, 6A A1.3)	>70%	>80%
26. Complete sensitivity of core biopsy (5.5.3, 6A A1.3)	>80%	>90%
27. Specificity of core biopsy (5.5.3, 6A A1.3)	>75%	>85%
28. Proportion of localised impalpable lesions successfully excised at the first operation (4T2, 5.8.2, 7A.3)	>90%	>95%
29. Proportion of image-guided FNAC procedures with insufficient result (4T2, 5.5.2)	<25%	<15%
30. Proportion of image-guided FNAC procedures from lesions subsequently proven to be malignant, with an insufficient result (4T2, 5.5.2)	<10%	<5%
31. Proportion of patients subsequently proven to have breast cancer with a preoperative FNAC or core biopsy at the diagnosis of cancer (7B.2)	90%	>90%
32. Proportion of patients subsequently proven to have clinically occult breast cancer with a preoperative FNAC or core biopsy that is diagnostic for cancer (7B.2)	70%	>70%

Table 1. (Continued)

Performance indicator	Acceptable level	Desirable level
33. Proportion of image-guided core/vacuum procedures with an insufficient result (4T2)	<20%	<10%
34. Benign to malignant open surgical biopsy ratio in women at initial and subsequent examinations (1T32, 4T2, 5.8.2, 7A.3)	≤1 : 2	≤1 : 4
35. Proportion of wires placed within 1 cm of an impalpable lesion before excision (4T2, 5.8.2, 7A.3)	90%	>90%
36. Proportion of benign diagnostic biopsies on impalpable lesions weighing less than 30 grams (5.8.2, 7A.3)	90%	>90%
37. Proportion of patients where a repeat operation is needed after incomplete excision (7A.4)	10%	<10%
38. Time (in wd) between		
Screening mammography and result (4T2)	15 wd	10 wd
Symptomatic mammography and result (5.9)	5 wd	
Result of screening mammography and offered assessment (4T2)	5 wd	3 wd
Result of diagnostic mammography and offered assessment (5.9)	5 wd	
Assessment and issuing of results (5.9)	5 wd	3 wd
Decision to operate and date offered for surgery (5.9)	15 wd	10 wd
39. Time (in wd) between		
Screening mammography and result ^a		
≤15 wd	95%	>95%
≤10 wd	90%	<90%
Symptomatic mammography and result ^a		
≤5 wd	90%	>90%
Result of screening mammography and offered assessment ^a		
≤5 wd	90%	>90%
≤3 wd	70%	>70%
Result of symptomatic mammography and offered assessment ^a		
≤5 wd	90%	>90%
Assessment and issuing of results ^a		
≤5 wd	90%	>90%
Decision to operate and date offered for surgery ^a		
≤15 wd	90%	>90%
≤10 wd	70%	>70%

Abbreviations used for reference to the European Guideline [2] chapters, e.g. 3T1 Chapter 3, table 1; 4.7 Chapter 4, paragraph 7.

^aTo assist in monitoring and comparing performance between and within screening programmes, this summary table of indicators includes recommendations on the minimum proportion of women for whom acceptable and recommended time periods should be observed.

NA, not applicable; OD, optical density; PMMA, polymethylmethacrylate; IR, incidence rate; FNAC, fine needle aspiration cytology; wd, working day.

context, further reference should be made to the source of each parameter within the guideline text as listed. On occasions, we have had to accept that different disciplines and different Member States show some variation of priorities and target levels. In all cases, we have attempted to list what we regard as the most widely used and generally appropriate professionally agreed levels for usage in a Pan-European setting. In any case, all targets should be constantly reviewed in the light of experience and revised accordingly with regard to results achieved and best clinical practice. As far as possible, targets given refer to women >50 years of age attending a screening programme.

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