

Guidelines for Quality Assurance in Mammography Screening

Fourth Edition
2015

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Quality Assurance
in Mammography Screening

Fourth Edition
2015

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Foreword

The National Screening Service (NSS) is part of the Health & Wellbeing Division of the Health Service Executive (HSE). The NSS has significant experience in developing, implementing and delivering organised, population-based, call/re-call screening programmes.

The NSS encompasses BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Bowel Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme. When all four programmes are fully implemented, over two million people in Ireland will be eligible for at least one screening programme.

BreastCheck plays a central role in breast cancer control in Ireland, providing free mammograms every two years to women aged 50 to 64. With over 2,700 women diagnosed every year, breast cancer remains the most commonly diagnosed cancer in women in Ireland. Survival has improved as a result of screening, symptomatic detection and improved treatment options.

BreastCheck is currently in its 16th year of screening in Ireland. To date, the programme has provided more than 1,201,000 mammograms to over 450,000 women and detected more than 7,400 cancers.

No screening test is 100 per cent effective; the benefit of an organised, population-based screening programme, such as BreastCheck, is in the repeat nature of the test at regular determined intervals. Some women will remain in the BreastCheck programme for 14 years and can have up to eight mammograms during this time. It is essential that these women remain confident in the service that BreastCheck provides. Quality assurance is at the centre of the programme and influences every aspect of the screening journey.

In fulfilment of a Programme for Government commitment and in line with EU guidelines on breast cancer screening, BreastCheck is extending upwards the screening age limit to include women aged 65 to 69. The total eligible population for BreastCheck will increase to approximately 544,000 women. To accommodate the additional screening demands safely and effectively, BreastCheck will implement extended screening over three screening rounds. Screening of the extended cohort is planned to commence in the fourth quarter of 2015.

Guidelines for Quality Assurance in Mammography Screening (fourth edition) is the result of a collaborative process encompassing all aspects of the screening pathway. Quality assurance is a continual process. This document builds on the standards set in the previous editions and reflects learned lessons and programme developments.

We would like to thank all those involved in developing these guidelines. In particular, we thank the many thousands of women who have participated in BreastCheck. Their continuing participation ensures that breast screening becomes a routine feature of healthcare in Ireland and contributes to the vision and goals of Healthy Ireland.



Dr Ann O'Doherty

Lead Clinical Director, BreastCheck



Ms Majella Byrne

Head, National Screening Service

Preface

Breast cancer is the most commonly diagnosed cancer in women in Ireland and has the second highest mortality rate. BreastCheck – The National Breast Screening Programme is an integral part of breast cancer control in Ireland and is a screening service for women aged 50 to 64. It is planned to extend the upper age limit to 69 commencing in late 2015. First established in 2000, BreastCheck has been available nationally since 2007. During this period, over 7400 women have been diagnosed with breast cancer.

The primary aim of breast screening is to reduce the number of breast cancer mortalities in the eligible population through early detection. However, screening has both positive and negative effects. In order to achieve maximum benefit from a breast screening programme, sensitivity and specificity need to be optimised and adverse effects minimised. These aims can only be achieved with a highly skilled, well-motivated multidisciplinary team and by a fully comprehensive quality assurance programme applied across the entire programme.

Quality assurance must include every individual and process involved in breast screening. Quality assurance systems and service standards are in place at all levels throughout the programme. BreastCheck is continually audited to ensure that it operates in line with the highest international standards.

The introduction of digital screening mammography was completed in 2008, and this transition is reflected in the current guidelines. The experience gained since the programme began in 2000 has contributed greatly to the revisions made to these guidelines; this publication is built on previous editions, which sought to establish a high-quality national programme equivalent to the best of other breast screening programmes internationally.

Our greatest challenge will be to maintain the standards achieved to date, particularly over the next few years as we extend the programme. I would like to thank the members of the Quality Assurance (QA) Committee and the QA Co-ordinator, who have worked conscientiously on this fourth edition of the guidelines.



Dr Gormlaith Hargaden

Chair of the Quality Assurance (QA) Committee

Members of the Quality Assurance (QA) Committee

Chair of QA Committee

Clinical Director, Eccles Unit

Clinical Director, Merrion Unit

Clinical Director, Southern Unit

Clinical Director, Western Unit

Head, National Screening Service

QA Radiologist

QA Pathologist

QA Surgeon

Epidemiologist/Director of Evaluation, National Screening Service

National Radiography Manager

Chief Physicist

QA representative of Breast Care Nurse group

QA representative of unit manager/administration group


BreastCheck Mission Statement

BreastCheck Mission Statement


BreastCheck – The National Breast Screening Programme aims to:

-  Reduce the number of deaths from breast cancer in Ireland amongst women aged 50-64.

The objective of the Programme is to:

-  Provide an effective screening service to the highest quality, so that the maximum number of breast cancers can be detected at the earliest possible stage.

The Programme aims to:

-  Protect the dignity and privacy of women; provide women with a choice and involvement in their own care; deliver a high quality programme dedicated to excellence and meeting the highest international clinical standards; be women centred, accessible and free of charge.

BreastCheck operates a team approach to the screening of women that includes mammography, diagnosis and treatment. It works in partnership with other healthcare providers. BreastCheck values the contribution and skill of its staff; it provides continuous training and development for staff and upgrading of equipment as required in a national screening programme.

BreastCheck provides free screening to all eligible women aged 50-64 through a network of static and mobile units. BreastCheck aims to invite women for screening by personal invitation on a two yearly cycle.

BreastCheck Women's Charter

BreastCheck Women's Charter

Screening commitment

- ★ All staff will respect your privacy, dignity, religion, race and cultural beliefs
- ★ Services and facilities will be arranged so that everyone, including people with special needs, can use the services
- ★ Your screening records will be treated in the strictest confidence and you will be assured of privacy during your appointment
- ★ Information will be available for relatives and friends relevant to your care in accordance with your wishes
- ★ You will always have the opportunity to make your views known and to have them taken into account
- ★ You will receive your first appointment within two years of becoming known to the programme
- ★ Once you become known to the programme you will be invited for screening every two years while you are aged 50 to 64 years
- ★ You will be screened using high quality modern equipment which complies with Guidelines for Quality Assurance

We aim

- ★ To give you at least seven days notice of your appointment
- ★ To send you information about screening before your appointment
- ★ To see you as promptly as possible to your appointment time
- ★ To keep you informed about any unavoidable delays which occasionally occur
- ★ To provide pleasant, comfortable surroundings during screening
- ★ To ensure that we send results of your mammogram to you within three weeks

If re-call is required

We aim

- ★ To ensure that you will be offered an appointment for an Assessment Clinic within two weeks of being notified of an abnormal result
- ★ To ensure that you will be seen by a Consultant doctor who specialises in breast care
- ★ To provide support from a Breast Care Nurse
- ★ To ensure you get your results from the Assessment Clinic within one week
- ★ To keep you informed of any delays regarding your results

If breast cancer is diagnosed

We aim

- ★ To tell you sensitively and with honesty
- ★ To fully explain the treatment available to you
- ★ To encourage you to share in decision-making about your treatment
- ★ To include your partner, friend or relative in any discussions if you wish
- ★ To give you the right to refuse treatment, obtain a second opinion or choose alternative treatment, without prejudice to your beliefs or chosen treatment
- ★ To arrange for you to be admitted for treatment by specialised trained staff within three weeks of diagnosis
- ★ To provide support from a Breast Care Nurse before and during treatment
- ★ To provide you with information about local and national cancer support groups and self-help groups

Tell us what you think

- ★ Your views are important to us in monitoring the effectiveness of our services and in identifying areas where we can improve
- ★ You have a right to make your opinion known about the care you received
- ★ If you feel we have not met the standards of the Women's Charter, let us know by telling the people providing your care or in writing to the programme
- ★ We would also like to hear from you if you feel you have received a good service. It helps us to know that we are providing the right kind of service - one that satisfies you
- ★ Finally, if you have any suggestions on how our service can be improved, we would be pleased to see whether we can adopt them to further improve the way we care for you

You can help by

Keeping your appointment time

Giving at least three days notice if you wish to change your appointment

Reading any information we send you

Being considerate to others using the service and the staff

Please try to be well informed about your health

Let us know

If you change your address

If you have special needs

If you already have an appointment

Tell us what you think - your views are important.

**Freephone 1800 45 45 55
www.breastcheck.ie**

1

Introduction

1. Introduction

1.1 Background

Over 2,700 women are diagnosed with breast cancer in Ireland each year. The risk of developing breast cancer increases with age, and 76 per cent of breast cancer cases in Ireland occur in women over the age of 50. The cumulative risk of a woman developing breast cancer before the age of 40 is 1 in 209, before the age of 50 is 1 in 48 and before the age of 65 is 1 in 15.

The aim of BreastCheck – The National Breast Screening Programme is to reduce the number of deaths from breast cancer in Ireland among women aged 50 to 64. Early diagnosis of breast cancer (i.e., detection of lesions less than 15mm in diameter) with optimal treatment reduces mortality from the disease. Mammography as a breast imaging technique has been comprehensively evaluated and remains the most reliable diagnostic test in the detection of small breast cancers. Any possible detrimental physical and psychological aspects of screening must be minimised so that the benefit outweighs any possible disadvantages of screening. The objectives and associated standards of quality assurance (QA) are designed to ensure that the programme can achieve this end.

1.2 Breast screening for cancer – ethical considerations

Healthcare professionals have an obligation to do no harm and a duty to provide reasonable care for patients who seek their assistance. As the majority of women invited to a breast screening programme will never become patients, this consideration is even more acutely important. In particular, the professionals involved in breast cancer screening must meet the standard of care established for their particular area of practice.

All imaging centres must be prepared to deal with the ethical and legal considerations related to diagnostic and therapeutic radiology. High-quality patient care, individual autonomy, technical advances and the established standard of care are some of the issues to be considered by facility management and staff. The development of policies and procedures to ensure that each centre delivers a high-quality service will go some way to addressing these issues.

Risk management and safety programmes are important measures to take to protect the woman and, consequently, decrease liability, minimise risk and protect the reputation of BreastCheck. Changes in healthcare accreditation standards and the litigious nature of society have placed additional requirements on healthcare facilities to maintain the competencies of all employees. Continuing professional education in all aspects of the mammographic process will form part of the QA programme and will be compulsory. Compliance with continuing medical education will take two routes:

1. Educational meetings and seminars away from the employment setting
2. In-service sessions designed to meet the needs of the facility

Professional and continuing education play important roles in the development of the diagnostic and treatment sciences for breast cancer management. Radiographers, radiologists, pathologists, surgeons and nurses must be able to adapt easily to ever-changing technology without losing sight of the patients. Accreditation standards and healthcare reform dictate that the knowledge and skill level of the breast cancer screening health professional be subject to ongoing clinical audit.

The expectations of our population are justifiably high, and it is important that all screening personnel take an active role in educating the patient about the diagnostic or therapeutic procedures involved in screening. Refer to Appendix 1 for an extract from Recommendation No. R (94) 11 of the Committee of Ministers to Member States on screening as a tool of preventive medicine.¹

1.3 Definition of terms

Quality management:

“Co-ordinated activities to direct and control an organization with regard to quality”²

Quality assurance:

“Part of quality management focused on providing confidence that quality requirements will be fulfilled”²

A screening service that meets quality assurance standards ensures that the entire diagnostic process will be quality focused. This means that adequate diagnostic information will be consistently produced while the risk to patients and personnel will be minimised.

Quality control:

“Part of quality management focused on fulfilling quality requirements”²

As applied to a diagnostic procedure, quality control covers monitoring, evaluating and maintaining at optimum levels all the characteristics of performance that can be defined, measured and controlled.

1.4 Quality assurance in BreastCheck

QA depends on effective management to define, document, implement, maintain and review the quality management system and relies on adherence to the requirements of the system by all staff. The system is constantly improved through a feedback mechanism. Each individual must contribute to quality and must be sufficiently trained and motivated to make this contribution effectively.

1.5 Quality standards

Standards in this document are frequently defined at both minimum and achievable levels to acknowledge variations in levels of expertise. The minimum standards are estimates of the level of performance required to achieve a target reduction of 20 per cent in mortality from breast cancer in the target age group. The estimates are based on the results of published randomised trials and on actual observed outcomes from other breast screening programmes to date. All screening units should reach the minimum standards and strive to reach the achievable standards. All standards are regularly reviewed and, if necessary, revised in the light of experience and technological advances. It is accepted that certain standards may vary according to external factors such as geographical situation and background incidence of breast cancer.

1.6 Guidelines for QA in mammography screening

This document outlines BreastCheck's QA requirements and includes detailed guidance for the medical, diagnostic and technical aspects of breast screening. The document specifies the standard guidelines that allow for a centralised system of assessment. It sets out the objectives, policies and organisational procedures that ensure that quality requirements are achieved. In fact, this guidelines document fully documents the quality management system for assuring quality in mammography screening.

The document is dynamic: additions and amendments are issued periodically following approval. The guidelines are reviewed and updated approximately every five years. The chairperson of the BreastCheck Quality Assurance (QA) Committee is responsible for overseeing the publication of each new edition of the document.

The document is presented in sections to reflect the various aspects of the multidisciplinary team. Cross-referencing between sections and communicating with the individuals involved will help the reader to get the most out of the document.

All sections of the document specify the high standards that must be upheld when:

- Monitoring the quality of the relevant parts of the service
- Providing feedback on quality issues
- Recommending corrective action, if necessary, and verifying the outcome of such action
- Advising colleagues on ways of improving quality, encouraging the continual professional development of colleagues and co-ordinating the introduction of the group policies and procedures
- Bringing quality deficiencies to the attention of the Head, National Screening Service and, if applicable, the HSE Director of Health & Wellbeing
- Performing quality audits
- Training to ensure quality

Although the aim of BreastCheck is to reduce mortality, well-documented interim performance indicators, such as tumour size and tumour stage, are required so that the programme can be continually evaluated. Issues that may give rise to a recommendation to cease (temporarily or otherwise) the screening programme include the following:

- Consistently low breast cancer detection rate, which remains unresolved after attempted corrective action
- Prolonged waiting times, such as for assessment or surgery
- Equipment problems and physical parameters
- Funding issues

Any decision to cease screening would be made by the Executive Management Team only.

1.7 The organisation

In any population-based screening programme, it is vital to balance the risks and benefits to ensure the emphasis is placed firmly on the latter. This is best achieved in an organisation that applies the principles of QA to its processes and procedures.

1.7.1 QA Committee

The functions of the QA Committee are:

- To oversee the implementation in their entirety of the guidelines for QA in mammography
- To receive reports on an agreed basis from the local QA teams in radiology, radiography, surgery and pathology
- To make recommendations to appropriate management in relation to the programme's clinical efficacy and QA in all clinical and technical disciplines. Appropriate management includes the Head, National Screening Service, the BreastCheck Executive Management Team and, if applicable, the HSE Director of Health & Wellbeing.
- To introduce changes that are deemed appropriate in QA techniques in specialty interests
- To ensure that all professionals participating in the screening programme are fully trained and comply with performance guidelines
- To formulate QA policy
- To ensure, in conjunction with the Programme Evaluation Unit (PEU), that results at local and national levels are produced in a complete and timely manner
- To ensure that the balance between the risk and benefits of screening is firmly on the latter

The QA Committee includes the following members of BreastCheck staff:

- Chair of QA Committee
- Clinical Director, Eccles Unit
- Clinical Director, Merrion Unit
- Clinical Director, Southern Unit
- Clinical Director, Western Unit
- Head, National Screening Service
- QA Radiologist
- QA Pathologist
- QA Surgeon

- Epidemiologist/Director of Evaluation, National Screening Service
- National Radiography Manager
- Chief Physicist
- QA representative of Breast Care Nurse group
- QA representative of unit manager/administration group

The position of chairperson will rotate approximately every three years.

1.7.2 QA Multidisciplinary Consultants Group

The QA Multidisciplinary Consultants Group comprises all consultants from the specialties of BreastCheck (i.e., radiology, pathology, surgery and epidemiology). The role of the group supplements the role of the QA Committee by focusing particularly on clinical data.

1.7.3 Imaging QA Group

The Imaging QA Group is chaired by the National Radiography Manager and includes radiography service managers, medical physicists and QA radiographers from each clinical unit. The group meets quarterly. Its terms of reference are:

- Monitoring and reviewing physico-technical QA
- Monitoring and reviewing clinical radiography QA
- Monitoring and reviewing QA issues from the picture archiving and communication system (PACS)
- Reporting, analysing and following up adverse incidents relating to equipment and QA
- Monitoring and reviewing equipment faults, service and maintenance issues and vendor company meetings

1.7.4 QA Co-ordinator

The responsibilities of the QA Co-ordinator include:

- Providing administrative support to the QA committees within BreastCheck
- Providing administrative support on quality-related issues to the chair of the QA Committee
- Co-ordinating the implementation and development of BreastCheck's quality programmes
- Monitoring and helping to ensure that the service complies with screening specifications and quality standards
- Identifying at an early stage contentious issues that can be addressed
- Encouraging the dissemination of good practice throughout the programme

- In conjunction with relevant professional bodies, assisting the chair of the QA Committee to implement national standards, targets and performance/process indicators
- Providing a resource to the QA committees for the development of quality policies and procedures
- Assisting with the preparation of annual reports and action plans

1.7.5 External QA

Regular, external review and certification is a fundamental aspect of validating the QA process and is being out on a regular basis. Adherence to a quality management system must be recognised in terms of certification. The inference from such certification is two-fold: firstly, that a certain level of performance has been achieved, and secondly, that a certificate may be withdrawn if standards are not maintained. To ensure that previous standards have not dropped, it has been decided that re-certification must be obtained every five years.

Ultimately, BreastCheck will seek recognition as a EUREF reference centre, which is the highest level of certification that can be achieved in accordance with the published EUREF requirements¹ of a reference centre. These requirements are updated every three years. The programme must meet the published requirements at organisational, professional and physico-technical levels and must also be considered capable of providing consultation services and training, both internally and externally. It must be able to function on a global scale in terms of furthering the processes of mammographic quality improvement, and it must justify and promote the values of population screening by mammography for breast cancer.

1.8 Appendices

Appendix 1: Extract from Recommendation No. R (94) 11 of the Committee of Ministers to Member States on screening as a tool of preventive medicine.1

(Only relevant sections of the recommendation are reproduced here.)

1. Introduction

- 1.1 For the purposes of this recommendation, screening means applying a test to a defined group of persons in order to identify an early stage, a preliminary stage, a risk factor or a combination of risk factors of a disease. In any case it is a question of detecting phenomena, which can be identified prior to the outbreak of the disease.
- 1.2 The object of the screening as a service is to identify a certain disease or risk factor for a disease before the affected person spontaneously seeks treatment, in order to cure the disease or prevent or delay its progression or onset by (early) detection.
- 1.4 Screening is only one method of controlling disease. It should be viewed in the whole context of reducing the burden of ill health to the individual and the community by, for example, socio-economic, environmental measures, health education and improvement of existing healthcare and disease prevention systems.
- 1.8 Screening is a tool which is potentially capable of improving the health of the population, but it also has adverse effects. Constant care should be taken to ensure that in any screening programme the advantages prevail over the disadvantages.
- 1.9 The general benefits of screening are often described. It is, however, also important to be aware of the adverse effects which can be:
- stigmatisation and/or discrimination of (non) participants;
 - social pressure to participate in the screening and undergo the intended treatment/ Intervention;
 - psychological distress where there is no cure for the disease or where the treatment and/ or intervention is morally unacceptable to the individual concerned;
 - exposure to physical and psychological risks with limited health gains;
 - creation of expectation which probably cannot be fulfilled;
 - individuals who are positively screened might experience difficulties such as access to insurance, employment, etc.;
 - severe side effects of invasive clinical diagnosis of false positives
 - delay in diagnosing false negatives;
 - unfavourable cost-benefit relationship of a screening programme.

- 1.10 The various problems which are encountered in the introduction and provision of screening are interrelated. Nevertheless, a distinction may be made between those concerned with:
- i. ethical and legal issues;
 - ii. selection of diseases (medically) suitable for screening;
 - iii. economic aspects and evaluation of screening;
 - iv. quality assurance;
 - v. organisation of a screening programme;
 - vi. scientific research.

2. *Ethical and legal values*

- 2.1 Effectiveness is a necessary prerequisite for the screening to be ethical. It should none the less be kept in mind that screening can be effective and still unethical.
- 2.2 Advantages and disadvantages of screening for the target population and the individual must be well balanced, taking into account social and economic costs, equity as well as individual rights and freedoms.
- 2.3 Failure to make known information on the positive and negative aspects of the screening is unethical and infringes the autonomy of the individual.
- 2.4 The decision to participate in a screening programme should be taken freely. The diagnoses and treatments, which may follow the screening, should also require a free and separate consent. No pressure should be used to lead somebody to undergo any of these procedures.
- 2.5 The right to privacy requires that the results of the tests as a general rule are not communicated to those who do not wish to be informed, are collected, stored and handled confidentially, and adequately protected. It is preferable not to screen individuals who do not wish to be informed of the results of the screening.
- 2.7 No personal data derived from the screening should be communicated to third parties unless the data subject has given consent to it or in accordance with national law.
- 2.8 When the screening programme is provided as a service and conducted also for research purposes, the decision to make available personal medical data stemming from the screening programme for research purposes should be taken freely, without undue pressure. The decision not to take part in the research should not in any way prevent the individual from participating in the screening programme.

1.9 References

1. European Commission. European guidelines for quality assurance in breast cancer screening and diagnosis, 4th ed [online], 2006, available: <http://www.euref.org/european-guidelines/4th-edition> [accessed 11 Dec 2014].
2. ISO 9000 2005 International Organization for Standardization.

2

Quality assurance
in client care

2. Quality assurance in client care

2.1 Introduction

The overall aim of client care within BreastCheck – The National Breast Screening Programme is to ensure that each woman receives the personal care she requires in a sensitive, appropriate and timely manner and with due regard to her safety, comfort and dignity throughout the screening process.

2.2 Quality requirements

The principles of good client care encompass four major areas:

1. Maximising good-quality communication throughout the process
2. Respect, openness, honesty and equality of treatment
3. Recognition of and appropriate response to individual women's differing needs
4. Motivation of self-care

2.2.1 Maximising good-quality communication

Communication is a two-way process. Environmental factors facilitate good communication (refer to Appendix 1). One of the requirements of a quality-assured programme is that staff provide continuity of care and communicate with each other appropriately and consistently. Women will be given opportunities to express their concerns or worries. Staff will be empathetic, and a trained breast care nurse will be available if required.

A greater understanding of the potential barriers that prevent women from availing of screening will be sought, and appropriate measures will be taken to address such barriers. Accurate, appropriate and relevant oral and written information will be provided.

2.2.2 Respect, openness, honesty and equality of treatment

The programme is open and accessible to all women within the selected age group. While every effort will be made to encourage women to avail of breast screening, the staff of the programme will recognise and respect every woman's right to make her own informed decisions about breast screening and will avoid inducing guilt in women who choose not to attend for screening. See section 3.12.4 for radiography-specific considerations.

There will be consistency and standardisation of the breast screening process throughout the country. Confidentiality will be maintained at all times.

2.2.3 Women's differing needs

Recognition will be given to the fact that women are not a homogeneous group; issues regarding class, race, culture, religion, education, language and sexuality will be considered.

