Health & Consumer Protection
Directorate-General

European guidelines for quality assurance in breast cancer screening and diagnosis

Fourth Edition

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Jan H.C.L. Hendriks | 1941-2004 |

This edition is dedicated to the memory of our colleague and friend Jan Hendriks who pioneered the quality assurance of breast radiology in The Netherlands and throughout Europe

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Preface

Markos Kyprianou*

The completion of the fourth edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis exemplifies the unique role the European Union can play in cooperation with national governments, professional organisations and civil society to maintain and improve the health of Europe's citizens.

Breast cancer is the most frequent cancer and accounts for the largest number of cancer-related deaths in women in Europe. Due to demographic trends, significantly more women will be confronted with this disease in the future. Systematic screening of the female population based on mammography offers the perspective of saving many lives while reducing the negative side-effects of treatment by detecting cancer at earlier stages, when it is more responsive to less aggressive treatment.

These benefits can only be achieved, however, if the quality of services offered to women is optimal – not only with regard to the screening examination, but also the further diagnostic procedures, and the treatment of women for whom the screening examination yields abnormal results. Quality assurance of population-based breast screening programmes is therefore a challenging and complex management endeavour encompassing the entire screening process. This is only one of the key lessons learned in the European Breast Cancer Network in which scientists, clinicians and paramedical staff as well as advocates, health care planners and administrators across Europe have shared experiences. By working together to develop and implement comprehensive guidelines, women throughout the Union will receive the same high level services for breast screening.

The financial support of the European Union for this multidisciplinary, pan-European forum has not only helped to establish Europe as the world leader in implementing population-based breast cancer screening programmes. It has also helped to reveal that implementation of high quality standards in regional and national population-based screening programmes naturally leads to further innovation and improvement in the quality of breast services provided outside of screening programmes. The potential benefit to women of extending the improvements in quality assurance of screening to the full range of breast cancer care is enormous, because many women seek medical assistance for breast problems outside of screening programmes. The editors and contributors to this edition are therefore to be applauded for extending the scope of the guidelines so as to include quality assurance of multidisciplinary diagnosis of breast cancer, standards for specialist breast units and a certification protocol for diagnostic and screening services.

This Publication of the fourth edition of the guidelines by the European Union will ensure that any interested organisation, programme or authority in the Member States can obtain the recommended standards and procedures and appoint appropriate persons, organisations and institutions for the implementation of those.

Let me finally thank the editors and contributors for their efforts in compiling this volume which I am confident will be useful to guide work on breast cancer screening and diagnosis for the years to come.

Brussels, January 2006

* European Commissioner for Health and Consumer Protection

Preface

Maurice Tubiana*

It is a great honour for me to have been asked to write a preface to this fourth edition of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis. My purpose will be to put them into perspective. At their meeting in Milan in June 1985, the heads of state of the Member States of the European Community (EC) decided to launch a European action against cancer. This decision was taken within the framework of the so-called 'Citizen' programme, the aim of which was to illustrate the practical advantages that a European cooperation could bring to the citizens of the Member States, in particular regarding health. Each of the 12 Member States appointed an expert in oncology, or in public health, in order to constitute the Committee of Cancer Experts. Sweden, which was not yet a member of the European Union (EU), was invited as an observer and also appointed an expert. The committee met for the first time in Brussels in November 1985, where the objectives of the action programme were discussed.

From the outset, reduction in the number of cancer deaths was the primary purpose of the European action. A reduction of 15% in the number of cancer deaths that would have occurred in the absence of such action appeared to be a difficult but realistic goal and was adopted by the committee. In fact, the Europe against Cancer programme achieved a reduction of 9% from 1985 to 2000 a result which is still appreciable. To move forward, the programme had to coordinate the efforts of various health professions as well as, political decision makers, governmental offices, and nongovernmental organisations in a common drive to achieve this goal. A further ambition was to show that actions on a European scale could enhance national strategies against cancer in each of the Member States.