The breast screening process can be divided into an initial screening phase, a re-call phase and a treatment phase. Women will have similar and differing needs during each phase, and these needs will be established and addressed. It is important to recognise that what is welcomed and works well for one woman can be unhelpful or unacceptable to another. Individual differences will be respected. Women will be encouraged to participate actively to ensure that the available services meet their needs.

2.2.4 Motivation of self-care

Women will be facilitated to take control, where possible, of their own health. Health promotion delivered through BreastCheck promotes the concept of breast awareness so that every woman knows what is normal for her and is aware of change. The complex relationship between knowledge, attitudes, beliefs and behaviours will be recognised.

2.3 Achieving the quality standards

2.3.1 BreastCheck Women's Charter

The quality standards outlined as the aims and aspirations of the BreastCheck Women's Charter are considered to be of the highest level, and the goal of all disciplines involved in breast screening is to achieve these standards. The Women's Charter is available to all women attending the screening services.

2.3.2 Breast screening research

It is the responsibility of the QA Committee to ensure that all aspects of the programme fulfil the objectives and principles outlined in this document. This will necessitate researching the process, including surveying women's perceptions and experiences of the service from the point of invitation to treatment.

2.3.3 Training and continuing medical education

The additional and continuing training needs of staff will be identified and met to ensure that the quality standards are maintained and improved.

2.4 Appendices

Appendix 1: Environment of centre/mobile unit

Each breast screening centre and mobile unit will have the following features and facilities:

1. Relaxing decor with background music; the music will aid relaxation and privacy in the mobile unit
2. A 'user-friendly' reception area
3. Signs indicating all facilities, including screening rooms, waiting room, toilets, etc.
4. A comfortable waiting area with appropriate decor and seating
5. Water facilities available in the waiting area
6. Television/video facilities in the waiting area
7. Current issues of magazines
8. Pens to complete any self-administered questionnaire
9. Notices in the waiting area informing women how to notify the screening staff of their satisfaction with or complaint about the service provided
10. Nearby parking facilities

3

Quality assurance in radiography

3. Quality assurance in radiography

3.1 Introduction

As mammography is the screening tool chosen for breast screening within BreastCheck – The National Breast Screening Programme, the radiographer will be closely involved with both the quality of the outcome of the service and each woman's satisfaction with the service. For the majority of women attending for breast screening, their main contact with the service will be with the radiographer; it therefore stands to reason that the radiographer will have a significant influence on women's perceptions of the breast screening service.

This section of the guidelines has been developed by the BreastCheck radiography and medical physics group. The group represents the primary radiographic responsibilities for technical and equipment QA.

The generic tests specified in this section are based on early experience with digital mammography in BreastCheck and on evolving practice in other screening programmes. It is expected that the tests will evolve to meet specific local requirements, emerging regulatory requirements and problems that may be encountered in the provision of services. It may be necessary to adapt the tests depending on the imaging equipment used in the programme, on staffing levels and on the organisation and management of the QA service.

The aim of these procedures is to optimise the quality of the clinical images, i.e., to achieve the best possible quality of the images at the lowest radiation dose and to minimise the number of repeat images for technical reasons.

It is vital that radiographic QA be seen as an important core activity within the screening process. Time must be set aside for performing the measurements, collating and analysing the data and problem solving. Ideally, one member of staff will take primary responsibility for QA. Adequate resources will be made available to allow radiographic staff to gain and maintain competency in QA.

It is important that all tests be thoroughly documented and maintained in the unit to facilitate troubleshooting, internal auditing and external assessment.

3.2 Objectives of radiography QA

The main objectives of the radiographic QA programme are interrelated. They include:

- Consistently achieving optimum image quality
- Minimising the radiation dose received
- Minimising the number of repeat images or re-calls due to technical reasons
- Optimising the woman's experience of and satisfaction with the service to promote continued acceptance and uptake of the programme

3.3 X-ray unit checks

BreastCheck radiography staff will conduct safety and functional checks at least monthly. During the checks, the radiographers will verify that:

- The modality is mechanically stable
- All moving parts of the unit work smoothly
- All relevant movements in compression are restricted
- The paddle releases at the end of an exposure
- All surfaces are smooth and free of cracks (e.g. paddles, detector cover, etc.)
- In the event that the exposure button is released prematurely, the exposure is terminated as required
- The radiation warning lights outside the room are operating correctly
- All radiation indicator lights on the user console are operating correctly
- Radiation warning signs are in place
- The protective lead glass screen is in good condition (e.g., no visible cracks)

3.4 Daily QA test

Each Full Field Digital Mammography (FFDM) unit is subject to routine calibrations and QA tests specified by the manufacturer. The manufacturer's QA tests will be performed as required.

Long-term reproducibility and image receptor stability

Equipment:	Uniformity test phantom (4cm PMMA block)
Method:	Expose the test block in automatic mode covering the entire detector. Record the exposure settings and tube loading (kV, mAs, target/filter combination). Evaluate the RAW image by calculating the mean pixel value and the Signal-to-Noise ratio (SNR) in a region of interest (ROI) (a square with an area of approx. 1cm ²) placed 6cm from the chest wall. Results can be viewed within the software application.
Tolerance:	Maximum variation of the SNR and mean pixel value between daily images <math>< \pm 10\%</math> For the exposure settings and tube loading, results at acceptance are used as reference.
Frequency:	Daily

3.5 Weekly QA test

Image receptor uniformity

Equipment:	Uniformity phantom (4cm PMMA block), image analysis software
Method:	One of the daily QA images is used and analysed by a physicist.
Tolerance:	The uniformity results are plotted on a chart, and trends are identified and investigated.
Frequency:	Weekly

3.6 Diagnostic monitor tests

MoniQA pattern

Equipment:	MoniQA software, MoniQA pattern
Method:	Visualise the MoniQA pattern to evaluate the following parameters: <ul style="list-style-type: none"> • Luminance • Corner lines • Geometric distortion • Gradient • Resolution
Tolerance:	Results at acceptance are used as reference.
Frequency:	Twice weekly

Luminance circles pattern

Equipment:	MoniQA software, luminance circles pattern
Method:	Evaluate the luminance circles pattern. Click on the four positions where the circles are located. At the fifth click, a new pattern is drawn with a different background.
Tolerance:	Results at acceptance are used as reference.
Frequency:	Twice weekly

3.7 Stereotactic localisation – biopsy

The stereotactic device is used for the precise positioning of guide wires and biopsy procedures in breast lesions.

Because of the need for accuracy of localisation, it is essential that regular testing be performed.

Prior to each use of the stereotactic biopsy unit, perform the calibration procedure according to the manufacturer's instructions.

To check accuracy, a Perspex phantom is used. The error in localisation should be within manufacturer guidelines.

3.8 Equipment management and service

The National Breast Screening Programme software application (hereafter referred to as the NBSP database) enables scheduled servicing information and equipment problems and downtime to be recorded online. Proper use of this function allows the programme to accurately record and analyse all equipment issues and connected problems that may not normally be apparent. Problems with imaging equipment components can be recorded individually. Radiographers will become familiar with this function and use it extensively to record equipment issues.

Post-service record forms will be completed by the service engineer and checked by a radiographer following a maintenance visit of an x-ray unit.

3.9 Radiographic practice

3.9.1 Compression: It has been shown that women will tolerate compression better if they understand the need for it and its importance and can indicate if the pressure becomes too uncomfortable. The radiographer explains to the woman that compression is needed to achieve a good-quality mammogram. Compression is necessary to ensure that:

- The breast remains still during the exposure so that there is no motion artefact
- A separation of the breast tissue occurs so that there is less superimposition of structures and improved visualisation
- The thickness of the breast is reduced so that the radiation dose is sufficiently lowered to ensure a high-quality image
- The proximity of the breast to the film reduces geometric unsharpness and scattered radiation is diminished, thus improving image contrast

3.9.2 Two-view mammography is performed at each round of screening. The standard views are:

- Cranio-caudal
- Mediolateral oblique

- 3.9.2 Prior to commencing the mammogram:
- The radiographer greets the woman and introduces herself to help establish a relationship with the woman.
 - The woman is asked to verify her name, address and date of birth.
 - For all initial mammograms, the woman is asked to sign the consent form in the presence of the radiographer, who also signs and dates the form.
 - The radiographer gives a detailed explanation of the examination to the woman, including the importance of and need for compression.
 - The radiographer notes any skin abrasions, skin tears or soreness, particularly on the underside of the breast; if present, the radiographer advises that mammography may aggravate the condition and may be more uncomfortable for the woman. In these instances, the woman is given the opportunity to make an informed decision about whether or not to proceed at this stage.
 - The radiographer explains the screening results notification procedure.
- 3.9.3 Information and relevant details obtained from the woman are documented in the appropriate way; the demographic and clinical details are recorded on the appropriate datasheets and on the NBSP database.
- 3.9.4 All images are viewed immediately by the radiographer on the acquisition station prior to concluding the examination and sending to picture archiving and communication systems (PACS).
- 3.9.5 Technical repeats (TRs) are carried out at the time of the examination, and the number and reason for all repeat images are recorded on the database. TRs and technical re-calls (TCs) are added together and monitored monthly. The TR plus TC target rate for the programme will be <3 per cent. Radiographers with TR plus TC rates above 4 per cent will be monitored and offered additional radiographic updates.
- 3.9.6 If clinical signs/symptoms merit re-call to assessment, a clinical re-call can be indicated and instigated by the radiographer carrying out the examination. All radiographers will be familiar with and adhere to the clinical re-call protocol as documented in the unit's standard operating procedure (SOP) 'Processing a Clinical Re-call'.
- 3.9.7 Radiographers will rotate between static and mobile sites and between screening and assessment procedures and will participate in multidisciplinary case conferences.
- 3.9.8 The screening interval is approximately two years (21–27 months). This requires monitoring and careful planning (in conjunction with administration personnel) to prevent 'slippage' of screening interval.
- 3.9.9 Radiographers will be actively involved in all aspects of QA/quality control protocols in collaboration with the physics team, the unit QA radiographer and the technical support staff of equipment manufacturers.
- 3.9.10 Radiographers will work in teams of two in the mobile screening unit to facilitate the smooth operation of the unit and to ensure that every woman has a positive screening experience.

3.10 Mobile units

Suitable sites for the mobile units must:

- Have sufficient access and space for a 40ft vehicle
- Be on level ground with safe access and egress for all individuals
- Have access to a 3-phase power supply
- Have a direct water supply
- Have adequate site security
- Have network line and mobile phone facilities
- Have access to toilet facilities nearby
- Have local support that the programme can liaise with

3.11 Mammography technique

3.11.1 Image quality assessment

Common criteria for image quality assessment include:

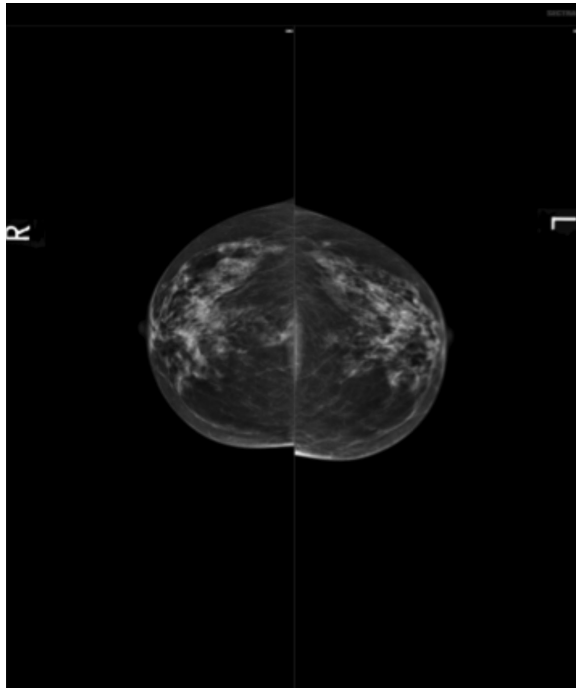
- Appropriate compression
- Absence of:
 - Skin folds
 - Overlying artefacts such as shoulders and breast tissue
 - Movement
 - Image processing artefacts such as ghosting
- Correct identifications
- Correct exposure and image processing
- Symmetrical images

3.11.2 Cranio-caudal projection

The cranio-caudal projection should show as much of the breast as possible. A correctly performed cranio-caudal projection will show virtually all the breast except the most lateral and axillary parts.

The criteria for the image assessment of the cranio-caudal view are:

- Medial border of breast shown
- As much as possible of lateral aspect of breast shown
- If possible, pectoral muscle shadow shown on posterior edge of breast
- Nipple in profile
- Symmetrical images



Adjusting the image receptor plate to the correct height for the woman is key to achieving a high-quality cranio-caudal image. The height of the image receptor plate can be best determined when observed from the medial side of the breast. Once the height of the image receptor plate has been set, the radiographer lifts the breast and gently but firmly pulls the breast tissue forward and away from the chest wall and places it on top of the image receptor plate. The breast should be at the centre of the breast support table. The breast should be held in place and the breast tissue smoothed out while applying compression. It may be necessary to take an additional view to more fully visualise the lateral aspect of the breast or to project the nipples in profile in difficult cases.

To summarise:

- The breast is centrally positioned with the nipple in profile.
- As much as possible of the breast tissue is visualised.

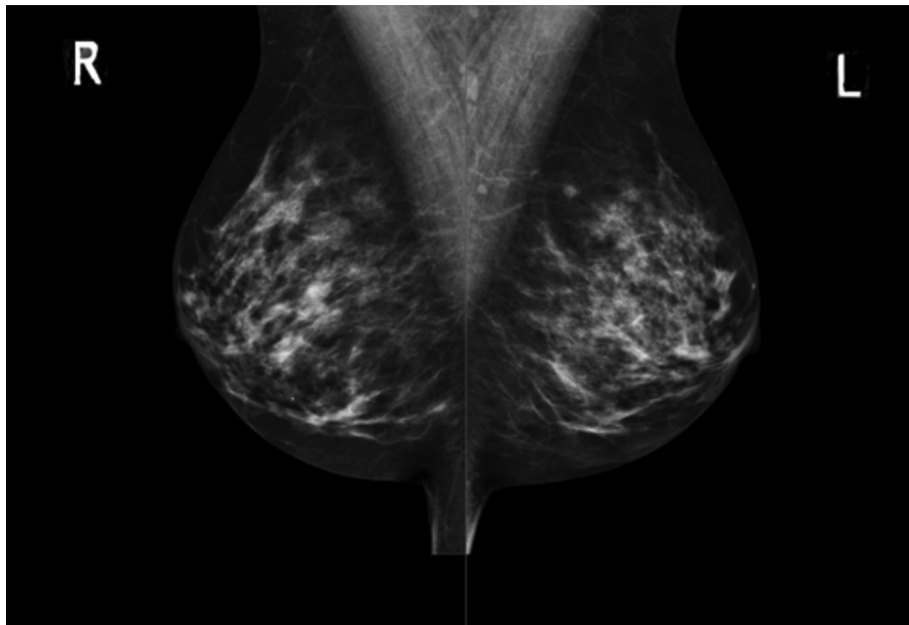
Common errors leading to poor-quality images include:

- Image receptor plate is too low (this is also more uncomfortable for the woman)
- Poor compression leading to poor image contrast and movement blur
- Skin folds in the lateral part of the breast
- Breast tissue not pulled forward as much as possible
- Nipple not in profile

3.11.3 Mediolateral oblique projection

The criteria for the image assessment of the mediolateral oblique view are as follows:

- All breast tissue clearly shown
- Pectoral muscle to nipple level
- Nipple in profile
- Inframammary angle clearly demonstrated
- Symmetrical images



Key aspects to achieving a high-quality mediolateral oblique image are the height of the breast support table, the angle being used, the lift, the spread and compression of the breast and the comfort of the woman.

To summarise:

- The whole breast is visualised with the nipple in profile.
- The pectoral muscle shadow is shown down the back of the breast at the correct angle.
- The inframammary angle is clearly demonstrated without overlying tissue.

Common errors:

- Image receptor too high or too low
- Image receptor not correctly angled in order to follow the line of the woman's pectoral muscle
- Inframammary angle not clearly shown
- Insufficient lift and poor compression, resulting in a droopy breast and poor image contrast

3.12 Professional requirements

3.12.1 Training

Radiographers in BreastCheck will hold or be in training for a recognised postgraduate qualification in mammography and will achieve the award within one year of taking up a post with the programme.

3.12.1.1 Aims of postgraduate mammography qualification

The aims of a specific course of study in mammography are to develop a high level of practical expertise in mammography; a sound theoretical knowledge of breast imaging, diagnosis and treatment; and critical evaluation and judgement skills. These outcomes will enable the radiographer to become a skilled practitioner of mammographic technique and an active member of the multidisciplinary team.

3.12.1.2 Learning outcomes

The desired learning outcomes of a postgraduate mammography course are that the radiographer:

- Is able to perform mammography to a consistently high standard and can adapt the technique to the needs of the individual
- Is able to critically appraise images, determine the diagnostic value of the examination and select and undertake appropriate additional projections or techniques, including biopsy and wire localisation techniques
- Is able to respond to the information needs of each woman being screened
- Is able to be an active and informed member of the QA/quality control team
- Will be committed to the quality of the service to ensure maximum acceptability and minimal anxiety to each woman being screened

3.12.1.3 Course requirements

Students are required to attend a recognised mammography training centre and undergo a programme of training that includes an academic module (minimum five days' duration) and a five-day practical training module (with a 1:1 student-to-trainer ratio). Students are required to perform a minimum of 250 mammography examinations and are assessed on radiographic performance by the course trainer. In addition, all course assignments and other learning outcomes (as designated by the relevant college) must be satisfactorily completed in conjunction with the clinical module.

3.12.2 Continuing medical education

Radiographers will be well-informed about the aims, targets and organisation of breast screening in Ireland and will be familiar with the programme literature. Radiographers will have up-to-date knowledge of advances in clinical practice and mammographic technique; they will maintain their skills in line with continuing professional development and will attend seminars, symposiums or update courses for their ongoing educational needs in consultation with their unit radiography services manager and within the annual training budget.

3.12.3 Image quality control

3.12.3.1 Image classification

Radiographers in BreastCheck will participate in image classification in relation to PGMI/other scoring systems to maximise the quality of images and minimise TRs. Targets for image quality are as follows:

- 75 per cent of images should be perfect or good.
- 97 per cent of images should be perfect, good or moderate.
- <3 per cent of examinations should be technically inadequate.

Review of examinations for quality of technique – overall and individual standard to be completed:

- Monthly review by unit radiography services manager
- Monthly peer review by unit radiographers
- Quarterly review by the national radiography manager and unit radiography services manager

Review of examinations for image consistency from static and mobile units:

- Monthly review by unit radiography services manager
- Quarterly review by national radiography manager and unit radiography services manager
- Twice-yearly review with national radiography manager, unit radiography services manager and physicist

3.12.3.2 Individual analysis

Each radiographer will identify their individual work by means of a marker on each mammogram and will co-operate with TR and TC analysis. Radiographers will never delete a sub-standard image. All images will be presented for reporting. Each radiographer will participate in relevant QA/quality control procedures and record keeping and will liaise with the physicist to ensure the imaging system is working at optimum levels on a daily, weekly and monthly basis.

All radiographers will participate in a formal individual appraisal every year. This will involve the national radiography manager, the unit radiography services manager and each radiographer in a review of recent images to highlight strengths, areas for improvements, opportunities for development and reflection by the radiographer of the previous year. Issues for discussion will be highlighted. The appraisal will be documented and signed, and each participant will receive a copy.

3.12.4 Consumer rights

The radiographer plays an important role in ensuring that the woman's experience and satisfaction with the screening service is optimised and that she experiences minimal anxiety during the whole screening process. The radiographer will be friendly and caring and will answer enquiries and provide an explanation of the procedure. The woman should feel that she can have the procedure stopped at any point – it is essential for the radiographer to recognise and respect that the woman can withdraw her consent to proceed with the examination. The radiographer will document an incomplete examination in the NBSP database.

3.12.5 Screening activity

The radiographer's time should be utilised efficiently and effectively. Staffing levels should reflect the workload; the minimum staffing level is 1.8 whole-time equivalent radiographers per 10,000 members of the eligible population. Every fully trained radiographer will be able to perform an average of 20 high-quality mammograms per day. Work practices should not place undue pressure on the radiographer, and adjustments will be made for women with special needs who may require more time to complete the examination.

Time will be assigned to allow for the monitors and weekly quality control procedures and for image review to be carried out. It is recommended that:

- A minimum of one radiographic session (3.5 hours) per week per screening unit is allocated to these QA criteria
- Radiographers participating in screening commit to the screening programme for a minimum of two days per week to maintain and develop their mammography skills

3.12.6 Multidisciplinary teamwork and education

Radiographers will work closely with other disciplines and be fully participating members of the multidisciplinary team. They will rotate through static and mobile units and through screening and assessment sessions and will participate in research and multidisciplinary conferencing. Links with radiographers in other specialist areas and general radiography will be encouraged.

3.13 Technical quality control

Each screening unit will carry out a QA regime to ensure the required standards are maintained on a day-to-day basis. In each unit, all radiographers will be involved in performing, monitoring and recording daily and weekly quality control tests. Each unit will have one nominated radiographer with overall responsibility for quality control (the QA radiographer).

3.13.1 Role of QA radiographer

As part of the radiographic team, the role of the unit QA radiographer is to facilitate the implementation of the radiography guidelines for QA in mammography within the programme, to provide support to all radiographers and to develop expertise in the area of radiography QA. A number of additional duties will be associated with the role. The QA radiographer will liaise with the radiography services manager/deputy radiography services manager, medical physics and radiographers and will be allocated a minimum of one session (3.5 hours) per week to perform these duties. The QA radiographer will:

- Participate in and monitor the results of daily and weekly quality control tests and ensure that documented QA protocols are being followed. These activities will help to ensure that the quality of mammographic images is optimised while the radiation dose is minimised.
- Highlight trend changes and solutions to the unit radiography services manager and physicist so that an appropriate plan of action can be identified and implemented
- Organise and monitor radiographer peer appraisal and liaise with the radiography services manager regarding staff performance
- Log all equipment faults in the NBSP database and identify ongoing issues
- Provide quarterly reports to the radiography QA group and keep the group updated of radiography QA issues within the screening unit
- Liaise closely with medical physics and the line manager in identifying and resolving QA issues
- Identify their own educational and development needs within this area and seek to address them as required
- Provide support to existing radiographers and training on all aspects of radiography QA to new staff members within the unit

All test results, scheduled services, equipment faults and downtime will be recorded on the NBSP database by the radiographic or medical physics team.

3.13.2 Role of PACS manager

The picture archiving and communication system (PACS) is the database of images taken over a given period of time. The radiology information system (RIS) is the workflow engine that uses the PACS to deliver an effective service. The PACS manager:

- Is responsible for the image and information integrity of the PACS database and has overall responsibility for administering, managing and supporting its integration with the RIS
- Is accountable for the day-to-day PACS/RIS service delivery within BreastCheck and reports to and liaises with the national radiography services manager
- Manages all issues relating to and affecting PACS imaging and is the central point of contact for advice, queries and troubleshooting across the four units
- Is the main point of contact with Sectra, the PACS service provider
- Is responsible for the delivery of PACS/RIS training to all staff; this includes super-user and end-user training across the organisation

Summary of quality control tests and frequencies:

Daily:	X-ray machine	Image receptor reproducibility and stability Manufacturers' recommended daily tests
Twice weekly:	Monitors	MoniQA pattern Luminance circles tests
Weekly:	X-ray machine	Image receptor homogeneity
Weekly or before each use:	Stereotactic biopsy device	Accuracy Manufacturers' recommended tests and calibration

Quality assurance
in radiology

4. Quality assurance in radiology

4.1 Introduction

In BreastCheck – The National Breast Screening Programme, the radiologist takes the greatest overall responsibility for mammographic image quality and diagnostic interpretation and so their role is of primary importance. The radiologist must have a thorough knowledge and understanding of the risks and benefits of breast cancer screening and of the dangers of using inadequately trained staff and sub-optimal equipment.