It appeared immediately that prevention and screening were the two main areas in which a European action could be more effective than uncoordinated national efforts. Other areas of lesser priority were: clinical research, information for the general public, and education of health professionals in oncology. The budget was modest (11 million euros per year) but, nevertheless, it enabled the expert committee to propose and to carry out an ambitious strategy in a few well defined areas.

The decision to include systematic population based screening for specific sites of cancer was taken by the Committee of Cancer Experts at the first meeting in Brussels in November 1985. It was at the second meeting in February 1986 in Paris that breast, cervical and colorectal cancers were considered. At that time evidence was growing that screening for breast cancer by means of mammography could reduce mortality from this disease, at least in women aged 50 years and over. Experience had been accumulating in Europe, notably in Sweden, the UK, the Netherlands, and Italy, that population screening was feasible, with participation rates varying between 70 and 90%. A plan was made to enable each of the 12 EC Member States to propose pilot projects within its borders. The benefits of a European pilot network co-funded by the European Community would result from the pooling and dissemination of knowledge and expertise. A European action could also provide a practical basis for a decision, in the event that governments consider the implementation of a national breast cancer screening programme.

A subcommittee on screening was appointed by the Committee of the European Cancer Experts in order to select and fund pilot studies in the Member States after full consent of the national authorities. Another aim of the subcommittee was to monitor the results obtained in each pilot study and to promote cooperation among all persons involved in this action: project leaders of the pilot studies, expert consultants, and members of the staff of the Europe against Cancer

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programme. A network of individuals involved in the program was set up and meetings were held every six months in order to discuss problems encountered by the pilot studies. During the meetings the need for common rules concerning quality assurance and data collection became apparent.

The existence of false negatives (undetected cancers) reduces the number of detected cancers. On the other hand, a high rate of false positives increases the anxiety of women because they provoke unnecessary examinations. Screening is worthwhile only if the increase in human life outweighs the economic and social costs (anxiety, unnecessary examinations) that it may produce. Thus it is mandatory to find a balance between sensitivity and specificity in order to reach an acceptable ratio between true positives and false positives. Improvement of benefits (fewer false negatives) and a decrease in the social and psychological burden (fewer false positives) can be achieved by the implementation of rigorous quality assurance, systematic training of health care personnel, follow-up of women who have been screened, and an annual evaluation of screening results.

We knew that modern medical undertakings require specific training, accreditation, quality assurance and evaluation, including audits by outside teams. In 1988-1990, many observers were sceptical; they felt that in many EU countries physicians accustomed to substantial professional freedom would not accept the standardization of diagnostic procedures and protocols inherent to population-based screening programmes, such as double reading of mammograms. Within the Screening Subcommittee, we were much more optimistic but realised that it was a difficult challenge. In 1990, the subcommittee decided that guidelines should be prepared in order to assist health professionals and project leaders. These draft guidelines were circulated among network members for comment and the final version of the first edition was adopted in 1992.

The first edition of the document ‘European Guidelines for Quality Assurance in Mammography Screening’ (Kirkpatrick et al, 1993) was available in each of the official languages of the European Community on request. It was extremely well accepted and deeply appreciated because it provided a basic tool for all those interested in breast screening. These guidelines contributed immensely to the success of the breast screening projects of the Europe against Cancer programme and had a great impact in all Member States. In France, for example, the national guidelines were based on the European guidelines which set the standards. A few years later the evolution of techniques and practices rendered necessary the publication of a second edition which was followed by a third four years later, both of which were very successful. Thus, the standards and recommendations in the third edition provided the regulatory framework for the population-based breast screening programme recently introduced in Germany. Without any doubt the current fourth edition will also become the basic reference for quality assurance of breast cancer screening.

The European guidelines, besides their contribution to the accomplishments of the breast screening projects, have had two beneficial consequences. First, they not only improved the quality of breast screening but also that of diagnosis and treatment of breast cancer, and they have greatly reduced the differences among EU countries in the quality of care of breast disease. The second favourable outcome has been the demonstration that, contrary to some preconceptions, the basic requirements of modern medicine are well accepted when efforts are made in EU countries. Training can be improved; accreditation, rigorous quality assessment and evaluation by outside experts can be implemented. Ultimately, progress depends not only on the dedication of practitioners, but also on the courage of politicians and administrators. Breast cancer screening and efforts in prevention, such as the fight against smoking, clearly show that European cooperation in public health can be fruitful.

Paris, September 2005

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Introduction

In presenting this fourth edition to you, we pay tribute to the success of its predecessor, published in 2001, which has been one of the most requested European Commission publications and used as the basis for the formation of several national guidelines. European Parliament subsequently requested the European Breast Cancer Network (EBCN) to produce a further edition. EUREF, as the guidelines co-ordinating organisation of the Network, and the guidelines Editors welcomed the opportunity to broaden the screening focus of previous editions, introducing further aspects of diagnosis and breast care, by collaborating with EUSOMA. The title of these guidelines has accordingly been altered to reflect this, with the addition of EUSOMA chapters on specialised breast units, quality assurance in diagnosis and loco-regional treatment of breast cancer. Important new chapters have been added on communication and the physico-technical aspects of digital mammography, while other chapters have been revised and updated. There is an executive summary for quick reference including a summary table of key performance indicators. Variations in style and emphasis have been unavoidable given the diverse sources of the contributions. However, the Editors have attempted to maintain conformity of approach.

Since the third edition, the European Union has gained 10 new Member States having varying levels of experience and infrastructure for breast screening and diagnosis. While this presents a new challenge for the EBCN, it is a pleasure to welcome our new colleagues and revisit the original concept of the Europe against Cancer Pilot Programmes, founded in 1988, the success of which led to the production of the first edition of the European Guidelines in 1993. This concept was to share multidisciplinary experience, disseminate best practice and provide a mechanism whereby support for the less experienced could be provided to ensure a more uniform standard of service delivery with the ability to progress as one with continuing advances in technical and professional knowledge.

Certain principles remain just as important in diagnosis as they are in screening. Training, multi-disciplinary teamwork, monitoring and evaluation, cost-effectiveness, minimising adverse effects and timeliness of further investigations are referred to constantly throughout subsequent chapters, reflecting their crucial place in any breast unit. A multidisciplinary team should include radiographers, pathologists, surgeons and nurses with additional input from oncologists, physicists and epidemiologists as appropriate. It is recognised that different team compositions will be suitable according to various stages of the screening, diagnostic and treatment processes.
Mammography is still the cornerstone of screening and much diagnostic work, so that a substantial part of these guidelines remain dedicated to those necessary processes and procedures which will optimise benefits, reduce morbidity and provide an adequate balance of sensitivity and specificity. It is essential that these guidelines be used to support and enhance local guidelines and not to conflict with them.

As pointed out in the third edition, there must be political support in order to achieve high quality screening, diagnostic and breast care services. Mechanisms for a meaningful quality-assured programme rely on sufficient infrastructure, financing and supervision, all of which require political goodwill to implement and maintain.
These guidelines have relied significantly upon knowledge and experience gained by the European Breast Cancer Network and its associated professionals. Over 200 professionals and client and patient advocates from 18 Member States of the European Union as well as Norway, Switzerland, Israel, Canada and the United States contributed to the current revised edition of the European guidelines. The new chapters and the major changes in the previous chapters were discussed and approved by the members of the European Breast Cancer Network (EBCN) at its annual meeting held 23-25 September 2004 in Budapest. The United Kingdom National Guidelines have formed the basis of some sections.