The radiologist ensures that protocols are in place for satisfactory and complete assessment (work-up) of women with screen-detected abnormalities. Women referred for assessment are examined in fully equipped centres that are staffed by properly qualified personnel. Staff in the centres work in collaboration with a radiologist who is experienced in and involved with the screening process.

The lead radiologist will form a skilled multidisciplinary professional team that incorporates clinical and non-clinical specialists involved in the entire process of screening and diagnosis. The team will include radiographers, pathologists, surgeons and nurses; additional input will be received from oncologists, physicists and epidemiologists, as appropriate. The lead radiologist will be intimately associated with the organisation of the screening programme.

The major responsibilities of the radiologist are to ensure that:

- A satisfactory QA system, which includes sufficient quality control mechanisms, is in place to provide a high level of image quality
- Radiological performance levels are sufficient to achieve the goals of the programme by effectively advancing the time of diagnosis of cancers arising in the screened population (and lowering the rate of advanced cancers)
- The adverse effects of screening are minimised

To reach these objectives, it is necessary to accept the need for QA standards and performance indicators, to comply with the standards and performance indicators wherever possible, to take part in both internal and external audit procedures and to ensure that remedial action is undertaken when parameters are consistently breached.

4.2 Radiology quality standards

4.2.1 Core radiological standards

4.2.1.1 Cancer detection rates

The criterion used to measure whether a maximal number of cancers is being detected is the invasive cancer detection rate (the number of invasive cancers detected per 1,000 women screened) at initial and subsequent rounds every two years. While it is recognised that there are geographical variations in the incidence of breast cancer, these variations are not sufficient to warrant setting different standards for different parts of the country. A possible reason for apparent poor performance is variation between units in the age distribution of the population screened. In areas where screening is established, the majority of women invited for initial-round screening will be in the 50-to-51-year-old age group. The cancer detection rate in initial-round screening of women in this age group is expected to be lower than the cancer detection rate in initial-round screening that includes women in the 50-64 age group. The invasive cancer detection rate for the initial round will therefore be measured for two age ranges: 50-51 years and 52-64 years. The standards are $>2.9/1,000$ and $>5.2/1,000$ respectively. The standard for the subsequent round is $>2.4/1,000$.

The standardised detection ratio (SDR) is the preferred method for correcting unit performance by age distribution and by variations in the underlying incidence of breast cancer. In the initial round of the programme, the effect of opportunistic background screening may also have an impact on detection rates. Depending on local demographics, there may also be an effect on detection rates in subsequent rounds, i.e., some asymptomatic women may self-refer for a mammogram in the intervening year.

4.2.1.2 Tumour size

The programme aims to detect small breast cancers. There is good scientific evidence that a tumour size of less than 15mm in diameter represents a prognostic threshold. The size of the tumour is the maximum diameter and is measured histologically from the fixed surgical specimen. The minimum standard is that ≥ 40 per cent of invasive cancers will be $<15\text{mm}$ at both initial and subsequent rounds. The achievable standard is that ≥ 50 per cent of invasive cancers will be $<15\text{mm}$ at both initial and subsequent rounds.

The standard for the number of cancers $\leq 10\text{mm}$ in size is in part a measure of radiological performance but is also significantly influenced by image quality. The minimum standard is that ≥ 20 per cent of invasive cancers will be $\leq 10\text{mm}$ in maximum diameter for initial screens and ≥ 25 per cent of invasive cancers will be $\leq 10\text{mm}$ in maximum diameter for subsequent screens. The achievable standard is that ≥ 25 per cent of invasive cancers will be $\leq 10\text{mm}$ in maximum diameter for initial screens and ≥ 30 per cent of invasive cancers will be $\leq 10\text{mm}$ in maximum diameter for subsequent screens.

As well as being related to tumour size, the prognosis of invasive breast cancer is correlated with other factors, including tumour type, histological grade and lymph node status.

4.2.1.3 Ductal carcinoma in situ (DCIS)

Detection at screening of ductal carcinoma in situ (DCIS), particularly the high-grade type, is believed to be a factor in contributing to long-term reduction in mortality from breast cancer. It is good practice to detect and treat DCIS. DCIS is detected at similar rates at initial and subsequent screening rounds and should represent between 10 and 20 per cent of all breast cancers detected. The minimum standard is 10 per cent. DCIS numbers include in situ carcinoma and in situ carcinoma with possible or definite microinvasion.

4.2.2 General radiological standards

4.2.2.1 Re-call rate

The number of women re-called for assessment is a measure of screen-reading specificity. Unfortunately, the specificity of mammography is limited. The positive predictive value of mammography for preclinical cancer varies according to the radiological appearance of non-palpable lesions but, with the exception of spiculate densities and linear branching microcalcifications, is usually below 50 per cent. Screen-reading specificity is dependent on the image quality, the proficiency of the radiologist and the viewing facilities. The aim of any screening programme is to have the lowest possible re-call rate while maintaining high cancer detection rates. The minimum standard for re-call to assessment is <7 per cent for the initial round, and the achievable standard is <5 per cent. The minimum standard for the subsequent round is <5 per cent and the achievable standard is <3 per cent. The standards exclude TCs. Repeating images for technical reasons should be minimised: the minimum standard is <3 per cent and the achievable standard is <1 per cent. Double-reading increases the re-call rate by approximately 10 per cent of the single-reading figure.

Where particularly high cancer detection rates are found, it may not be possible to greatly reduce referral rates for assessment. It should also be borne in mind that low re-call rates might be associated with lower cancer detection rates. The radiologist who re-calls the woman for assessment should, where possible, be the radiologist involved in the triple assessment of that woman.

4.2.2.2 Benign surgical biopsies

Surgical open biopsy is defined as a formal operative excision of tissue for histological examination and excludes needle core biopsy. The number of benign surgical biopsies performed as a result of screening should be as low as possible. Every effort is made to obtain a definitive diagnosis by using non-operative techniques such as core biopsy, vacuum biopsy and fine needle aspiration cytology (FNAC). Some benign biopsies are unavoidable where imaging, clinical or histological features or patient choice necessitates formal excision for a definitive diagnosis.

The minimum standard for the benign open biopsy rate in the initial round is <3.6/1,000 women screened, and the achievable standard is <1.8/1,000. In the subsequent round, the minimum standard is <2/1,000 and the achievable standard is <1/1,000.

4.2.2.3 Pre-operative diagnosis

A pre-operative diagnosis of malignancy is highly desirable as it allows for informed pre-treatment counselling of the patient and facilitates one-stage surgical treatment. Radiologists involved in screening are skilled in the techniques required for pre-operative diagnosis. The minimum standard is that ≥ 90 per cent of cancers should be diagnosed pre-operatively, and the achievable standard is ≥ 95 per cent. These standards apply to both invasive and in situ carcinomas diagnosed by FNAC, core biopsy or vacuum biopsy.

4.2.2.4 Image-guided localisation of impalpable lesions

A substantial proportion of screen-detected abnormalities will be impalpable and will require some form of image-guided localisation procedure prior to surgery. Radiologists involved in screening are skilled in the techniques required for localisation of impalpable lesions requiring excision. Accuracy of localisation is a prerequisite for a successful surgical outcome. The proportion of localised impalpable radiographic lesions excised (completely or incompletely) at the first operation should be > 95 per cent.

The radiologist needs to be constantly aware of how the screening programme is performing and will encourage a process of continual quality improvement with performance feedback to team members.

In planning the screening programme and implementing its organisation, sufficient resources must be identified and allocated to facilitate the achievement of the desired standards. Particular attention needs to be paid to levels of staffing and equipment to ensure they are adequate.

4.3 General screening standards

4.3.1 Attendance rates

To achieve the desired reduction in mortality of 20 per cent, the screening programme requires a minimum attendance for screening of 70 per cent of eligible women. This standard relates to women aged 50-64 years who are called or re-called for screening as part of the programme. This will require a co-ordinated effort by BreastCheck, the Department of Health, the HSE, community health services and general practitioners. The higher the level of attendance achieved, the greater the likelihood of significantly reducing the mortality from breast cancer in the target age group.

4.3.2 Early re-call

This standard applies to women who are re-called for screening assessment at an interval shorter than the normal screening interval (two years) after a previous screen and attendance for assessment. Every effort is made to obtain a definitive diagnosis at initial assessment. It is not acceptable practice to place women on early re-call without first explaining the reasons in person. This means that all women on early re-call should have attended previously for assessment. Early re-call will not be a routine feature of BreastCheck and will be used only in exceptional circumstances. The early re-call rate should be less than 1 per cent. No more than one early re-call outcome should be used per woman per normal screening cycle.

4.3.3 Screening interval

The long-term effectiveness of the programme is dependent on women in the target age group continuing to be screened at regular intervals. Over 90 per cent of women should be re-invited within 24 months of the previous invitation to screening.

4.3.4 Results of diagnostic procedures

Radiological, pathological and clinical correlation of all results will be performed at a multidisciplinary team meeting. The patient and her general practitioner will be notified of these results within one week. Women should be informed of a malignant diagnosis in person.

4.4 Image quality

Radiologists are responsible for ensuring that the quality of mammography is optimal for the detection of breast cancer. Radiologists must be satisfied that the mechanisms for radiographic and physics QA are carried out and standards achieved and adhered to. The radiologist must know about the positioning techniques used by the radiographer and must assess the factors involved before reporting on the mammogram. The key criteria are as follows: the whole breast to be imaged, the outline of the pectoral muscle to be shown down to nipple level, the nipple to be in profile and the inframammary angle to be clearly demonstrated (see chapter 3). Visualising the skin is no longer a primary requirement as penetration of breast tissue is more important for the detection of small cancers.

The radiologist must also be conversant with the aspects of exposure and image processing that play a vital role in determining the quality of the final image. The basic inter-relationship of kV, target filter, contrast and resolution must be understood. Adequate compression and lack of motion artefact are also important diagnostically. Detector artefacts and skin folds indicate sub-optimal technique but may not be sufficient to interfere with diagnosis. Further details of these issues can be found in chapter 7.

The main advantage of digital mammography is that the processes of image acquisition, display and storage are decoupled. Consequently, digital mammography allows each step to be optimised individually. The real flexibility and benefit of digital technology is in softcopy display and consequently softcopy reading. Optimal reading environments, high-resolution monitors and user-friendly image display are essential for successful softcopy reading (see section 4.6.1.2 for details). It is important that images that are similar from case to case be systematically reviewed using a default protocol. Additional images taken by the radiographers should be kept to a minimum as the 'mosaic' of the additional images makes softcopy reading more troublesome.

Ultimately, having analysed the image quality with regard to all these features, the radiologist will be resolute in refusing to accept mammograms that do not meet the criteria for adequate diagnosis. These images will be repeated, and the numbers of women subject to technical re-call will be recorded. All repeat examinations will be recorded, whether at the time of screening due to a technical problem being identified by the radiographer or at a later date if the radiologist judges the images to be inadequate for diagnostic purposes.

4.5 Radiologist performance issues

Because good teamwork enhances the screening process and is likely to improve outcomes, the radiologist needs to work closely with other professional colleagues as part of a multidisciplinary team. To maintain radiological performance standards, it is vital that the radiologist has direct access to key performance indicators, not only to screening and assessment results but also to cytological and pathological records (refer to Table 1).

Feedback of results at all stages is an important learning and quality-enhancing process, and mechanisms are in place to achieve this. Records are kept of the results and outcomes of all women in the programme. Regular multidisciplinary review meetings are held to discuss both pre-operatively and post-operatively cases. This is beneficial for feedback purposes as well as providing an ideal mechanism for refining case management decisions. The review of interval cancers by radiologists is regarded as mandatory because it is such an excellent feedback and educational process.

A delay in communicating results, performing assessment or carrying out surgery is likely to cause distress and anxiety. This is bad practice and must be avoided. Standards are set for all stages of the process, as detailed in Table 1.

Table 1: Minimum and achievable standards for BreastCheck

Stage of process	Minimum standard	Achievable standard
Percentage of invited women attending for screening	≥70%	80%
Invasive cancer detection rate:		
Initial screen 50-51 yrs.	>2.9/1,000	
Initial screen 52-64 yrs.	>5.2/1,000	
Subsequent screen	>2.4/1,000	
DCIS as proportion of all breast cancers detected	10%	10-20%
Proportion of invasive cancers detected at initial screening ≤10mm	≥20%	≥25%
Proportion of invasive cancers detected at subsequent screening ≤10mm	≥25%	≥30%
Invasive cancers <15mm detected at both initial and subsequent screens	≥40%	≥50%
Percentage of women sent their screening mammogram results within three weeks of screening	≥90%	100%
Percentage of women sent their triple assessment results within one week of assessment	≥90%	100%
Re-call for assessment rate in women at initial examination	<7%	<5%
Re-call for assessment rate in women at subsequent examination	<5%	<3%
TR plus TC rate	<3%	<1%
Benign open biopsy rate per 1,000 women screened:		
Initial screen	<3.6	<1.8
Subsequent screen	<2.0	<1.0
Proportion of screen-detected breast cancer with a pre-operative diagnosis of malignancy (core biopsy reported as definitely malignant) ^{5.4, 6.2.1}	≥90%	≥95%
Proportion of screened women subjected to early re-call following diagnostic assessment	<1%	0%
Interval cancer rate per 1,000 women screened in the two years following a normal screening episode:		
Year 1	<0.75/1,000	≤0.5/1,000
Year 2	<1.25/1,000	≤0.75/1,000
Percentage of eligible women whose re-invite offered appointment is within 24 months of the previous screen	≥90%	100%

Stage of process	Minimum standard	Achievable standard
Time interval between first assessment appointment and surgical assessment (patient requiring surgical opinion)	One week	Same day assessment
Percentage of women offered an admission date within three weeks of the decision to operate for diagnostic purposes	≥90%	100%
Percentage of women admitted within three weeks of being informed that they need surgical treatment	≥90%	100%
Number of visits required to make a diagnosis of malignancy	No more than 10% require >3 visits	0% require >3 visits
Proportion of localised impalpable radiographic lesions excised (completely or incompletely) at the first operation	95%	>95%

4.6 Achieving the quality standards

4.6.1 Screening and screen reading

4.6.1.1 Two-view screening

Screening mammography using two views of each breast (mediolateral oblique plus cranio-caudal) has been shown to be more effective than single oblique view screening. The use of two views provides a higher sensitivity and specificity for the detection of breast cancer. Therefore, two views of each breast will be performed for all women at initial-round and subsequent-round screening.

4.6.1.2 Viewing conditions

Radiologists will ensure that facilities for screen reading are suitable. Optimal reading environments, high-resolution monitors and user-friendly image display are essential for successful softcopy reading. Reporting work stations are located in a quiet darkened room as their light output is considerably less than that from a conventional viewing box. Work stations include two high-resolution (5-megapixel) monitors and a dedicated pad that enables the radiologist to progress through the reading protocol with ease.

4.6.1.3 Previous mammograms

Previous mammograms are available to the radiologist at the time of screen reading. It is the responsibility of the radiologist to decide whether or not it is necessary to obtain previous mammograms held at another unit or hospital.

4.6.1.4 Clinical re-call

Clinical re-calls are brought to the attention of the radiologist by the radiographer. It is the responsibility of the radiologist to assess the significance of these findings and to ensure that appropriate further assessment takes place.

4.6.1.5 Double reading

Double reading will be performed on all mammograms at both initial and subsequent rounds. Units may adopt one of the following three methods for deciding if a woman is re-called for assessment:

- The woman is re-called if either of the two readers re-calls her to gain the maximum possible increase in sensitivity (once the decrease in specificity is not too high).
- The practice of arbitration by a third screening radiologist may be used in cases of discordant double reading. Overall re-call rates will be kept to the standards described previously.
- A consensus decision is made by two or more radiologists.

4.6.1.6 Categorisation of results

For audit purposes, radiological findings will be categorised as follows:

- R1 – Normal/benign
- R2 – A discrete lesion having benign characteristics
- R3 – An abnormality present of indeterminate significance but probably benign
- R4 – An abnormality present of indeterminate significance but probably malignant
- R5 – Malignant features

Along with the clinical director, the radiologist is responsible for ensuring that:

- Methods are in place to accurately record the results of screen reading
- The results of the mammogram are conveyed to the woman in writing in a timely manner (within three weeks)
- Any further assessment required is instigated without delay
- Methods are in place to ensure that all studies are accounted for at the end of each reading session

4.6.2 Assessment procedures and pre-operative diagnosis

Women who have an abnormality on screening mammography that requires further evaluation will be re-called to an assessment clinic for triple assessment. Women who are re-called will understandably be very anxious and will be treated in a timely manner in a sympathetic and professional environment. The aim of the process is to establish a diagnosis of malignant or benign pathology in order to plan further treatment or to return the woman to routine re-call.

Assessment clinics will take place on site in each of the static screening units. A radiologist who is fully trained and experienced in breast screening should lead the clinics. The clinics will be attended by a radiologist, a breast surgeon, a breast care nurse and appropriate radiography staff. Clerical support will be provided to ensure that each decision made in relation to a woman is recorded. The process of triple assessment will involve further imaging, including supplementary mammographic views and ultrasound, clinical examination and, where indicated, core needle biopsy for histology. The facilities and skills required to perform image-guided procedures will be available. All image-guided sampling techniques (stereotactic and ultrasound-guided) should have imaging performed to confirm the precise sampling site. In suspected cases of cancer, the radiologist will assess the axilla using ultrasound in an effort to determine if there are metastatic lymph nodes. Ultrasound-guided FNAC or core biopsy of suspicious nodes are performed, where possible, for further assessment. Using the triple assessment approach, equal weighting will be given to clinical, radiological and pathological opinion.

The radiologist will aim to arrive at a clear and definitive decision at assessment regarding the nature of the screen-detected abnormality and will ensure that the woman understands fully the implications of the investigations performed. If there is no significant abnormality on further assessment, the outcome of the assessment will be categorised as R1 or R2 and the woman will be returned to routine re-call. If a confirmed abnormality requires a tissue diagnosis, the outcome of assessment will be categorised as R3, R4 or R5 and needle biopsy will be performed at the same visit. Unless the radiologist is very experienced, it is advisable that all solid lesions on ultrasound be biopsied as it is often not possible to reliably differentiate between benign and malignant lesions on the basis of sonographic appearances alone. The results of all three components of the woman's assessment will then be discussed at the on-site, weekly multidisciplinary meeting.

A multidisciplinary meeting/case conference will take place on a regular basis at each static unit or associated host hospital. Ideally, the meeting will be attended by all radiologists, pathologists, surgeons, radiographers and breast care nurses involved in the programme. Radiation oncologists and medical oncologists involved in the programme may be involved in the medical review of cases of diagnosed breast cancer. The correlation of clinical, radiological and pathological results will be performed and the outcome documented. Further management should be arranged immediately.

4.7 Interval cancers

Interval cancers are defined as breast cancers that arise after a negative screening episode (which may include assessment) and before the next scheduled screening round. While interval cancers are an inevitable part of any screening programme, their number should be kept to a minimum. A high proportion of interval cancers will reduce the likelihood of achieving a reduction in mortality in the population being screened; therefore, to monitor the performance of the programme, it is fundamentally important that the number of interval cancers be accurately recorded. As the number of interval cancers occurring in individual screening units each year is relatively small, individual unit interval cancer data are only likely to be meaningful when several years' data are available. However, individual units will actively continue to participate in the collection and collation of interval cancer data. See section 8.5.3 for more information.

The review and sub-classification of interval cancers is an essential part of continuing education for screening radiologists and will be included as part of routine radiological audit. Sub-classifying interval cancers is the responsibility of screening radiologists and is not part of the routine evaluation of screening performance.

Radiologists will ensure that mechanisms are in place to capture all available interval cancer data in their area. Clinicians who manage patients with breast problems are encouraged to inform their local unit of all breast cancers that they diagnose in patients over 50 years. Radiologists will encourage clinicians to request mammography on all patients with possible screening interval breast cancers.

The review of imaging features will identify a proportion of interval cancers where earlier diagnosis may have been achievable (false negative interval cancers and minimal signs). Radiologists in BreastCheck will establish forums for reviewing and sub-classifying interval cancers. It is recommended that all interval cancers be reviewed by a minimum of two radiologists. Where there is disagreement on classification, the opinion of a third independent radiologist should be sought. The initial and any subsequent screening films/images will first be reviewed sequentially without sight of any mammogram taken at the time of diagnosis (blind review). A decision in relation to the presence of any significant mammographic signs will be made and documented. The screening mammograms are then reviewed again with knowledge (informed review) of the site of the interval cancer. The interval cancer will then be sub-classified into one of the following five categories:

- 1. Unclassified:** Mammography not performed at the time of diagnosis. Presence of mammographic signs of malignancy cannot be confirmed.
- 2. True interval cancer:** The screening mammograms are normal while the mammogram performed at the time of diagnosis clearly demonstrates features of malignancy.
- 3. Occult interval cancer:** Neither the screening mammogram nor the mammogram performed at the time of diagnosis shows features of malignancy.
- 4. False negative interval cancer:** An abnormality on blind review is present on the screening mammogram at the site of the malignancy demonstrated on the mammogram at the time of diagnosis. These signs would normally be considered sufficient to re-call the woman for further assessment. False negative cancers should not comprise greater than 20 per cent of the total number of interval cancers.

5. Interval cancer with minimal signs: These may be of two types:

- Identified on blind review: On blind review of the screening mammogram there is an abnormality present at the site of the malignancy demonstrated on the mammogram performed at the time of diagnosis. However, according to current radiological practice, these signs would not be considered sufficient to re-call the woman for further assessment.
- Identified on retrospective review: On informed review of the screening mammogram, a subtle sign is recognised at the site where a cancer developed.

In a screening programme, the proportion of occult interval cancers is largely dependent on the age of the population screened and the proportion of true interval cancers is primarily decided by the screening interval. Both types of interval cancer are independent of radiological performance. However, false negative interval cancers and cancers with minimal signs are of particular relevance to radiologists as these are the sub-groups that radiological practice can directly influence.

Once a cancer has been confirmed and classified as an interval cancer, the woman's name, date of birth and screening number will be supplied to the Programme Evaluation Unit (PEU) to enable accurate information to be exchanged with the National Cancer Registry. If a woman is diagnosed with an interval cancer and seeks a review or discussion regarding her case, this will be facilitated through the clinical director of the unit concerned.

Breast cancers arising in women who have previously attended for screening but failed to attend the invitation for screening immediately prior to diagnosis are classified as cancers in lapsed attenders and not as interval cancers.

4.8 Quality assurance: the organisation

4.8.1 QA Committee

(Refer to section 1.7.1 in chapter 1 for more detail.)

4.8.1.1 Mono-specialty Radiology QA Group

Reporting to the QA Committee, the Mono-specialty Radiology QA Group includes all the radiologists employed by BreastCheck. Meetings take place at least once a year to discuss QA issues, review QA standards and formulate changes and recommendations, as appropriate. The QA radiologist chairs the group on a three-yearly rotational basis and organises and minutes the meetings.