The Editors are conscious of the importance of raising and maintaining standards across all the Member States. While never abandoning those standards crucial for mortality reduction, we have as far as possible attempted to set out an equitable balance of best practice and performance indicators which can be used across a wide spectrum of cultural and economic healthcare settings. As with any targets, these can be constantly reviewed in the light of future experience. It is not the purpose of these guidelines to promote recent (and often costly) research findings

until they have been demonstrated to be of proven benefit in clinical practice, neither should this edition be regarded as a text book or in any way a substitute for practical clinical training and experience.

The third edition correctly forecast an increase in the use of digital mammographic techniques, although the logistical use of these in screening is still being evaluated. This edition therefore includes a section on physico-technical guidelines for digital mammography – the production of which was eagerly awaited by equipment manufacturers and professionals alike. Over the next five years we are likely to see an increase in three-dimensional imaging techniques – using ultrasound, digital mammography with tomosynthesis, and even computed tomography.

We believe that a major change will occur with more widespread use of accreditation/ certification of clinics and hospitals providing breast services. A process of voluntary accreditation is seen as central in the drive towards the provision of reliable services. Women, as well as purchasers and planners of healthcare services, should be able to identify those units where they will receive a guaranteed level of service, and one obvious way to provide this knowledge is through a mechanism of external inspection of processes and outcomes resulting in the granting of a certificate. Even highly centralised and quality assured national screening programmes require each unit to undergo full external multi-disciplinary review on a regular basis. We believe that Europa Donna could play an important role in encouraging women to recognise the importance of such an enterprise.

As nominated representatives of EUREF and EUSOMA we are proud to introduce this fourth edition of the European Guidelines to you. Although the largest version yet, we trust that it remains manageable and will be of continued benefit to those colleagues striving to improve their services, and to those many women in need of them.

Dr Nick Perry,
Chairman of the European
Reference Organisation for
Quality Assured Breast Screening
and Diagnostic Services

Professor Luigi Cataliotti,
President of the European
Society of Mastology

Executive Summary

Breast cancer is currently the most frequent cancer and the most frequent cause of cancer-induced deaths in women in Europe. 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 editors of the fourth edition have maintained focus on screening for breast cancer 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. By so doing we support the resolution of the European Parliament in June 2003 (OJ C 68 E, 2004), calling on the EU member states to make the fight against breast cancer a health policy priority and to develop and implement effective strategies for improved preventive health care encompassing screening, diagnosis and treatment throughout Europe.

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

Our incorporation of additional text and sections on diagnostic activity has resulted in an expanded fourth edition. We have prepared this Executive Summary in an attempt to underline what we feel to be the key principles that should support any quality screening or diagnostic service. However the choice of content 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 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 (OJ C 68 E, 2004).

- 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 to achieving these aims.

- Results of randomised trials have lead to the implementation of regional and national population based screening programmes for breast cancer in at least 22 countries within the past 20 years (Shapiro et al. 1998).

- An international agency for research on cancer (IARC) 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 (IARC Working Group on the Evaluation of Cancer Preventive Strategies 2002). This is consistent with the European Council Recommendation Recommendation of 2 December 2003 on Cancer Screening (OJ L 327/34-38).

- 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. Information provided must be balanced, honest, adequate, truthful, evidence-based, accessible, respectful and tailored to individual needs where possible.

- 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.

- Physico-technical quality control 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.

- 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. Extensive clinical, comparative and logistical evaluations are underway.

- The role of the radiographer is central to producing high quality mammograms which, in turn, are crucial for the early diagnosis of breast cancer. Correct positioning of the breast on the standard lateral oblique and cranio-caudal views is necessary to allow maximum visualisation of the breast tissue, reduce recalls for technical inadequacies and maximise the cancer detection rate.

- 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 sub-optimal equipment. For quality loop purposes the radiologist performing the screen reading should also be involved at assessment of screen detected abnormalities.

- 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 healthcare 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 healthcare 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.