The following quality standards are reviewed by the group:

- Breast cancer detection rates, including DCIS
- Tumour size
- Re-call rates
- Image-guided procedure rates and accuracy
- Benign surgical biopsy rates
- Pre-operative diagnosis rates

- Interval cancers
- The continuing medical education of the radiologists

Any quality deficiency or variation in QA between centres will be monitored, and necessary remedial action will be taken.

4.8.1.2 Role of the clinical director in QA

The lead radiologist in each unit will be the clinical director. The clinical director is responsible for ensuring the quality of all aspects of the radiological process, which includes ensuring that all of the clinical parameters in breast cancer screening are achieved. Specific responsibilities include:

- Ensuring that the radiologists involved in the screening programme meet the required quality standards in mammography, diagnostic ultrasound, fine needle aspiration and core biopsy
- Organising and chairing the weekly multidisciplinary conferences
- Collating, managing and distributing reports relating to all aspects of quality data to the Head, National Screening Service and QA Committee
- With the radiography services manager, having an input into the application of breast screening radiographic standards
- Ensuring that adequate clinical facilities are available to achieve the target of two-year interval screening
- Ensuring that the Head, National Screening Service and BreastCheck Executive Management Team are informed of initiatives and developments that will improve the programme

4.8.2 Individual QA radiology

If required, data will be collected and made available. QA parameters can be monitored for each screening radiologist. Examples include:

- Number of screens read as first and second reader
- Number of screens with single reading
- Number of re-calls as first reader
- Number of screens re-called by second reader and not by first reader
- Percentage of re-calls (whether first or second) overridden by third radiologist
- Number of women actually re-called after arbitration double reading
- Number of invasive cancers confirmed
- Number of cancers <15mm
- Number of cancers ≤10mm
- Number of patients with DCIS
- Number of women assessed by each individual radiologist

4.9 Professional requirements and appointment criteria

The guidelines for appointing consultant radiologists to BreastCheck will be those recognised by Comhairle na hOispidéal.

Each screening radiologist will:

- Be medically qualified and registered to practise in Ireland
- Have had specific training in both diagnostic (symptomatic) mammography and screening mammography
- Participate in a continuing medical education programme to an acceptable level and in any relevant external quality assessment scheme
- Have a level of expertise in breast imaging that is acceptable to the Mono-specialty Radiology QA Group. This training may be achieved on a proleptic basis, with agreement, where a successful candidate falls short of these requirements.
- Undertake to read a minimum of 5,000 screening cases per year in centralised programmes

In addition, each radiologist will:

- Be involved with assessment as well as basic screening
- Have access to pathology and surgical follow-up data
- Attend multidisciplinary review and clinical management meetings
- Be involved with symptomatic breast work, ideally having skill in clinical examination of the breast
- Be fully experienced in all assessment techniques, including ultrasound, FNAC and core biopsy

4.10 Breast screening trials and research

All BreastCheck radiologists will be encouraged and supported to participate in research at all levels.

The core of research in mammography is to establish better criteria for the early detection of cancer and to eliminate false negative interval cancers. The objective of quality-assured mammography is to minimise the number of women being referred for surgical or open biopsies. The recognition that adjunctive techniques can play a major role in defining the importance of subtle parenchymal changes on routine mammography must be part of the screening process.

While research will be encouraged and monitored, ethical approval for planned research must first be granted from the ethics committees of the relevant institutions.

5

Quality assurance in pathology

5. Quality assurance in pathology

5.1 Introduction

The guidelines in this chapter are based on best practice protocols; they are informed by the experience of screening programmes in the United Kingdom (UK)¹, Sweden and the Netherlands and by our own experience in BreastCheck – The National Breast Screening Programme². The guidelines are also informed by the experience of pathologists receiving breast pathology specimens in the United States (US).³

As part of the triple assessment approach, the histopathologist plays a key role in the non-operative assessment and diagnosis of mammographic screen-detected lesions.⁴ The definitive diagnosis of breast cancer is almost always made by the pathologist.

A detailed examination of operative excision specimens provides information on critical pathological parameters used to predict prognosis.¹ Specific predictive testing determines the likely response to therapeutic agents and guides further patient management.⁵

Specimens derived from mammographically screened patients often differ from those taken from symptomatic patients.¹ The differences relate primarily to (a) the handling of specimens in the laboratory and (b) the difficulties in evaluating borderline lesions that are more common in screened women.

Information derived from the pathologic evaluation of breast screening specimens also serves to audit aspects of the breast screening radiology and surgical services and permits continual evaluation of the efficacy of the screening programme with particular reference to the detected percentage of in situ carcinoma and invasive tumours less than 15mm in diameter.

Close liaison between the histopathologist, radiologist and clinician is integral to breast screening, which is the paradigm of multidisciplinary medicine. Reporting and documenting key data consistently is central to the provision of a clinically relevant breast screening pathology service that is regulated by internal and external quality assurance.⁴

5.2 QA standards

The objectives for the pathology service are:

- To provide a high-quality, efficient and safe non-operative diagnostic service to maximise the non-operative cancer diagnosis rate and minimise the number of unnecessary open biopsies
- To ensure the accurate identification and pathological characterisation of lesions producing mammographic abnormalities
- To promote consistency of diagnostic categorisation
- To standardise and enhance the quality and consistency of prognostic information in pathology reports

5.2.1 Non-operative diagnosis: QA measures for cytology and needle core biopsy

According to UK guidelines^{1,3}, QA outcome measures for cytology and needle core biopsy are defined as follows:

- **Absolute sensitivity**
The number of carcinomas diagnosed as such (C5 or B5) expressed as a percentage of the total number of carcinomas sampled
- **Complete sensitivity**
The number of carcinomas that were not definitely negative or inadequate on fine needle aspiration cytology (FNAC) or core expressed as a percentage of the total number of carcinomas
- **Specificity (full)**
The number of correctly identified benign lesions (the number of C2 or B2 results minus the number of false negatives) expressed as a percentage of the total number of benign lesions sampled
- **Positive predictive value of a C5/B5 diagnosis**
The number of correctly identified cancers (number of C5 or B5 results minus the number of false positive results) expressed as a percentage of the total number of positive results (C5 or B5)
- **Positive predictive value of a C4/B4 diagnosis**
The number of cancers identified as suspicious (number of C4 or B4 results minus the number of false suspicious results) expressed as a percentage of the total number of suspicious results (C4 or B4)
- **Positive predictive value of a C3/B3 diagnosis**
The number of cancers identified as atypia (number of C3 or B3 results minus the number of benign atypical results) expressed as a percentage of the total number of atypical results (C3 or B3)
- **False negative case**
A lesion that turns out (within a period of two years) to be carcinoma despite a negative cytology or core result. (This will by necessity include some patients in whom an area different from the lesion was sampled but who present with an interval cancer.)
- **False positive case**
A lesion that was given a C5 or B5 result and that turns out at open surgery to be a benign lesion
- **False negative rate**
The number of false negative results expressed as a percentage of the total number of carcinomas sampled
- **False positive rate**
The number of false positive results expressed as a percentage of the total number of carcinomas sampled
- **Inadequate rate for FNAC**
The number of inadequate FNAC specimens expressed as a percentage of the total number of cases aspirated

5.2.2 Achievement methods

- Adherence to non-operative guidelines
- Multidisciplinary team review
- Participation in external quality assurance schemes
- Technical FNAC expertise
- Medical FNAC expertise

5.2.3 Operative specimens: QA standards for diagnosis and prognostication

Objectives	Outcome measurements	Targets	Achievement methods
1. Lesion characterisation	% specimens with mammographic lesion not identified histologically	Minimum <1% Achievable 0%	<ul style="list-style-type: none"> • Specimen x-ray • Dissection protocols • Slice x-ray • Adequate tissue sampling • Correlation of radiology and pathology findings
2. Consistency in diagnosis (UK NHS EQA scheme diagnostic consistency measurements)	Invasive carcinoma Ductal carcinoma in situ including microinvasion	Minimal k = 0.8 Achievable 0.9 Minimal k = 0.7 Achievable 0.8	<ul style="list-style-type: none"> • High-quality sections • Technical EQA scheme • Standardised terminology • Dissection protocols • Medical EQA scheme • Continuing medical education – breast pathology • Consultation process • R&D – borderline lesions
3. Standardisation and consistency of prognostic information	% invasive carcinomas graded and sized Consistency of tumour grading EQA scheme Consistency of tumour sizing EQA scheme +/-3mm of median	Minimal >90% Achievable >99% Minimal k = 0.5 Achievable 0.7 Minimal = 88% Achievable 90%	<ul style="list-style-type: none"> • Dissection protocols • Standardised approach • Grading criteria • Guidance on tumour size • Medical EQA scheme • Consultation process

5.3 Managing QA

5.3.1 Internal QA

- Each laboratory involved in breast screening should be either accredited or seeking accreditation.
- The lead histopathologist will have overall responsibility for the management of the pathology component of the screening programme.
- The histopathologist will be a member of the multidisciplinary team and will participate in regular case management meetings.
- All histopathologists with responsibility for reporting screening specimens will be appropriately trained.
- It is recommended that all histopathologists involved in breast screening reporting attend the multidisciplinary meeting on a regular basis.
- Histopathologists with responsibility for reporting screening specimens should participate in an external slide scheme (see below).
- All laboratory procedures will be well documented and reviewed regularly (e.g. annually).
- Histopathologists should have access to specimen radiography.
- Histopathologists should have adequate technical and secretarial support.
- The pathology service should meet internationally agreed standards.
- Radiologists and surgeons should be satisfied with the quality and delivery of the pathology service.
- Liaison between pathology laboratories and the National Cancer Registry will be fostered.

5.3.2 External QA

- External review: To ensure that performance meets agreed standards, pathology departments involved in breast screening should be visited periodically by a QA team, which may inspect local facilities. The QA team may include overseas experts in the management of pathology QA (in breast screening). The outcome of these visits should be reported to BreastCheck's QA Committee, the host hospital, the health authorities and the national co-ordinating team. Appropriate action will be taken where performance is deemed to be inadequate.
- Interdepartmental review meeting: Pathology screening units will monitor and compare their QA activities regularly.

- Histopathology EQA slide scheme: Histopathologists with responsibility for reporting breast screening (BreastCheck) specimens currently participate in the British National Health Service (NHS) EQA histopathology slide scheme. This involves reviewing a set of 15 slides twice yearly to evaluate the extent to which diagnosis and prognostication are consistent. Each pathologist is given a score to indicate their measure of agreement with the majority opinion for diagnosis. Detailed results of prognostic/predictive parameter assessment are provided, and the participant can evaluate their performance against the majority opinion.
- Technical EQA scheme: Each laboratory should participate in the immunohistochemistry EQA scheme.

5.3.3 Data collection

- The lead histopathologist in each breast screening unit will have overall responsibility for pathology data collection and will monitor problems associated with inconsistent histological and cytological data gathering and recording.
- The pathology data sheets will be reviewed at regular intervals and modified as required. This should be done in consultation with other groups, particularly with the Programme Evaluation Unit (PEU).

5.3.4 Education and training

- BreastCheck is committed to continuing medical education and continuing professional development for all employees. Consultant histopathologists and technologists involved in the delivery of the pathology service are encouraged and required to identify and fulfil their educational needs on an ongoing basis.
- The programme will develop educational programmes for employees, and local, national and international experts will be involved in delivering such programmes.
- It is recommended that a meeting of participating pathologists take place once or twice annually to review and discuss the results of the EQA slide schemes and to evaluate and, if necessary, modify aspects of the breast screening pathology service.
- Histopathologists will be familiar with the QA parameters of the entire programme (e.g., those relevant to surgery and radiology).
- There should be close links with the Faculty of Pathology, the Royal College of Physicians of Ireland, the Irish Society for Clinical Cytology and the Academy of Medical Laboratory Science.
- Novel approaches to help all participants keep up to date will be considered, including the use of multimedia techniques and telepathology.

5.3.5 Research and development

Laboratories involved in the programme are encouraged to carry out their own research, apply for funding from appropriate agencies and foster a spirit of co-operation and collaboration with other medical and scientific departments.

5.3.6 Mono-specialty Pathology QA Group

Terms of reference:

- To recommend minimum acceptable standards and to guide and advise on the pathological examination of breast tissue
- To consider ways of achieving objectives and to identify resource implications

Key functions:

- Advise the screening programme on pathology-related issues.
- Provide support and information for pathologists who are not specifically involved in the screening programme.
- Identify and promote the educational needs of histopathologists and medical scientists involved in the screening programme.
- Monitor the data provided by histopathologists.
- Review the pathology information system.
- Monitor the consistency of pathology reporting in BreastCheck.
- Monitor the performance of the non-operative diagnostic service.
- Facilitate the exchange of information between histopathologists and the National Cancer Registry.
- Facilitate the exchange of information and pathological material between pathologists and the wider research community.

5.4 Non-operative diagnosis

Triple assessment performed on women judged to have an abnormality on the basic screen aims to achieve a diagnosis by combining the results of further imaging with clinical examination and the use of FNAC or needle core biopsy (NCB). This approach to diagnosis minimises the need for open surgery in women with benign breast disease and permits definitive one-stage surgery in women with malignant disease. The proportion of screen-detected breast cancer with a pre-operative diagnosis of malignancy (core biopsy reported as definitely malignant) should be ≥ 90 per cent. Non-operative diagnosis requires good communication between the clinician, radiologist and histopathologist. In particular, the results of FNAC/NCB must be interpreted in conjunction with the radiological and clinical findings and never in isolation.

5.4.1 General points

5.4.1.1 Specimen details

Each specimen should be accompanied by a fully completed request form. The following details should be recorded in the final pathology report:

- Specimen side: left or right
- Specimen type: FNAC or NCB
- Image: guided or freehand
- Imaging technique: ultrasound or stereotaxis
- Radiological assessment of lesion, including R code

5.4.1.2 Specimen x-ray

NCBs carried out for calcification may, if required, be x-rayed in the laboratory.

5.4.2 Fine needle aspiration cytology (FNAC)

FNAC may be image-guided using ultrasound or stereotaxis or freehand if the lesion is palpable. Samples are prepared using the direct smear, cytospin or thin layer technique. Direct smears are air-dried for May Grünwald Giemsa (MGG)/Diff Quik (DQ) and alcohol fixed for Papanicolaou (Pap) or haematoxylin and eosin (H&E) staining. Cytospin and thin layer preparations are stained with Pap and/or H&E.

When interpreting and reporting on FNAC specimens, the specimens are assigned to one of the following five categories as defined by the UK NHS BSP guidelines.⁴

C1: Non-diagnostic/inadequate

The specimen is poorly cellular (less than five groups of epithelial cells) or unsuitable for assessment due to drying, crush or spreading artefact or to contamination by blood. A C1 diagnosis should not be taken as reassurance that a lesion is benign.

C2: Benign

The sample is adequate (at least five groups of epithelial cells) and displays the features of benign breast change. This usually takes the form of regular monolayers of benign ductal epithelial cells with a background population of individual and paired stromal nuclei. The exact composition of the aspirate depends on the nature of the lesion. Apocrine cells and foamy macrophages are frequent findings in aspirates from cystic change. Fibroadenomas produce cellular aspirates containing connective tissue fragments and large numbers of stromal nuclei. In certain settings, an aspirate that does not contain epithelial cells, such as cyst fluid and aspirates from lesions suggestive of fat necrosis or abscess, may be reported as C2.

Interpretation of benign cytological findings highlights the importance of triple assessment and multidisciplinary review. A non-specific benign picture may be inappropriate for a discrete lesion as the sample may have originated from benign breast tissue adjacent to rather than from within the lesion. A specific benign diagnosis (e.g., fibroadenoma, fat necrosis, intramammary lymph node) should be made only if the typical cytological features are present.

C3: Atypia, probably benign

The cytological features suggest a benign process or lesion but some atypical features, such as increased cellularity, loss of cell cohesion, nuclear pleomorphism or nucleoli, are present. The identification of papillary structures warrants a C3 diagnosis at least and, depending on the degree of nuclear atypia, may be reported as C4. C3 lesions require further investigation.

C4: Suspicious, probably malignant

The appearances are suspicious of malignancy but there is insufficient evidence for a firm diagnosis. The specimen may be poorly cellular with only a small number of malignant cells present or may include large numbers of benign cells in addition to malignant cells. A single population of small cells with only mild nuclear atypia may be seen in lobular or tubular carcinoma. C4 lesions require further investigation.

C5: Malignant

The specimen displays unequivocal cytological evidence of malignancy. Typically the aspirate is cellular and is characterised by a single population of cells with nuclear pleomorphism, irregular chromatin and the presence of nucleoli. There is loss of cell cohesion and dispersal of malignant cells. Necrosis may be seen, more commonly in high-grade tumours. It is not possible to accurately differentiate between in situ and invasive carcinoma on FNAC alone.

Certain conditions (e.g., fibroadenoma, silicone granuloma, apocrine change, radiotherapy change) may produce a cytological picture resembling C5 leading to a false positive diagnosis of malignancy. Therapeutic surgery must never be carried out on the basis of a C5 diagnosis in the absence of radiological and/or clinical evidence of malignancy.

5.4.3 Needle core biopsy

NCB is image-guided by the use of ultrasound or stereotaxis. While acknowledging the utility of FNAC in the evaluation of axillary lymph nodes, NCB is the preferred method of non-operative diagnosis of primary breast lesions in the programme. Sensitivity is related to needle size and to the number of samples taken. NCBs for evaluating microcalcification are x-rayed to ensure that the sample is representative. Specimens are formalin fixed and paraffin embedded, and sections are cut and stained with H&E. It is usual to examine two or three levels and to retain parallel spare sections for immunohistochemistry. Further levels may be necessary to detect microcalcification. Cytokeratin immunohistochemistry is useful in the investigation of paucicellular lobular carcinoma. Myoepithelial cell markers (such as p63) assist with distinguishing radial scar from tubular carcinoma and sclerosing adenosis from invasive carcinoma.^{6,7} Estrogen receptor (ER), progesterone receptor (PR) and HER-2/neu status can usually be determined on NCB but may need to be repeated on excision specimens as per guidelines.

When interpreting and reporting on NCB specimens, specimens are assigned to one of the following five categories as defined by the UK NHS BSP guidelines.⁴

B1: Normal tissue

This indicates a core of normal tissue that may comprise glandular breast parenchyma, stroma, adipose or lymphoid tissue. Correlation with the radiological and clinical findings is necessary to determine whether the presence of normal tissue accounts for the screen-detected abnormality. A specimen of normal tissue from a patient who has a stellate lesion on mammogram would suggest that the lesion was not sampled. In contrast, normal-appearing tissue would be expected from lesions such as lipoma, involutional change, hamartoma and intramammary lymph node. The B1 category is also used for specimens that are considered to be unsatisfactory for histological assessment. The reason such specimens are deemed unsatisfactory is indicated.

B2: Benign

There is evidence of a benign process or lesion, such as cystic change, ductectasia, fat necrosis, sclerosing adenosis or fibroadenoma. NCBs performed for calcification are examined with polarised light for the detection of calcium oxalate crystals (Weddelite), which are not easily seen on H&E preparations.

An attempt should be made to correlate the amount of calcification on H&E sections and NCB specimen x-ray and if notably discrepant, additional levels examined. The pathological findings must account for the radiological abnormality, and multidisciplinary review is essential before the patient is reassured.

B3: Lesions of uncertain malignant potential

This category is used for benign and atypical lesions that may be associated with the presence of breast cancer or the risk of developing it.

Radial scar/complex sclerosing lesions are associated with co-existent malignancy in up to 25 per cent of cases, and apparently benign papillary lesions on core biopsy may harbour foci of ductal carcinoma in situ (DCIS) when the entire lesion is examined.^{6,7}

In situ lobular neoplasia (atypical lobular hyperplasia [ALH] and lobular carcinoma in situ [LCIS]) is a risk factor for malignancy bilaterally in the breasts and does not in itself present a mammographic abnormality.⁸ Careful radiological and pathological correlation is needed to determine whether the targeted lesion was identified or whether further investigation (including excisional biopsy) is merited.⁹

An atypical intraductal epithelial proliferation on NCB may display some but not all of the features of DCIS. Taking account of the strict histological requirements for a diagnosis of DCIS, these proliferations are categorised as atypical intraductal epithelial proliferation. Up to 50 per cent of lesions diagnosed as atypical on NCB prove to be malignant on subsequent excision. Depending on the degree of change, atypia may be assigned to either the B3 or B4 category.⁷

Fibro-epithelial lesions with features suggestive of phyllodes tumour (e.g., increased stromal cellularity, stromal overgrowth, stromal mitotic activity) are also assigned to the B3 category, as are mucocoele-like lesions since paucicellular mucinous carcinoma cannot be reliably excluded on NCB.⁷ Columnar cell lesions (CCLs) with atypia (flat epithelia atypia [FEA]) also merit a B3 diagnosis.¹⁰

B3 lesions require further evaluation, usually surgical excision, for complete histological examination. Provided the lesion has been thoroughly sampled on NCB, minor degrees of atypia (microfocal) and small papillomata may be reported as B2.

B4: Suspicious of malignancy

The appearances are strongly suspicious of malignancy but there is insufficient abnormality for a firm diagnosis or interpretation is compromised by poor fixation or crush artefact. Small, detached fragments of invasive tumour in the presence of otherwise benign breast tissue are best assigned to this category.

A diagnosis of DCIS is often suspected but cannot be confirmed due to the limited tissue available for study, leading to a B4 diagnosis. B4 lesions require further investigation, either by repeat NCB or open surgical excision.

B5: Malignant

There is unequivocal evidence of malignancy, either in situ (ductal) or invasive. Due to sampling error, approximately 20 per cent of lesions reported as in situ carcinoma on NCB will have accompanying invasion in the resected specimen, although it is argued that this difficulty may be partly addressed by large core biopsy techniques (e.g. mammotome). DCIS is sub-classified as B5a and invasive tumours as B5b.

In situ neoplasia showing ambiguous features (i.e., mixed ductal and lobular) and/or pleomorphic LCIS are best categorised as B5a, although E-cadherin staining (or P120 catenin) may assist the distinction from DCIS.¹¹

The B5 category is also appropriate for other malignant lesions, such as malignant phyllodes tumour, lymphoma and metastatic melanoma. It is important to specify the nature of these lesions for therapeutic reasons. If there is any doubt, further tissue should be requested for additional studies.

Certain histological conditions may mimic malignancy and should be borne in mind when assessing NCBs. The appropriate identification of sclerosing adenosis and radial scar may be assisted by the use of myoepithelial cell markers such as p63 stain. Misdiagnosis of radiotherapy change can be avoided by obtaining an adequate clinical history. Spindle cell lesions are difficult to assess on NCB. Immunohistochemistry for cytokeratins may be useful to exclude metaplastic carcinoma.¹² If in doubt of the diagnosis, an excision biopsy is advisable.