- The provision of rapid diagnostic clinics where skilled multidisciplinary advice and investigation can be provided is advantageous for women with significant breast problems in order to avoid unnecessary delay in outline of management planning or to permit immediate discharge of women with normal/benign disease.

- 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.

- 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

- 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.

- 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 pre-operative and post-operative meetings of the full multi-disciplinary team.

- 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.

- The pathologist is a key member of the multidisciplinary team and must participate fully in pre-operative and post-operative case discussions. Accurate pathological diagnosis and the provision of prognostically significant information are vital to ensure appropriate patient management as well as accurate programme monitoring and evaluation.

- Patient support must be provided by specialist breast care nurses or appropriately psychologically professionally trained persons with expertise in breast cancer. They must be available to counsel, offer practical advice and emotional support.

- Quality assurance programmes should be mandatory for breast cancer services in order to qualify for funding from healthcare providers.

- Evaluation of the impact of screening requires the complete and accurate recording of all individual data pertaining to the target population, the screening test, its result, decisions made and the eventual outcome in terms of diagnosis and treatment.

- 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.

References

Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC) OJ L 327/34-38.

European Parliament Resolution. “Breast Cancer in the European Union”, OJ C 68 E (18.03.2004) p. 611.

IARC Working Group on the Evaluation of Cancer Preventive Strategies. Breast cancer screening. IARC Handbooks of Cancer Prevention, volume 7. Lyon: IARC Press, 2002, ISBN 92 832 300 8.

Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) European Guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. Office for Official Publications of the European Communities, Luxembourg.

Shapiro S, Coleman EA, Broeders M, Codd M, de Koning H, Fracheboud J, et al. for the International Breast Screening Network, and the European Network of Pilot Projects for Breast Cancer Screening. Breast cancer screening programmes in 22 countries: current policies, administration and guidelines. Int J Epidemiol 1998;27:735-42.

Summary table of key performance indicators

Introduction

For ease of reference we have included a summary table of key performance indicators from these guidelines. Please note that the numbering of the indicators is not indicative of importance. For more complete information regarding definition and context, further reference should be made to the source of each parameter within the 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 over 50 years of age attending a screening programme.

Abbreviations used for reference to the chapters, e.g.:
3T1 Chapter 3, table 1
4.7 Chapter 4, paragraph 7

Performance indicator	Acceptable level	Desirable level
1. Target optical density[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 time scale 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%

Performance indicator	Acceptable level	Desirable level
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 incidence rate in the absence of screening (IR)[1T33, 4T1]		
• initial screening examinations	3 x IR	> 3 x IR
• subsequent-regular screening examinations	1.5 x IR	> 1.5 x IR
15. Interval cancer rate as a proportion of the underlying, expected, breast cancer incidence rate 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%

Performance indicator	Acceptable level	Desirable level
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 pre-operative 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 pre-operative FNAC or core biopsy that is diagnostic for cancer[7B.2]	70%	> 70%
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 prior to 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 working days) 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	
• decision to operate and date offered for surgery[5.9]	15 wd	10 wd
39. Time (in working days) between:		
• screening mammography and result [1)]		
≤ 15 wd	95%	> 95%
≤ 10 wd	90%	> 90%
• symptomatic mammography and result [1)]		
≤ 5 wd	90%	> 90%
• result of screening mammography and offered assessment [1)]		
≤ 5 wd	90%	> 90%
≤ 3 wd	70%	> 70%

Performance indicator	Acceptable level	Desirable level
• result of symptomatic mammography and offered assessment [1)] ≤ 5 wd	90%	> 90%
• assessment and issuing of results [1)] ≤ 5 wd	90%	> 90%
• decision to operate and date offered for surgery [1)] ≤ 15 wd	90%	> 90%
≤ 10 wd	70%	> 70%

[1)] To assist in monitoring and comparing performance between and within screening programmes, this summary table of indicators includes recommendations on the minimum proportion of women who should observe acceptable and recommended time periods.