5.4.4 Hormone receptor studies

Hormone receptor status (ER, PR) and HER-2/neu can be determined on the NCB specimen. If there is insufficient tissue in the NCB or if invasive carcinoma is subsequently detected in the surgical excision specimen following an NCB diagnosis of DCIS, the studies are repeated on tissue from the invasive tumour. Recent guidelines indicate that HER-2 status should also be reassessed on the excised specimen in grade 3 invasive tumours that were HER-2 negative on core biopsy.⁵

5.5 Operative specimens: macroscopic examination

5.5.1 General points^{1, 13, 14}

5.5.1.1 Specimen details

Received specimens should be orientated with clips and/or sutures according to local practice and accompanied by a fully completed request form. The specimen side, left or right, and the type of specimen (e.g., localisation biopsy, diagnostic biopsy, wide local excision (WLE), re-excised margins, mastectomy, sentinel lymph node (SLN) biopsy, axillary lymph nodes) are recorded at the beginning of the macroscopic description.

5.5.1.2 Specimen dimensions and weight

All specimens are measured in three dimensions. Diagnostic biopsy, WLE and re-excision specimens are also weighed. A diagnostic biopsy should weigh less than 30 grams. It is not necessary to weigh mastectomy specimens.

5.5.1.3 Specimen radiography

Specimens containing mammographically detected abnormalities are x-rayed following surgery to ensure that the abnormality has been removed. The x-ray may be available to the laboratory with the specimen to enable the histopathologist to correlate the radiological and macroscopic findings. If the specimen x-ray is not available, whole specimen radiography may be performed in the pathology department. Specimen slice x-ray is also carried out if the lesion is not visible macroscopically and for the assessment of calcification in which there may be little or no discernible gross abnormality. Maintaining slice orientation is critical in the assessment of lesion size and margin identification. Block selection is directed by the macroscopic and x-ray findings. Documenting the blocks sampled on the specimen slice x-rays provides a useful adjunct to the recorded block list.

5.5.1.4 Margin marking

The specimen margins are inked prior to dissection to facilitate microscopic assessment of excision status. A variety of marking compounds is available (e.g., India ink and Alcian Blue). Pre-treating the specimen with absolute alcohol enhances the adherence of India ink, and immersing the inked specimen in acetic acid or Bouin's fluid expedites the drying process. Differential inking may be employed to assist the identification of specific margins.¹⁵

5.5.1.5 Lesion size

Invasive carcinoma is usually visible macroscopically, which permits gross assessment of tumour size. This is subsequently confirmed microscopically as macroscopic examination does not always provide an accurate assessment of tumour size.

The presence and extent of DCIS are frequently invisible to the naked eye. The assessment of DCIS is greatly assisted by slice x-ray. Specimens containing DCIS are sliced at approximately 5mm intervals, usually perpendicular to the long axis of the specimen. The slices are carefully placed sequentially on an x-ray plate in a manner that maintains orientation. Block selection is guided by the presence of calcification on slice x-ray and any macroscopic changes. It is recommended that blocks are also taken from slices on either side of calcification as the latter frequently under-represents the extent of DCIS. The extent of DCIS is calculated by multiplying the slice thickness by the number of consecutive slices shown to contain DCIS microscopically.

5.5.1.6 Distance from margins

The distance of the abnormality (tumour/calcification) from the margins is noted and confirmed microscopically. It is important to differentiate between the radial and anterior/posterior margins. A positive radial margin is usually amenable to surgical treatment in the first instance. The posterior margin of a therapeutic specimen would typically include the pectoral fascia, and further surgery would not be appropriate for involvement of this margin. The anterior margin is often subcutaneous and not amenable to further surgical excision. It is also useful to specify individual radial margins as the surgeon may opt to confine re-excision to the involved margin. Margins less than 2mm are usually documented with their precise dimension while those greater than or equal to 2mm can be stated as such.

5.5.1.7 Axillary lymph nodes

Depending on local practice, axillary lymph nodes may be received attached to a WLE or mastectomy, as a separate single specimen or divided into individual levels. Axillary lymph nodes may be dissected in the fresh or fixed state. Clearing the fat with alcohol may increase the lymph node yield but is time-consuming and is not common practice. Using a combination of palpation and slicing, the lymph nodes are removed from the fat. Small deposits of tumour are not apparent macroscopically, and it is advisable to submit all lymph nodes in their entirety for histological examination.

5.5.1.8 Sentinel lymph node (SLN)

SLN biopsy is accepted as an alternative to full axillary node surgery as a staging procedure for breast cancer.¹⁶ The hypothesis underlying the SLN concept is that tumour cells drain into one or more SLNs before spreading to other nodes. A negative SLN should imply that the remaining lymph nodes are also negative. The SLN is localised using vital dye and/or radioactive tracer and removed for examination. The SLN is divided into two or more pieces at 2mm intervals. The current accepted protocol for SLN examination requires that the SLN is processed in its entirety for histological examination, i.e., all pieces must be processed for examination. Additional H&E levels or immunohistochemical studies may detect higher rates of isolated tumour cells or micrometastases. However, the clinical impact on outcome of these small metastases is minimal.¹⁷ The role of intra-operative assessment and of SLN biopsy post-neoadjuvant therapy in SLN biopsy have yet to be defined.

5.5.1.9 Receptor studies

ER and PR status are determined by immunohistochemistry. HER-2/neu status may be determined by immunohistochemistry and fluorescent in situ hybridisation (FISH) or dual-colour dual-hapten chromogenic in situ hybridisation (D-DISH).⁵ Hormone receptor and HER-2/neu status are assessed on NCBs (see section 5.4.4).

5.5.2 Specific specimen types: approach to examination

5.5.2.1 Diagnostic

Needle localisation biopsy

Surgical biopsy is performed in those patients in whom non-operative techniques fail to provide a firm diagnosis. Radiographic needle localisation is used to assist the removal of impalpable lesions.

Specimen x-ray

Specimen x-ray is performed following surgery to ensure that the lesion has been removed. The specimen should be received in the laboratory intact and fresh and accompanied by a specimen x-ray or with access to digital images taken in theatre. Specimen x-ray may also be performed in the laboratory.

Margin marking

Although needle localisation biopsy is a diagnostic and not a therapeutic procedure, specimen margins are marked to enable the histopathologist to comment on margin status in cases of malignant disease. This facilitates the surgeon's discussions with the patient, who may be advised that further therapeutic surgery is necessary although there may be no residual tumour in the resected specimen. A variety of marking compounds is available. Pre-treatment of the specimen with alcohol enhances ink adherence, and immersion in acetic acid or Bouin's fluid facilitates the drying process (see section 5.5.1.4). Differential inking may be employed to assist the identification of specific margins.

Tissue for research and fixation

If the biopsy has been performed for assessment of a mass lesion/density, it may be appropriate to incise the specimen to assist fixation. If appropriate consent and ethical approval have been obtained and depending on the size of the lesion, a small piece of tissue may be removed and submitted for research studies. Histological diagnosis must never be compromised, and in cases of doubt, the entire lesion is retained for histology. Biopsies for calcification are best not incised until fully fixed, and all tissue is retained for histology. All biopsies are immersed in formalin for fixation, usually overnight.

Specimen dissection

The specimen is weighed and measured. It is recommended that open diagnostic biopsies weigh less than 30 grams. The specimen is sliced at approximately 5mm intervals, perpendicular to the long axis of the specimen and not necessarily along the needle tract. To facilitate specimen slicing, it may be necessary to remove the needle; depending on the type of needle used, this may be done prior to or during specimen dissection.

Slice x-ray

Specimen slice x-ray is mandatory in biopsies performed for the evaluation of lesions that are not obvious macroscopically and for the assessment of calcification in which there may be little or no discernible gross abnormality. The slices are placed sequentially on an x-ray plate, and the patient's pathology number is entered using radio-opaque letters and numbers or, in the case of digital specimen radiographic image, via the associated software. Care must be taken to maintain orientation if the specimen has been received orientated.

Frozen section

Frozen section (FS) is contra-indicated in routine evaluation of any lesion removed for diagnostic or therapeutic management due to inherent potential specimen (lesion and margin) distortion. Specific individual cases where FS may be relevant are discussed with the histopathologist prior to surgery.

Block selection

Using the x-ray image and macroscopic appearances for guidance, blocks are selected for histological examination. It is recommended that blocks are also taken from slices on either side of calcification as the latter frequently under-represents the extent of DCIS. Marking the block sites on the x-ray (or on a digital image printout) provides a useful adjunct to the recorded block list.

It is not necessary to perform slice x-ray of specimens containing an obvious lesion. The lesion is measured, and the gross characteristics and proximity to margins are recorded. Small lesions can be submitted in their entirety for histological examination. A minimum of three sections should be examined in lesions measuring greater than 20mms. It is usual to examine some macroscopically normal tissue on either side of the lesion. If feasible, specimens removed for assessment of calcifications are examined in their entirety microscopically.

5.5.2.2 Therapeutic

WLE

WLE is intended as a definitive therapeutic procedure, and particular attention is paid to the examination of the surgical excision margins.¹⁸ Specimen x-ray may be used to assist margin assessment intra-operatively. Due to the small size and impalpable nature of many screen-detected tumours, surgical excision may be assisted by needle localisation.

The approach to macroscopic examination described for needle localisation biopsies is also applicable to WLE specimens. If the specimen contains an obvious tumour or if the lesion has been removed previously, it is feasible to leave the specimen intact anteriorly. This helps to maintain orientation and is useful in the event of needing to re-examine the specimen at a later date. In specimens removed for calcification or in which there is no obvious lesion, the slices are separated and their orientation is maintained, and then they are x-rayed. If an open biopsy has already been performed, the biopsy site and any residual tumour are identified and the relationship to the specimen margins documented. Ideally, the orientation of the specimen should be designated by the surgeon with marking sutures.

Block selection is directed by the gross and/or radiological findings as described earlier. Positive margins are a major determinant of local recurrence, and resection margins are thoroughly sampled. Re-excision is carried out when a radial margin is involved, which should be distinguished from

involvement of the posterior margin, where further surgery may be inappropriate. It is also important to specify which radial margin is involved as the surgeon may opt to confine re-excision to that margin.

Cavity biopsies

It is the practice of some surgeons to 'biopsy' the cavity margins when performing WLE. The presence of tumour in these biopsies indicates an inadequate clearance and represents an indication for further surgery. Ideally, these specimens are submitted in their entirety for histological examination.

Re-excision of margin(s) during first WLE

Depending on the specimen x-ray findings or the outcome of intra-operative tumour margin status by the pathologist, the surgeon may 're-excise' one or more margins at the time of WLE. The new margin should be marked with a suture to permit orientation and inking. The specimen is examined for the presence of residual tumour and blocks taken accordingly.

Re-excision following attempted WLE

This may take the form of a repeat WLE ('global re-excision') in which all the tissue around the cavity is removed. This type of specimen is treated in the same way as WLE performed following open diagnostic biopsy. Alternatively, a specific margin may be re-excised. The 'new' margin is identified, and the specimen is examined for the presence of residual tumour and blocks taken accordingly.

Mastectomy

Mastectomy specimens are sliced at approximately 1cm intervals in the fresh state; tissue paper is inserted between the slices to assist fixation. It is usual to leave the skin intact unless slice x-ray is required. The tumour may be contained within the specimen or may have been partly or totally removed during a diagnostic biopsy or attempted WLE. Blocks of tumour, margins, nipple and macroscopically uninvolved breast tissue are examined.

Axillary lymph nodes

Axillary lymph nodes may be received as a separate specimen, divided into individual levels, and are dissected in the fixed state. Using a combination of palpation and slicing, the lymph nodes are removed from the fat. Level II and level III specimens may be small and may all be embedded for histological examination. Small deposits of tumour are not apparent macroscopically, and it is now recognised practice to submit all lymph nodes in their entirety for histological examination.

SLN biopsy

SLN is localised using vital dye and/or radioactive tracer and removed for examination.¹³ Current accepted practice for SLN evaluation involves slicing the lymph node at 2mm intervals and processing it in its entirety (see section 5.5.1.8). Examination of deeper levels, immunohistochemistry and intra-operative assessment are not standard practice in the evaluation of SLN.

5.5.3 Itemised protocols

5.5.3.1 Localisation biopsy/WLE requiring slice x-ray

Slice x-ray is mandatory in the assessment of specimens performed for the evaluation of calcification, excision of DCIS and when there is no lesion visible macroscopically. It is sometimes useful, but not essential, to perform slice x-ray on specimens containing a discrete lesion.

- Check the patient's name, histology number and specimen type and side on the request form and on the specimen container.
- Check details on the specimen x-ray.
- Examine the specimen x-ray.
- Orientate the specimen (if received with orientating sutures/clips).
- Record the weight and dimensions of the specimen. Needle-guided diagnostic biopsies (not WLE specimens) should not exceed 30 grams.
- Mark the resection margins by immersing the specimen in absolute alcohol and drying with tissue paper to promote the retention of ink at the margin surface.
- Differential inking is particularly useful in assisting margin identification in small specimens. Coloured inks may be applied directly to the specimen or superimposed on India ink if necessary.
- Leave to fix overnight.
- Gently remove the guide wire. Take care not to damage the tissue. The wire may be removed before slicing or during slicing, depending on where the tip is positioned.
- Slice the specimen serially at approximately 5mm intervals. Carefully examine the cut surface of each slice. Describe any abnormalities with measurements and proximity to margins, where appropriate.
- Carefully position the slices on the x-ray plate (covered in plastic). X-ray the specimen slices using the Faxitron machine.
- Describe any abnormalities apparent on x-ray (or digital image).

Blocks for histology

- Using the specimen slice x-rays for guidance, select blocks of tissue for processing. In the case of biopsies up to 3cms and where the abnormality cannot be identified on specimen x-ray, all the tissue should be embedded.
- Careful block identification facilitates the histological assessment and permits exact correlation of the histological findings with the mammographic abnormality.
- Should the specimen contain a tumour, include a full cross section in the blocks with margins, specifying the margin position for an orientated specimen.
- Those slices not submitted for histological examination are retained separately so that they can be identified, if necessary, at a later stage.

5.5.3.2 Wide local excision (WLE)

WLE is intended as a definitive therapeutic procedure. Precise examination of the gross specimen and careful block taking is of paramount importance in order to assess the completeness of excision and proximity of the tumour to the individual margins of the specimen.

The tumour may be contained within the specimen when the diagnosis has been established non-operatively by FNAC/NCB. Alternatively, part or all of the tumour may have been removed during a diagnostic biopsy.

Due to the small size and impalpable nature of many screen-detected tumours, surgical excision may be assisted by needle localisation. Depending on the gross findings, some of these specimens may require slice x-ray and are treated as described in the previous protocol.

Fresh WLE

- Check the patient's name, histology number and specimen type and side on the request form and on the specimen container.
- Check details on the specimen x-ray.
- Record the weight and dimensions of the specimen.
- Identify orientating sutures/clips.
- Taking care to avoid skin when present, ink the specimen by immersing it in absolute alcohol and drying it with tissue paper to promote the retention of ink at the margin surface.
- Differential inking is useful in assisting margin identification.
- With the skin surface down, make a few parallel slices into the specimen while leaving the skin intact. If there is no skin attached and if the specimen contains an obvious tumour, it is useful to leave the specimen intact anteriorly to maintain orientation.
- Identify the tumour and record proximity to margins if the surgeon requires intra-operative assessment of margin status.
- If there is tumour in the specimen, a small piece of tumour and some normal tissue may be snap frozen.
- Place some tissue paper between the slices and allow to fix overnight.

Fixed WLE – (no previous surgery) – prepared fresh as above

- Check the patient's name, histology number and specimen type and side on the request form and on the specimen container.
- Check details on the specimen x-ray.
- Record the weight and dimensions of the breast tissue and skin (if present).
- Identify orientating sutures/clips. There may be some skin attached identifying the anterior aspect, and a thin film of fascia or focally attached skeletal muscle may be apparent over the posterior margin.

- Note any abnormalities of the skin.
- The specimen will have been sliced into in the fresh state. Now slice it further.
- Identify, describe and measure the tumour. State its precise location with respect to all margins (superior, inferior, anterior, posterior, medial and lateral).
- Examine the remaining breast tissue and note any abnormalities.

Blocks for histology

- Tumour x 2 or 3. At least one block should contain the tumour in full cross section. If the tumour is large, a composite block may be necessary.
- Depending on the position of the tumour, tumour blocks may include margins.
- All margins
- Remaining breast – representative blocks
- Skin
- Always specify the margins in the block list.
- As required, trim away stray ink, which might be obvious at cut-up but not so obvious in the section and which may lead to unnecessary surgery.

Fixed WLE (tumour partly or totally removed in diagnostic biopsy) – prepared fresh as above

- Check the patient's name, histology number, specimen type and side on the request form and on the specimen container.
- Check details on the specimen x-ray, if received.
- Record the weight and dimensions of the breast tissue and skin (if present).
- Identify orientating sutures/clips. There may be some skin attached identifying the anterior aspect, and a thin film of fascia may be apparent over the posterior margin.
- Note any abnormalities of the skin.
- The specimen will have been sliced into in the fresh state. Now slice it further.
- Identify the biopsy site and note relationship to all margins. Look for residual tumour.
- Examine the remaining breast tissue and note any abnormalities.

Blocks for histology

- Multiple blocks from biopsy site. These blocks may include resection margins depending on the position of the biopsy site.
- All margins
- Remaining breast – representative blocks
- Skin
- Always specify the margins in the block list.
- As required, trim away stray ink, which might be obvious at cut-up but not so obvious in the section and which may lead to unnecessary surgery.

5.5.3.3 Mastectomy

Mastectomy specimens are usually received fresh with lymph nodes sent separately and divided into levels.

A simple mastectomy means that the patient has not had axillary surgery. A mastectomy may be accompanied by an SLN, an axillary sample or a level I or level II dissection. A modified radical mastectomy has a level III axillary clearance and some pectoralis minor muscle attached.

The tumour may be contained within the specimen when the diagnosis has been established non-operatively by FNAC/NCB. Alternatively, part or all of the tumour may have been removed during a diagnostic biopsy or attempted wide excision.

Mastectomy for DCIS

Mastectomy specimens for DCIS may be divided into four or five coronal slices and x-rayed to facilitate identification and blocking of the calcified tissue. It is important to examine the entire lesion microscopically to facilitate the detection of invasive foci.¹⁸

Fresh mastectomy specimen for invasive carcinoma

- Taking care to avoid the skin and axillary tissue when present, ink the specimen by immersing it in absolute alcohol and drying it with tissue paper to promote the retention of ink at the margin surface.
- With the skin surface down, make deep vertical slices through the specimen (each approximately 10mm thick), leaving the skin intact.
- If there is tumour in the specimen, a small piece of tumour and a piece of normal tissue may be snap frozen as per research/biobanking protocols. This will not apply if the tumour has been removed previously.
- Place some tissue paper between the slices and allow to fix overnight.

Fixed mastectomy for invasive carcinoma (no previous surgery) – prepared fresh as above

- Check the patient's name and histology number on the request form and specimen container.
- Orientate the specimen. This is assisted by knowing which breast was removed (recorded on request form) and by the presence of marking sutures.
- Record the dimensions of the skin and underlying breast tissue.
- Note any abnormalities of the skin. Record the location and length of any surgical scars. Examine the nipple.
- The specimen will have been sliced into in the fresh state. Now slice it further.
- Locate, describe and measure the tumour. State its precise location with respect to quadrants and all margins (superior, inferior, anterior, posterior, medial and lateral).
- Examine the remaining breast tissue and note any abnormalities.

Blocks for histology

- Tumour x 2 or 3. At least one block should contain the tumour in full cross section. If the tumour is large, a composite block may be necessary.
- Tumour blocks may include margins depending on the position of the tumour.
- Nearest posterior margin
- Any other margins near the tumour
- Remaining breast – representative sections
- Skin
- Nipple

Fixed mastectomy (tumour partly or totally removed in diagnostic biopsy/WLE) – prepared fresh as above

- Orientate the specimen. This is assisted by knowing which breast was removed (recorded on request form) and by the presence of orientating sutures.
- Record the dimensions of the skin and underlying breast tissue.
- Note any abnormalities of the skin. Record the location and length of any surgical scars. Examine the nipple.
- The specimen will have been sliced into in the fresh state. Now slice it further.
- Identify the biopsy site. Note relationship to all margins. Look for residual tumour.
- Examine the remaining breast tissue and note any abnormalities.

Blocks for histology

- Multiple blocks from biopsy/WLE site
- Nearest posterior margin
- Any other margins near the biopsy site
- Remaining breast – representative sections
- Skin
- Nipple

5.5.3.4 Axillary lymph node clearance

This type of specimen is usually divided into three levels, level I, level II and level III, and each level is submitted in a separately labelled container. There may also be an accompanying SLN.

- Check the patient's name, histology number and specimen type and side on the request form and on the specimen container.
- Axillary tissue should not be inked.
- Record the measurements and weight of the axillary tissue specimens.
- Carefully palpate and dissect out as many lymph nodes as you can find. It may be helpful to use a small pair of scissors for this purpose.
- Finely slice the axillary tissue to locate any further lymph nodes.

Blocks for histology

- All lymph nodes are examined.
- Large lymph nodes are divided into two or more pieces.
- Macroscopically involved lymph nodes may be sampled rather than all embedded.
- Record the number of lymph nodes in each cassette.
- Levels II and III specimens are frequently small and may all be embedded.

5.5.3.5 Sentinel lymph node (SLN)

At a minimum, the SLN is divided into two or more pieces at 2mm intervals and processed in its entirety for histological examination (see section 5.5.1.8).

5.6 Aspects of microscopy including pathology parameters in malignant disease

The histopathologist has the opportunity to evaluate the entire lesion and usually the surrounding breast tissue. Correlation of the pathological features with the mammographic or clinical findings is essential to ensure that the abnormality has been excised and adequately examined. The following sections highlight important points relating to the assessment and reporting of operative specimens.¹

5.6.1 Benign lesions

Benign lesions commonly detected by screening include fibroadenoma, intraduct papilloma, radial scar/complex sclerosing lesion and benign phyllodes tumour. Benign calcification is most often due to sclerosing adenosis, simple cysts or involutional change. Epithelial hyperplasia may present in association with other benign changes forming a density on mammography or may be detected as an area of calcification. Some benign lesions are associated with atypical hyperplasia or malignant change.

5.6.1.1 Fibroadenoma

A fibroadenoma is a benign malformation composed of connective tissue and epithelium exhibiting a pericanalicular and/or intracanalicular pattern. Benign changes identical to those seen elsewhere in the breast can occur in fibroadenomata. The stroma may be cellular or hyalinised and may show calcification. Fibroadenomata are frequently detected at screening, presenting as mass lesions or as calcification.

5.6.1.2 Papilloma

Confirmation of the diagnosis of intraduct papilloma may be assisted by the use of p63 stain to highlight the presence of myoepithelial cells covering the stromal cores. ADH/DCIS is occasionally identified within otherwise benign papillomas, associated with increased risk of subsequent malignancy. Local excision and mammographic surveillance is the current treatment of choice for these atypical lesions.

5.6.1.3 Radial scar/complex sclerosing lesion

Typically, these lesions are characterised by the presence of a central area of elastosis containing entrapped tubular structures lined by epithelial and myoepithelial cells, bordered by aggregated terminal duct lobular units that commonly show epithelial hyperplasia and sclerosing adenosis. Appreciating the structure of the lesion and examining the tubular structures will help with distinguishing it from tubular carcinoma. In cases of doubt, immunohistochemical stains (e.g. p63 stain) may be used to demonstrate the presence of a myoepithelial cell layer around the tubules. These lesions require diagnostic excision and thorough histological sampling as up to 25 per cent contain areas of atypical or malignant change.⁶

5.6.1.4 Phyllodes tumour

The distinction of benign phyllodes tumour from intracanalicular fibroadenoma may be difficult even when the entire lesion is available for examination. Phyllodes tumour is characterised by the so-called 'leaf-like' architecture in which papillary projections, frequently lined by hyperplastic epithelium, extend into cystic spaces.¹⁹ Typically, the stroma is more cellular than in fibroadenoma and there may be a degree of atypia and increased mitotic activity. Phyllodes tumours are classified as benign, borderline or malignant based on assessment of tumour outline, stromal characteristics and mitotic count.²⁰ Irrespective of classification, proximity of the lesion to the surgical resection margin is the major determinant of local recurrence.

5.6.1.5 Benign calcification

Correlation of the nature, distribution and extent of calcification on the histological slides with that seen on slice x-ray is essential to ensure that all the calcification has been examined microscopically.¹⁴ Appreciating that particular foci of calcium are not represented in the slides followed by deeper levels will ensure thorough evaluation.

5.6.1.6 Epithelial hyperplasia without atypia

Epithelial hyperplasia is characterised by a mixed intraductal proliferation of cells showing a cohesive arrangement with 'swirling'.²¹ Intercellular spaces are irregular, peripheral and slit-like without the rigid bridges/bars seen in DCIS. Mitotic figures and necrosis are rare.

5.6.1.7 Columnar cell lesions (CCLs)

CCLs of the breast comprise a group of conditions characterised by dilatation of terminal duct lobular units (TDLUs) lined by cells showing columnar morphology, frequently with apical snouts, luminal secretions and calcification.⁹ These morphological changes have been recognised by histopathologists for many years (variously known as blunt duct adenosis, columnar metaplasia, metaplasia cylindrique, columnar cell alteration with prominent apical snouts and secretions, clinging carcinoma) but have recently assumed a new significance due to their increased detection as mammographic calcification, the potential for overdiagnosis as DCIS and their possible relationship to invasive carcinoma. CCLs encompass columnar cell change in which the dilated acini are lined by one or two layers of columnar epithelial cells, and columnar cell hyperplasia in which the acini are lined by more than two layers of cells. In non-atypical CCLs, the dilated acini have an undulating outline and the lining cells have uniform, ovoid nuclei orientated perpendicular to the basement membrane with evenly dispersed chromatin, inconspicuous nucleoli and infrequent mitotic activity. See also section 5.6.2.3.

5.6.1.8 Mucocoele-like lesions

Mucin extravasation in biopsy material may sometimes accompany fibrocystic change. These cases require thorough evaluation with submission of all material, with levels, to exclude hypersecretory DCIS and/or an adjacent paucicellular mucinous carcinoma.

5.6.2 Atypical lesions

5.6.2.1 Atypical ductal hyperplasia (ADH)

ADH is an intraductal proliferation that exhibits some but not all of the features of DCIS and frequently merges with DCIS. Although specific criteria have been proposed, ADH poses considerable diagnostic difficulties with inter- and intra-observer variation even among experienced pathologists.²¹ Molecular data demonstrate overlap with DCIS in keeping with the morphological features. These data are at variance with the epidemiological data that suggest that ADH is a risk factor for the development of invasive malignancy in either breast, unlike DCIS, which is a precursor lesion with the risk of invasive malignancy virtually confined to the affected quadrant.

5.6.2.2 Atypical lobular hyperplasia (ALH) and lobular carcinoma in situ (LCIS)

ALH and LCIS are regarded as a disease continuum characterised by distension of terminal duct lobular units by small, uniform, non-cohesive cells frequently containing intracytoplasmic lumina.⁸ The risk of invasive malignancy is greater in LCIS, and criteria have been established for the separation of the two entities. While in situ lobular neoplasia has traditionally been regarded as a risk factor for the development of invasive malignancy in either breast, recent evidence (both epidemiological and molecular data) suggests that it also behaves as a precursor lesion, particularly the pleomorphic subtype.¹¹

Carcinoma in situ with mixed ductal and lobular features, including pleomorphic lobular carcinoma in situ (PLCIS), is characterised by a population of dyshesive cells as in classical LCIS but with a greater degree of cytological atypia.¹¹ Necrosis and calcification may be present. The cytological features of individual cells are similar to those found in high-grade DCIS but the cells are E-cadherin negative. It is likely that carcinoma in situ with mixed ductal and lobular features, including PLCIS, is a precursor lesion rather than a risk factor; currently, these lesions are usually managed according to DCIS protocol.

5.6.2.3 Atypical columnar cell change (flat epithelial atypia)

This refers to cytological atypia occurring in a CCL⁹ (see 5.6.1.7). The dilated acini assume a rigid contour and are lined by one or more layers of columnar epithelial cells showing cytological atypia with round rather than elongated nuclei. Lymphocyte infiltration of the affected TDLU is a common feature. Architectural atypia is not a feature of atypical CCLs, and, if present, a diagnosis of ADH/low-grade DCIS should be considered. Morphological, immunohistochemical and genetic studies suggest that atypical CCLs may constitute the earliest stage of low-grade invasive breast carcinoma. The current recommendation is that the finding of atypical CCL on NCB is an indication for diagnostic biopsy to exclude a more significant lesion in the vicinity.

5.6.3 Malignant lesions

The purpose of screening to detect 'early' breast cancer has resulted in a significant increase in the detection of DCIS, which accounts for approximately 20 per cent of screen-detected lesions. Small invasive carcinomas (<15mm) with good prognostic features are also commonly detected. All varieties of malignant breast lesions, including lymphomas, sarcomas and metastatic tumours, are encountered in screening. The information derived from the histological examination of screen-detected malignant lesions is used to predict the likely clinical course of the lesion and to direct the further management of patients with symptomatic cancers.

5.6.3.1 Ductal carcinoma in situ (DCIS)

The research efforts of the last two decades suggest that histological grade, lesion extent and margin width are the key indices in DCIS.²²

Grade

Cytological grade has replaced the assessment of architecture as the basis for DCIS classification.²³ A number of classification systems have been proposed, which variously take account of cell polarisation and necrosis in addition to cytological grade. The United Kingdom National Health Service Breast Screening Programme (UK NHSBSP) Working Group proposes that DCIS be classified as high, intermediate or low grade based solely on the assessment of nuclear features.¹

Size

DCIS lesions that measure in excess of 4cms are associated with a greater incidence of (i) microinvasion, (ii) early invasion, (iii) positive margins following attempted conservation surgery and (iv) local recurrence. The assessment of lesion size requires careful correlation with the macroscopic specimen. DCIS is usually a unicentric process and tends to involve consecutive tissue slices. The maximum dimension of DCIS in any one section is taken as the first dimension of the area involved by DCIS. Multiplying the slice thickness by the number of slices involved gives a reasonably precise estimate of the second dimension.¹⁴

Margins

The distances of DCIS from the nearest margins are recorded. The location of these margins is also specified; in particular, the posterior and radial margins are differentiated. Margin width is rapidly emerging as the most significant factor in determining the likelihood of local recurrence following conservation surgery for DCIS.²⁴

Other

In evaluating DCIS, it is usual to comment on architectural patterns (solid, cribriform, micropapillary, papillary) and the presence or absence of necrosis and microinvasion. Invasive carcinoma accompanying a predominant DCIS lesion is assessed as described below.

Microinvasion

The current TNM classification²⁵ (see Appendix 2) proposes that microinvasive carcinoma is a tumour in which the dominant lesion is DCIS (or, less often, LCIS) but in which there are one or more clearly separate foci of invasion stroma beyond the basement membrane, none measuring more than 1mm in maximum dimension. Microinvasive carcinoma is a relatively rare condition.²⁶ Currently, the prognosis of microinvasion is considered to be comparable to high-grade DCIS.

5.6.3.2 Invasive carcinoma

The following parameters have been shown to be associated with clinical outcome; together, they constitute a tumour profile that is used to decide on patient treatment.

Type

The common types of breast cancer include ductal NOS (not otherwise specified), lobular, tubular, tubular mixed, cribriform and mucinous.²⁰ Tubular, cribriform and mucinous carry a better prognosis than ductal NOS. The prognosis of tubular mixed is determined by the grade of the accompanying ductal NOS component. Lobular carcinoma is associated with an increased incidence of multifocality.

Pure special-type carcinomas require 90 per cent of the tumour to show special-type characteristics to be so designated (e.g., tubular carcinoma).²⁰ Mixed tumour type is more commonly encountered (usually accompanied by ductal NOS), and tumours may be assigned to this category provided the special-type carcinoma constitutes greater than 50 per cent of the tumour volume.

Basal-like carcinoma is a recently recognised variant of high-grade breast carcinoma with a distinct morphological and immunohistochemical profile.²⁰ The typical morphological features include a pushing margin, high-grade cytology, necrosis, central scarring and an associated peritumoral lymphocytic infiltrate. The tumours express basal/myoepithelial cell markers, including CK 5/14, S100 and SMA, and are commonly ER, PR and HER-2/neu negative (triple negative). The therapeutic options for patients with these tumours are limited. Apart from documenting triple negative status, there is currently insufficient evidence to justify routine basal/myoepithelial cell markers to identify these tumours except where the possibility of familial (BRCA1) predisposition arises. If specific therapeutic regimens emerge, then precise pathological classification among high-grade carcinomas may become relevant as a predictive indicator.

Grade

Tumour grade is a powerful predictor of prognosis and is assessed on all types of invasive breast carcinoma.²⁷ According to Elston's modification of the Bloom and Richardson method, tumours are graded as 1, 2 or 3 based on evaluation of tubule formation, nuclear pleomorphism and mitotic activity, as follows:

<i>Tubule formation</i>	Score
Majority of tumour (>75%)	1
10–75%	2
Little or none (<10%)	3
<i>Nuclear pleomorphism</i>	
Small, regular nuclei	1
Larger nuclei with visible nucleoli and moderate variability in size and shape	2
Marked variation in nuclear size and shape	3
<i>Mitotic count (per 10 high-power fields)</i>	Score
Low	1
Intermediate	2
High	3

The size of a high-power field varies between microscopes, and it is necessary to standardise the mitotic count for individual microscopes.¹⁴ This is achieved by measuring the field diameter of the microscope with a graticule and plotting the value on a standardised graph to determine the cut-off levels for each score. Mitoses are counted at the periphery of the tumour. Care is taken to exclude apoptotic cells.

The scores for tubule formation, nuclear pleomorphism and mitotic count are added and the total score used to assign tumour grade (grade 1 = 3-5 points, grade 2 = 6-7 points and grade 3 = 8-9 points).

Extensive intraduct component

DCIS occupying 25 per cent of the mass lesion together with the presence of DCIS in adjacent breast tissue constitutes extensive intraduct component.²² In the past, this was regarded as a firm contraindication to conservation surgery. More recently, it has been suggested that conservation surgery may be appropriate in these patients provided that excision is complete.

Size

Tumour size is confirmed microscopically because macroscopic assessment may overestimate the size of the invasive element due to the presence of fibrosis and/or DCIS. The size of the invasive tumour is recorded in addition to DCIS if DCIS extends beyond the invasive component; in this case, the size of the combined DCIS and invasive tumour is also recorded (whole tumour size).

The size of the invasive component rather than overall tumour size relates to axillary nodal metastases and survival.²⁸ The DCIS component may be important in determining local recurrence following conservation surgery.

Lymphovascular invasion

Lymphovascular invasion (LVI) is an independent prognostic parameter and may be used to select node negative patients for adjuvant chemotherapy.²⁹ To avoid misinterpreting tumour retraction artefact, the tissue surrounding the tumour rather than the tumour itself should be examined for LVI. In accordance with the NHS BSP guidelines⁴, it is suggested that LVI is reported as either absent, possible or present. The presence of unifocal, multifocal (two or more foci) or extensive LVI should be recorded.³⁰

Margin status

The risk of local recurrence following conservation surgery is significantly reduced by adequate clearance of invasive carcinoma and any associated DCIS.²⁴ The distance of the DCIS and invasive components from the nearest margins and the location of these margins are recorded.

Lymph node status

Lymph node status is the most powerful prognostic indicator in breast carcinoma.²⁵ The number of involved lymph nodes and the total number of lymph nodes examined are recorded (also specified per level, if appropriate). The SLN is included in the overall count; its status is individually specified and the size of metastatic deposits (macro or micrometastasis) is recorded. The presence of isolated tumour cells is noted but regarded as lymph node negative in accordance with the TNM classification²⁵ (see Appendix 2). The presence of extranodal extension is also documented.

Biological markers

ER status, which is used to select patients for hormonal therapy, is routinely evaluated immunohistochemically on paraffin tissue sections.³¹ PR status is also determined because a small percentage of ER negative tumours are PR positive and may be hormone sensitive.

HER-2/neu status is evaluated to assess the patient's suitability for Herceptin therapy. Current methodology for HER-2/neu evaluation involves immunohistochemical staining in the first instance and the allocation of a score of either 0, 1+, 2+ or 3+. Tumours with 3+ staining in at least 30 per cent of the tumour sample are regarded as HER-2/neu positive. Tumours with 0 and 1+ scores are considered to be HER-2/neu negative. Tumours with 2+ scores are referred for FISH or D-DISH testing. HER-2/neu scoring is in accordance with strict guidelines.⁵

5.7 Sample proforma reports

5.7.1 DCIS (excision specimen)

Microscopy

The radiological and/or macroscopic abnormality corresponds to low/intermediate/high-grade DCIS with a solid/cribriform/micropapillary/papillary/mixed-growth pattern and no/focal/marked necrosis.

The maximum dimension of the area involved by DCIS is mms. There is no invasion.

or

There is a focus/are foci of microinvasion (each focus <1mm).

or

There is associated invasive ductal carcinoma.

This measures mms and is grade 1/2/3.

Lymphovascular invasion is/is not seen.

Margins (if less than 2mms), delete as appropriate:

Anterior mms, (DCIS), (invasion)

Posterior mms, (DCIS), (invasion)

Superior mms, (DCIS), (invasion)

Inferior mms, (DCIS), (invasion)

Medial mms, (DCIS), (invasion)

Lateral mms, (DCIS), (invasion)

Calcification present: yes/no. Benign/malignant/both.

Nipple (if submitted): involved/not involved by Paget's disease.

SLN:

The SLN is positive/negative for metastatic carcinoma.

(If positive, specify if macrometastasis or micrometastasis and comment on presence or absence of extranodal spread.)

Additional information:

ER status: positive/negative

PR status: positive/negative

pTNM

5.7.2 Invasive breast carcinoma (excision specimen)

Microscopy

Invasive ductal/lobular/mucinous/tubular/other carcinoma,
grade 1/2/3 (tubules 1,2,3, nuclear pleomorphism 1,2,3, mitotic count, 1,2,3).

There is/is no associated DCIS, low/intermediate/high grade with a solid/cribriform/micropapillary/
papillary/mixed growth pattern and no/focal/marked necrosis.

Invasive tumour size: mms.

Whole tumour size: mms.

Lymphovascular invasion is/is not identified.

Margins (if less than 2mms), delete as appropriate:

Anterior mms, (DCIS), (invasion)

Posterior mms, (DCIS), (invasion)

Superior mms, (DCIS), (invasion)

Inferior mms, (DCIS), (invasion)

Medial mms, (DCIS), (invasion)

Lateral mms, (DCIS), (invasion)

Calcification present: yes/no. Benign/malignant/both.

SLN:

The SLN is positive/negative for metastatic carcinoma.

(If positive, specify if macrometastasis or micrometastasis and comment on presence or absence of
extranodal spread.)

Axillary lymph node clearance:

..... / lymph nodes are positive for metastatic carcinoma.

or

..... lymph nodes are negative for metastatic carcinoma.

(level 1 - ... / ... level 2 - ... / ... level 3 - ... / ...)

Extranodal spread: present/absent.

Additional information:

ER status: positive/negative

PR status: positive/negative

HER-2/neu status: positive/negative

pTNM

5.8 Data sheets

A data sheet is completed for each pathology specimen (FNAC, NCB, diagnostic and therapeutic
operative specimens). The sheets are completed and signed by the consultant histopathologist, and
the information contained therein is recorded on the NBSP database.

5.9 Appendices

Appendix 1: HER-2/neu

HER-2/neu: Clinical testing in breast cancer treatment⁵

HER-2/neu (also known as c-erbB2 and HER-2) is a member of the epidermal growth factor family of tyrosine kinase receptors of which four different isoforms are recognised (HER 1-4). The receptors are capable of forming homo or heterodimers, and HER-2/neu is the only member of the family that does not have a known ligand. Since its description by Slamon et al in 1987, it is now accepted that 15 to 30 per cent of invasive breast carcinomas demonstrate HER-2/neu amplification/overexpression, which portends a worse prognosis. In recent years, the role of HER-2/neu has assumed more importance with the development of a humanised monoclonal antibody (trastuzumab-Herceptin), which has been endorsed by the UK National Institute for Clinical Excellence (NICE) for the treatment of metastatic breast cancer. There is also evidence that HER-2/neu positivity denotes sensitivity to anthracycline-based chemotherapy regimens, and there is accumulating data to suggest that HER-2/neu positivity correlates with Tamoxifen resistance in ER positive tumours.

Methodology

HER-2/neu status is estimated using two methodologies: (i) immunohistochemistry and (ii) in situ hybridisation (ISH), either fluorescent (FISH) or dual-colour dual-hapten chromogenic in situ hybridisation (D-DISH). Immunohistochemistry employs a standard technique, which can be applied routinely in most laboratories. This is a colourimetric assay in which membrane staining is assessed on a scale from 0 to 3+. Scores of 0/1+ are interpreted as negative while 3+ in at least 30 per cent of the tested tumour indicates a positive result. A number of studies have demonstrated that strongly positive and negative immunohistochemical staining shows concordance with the presence or absence, respectively, of HER-2/neu gene amplification on ISH. Using current guidelines, patients who are deemed 3+ on immunohistochemistry are considered for specific HER-2/neu therapy. In contrast, 2+ staining is regarded as a borderline (equivocal) result, and the current two-tier model recommends that these cases be referred for ISH testing.

ISH is regarded by some as the gold standard for HER-2/neu testing; while methods such as polymerase chain reaction are available, these are recommended for research use only. ISH employs two differentially labelled fluorescent probes directed respectively to HER-2/neu and chromosome 17 (to control for aneusomy). The signals are counted in between 20-60 cells and expressed as a ratio (HER-2/neu:Ch 17). Values greater than 2.2 indicate amplification of the HER-2/neu gene.

Current recommendations

Recent ACP and ASCO/CAP guidelines have been issued for HER-2/neu testing.⁵ The guidelines acknowledge the presence of a dual testing algorithm and stress the importance of QA and participation in EQA schemes. It is recognised that testing is more accurate with better concordance when performed in specialist centres. Therefore, it is advised that testing be limited to high-volume reference laboratories. Ideally, immunohistochemistry is restricted to centres with a case load of 250 per year with a minimum annual throughput of 100 cases applying to ISH. Comprehensive standardisation and validation of an HER-2 analytic method must be carried out prior to routine diagnostic use.

Appendix 2: TNM clinical classification

TNM is classified as follows:²⁵

T – Primary tumour

Tx	Primary tumour cannot be assessed
T0	No evidence of primary tumour
Tis	Carcinoma in situ
Tis (DCIS)	Ductal carcinoma in situ
Tis (LCIS)	Lobular carcinoma in situ
Tis (Paget)	Paget's disease of the nipple with no tumour

Note

Paget's disease associated with a tumour is classified according to the size of the tumour.

T1		Tumour 2cm or less in greatest dimension
	T1mic	Microinvasion 0.1cm or less in greatest dimension
	T1a	More than 0.1cm but not more than 0.5cm in greatest dimension
	T1b	More than 0.5cm but not more than 1cm in greatest dimension
	T1c	More than 1cm but not more than 2cm in greatest dimension
T2		Tumour more than 2cm but not more than 5cm in greatest dimension
T3		Tumour more than 5cm in greatest dimension
T4		Tumour of any size with direct extension to chest wall or skin only as described in T4a to T4d

Note

Chest wall includes ribs, intercostal muscles and serratus anterior muscle but not pectoral muscle.

T4a	Extension to chest wall
T4b	Oedema (including peau d'orange) or ulceration of the skin of the breast or satellite skin nodules confined to the same breast
T4c	Both 4a and 4b, above
T4d	Inflammatory carcinoma*

Note

*Inflammatory carcinoma of the breast is characterised by diffuse, erythema and peau d'orange involving a third or more of skin of the breast, usually with no underlying mass. If the skin biopsy is negative and there is no localised measurable primary cancer, the T category is pTX when pathologically staging a clinical inflammatory carcinoma (T4d). Dimpling of the skin, nipple retraction or other skin changes, except those in T4b and T4d, may occur in T1, T2 or T3 without affecting the classification.

N – Regional lymph nodes

pNX		Regional lymph nodes cannot be assessed (e.g., not removed for study or previously removed)
pN0		No regional lymph node metastasis**
pN1mi		Micrometastasis (larger than 0.2mm but none larger than 2mm in greatest dimension)
pN1		Metastasis in 1-3 ipsilateral axillary lymph node(s), and/or internal mammary nodes with microscopic metastasis detected by SLN dissection but not clinically apparent
	Pn1a	Metastasis in 1-3 axillary lymph node(s), including at least one larger than 2mm in greatest dimension
	Pn1b	Metastasis in internal mammary lymph nodes with microscopic metastasis detected by SLN dissection but not clinically apparent
	Pn1c	Metastasis in 1-3 axillary lymph nodes and internal mammary lymph nodes with microscopic metastasis detected by SLN dissection but not clinically apparent
Pn2		Metastasis in 4-9 ipsilateral axillary lymph nodes, or in clinically apparent ipsilateral internal mammary lymph node(s) in the absence of axillary lymph node metastasis
	Pn2a	Metastasis in 4-9 axillary lymph nodes, including at least one that is larger than 2mm
	Pn2b	Metastasis in clinically apparent internal mammary lymph node(s), in the absence of axillary lymph node metastasis
Pn3		Metastasis in 10 or more ipsilateral axillary lymph nodes; or in ipsilateral infraclavicular lymph nodes; or in clinically apparent ipsilateral internal mammary lymph nodes in the presence of 1 or more positive axillary lymph nodes; or in more than 3 axillary lymph nodes with clinically negative, microscopic metastasis in internal mammary lymph nodes; or in ipsilateral supraclavicular lymph nodes
	Pn3a	Metastasis in 10 or more axillary lymph nodes (at least one larger than 2mm) or metastasis in infraclavicular lymph nodes
	Pn3b	Metastasis in clinically apparent internal mammary lymph node(s) in the presence of positive axillary lymph node(s); or metastasis in more than 3 axillary lymph nodes and in internal mammary lymph nodes with microscopic metastasis detected by SLN dissection but not clinically apparent
	Pn3c	Metastasis in supraclavicular lymph node(s)

Note

**Cases with only isolated tumour cells (ITC) in regional lymph nodes are classified at pN0. ITC are single tumour cells or small clusters of cells, not more than 0.2mm in greatest dimension or 200 individual cancer cells in a single section, that are usually detected by immunohistochemistry or molecular methods but which may be verified on haematoxylin and eosin (H&E) stains.

M – Distant metastasis

MX	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis

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Quality assurance
in surgery

6. Quality assurance in surgery

6.1 Introduction

The guidelines in this chapter set out the standards of quality required in the surgical investigation and management of women invited for breast cancer screening in BreastCheck – The National Breast Screening Programme.

6.2 Overall surgical QA

6.2.1 Diagnosis prior to surgery

The great majority of patients with breast cancers, both palpable and impalpable, have a diagnosis made before formal surgical operation. The proportion of screen-detected breast cancer with a pre-operative diagnosis of malignancy (core biopsy reported as definitely malignant) should be ≥ 90 per cent.

6.2.2 Rates of uptake and investigation

As a member of the multidisciplinary screening team, quality criteria relating to the general performance of a unit are relevant to the surgeon. The surgeon is involved in efforts to maximise the number of women accepting the invitation for screening (≥ 70 per cent) and to minimise the number of women re-called for further investigations. The minimum standard for re-call to assessment is < 7 per cent for the initial round with an achievable standard of < 5 per cent. The minimum standard for the subsequent round is < 5 per cent with an achievable standard of < 3 per cent.

6.2.3 Cancer detection rates

The surgeon is concerned with efforts made to maximise the number of cancers detected. (The invasive cancer detection rate for the initial round will be measured for two age ranges: 50-51 years and 52-64 years. The standards are $> 2.9/1,000$ and $> 5.2/1,000$ respectively. The standard for the subsequent round is $> 2.4/1,000$. The minimum standard for ductal carcinoma in situ (DCIS) as a proportion of all breast cancers is 10 per cent with an achievable standard of 10-20 per cent.)

The surgeon is also concerned with efforts made to maximise the number of small (less than 15mm in diameter) invasive cancers so that 40 per cent of the invasive cancers detected at screening are small. To detect a representative proportion of DCIS cases, a minimum 10 per cent of all cancers detected should be in this category.

6.2.4 Benign open biopsy rate

The minimum standard for the benign open biopsy rate in the initial round is $< 3.6/1,000$ women screened and the target is $< 1.8/1,000$. In the subsequent round, the minimum standard is $< 2/1,000$ and the target is $< 1/1,000$.

6.2.5 Assessment

The surgeon should be present at the assessment clinic and is fully involved in the assessment of screen-detected cancers. Where possible, the assessment by the surgeon takes place at the first visit to the assessment clinic. The surgeon sees all patients before accepting them for surgery. The interval between the diagnosis and surgical assessment should not exceed one week.

6.2.6 Admission for surgery for diagnosis

The percentage of women who are offered an admission date within three weeks of the surgical decision to operate for diagnostic purposes should be ≥ 90 per cent.

6.2.7 Admission for surgery for treatment

The percentage of women who are offered an admission date within three weeks of informing the woman that she needs surgical treatment should be ≥ 90 per cent (not including women who first need workup, investigations, chemotherapy, neoadjuvant chemotherapy or neoadjuvant radiotherapy).

6.3 Benign open localisation biopsy technique

6.3.1 Identification of impalpable lesions

More than 95 per cent of impalpable lesions should be correctly identified at the first localisation.

The proportion of localised impalpable radiographic lesions excised (completely or incompletely) at the first operation should be >95 per cent.

6.3.1 Benign biopsy specimens

More than 80 per cent of biopsies that prove to be benign should weigh less than 30 grams, and a weight of less than 15 grams is a realistic target. Surgeons will have access to the specimen x-ray within as short a time as possible (within 15 minutes is acceptable, but within 10 minutes may be achievable).

6.4 Surgical treatment

6.4.1 Surgical margins

To ensure complete excision, specimens will be orientated by the surgeon and histological examination of the margins will be carried out.

In patients with a pre-operative diagnosis, the surgeon will endeavour to obtain a clear margin and to obtain a rim of uninvolved breast tissue around the primary lesion.

The distance from the primary lesion to the margins will be clearly documented in the final pathology report, i.e., >0 mm, >1 mm, >2 mm or >5 mm from the lesion.

The decision to perform a repeat operation will be at the discretion of the treating surgeon, who will take into account the pathology of the lesion, its location, size and grade, the multidisciplinary meeting discussion and the patient's preference.

The number of repeat operations for an individual patient will be kept to a minimum, bearing in mind the principles of conservative surgery, cosmetic surgery and oncologically sound surgery.

6.4.2 Treatment options

Breast-conserving surgery is the treatment of choice for the majority of small-sized screen-detected breast cancers. All surgeons involved in the treatment of screen-detected cancers will be aware of the different treatment options available for each woman. Each woman will receive information on the treatment options and will, where appropriate, be offered a choice of treatment or allocated treatment within a clinical trial. A specialist breast care nurse will be present when the diagnosis of cancer is given. Refer to Appendix 1 for more details.

6.4.3 Lymph node histology

Histological lymph node status should be obtained on >95 per cent of invasive tumours, either by sentinel lymph node (SLN) biopsy, sampling or formal axillary clearance.

6.4.3.1 SLN biopsy

SLN biopsy is an established procedure to assess the axilla in BreastCheck. SLN biopsy should be considered for most programme screen-detected cancers and early breast cancers.

6.4.3.2 Axillary sampling

Axillary sampling should only be used in the context of SLN failure or other exceptional circumstances and should aim to remove four nodes.

6.4.3.3 Axillary clearance

More than 10 nodes should usually be found at axillary clearance.

6.4.3.4 Axillary radiotherapy

Prophylactic axillary radiotherapy after axillary clearance is inappropriate. In the case of DCIS, neither clearance nor radiotherapy to the axilla should be used.

6.4.4 Surgical rates

Surgeons treating screen-detected breast cancers should treat a minimum of 50 patients with breast cancer per year.

6.5 Surgical follow-up

The surgeon will ensure that all women with breast cancer are referred to a symptomatic service.

6.6 QA audit

The surgical QA standards achieved will be monitored, and the lead surgeon will be responsible for the QA audit in each unit.

6.7 Appendices

Appendix 1: Managing screen-detected breast cancer and DCIS

Diagnosis of breast cancer

Diagnosing breast cancer should be done without the necessity of open surgical biopsy in the majority of cases by using non-operative techniques such as stereotactic or ultrasound-guided core biopsy. When a diagnostic open biopsy is required, less than 30 grams of tissue should be removed in the majority of instances.

Therapeutic surgery for invasive breast cancer

In screen-detected lesions, breast conservation is feasible in the majority of cases. The principles of surgery should be to remove the cancer with a rim of normal breast tissue around it. Some overlying skin may be excised with the lesion and haemostasis secured so that a drain is rarely necessary. The specimen should be marked MAS with 1, 2 and 3 clips where:

M = Medial

A = Anterior

S = Superior

This is to allow radiopathological correlation and assessment of the margins. An intra-operative specimen radiograph should be obtained for all screen-detected lesions.

A separate nipple margin may be taken if considered necessary by the multidisciplinary meeting.

The pathologist should then assess all radial margins and note for each the macroscopic and microscopic clearance in millimetres.

After histological assessment and multidisciplinary meeting discussion and in line with best international practice, a decision should be made on further surgery based on the multidisciplinary meeting decision and patient preference.

The tumour bed is marked with metallic ligaclips to facilitate radiotherapy.

Mastectomy

Potential indications for mastectomy in screen-detected breast cancer include:

- Multi-centric disease
- Positive margins following re-excision
- Patient preference
- Contra-indications to radiotherapy
- Anticipated poor cosmetic result

All patients requiring mastectomy should be counselled about breast reconstruction.

Axillary surgery

At least 95 per cent of patients with invasive breast cancer have pathological assessment of their axillary nodal status. Pre-operative assessment with USS \pm FNA will help define those requiring axillary clearance. SLN biopsy is appropriate in T1 and T2 tumours.

SLN assessment

SLN assessment is minimally invasive and has advantages over conventional axillary surgery in that it yields improved staging information by allowing the pathologist to perform extra assessment on the node most likely to yield metastases/micromets.

Treatment of DCIS

DCIS is a predisposing factor for breast carcinoma. Surgery involves the same critical techniques, i.e., wire guided, specimen orientation and imaging assessment, as those used for invasive non-palpable breast cancer. Currently, the issue regarding an appropriate margin is controversial, and, in line with best international practice, this decision should be made following the multidisciplinary meeting and discussion with the patient.

Local excision of the lesion is not appropriate for extensive DCIS. A patient having a mastectomy with DCIS should have a sentinel node biopsy (SNB). A patient with DCIS and having a wide local excision should not have SNB. However, there are exceptions where there is evidence of microinvasion and where there is a radiological or clinical mass lesion.

Adjuvant therapy

All patients should have access to an oncologist, and it is recommended that estrogen receptor (ER), progesterone receptor (PR) and HER-2/neu status (in invasive cancer only) be obtained to guide the choice of adjuvant therapy. All patients undergoing breast-conserving surgery should be considered for radiation therapy as no subgroup of patients has been definitively identified in whom radiation therapy can be safely omitted.

Trials

Wherever possible, patients should be entered into clinical trials because there is increasing evidence that patients in trials get better treatment and have a better outcome.

Quality assurance
in physics

7. Quality assurance in physics

7.1 Introduction

The guidelines in this chapter set out the responsibilities of the medical physics department of BreastCheck – The National Breast Screening Programme for the physical and technical aspects of mammography imaging equipment. The guidelines cover imaging equipment, measurements, tolerances and frequencies, results and actions.

The tests referred to in this chapter represent those required by reference to current accepted practice internationally. The tests have been drawn principally from the European Commission (EUREF) guidelines^{1,2}, the IAEA guidelines³ and other European and international screening organisations.

The BreastCheck guidelines are evolutionary in nature and subject to continuing development, amendment and modification to ensure that they meet specific local requirements and emerging regulatory requirements and guidelines and that they address practical problems that may be encountered in the performance of measurements. Ongoing modification will be required to accommodate new imaging equipment used in BreastCheck, the level and type of equipment for physics QA, scientific staffing and the overall organisation and management of the QA service.

The physics service centrally maintains a live measurement protocol spreadsheet, which details the current QA protocol at any given time and notes updates and deviations from these guidelines.

Technical and physics QA provides the only objective assessment of two important parameters – image quality and radiation dose – and is most appropriately carried out by medical physicists and radiographers in close co-operation and consultation with radiologists in BreastCheck.

7.2 Physics QA programme for mammography screening

For successful x-ray mammography screening, mammograms must contain the optimal diagnostic information obtainable. The image quality must be stable with respect to information content. The radiation dose to the breast must be as low as reasonably achievable for the diagnostic information required. These demands on image quality hold for every mammogram produced, and the QA programme ensures that high-quality images are achieved consistently.

The QA of physical and technical aspects of mammography includes equipment specification, acceptance testing and routine quality control. The QA programme for mammography screening must be able to guarantee optimal performance and status of the entire imaging chain, including:

- Image acquisition, which includes the x-ray generation, image receptor and image receptor corrections
- Image processing, which includes the image processing software
- Image presentation, which includes the diagnostic monitors and image presentation software

Following the installation of any new x-ray or ancillary imaging equipment, a detailed series of acceptance and commissioning tests must be performed to ensure that the equipment meets specification and to establish the baseline performance of the equipment. Routine quality tests must

then be performed at regular intervals and after engineering interventions, maintenance, repairs or software upgrades to detect whether any change in the performance of the equipment has occurred.

In addition to the routine quality tests carried out on all machines, each system will be subject to specific tests recommended by the manufacturers.

A subset of routine daily and weekly measurements should be performed by local radiographic staff, while more extensive acceptance and routine quality measurements should be undertaken by a medical physics expert.

For reporting consistency, comparability and trend analysis, the results from all screening centres and mobile units will be collected and analysed centrally.

7.3 Medical physics responsibilities

The medical physics department of BreastCheck is responsible for the provision of physics services to the screening programme. To ensure that the medical physicists' knowledge of mammography physics and QA remains comprehensive and that their professional practice is of the highest standards, each medical physicist will undertake sufficient and appropriate continuing training and professional development activities.

The medical physics department and function is subject to a quality management and evaluation programme consistent with the quality strategies of BreastCheck. With respect to the physics service, quality management includes:

- Providing a physics QA programme in compliance with established standards and protocols
- Documenting requirements and standards
- Evaluating practice against current guidelines and ensuring consistency with accepted practice in Europe and internationally
- Evaluating satisfaction with the physics service
- Evaluating the service by internal and external audit

The delivery of the service is evaluated in order to effect changes in practice and management. To facilitate this, written records of the following items should be maintained:

- All survey measurements, analysis and results
- All QA reports
- All patient dose surveys
- Calibration certificates for the test and quality control equipment
- Training and continuing professional development of staff

The following sections provide details on aspects of BreastCheck QA that are dependent on medical physics services and support. Many of the items specified are covered by statutory legislation, in particular SI 125(2000), SI 478(2002), SI 303(2007) and SI 459(2010).

7.3.1 Advice on equipment selection

The physicist will provide advice on purchasing new equipment and relocating existing equipment. In addition, the physicist will provide advice on when equipment should be replaced. Equipment refers to all imaging, PACS, image processing and display systems as well as radiation protection and quality control instrumentation.

7.3.2 Equipment commissioning

Acceptance testing and commissioning of all new equipment prior to its clinical use to include imaging performance, radiation protection aspects, patient safety and conformance to RPII licence conditions.

7.3.3 Radiation protection

The chief physicist acts as radiation protection advisor (RPA) for all BreastCheck equipment and facilities. Responsibilities include liaising with the Radiological Protection Institute of Ireland (RPII) on licence and regulatory issues, risk assessment, design of new facilities and radiation safety issues within BreastCheck.

7.3.4 Quality surveys

Regular major equipment QA surveys will be performed twice annually. The surveys will include an analysis of results, a written report, liaison with users and equipment vendor service, recommendations and follow-up. Additional sub-system quality surveys will be performed following engineering interventions and software upgrades that may impact client radiation dose or image quality performance and following the movement of mobile mammography systems.

7.3.5 Routine quality monitoring

Equipment and image quality will be monitored on a daily and weekly basis. This function is performed in close co-operation with radiographic staff and will include data analysis and reporting of results.

7.3.6 QA of assessment and ancillary equipment

All ancillary and assessment imaging equipment, which includes ultrasound equipment, biopsy equipment, image processing and display systems and specimen x-ray cabinets, must conform to acceptable quality standards.

7.3.7 Advice on equipment use

The physicist will advise on the optimal function and use of imaging equipment. He/She will investigate and recommend image quality and radiation dose optimisation strategies for x-ray mammography and will offer advice in respect of radiation protection and safety.

7.3.8 Imaging optimisation

The physicist will conduct research to produce evidence-based data to support advice on the operation of imaging equipment to achieve the optimal balance of image quality and client radiation dose for current practice and in respect of the implementation of new imaging technology.

7.3.9 Assessment of image quality

The physicist is responsible for performing objective tests and assessing image quality.

7.3.10 Assessment of dose and risk

The physicist is responsible for regularly measuring the radiation dose to the breast. This includes providing advice on the choice of equipment and techniques for dose assessment and the critical evaluation of results. Mean glandular dose (MGD) is measured as part of routine QA, and actual patient doses are measured annually as part of a comprehensive survey.

7.3.11 QA systems and manual

In collaboration with all breast-screening professionals, the medical physics department is involved in establishing and reviewing appropriate aspects of the QA systems and manuals for the programme.

7.3.12 Teaching and training

The medical physics department provides input into the formal teaching and training of physicists, radiologists and radiographers working in breast imaging and breast screening.

7.3.13 Research and development

Research and development activity is an important aspect of the development and maintenance of expertise and impacts positively on the quality and value of the service provided. All medical physicists are encouraged and facilitated to undertake research and developmental activity.

7.4 X-ray tube and generator

7.4.1 Electrical safety

The responsibility for electrical safety at installation lies with the equipment supplier. At installation, the physicist will ensure that appropriate electrical safety checks are performed by the installing engineer. At acceptance, the physicist will ensure that all electrical cables and connectors are visually inspected.

7.4.2 Mechanical safety and function

At acceptance, the physicist will check that the equipment is complete by reference to the specification. All manual and automatic mechanical functions should be systematically checked by the physicist. The physicist will verify that:

- All documentation is available
- The unit is mechanically stable under normal operating conditions
- All moving parts run freely without undue friction
- All brakes and locks function correctly
- All foot switches operate correctly
- Powered movement of the table is prevented when compression is applied
- Automatic release of the compression plate after exposure functions correctly
- Automatic release override functions correctly
- Emergency compression release functions correctly
- The automatically applied compression force does not exceed 200N
- Compression force does not diminish when applied for an extended period
- The breast thickness and force indicator on the mammography unit are accurate
- There are no sharp edges or surfaces on any surface coming into contact with the patient or operator

7.4.3 Radiation safety

Mammography units differ from general x-ray units in the use of lower energy radiation and a specialised geometry. The x-ray field is permanently aligned with the patient support table, which also acts as a primary beam absorber.

7.4.3.1 X-ray room protection

A check of room shielding may be made against the RPA requirements at the design stage or by transmission measurements at the acceptance stage.

Lead-equivalence of protective screens should be marked and checked.

Environmental radiation under normal working conditions may be checked, if necessary, using monitoring badges positioned around the room.

7.4.3.2 Visual inspection

An inspection of the equipment and room for radiation protection aspects should be made by the physicist. The physicist will verify that:

- The exposure switch is behind the lead screen
- Exposure terminates if the button is released prematurely
- The design of the exposure switch prevents the inadvertent production of x-rays
- All controls are clearly marked
- All indicator lights are functioning correctly
- The emergency stop operates correctly
- The radiation signs are satisfactory
- The lights in the room in use are working
- The Pb equivalence of the protective screens is marked
- The condition of the protective screens is satisfactory

7.4.3.3 Leakage radiation

Defects in tube shielding are unusual but in view of the proximity of the tube housing to the woman being examined, it is important that leakage radiation be checked, particularly in the orientation where a woman undergoing screening may be exposed.

Equipment:	Radiation dosimeter and 180cc ionisation chamber
Method:	Position a lead beam blocker over the end of the diaphragm assembly so that no primary radiation is emitted. Using a 180cc ionisation chamber, air kerma measurements are made in front of the tube housing using the tube leakage factors as specified.
Tolerance:	1mGy/hr at 1m from the focus at the maximum rating averaged over an area not exceeding 100cm ²
Frequency:	The test should be performed at acceptance and following tube replacement or any maintenance on the tube housing assembly.

7.4.3.4 Alignment of x-ray field and missed tissue at chest wall

Alignment of the x-ray field with the detector should be such that the whole detector is exposed with no appreciable overlap. Measurements are made for standard collimation configurations used clinically.

Equipment:	Fluorescent screen, Gafchromic film, radio-opaque markers
Method:	The alignment of the light field, x-ray field and image receptor at the lateral edges of the breast support table may be determined qualitatively using a fluorescent screen or quantitatively. Alignment of the light field, x-ray field and image receptor at the chest wall edge of the breast support table are determined quantitatively.
Tolerance:	Lateral alignment should be <+/-10mm of the detector edge. Alignment at the chest wall side should be <+5mm. No primary x-ray exposure should be observed outside the detector table area.
Frequency:	Acceptance, routine QA

7.4.4 X-ray source

7.4.4.1 Tube voltage reproducibility and accuracy

A number of tube voltages are checked within the range of clinically used settings.

Equipment:	kV meter
Method:	Position the kV meter at the reference point (6cm from the chest wall edge and centred laterally). The accuracy is measured for a range of clinically used spectra at fixed mAs. For a single spectrum and each focal spot size, the reproducibility is measured by repeated exposures at a reference kV value.
Tolerance:	Accuracy <±1kV, reproducibility <±0.5kV
Frequency:	Acceptance, routine QA

7.4.4.2 Tube output

Sufficiently high tube output and consistency is important for mammography as it results in shorter exposure times and ensures adequate penetration of large/dense breasts. Marked changes may be indicative of problems requiring investigation.

Equipment:	Dosimeter
Method:	The compression paddle is removed and the detector protected with a steel plate for these tests. The specific tube output ($\mu\text{Gy/mAs}$) and the output rate (mGy/s) is measured for each target/filter combination. Correct for the distance from the focal spot to the detector and calculate the specific output at 1 metre and the output rate at a distance equal to the focus-to-film distance (FFD).
Tolerance:	Measurements should be consistent with established values typical for all beam qualities and >70% of value at acceptance testing.
Frequency:	Acceptance, routine QA

7.4.4.3 Beam quality – half-value layer (HVL)

The HVL provides an indication of radiation beam quality and will affect dose and image contrast. The HVL is measured under conditions of narrow beam geometry and with the compression plate in place. Measurements are made for different target/filter configurations commonly used in clinical practice.

HVL may be calculated from the formula:

$$HVL = \frac{X_1 \ln \frac{2Y_2}{Y_0} - X_2 \ln \frac{2Y_1}{Y_0}}{\ln \frac{Y_2}{Y_1}}$$

where the exposure reading is denoted Y_0 , Y_1 , Y_2 for added Al foil thickness, $X_0=0$, X_1 and X_2 .

Equipment:	Ion chamber dosimeter and high-purity (>99%) Al foils or direct measurement using a solid-state dosimeter
Method:	Measurements are made at all clinically used beam qualities and with the compression paddle in place.
Tolerance:	Measurements should be consistent with established values typical for all beam qualities.
Frequency:	Acceptance, routine QA

7.4.4.4 Automatic exposure control (AEC)

It is vital that the AEC functions correctly in the production of good mammograms. The AEC system adjusts target, filter and tube voltage such that image quality is sufficient and dose is within an acceptable range.

All AEC measurements are performed with the compression paddle in place.

Back-up timer

Equipment:	Steel plate, dosimeter
Method:	Cover the detector with a steel plate to force operation of the back-up timer. Record the mAs value and exposure time at which the system terminates the exposure in clinical AEC mode.
Tolerance:	The back-up timer should function properly.
Frequency:	Acceptance, routine QA

Short-term reproducibility

Equipment:	Standard PMMA test block (45mm)
Method:	Acquire a number of consecutive RAW images of the standard test block using standard clinical AEC settings. Record the mean pixel value and standard deviation measured in an ROI placed at the reference point and calculate SNR (=MPV/SD).
Tolerance:	Deviations of SNR should be <5%.
Frequency:	Acceptance, routine QA

Object thickness and clinical AEC operation

Equipment:	Large area PMMA plates (10mm)
Method:	Expose PMMA plates in the thickness range from 20 to 70mm with compression applied to achieve equivalent breast thickness (using spacers if necessary) under standard AEC clinical conditions. PMMA plates are placed on the detector in order to include the area used as AEC sensor. Record the exposure factors and calculated dose value displayed for each exposure.
Tolerance:	Deviation of measured thickness should be $\leq \pm 3\text{mm}$.
Frequency:	Acceptance, routine QA

AEC local dense area

Equipment:	Large area PMMA plates (10mm), small area PMMA plates (5mm)
Method:	Position 30mm PMMA on the detector table using spacers to achieve an equivalent compressed breast thickness of 40mm. Position a 5mm small PMMA plate on the compression paddle and within the AEC sensor area to simulate a high-density area and expose under automatic control. Repeat for increasing thickness of dense area (10mm, 15mm, 20mm). Record the mean pixel value and standard deviation measured in an ROI within the simulated dense tissue and calculate SNR (=MPV/SD).
Tolerance:	SNR of each image should be within 20% of average SNR.
Frequency:	Acceptance, routine QA

Signal difference-to-noise ratio (SDNR)

Equipment:	Large area PMMA plates (10mm), 0.2mm thick Al foil (10mm x 10mm)																
Method:	<p>Image PMMA plates of 20mm thickness, with an Al foil of 0.2mm thickness at the reference point (6cm from the chest edge), in manual mode and with settings as close as possible to the clinical AEC settings observed from the 'clinical AEC operation' test. Measure the mean pixel value and standard deviation in an ROI inside and outside the Al object on the acquired RAW images. Calculate SNR and SDNR. Repeat this measurement for 30mm, 40mm, 45mm, 50mm, 60mm and 70mm PMMA thickness.</p> <p>Image quality is evaluated for one breast thickness (at the equivalent of 50mm PMMA) using contrast threshold measurements derived from CDMAM phantom analysis. At other PMMA thicknesses, SDNR is related to the SDNR at 50mm PMMA to ensure sufficient image quality through the range of breast thickness.</p>																
Tolerance:	<p>Compare SDNR values with typical system values and results at acceptance testing.</p> <table border="1"> <thead> <tr> <th>PMMA thickness (cm)</th> <th>SDNR (relative to 5cm PMMA) (%)</th> </tr> </thead> <tbody> <tr> <td>2.0</td> <td>>115</td> </tr> <tr> <td>3.0</td> <td>>110</td> </tr> <tr> <td>4.0</td> <td>>105</td> </tr> <tr> <td>4.5</td> <td>>103</td> </tr> <tr> <td>5.0</td> <td>>100</td> </tr> <tr> <td>6.0</td> <td>>95</td> </tr> <tr> <td>7.0</td> <td>>90</td> </tr> </tbody> </table>	PMMA thickness (cm)	SDNR (relative to 5cm PMMA) (%)	2.0	>115	3.0	>110	4.0	>105	4.5	>103	5.0	>100	6.0	>95	7.0	>90
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7.0	>90																
Frequency:	Acceptance, routine QA																

7.4.4.5 Compression and plate alignment

The compression of the breast should be firm but tolerable.

The compression force is measured and attention paid to reproducibility and accuracy of the force and distance measurements on the x-ray set.

Equipment:	Compression scale, compressible foam material.
Method:	Place the compression scale on the detector table surface and measure compression force at a number of force settings. Measure the maximum compression. Evaluate the alignment of the compression device at maximum force, measuring the distance between detector table surface and compression device at each corner.
Tolerance:	The indicated compression force should not exceed 200N. The indicated compression force should be within $\pm 20\text{N}$ of the measured value. Maximum misalignment of the compression device should be $<5\text{mm}$ for symmetric load.
Frequency:	Acceptance, routine QA

7.4.5 Image receptor

7.4.5.1 Detector response function and noise evaluation

The measurement of the detector response is performed to check compliance with manufacturer specifications, linearity of response and pixel value offset and to establish that quantum noise represents the largest noise component in the clinical dose range.

Equipment:	Al plate (2mm), dosimeter
Method:	Position the Al plate as close as possible to the tube output port and remove the compression paddle and grid. For clinically used beam qualities and a range of mAs values from half to twice the typical detector input dose, acquire RAW images. Measure the input dose to the detector and the mean pixel value and the standard deviation at the reference point on the acquired images. For the response function, plot the mean pixel value against exposure and determine linearity by plotting a best fit through all measured points. Calculate the correlation coefficient (R^2). Determine the zero crossing to check the presence of any pixel value offset. Calculate the individual noise components and plot the relative noise against detector dose to observe that quantum noise represents the largest noise component in the clinical dose range. Plot the simplified noise relationship that assumes quantum noise only and calculate the exponent of detector dose.
Tolerance:	Linear response function $R^2 > 0.99$. Confirm quantum noise is the largest noise component in the clinical dose range. Monitor dose exponent value, which should be -0.5 for systems with quantum noise only.
Frequency:	Acceptance, routine QA

7.4.5.2 Image receptor uniformity and variance

Equipment:	Large area PMMA plates
Method:	<p>Uniformity images (RAW) of the detector are obtained by exposing PMMA plates covering the entire detector for all target/filter combinations. The thickness of PMMA and exposure factors used for each target/filter combination should be consistent with typical clinical operation. A second image with the PMMA plates rotated through 180° should be acquired to exclude results due to in-homogeneities in the PMMA slabs.</p> <p>The image uniformity is visually assessed on a 5mp monitor and quantitatively assessed using ROI analysis with image analysis software. The analysis should highlight ROIs (10 mm x 10 mm) with a mean pixel value that differs by more than ±15% from the mean pixel value of the whole image and ROIs with a mean SNR that differs by more than ±15% from the mean SNR of all ROIs. The numbers of deviating ROIs should be recorded for each target/filter combination.</p> <p>The detector variance is assessed using image analysis software to produce variance images (ROI of 2 mm x 2 mm).</p>
Tolerance:	<p>The uniformity results are plotted on a chart and trends identified and investigated if they deviate from baseline.</p> <p>The variance image is sensitive to image artefacts and supports visual artefact analysis by indicating deviations automatically.</p>
Frequency:	Acceptance, routine QA

7.4.5.3 Detector element failure

Equipment:	Wire grid screen-film contact test phantom
Method:	<p>Where possible, inspect the most recent 'bad pixel map' on the x-ray system. Evaluate the up-to-date information on bad columns and bad dels (detector elements) from the manufacturer and compare the position and number of defective dels to previous maps.</p> <p>Acquire a RAW image of a screen-film contact phantom. Large clusters of defective dels and dels from which the reading is influenced by neighbouring defective dels may become visible in the image of a screen-film contact grid phantom.</p>
Tolerance:	Review for artefact
Frequency:	Acceptance, routine QA

7.4.5.4 Uncorrected defective detector elements

Equipment:	Large area PMMA plates
Method:	Uniformity images (RAW) of the detector receptor are obtained by exposing PMMA plates covering the entire detector for all target/filter combinations. The thickness of PMMA and exposure factors used for each target/filter combination should be consistent with typical clinical operation. A second image with the PMMA plates rotated through 180° should be acquired to exclude results due to in-homogeneities in the PMMA slabs. Image analysis software should be used for the evaluation of uncorrected defective detector elements. Such a package should highlight ROIs with pixels that differ by more than 20% from the mean pixel value in the same ROI. The numbers of ROIs with deviating pixels should be recorded for each target/filter combination.
Tolerance:	The results assist the visual assessment of the detector performance. There are no established limits on the permitted number of uncorrected defective detector elements.
Frequency:	Acceptance, routine QA

7.5 Dosimetry

7.5.1 Measurement

Measurements of breast radiation dose are described in detail in a number of publications.^{4,5,6,7,8}

For routine QA measurement, an assessment of the mean glandular dose (MGD) to different breast thickness is made.

Accurate measurements are made of the entrance surface air kerma (ESAK) required for correct exposure of the phantom and of the radiation quality (HVL).

Equipment:	Dosimeter			
Method:	Protect the detector with a steel plate. Place the dosimeter at the reference point, 6cm from the chest wall edge. Measure the entrance dose using manual settings to simulate settings observed in the 'clinical AEC operation' test. Calculate the MGD for a breast equivalent to each PMMA thickness. The measure is repeated for each clinically used mode of the mammography system.			
Tolerance:	PMMA thickness	Equiv. breast thickness	Maximum MGD to equivalent breast	
			Acceptable level	Achievable level
	(cm)	(cm)	(mGy)	(mGy)
	2.0	2.1	<1.0	<0.6
	3.0	3.2	<1.5	<1.0
	4.0	4.5	<2.0	<1.6
	4.5	5.3	<2.5	<2.0
	5.0	6.0	<3.0	<2.4
	6.0	7.5	<4.5	<3.6
	7.0	9.0	<6.5	<5.1
Frequency:	Acceptance, routine QA			

7.5.2 BreastCheck breast dose survey

BreastCheck maintains compliance with the European Council Directive 97/43/Euratom and consequent Irish legislation by performing a comprehensive annual dose survey of the entire screening programme. The use of breast MGD is recommended for dosimetric purposes in mammography. Breast MGD cannot be measured directly but can be estimated from x-ray system performance measurements and client exposure measurements and by using appropriate conversion factors. For the annual breast dose survey, MGD is measured for 100 consecutive women examined on each system.⁹

The International Commission on Radiological Protection (ICRP) recommends the use of diagnostic reference levels (DRL) to improve dose optimisation in radiological examinations. Diagnostic reference levels are defined as dose levels for typical medical x-ray examinations for groups of standard-sized patients and for broadly defined types of equipment. All practices using x-ray imaging are encouraged to establish DRLs and to ensure that they are not exceeded for standard procedures when good and normal practice is being followed.¹⁰

The BreastCheck DRL is based on the average MGD for mediolateral oblique views obtained for compressed breast thicknesses in the range commensurate with the average breast thickness recorded in a survey. The 95th percentile of the distribution of resultant MGD values obtained for all x-ray units in a survey is used as the diagnostic reference value for the screening programme.⁹

7.6 Image quality

The information content of an image may best be defined in terms of just visible contrast and detail and characterised by a contrast-detail curve. The basic conditions for good imaging performance and consistency of a system can be assessed by measuring spatial resolution, threshold contrast visibility and exposure time. Artefact evaluation and ghost image tests are also desirable to guarantee optimal image quality.

Image quality can also be assessed using a variety of subjective test objects, including the Leeds TOR MAM phantom and Huttner resolution pattern.

7.6.1 Threshold contrast visibility

Equipment:	CDMAM phantom, PMMA plates, EUREF CDMAM analysis software
Method:	Place the CDMAM phantom with a 20mm of PMMA above and below (total thickness equivalent to 50mm of PMMA) on the detector table surface. Select the appropriate clinical exposure setting and acquire eight RAW images, moving the phantom marginally between the images to obtain images with different relative position of the details and the detector elements. Analyse the images with the EUREF CDMAM analysis software. The software determines the threshold gold thicknesses for each detail diameter.
Tolerance:	Results should exceed the acceptable limits according to the European (EUREF) guidelines. ¹
Frequency:	Acceptance, routine QA

7.6.2 Modulation transfer function (MTF)

Equipment:	Edge phantom, Al plate (2mm), steel edge phantom, image analysis software
Method:	<p>Position the Al plate as close as possible to the tube output port and remove the compression paddle and grid. Use a manual exposure to produce an air kerma at the detector that is approximately three times the detector air kerma for AEC controlled images.</p> <p>Place the steel edge phantom on the detector table surface with one corner at the reference point, 6cm from the chest edge. The angle of the edge with respect to the pixel matrix should range between 1° and 3°. Acquire a RAW image.</p> <p>Use the image analysis software to calculate the MTF and record the spatial frequency at the 50% point.</p>
Tolerance:	<±10% change in the spatial frequency at the 50% point MTF point
Frequency:	Acceptance, routine QA

7.6.3 Exposure time

Equipment:	Exposure time meter, standard PMMA test block (45mm), additional PMMA plates
Method:	Expose 45mm of PMMA in manual mode using the parameters selected in the 'clinical AEC operation' test and record the exposure time of the image acquisition.
Tolerance:	Acceptable <2s, achievable <1.5s
Frequency:	Acceptance, routine QA

7.6.4 Ghost image/erasure thoroughness

Equipment:	Standard PMMA test block (45mm), Al foil (0.1mm)
Method:	<p>Acquire a RAW image of the standard test block using clinical AEC settings. The block is positioned such that half of the detector is covered and half is uncovered. For the second image, the standard test block covers the entire detector and the Al foil is placed exactly centred on top of the standard block. The time between both images should be approximately one minute.</p> <p>Measure the mean pixel value (MPV) in two ROIs under the Al foil from the area with and area without ghosting and in a background ROI. The ghost image factor can be calculated from the relative MPV measurements.</p>
Tolerance:	Ghost image factor <0.3
Frequency:	Acceptance, routine QA

7.6.5 Image quality phantoms

Equipment:	Image quality phantoms (TOR MAM and Huttner resolution pattern)
Method:	Using additional PMMA to simulate a variety of real breast thickness, image the TOR MAM phantom on the breast table using clinical exposure factors and evaluate the processed images on a 5MP diagnostic monitor. For resolution, image the Huttner phantom on the standard PMMA test block (45mm) and evaluate the RAW images on a 5MP diagnostic monitor.
Tolerance:	Reference to baseline measurements at acceptance
Frequency:	Acceptance, routine QA

7.7 Diagnostic monitors

Diagnostic monitor tests are based upon the work of the American Association of Physicists in Medicine Task Group 18 (AAPM TG18).¹¹ The TG18 test patterns described in this section should be available from the manufacturer or can be downloaded from the TG18 website (<http://deckard.mc.duke.edu/~samei/tg18>). There is also freely available software that facilitates the display of TG18 test patterns for monitor evaluation (MoniQA). Test patterns are displayed at full resolution (exactly one display pixel for each pixel in the digital image) for evaluation.

Because most of the quality tests in this chapter are highly sensitive to ambient light, all of the tests should be performed under clinical conditions (room light, light boxes and other display devices should be at the same luminance level as under clinical conditions).

7.7.1 Ambient light

Equipment:	Illuminance meter
Method:	Measure the ambient light at the centre of the display with the light detector facing outwards and the display switched off.
Tolerance:	Ambient light should be less than 20 lux for primary display devices.
Frequency:	Acceptance, routine QA

7.7.2 Contrast visibility

Equipment:	TG18-QC test pattern
Method:	<p>The TG18-QC pattern contains several items for evaluating the contrast visibility of a display.</p> <p>Each of the 16 luminance patches located approximately equidistant from the centre of the image contains four corner squares at equal low contrast steps to the patch.</p> <p>The two patches in the bottom with minimum and maximum pixel value, surrounding the test pattern name, contain a centre square with a pixel value of 5% and 95% of the maximal grey level respectively. The letters in the words “QUALITY CONTROL” in the three rectangles below these patches are displayed with decreasing contrast to the background. To keep track of contrast degradation, the visible part of each letter should be written down and checked with the visibility at acceptance. If contrast visibility is not sufficient, it may help to dim the room lights. However, if this is done, the lights should also be dimmed while using the displaying system clinically.</p>
Tolerance:	All corner patches should be visible, and the 5% and 95% pixel value squares should be clearly visible.
Frequency:	Acceptance, routine QA

7.7.3 Resolution

Equipment:	AAPM TG18 LPV/H pattern
Method:	Evaluate the AAPM TG18 LPV/H pattern to check display resolution visually.
Tolerance:	All line patterns should be discernible.
Frequency:	Acceptance, routine QA

7.7.4 Display artefacts

Equipment:	TG18-QC test pattern; dead pixel display pattern
Method:	Evaluate the TG18-QC for image artefacts. The image should be carefully checked for defect pixels (LCD only), steps in the black-to-white and white-to-black ramp bars and artefacts near the black-to-white and white-to-black transitions (video card). Also pay attention to temporal instability (flicker) and spatial instability (jitter). A dead pixel display pattern can help with the visualisation of dead pixels (available in the MoniQA software).
Tolerance:	No disturbing artefacts or dead pixels should be visible.
Frequency:	Acceptance, routine QA

7.7.5 Greyscale display function

Equipment:	Luminance range pattern. The greyscale display function can be determined by measuring the luminance of the 18 AAPM luminance test patterns (TG18-LN12-01 through TG18-LN12-18).
Method:	In this measurement, it is determined whether a display conforms to the DICOM Greyscale Standard Display Function (GSDF). The GSDF can be determined by measuring the luminance of the 'luminance range pattern'. The test pattern should be displayed full-screen and the luminance has to be measured at the centre of the screen. The shape of the GSDF depends on the ambient light in the room. Therefore, room lights, light boxes and other display devices should be at the same luminance level as when the system is used clinically. A luminance meter should be used to include the influence of ambient light.
Tolerance:	The calculated contrast response should fall within $\pm 10\%$ of the GSDF contrast response for primary class displays ($\pm 20\%$ for secondary class displays).
Frequency:	Acceptance, routine QA

7.7.6 Luminance range

Equipment:	Luminance range pattern. The AAPM luminance test patterns TG18-LN12-01 and TG18-LN12-18 can be used.
Method:	Measure the maximum and minimum luminance of the display device. The ratio of maximum and minimum display luminance in the presence of ambient light is an indicator of the luminance contrast response capabilities of the monitor. Luminance should be measured using a luminance meter to include the influence of ambient light.
Tolerance:	The maximum-to-minimum luminance ratio should be at least 250 for the primary display device or 100 for secondary display devices. The difference of maximum luminance between displays belonging to one displaying station should not exceed 5% of the lowest.
Frequency:	Acceptance, routine QA

7.7.7 Luminance uniformity

Equipment:	Luminance uniformity pattern. The test patterns TG18-UNL10 and TG18-UNL80 can be used.
Method:	Evaluate the pattern luminance uniformity. Measure the display luminance at five locations for each monitor.
Tolerance:	Maximum luminance deviation of a display device should be less than 30% for CRT displays and LCD displays ($(L_{\max} - L_{\min}) / L_{\text{centre}} < 0.3$).
Frequency:	Acceptance, routine QA

7.8 Specimen x-ray cabinets

In breast imaging, specimen x-ray cabinets are used for imaging sections of breast tissue or biopsy samples once they have been removed from the patient.

Routine testing is necessary to ensure adequate operation and radiation safety. Tests are made following installation of the cabinet and annually thereafter. Physicists also check the equipment when the x-ray tube within the unit is replaced or significant engineering intervention, maintenance or software upgrade is carried out.

Before testing the unit, safety checks are carried out to ensure that:

- The unit has a key-operated power switch
- There is a functional 'mains-on' warning light
- There is an indication of x-rays being emitted
- X-ray exposures are not possible with the cabinet doors open
- X-ray exposures terminate when the door is opened and they do not recommence when the door is closed unless the 'start' button is also depressed

7.8.1 Radiation leakage

Equipment:	Contamination monitor, dosimeter
Method:	Note any exterior leakage radiation detected, ensuring that all sides of the cabinet are scanned with the contamination monitor during x-ray exposure under maximum scatter conditions. If leakage radiation is detected, a dose-rate meter is required to quantify the leakage.
Tolerance:	Dose rates should be $<2.5\mu\text{g}/\text{h}$ @10cm.
Frequency:	Acceptance, routine QA

7.8.2 Tube output

Equipment:	Dosimeter
Method:	Check the consistency of the output with exposure time.
Tolerance:	Consistent with baseline measurements
Frequency:	Acceptance, routine QA

7.8.3 Exposure time

Equipment:	Exposure time-meter
Method:	Record accuracy of measured time.
Tolerance:	Exposure time is consistent with set time.
Frequency:	Acceptance, routine QA

7.8.4 Automatic exposure control (AEC)

Equipment:	A set of 10mm PMMA plates
Method:	Ensure PMMA fully covers the active AEC detector area and increase the PMMA thickness from 10mm to 30mm and record exposure factors and mean pixel value for each thickness. Assess reproducibility of the AEC by making repeat exposures at one thickness.
Tolerance:	Mean pixel values should remain consistent across varying thickness of PMMA. AEC should also be reproducible for repeat exposures.
Frequency:	Acceptance, routine QA

7.8.5 Magnification factor

Equipment:	Radio-opaque marker
Method:	Place the marker on the surface of the cabinet and acquire an image. Take a distance measurement on the image and repeat using the magnification table provided.
Tolerance:	Measurements should be accurate for the magnification factor selected.
Frequency:	Acceptance, routine QA

7.8.6 Image quality

Equipment:	TOR MAM phantom
Method:	Acquire a processed image of the phantom under AEC and evaluate the image on the cabinet display.
Tolerance:	Results at acceptance are used as reference.
Frequency:	Acceptance, routine QA

7.8.7 Resolution

Equipment:	Huttner resolution test object
Method:	Acquire a RAW image of the resolution test object under AEC and evaluate the image on the cabinet display.
Tolerance:	Results at acceptance are used as reference.
Frequency:	Acceptance, routine QA

7.9 Ultrasound

High-quality ultrasound is essential to the provision of adjunct imaging at BreastCheck assessment clinics. Ultrasound small parts phantoms are used to acquire images for subjective and objective analysis of image quality.

The following performance parameters are investigated: low contrast penetration depth, axial resolution, lateral resolution, anechoic target detection and greyscale target detection.¹² Additionally, a number of functional and image quality tests are performed monthly for trend analysis.

7.9.1 Sensitivity/penetration depth

Equipment:	Ultrasound small parts phantom
Method:	Measure the depth of the speckle-noise boundary in a uniform area of the phantom.
Tolerance:	Consistent with baseline measurements <5% or 5mm
Frequency:	Acceptance, routine QA

7.9.2 Resolution

Equipment:	Ultrasound small parts phantom
Method:	Acquire images of phantom resolution targets and assess qualitatively.
Tolerance:	Consistent with baseline measurements
Frequency:	Acceptance, routine QA

7.9.3 Anechoic target visualisation

Equipment:	Ultrasound small parts phantom
Method:	Acquire images of phantom anechoic targets and assess qualitatively.
Tolerance:	No reduction in the size of the smallest anechoic target seen No reduction in the number of low-contrast targets seen
Frequency:	Acceptance, routine QA

7.9.4 Greyscale target analysis

Equipment:	Ultrasound small parts greyscale phantom
Method:	Use the image analysis software to assess the greyscale targets.
Tolerance:	Consistent with baseline measurements
Frequency:	Acceptance, routine QA

7.9.5 Crystal dropout and defective elements

Equipment:	Paper clip
Method:	Observe disruptions to the image integrity of an image acquired in air. Observe an image generated by sliding a paper clip over the surface of the transducer.
Tolerance:	No dead elements or areas of reduced signal or non-uniformities should be observed.
Frequency:	Acceptance, routine QA

7.9.6 Uniformity and measurement accuracy

Equipment:	Ultrasound small parts phantom
Method:	Image point targets on the phantom and compare measured distance with actual separation of targets.
Tolerance:	Distance measurement accurate to 1mm
Frequency:	Acceptance, routine QA

7.10 Small-field biopsy mammography systems

This section proposes suitable test protocols for acceptance testing and routine performance testing of small-field digital imaging systems.¹³

7.10.1 Beam alignment

Equipment:	Fluorescent screen, Gafchromic film, radio-opaque markers
Method:	The alignment of the light field, x-ray field and image receptor at the lateral edges of the breast support table may be determined qualitatively using a fluorescent screen or quantitatively. Additionally, measure the image field size at system acceptance.
Tolerance:	Alignment should be <+/-10mm on all sides.
Frequency:	Acceptance, routine QA

7.10.2 X-ray field uniformity

The uniformity of the digital image can be measured by assessing the pixel values resulting from the exposure of a uniform test object, such as Perspex or aluminium. Measure the pixel value for an ROI at the centre of the image and at each of the four corners. Then,

$$\text{Deviation from centre mean} = \frac{(\text{Corner ROI Mean} - \text{Centre ROI Mean}) \times 100}{\text{Centre ROI Mean}}$$

The presence of artefacts should be evaluated; note that the uniformity may be temperature dependent.

Equipment:	Standard PMMA test block (45mm)
Method:	Place a 45mm test block of Perspex on the breast support platform. Expose at clinical setting under AEC and normal resolution. Visually inspect the image. Record the pixel value in the centre of the image and at the four corners. Calculate the percentage deviation of the corner-means from the central ROI mean value. Repeat with a 60mm thickness of Perspex to assess the uniformity for a longer exposure time. Calculate the percentage deviation of the corner-means from the central ROI mean value.
Tolerance:	Deviation should not exceed 10%. No artefacts should be observed on clinical images.
Frequency:	Acceptance, routine QA

7.10.3 Automatic exposure control (AEC)

Correct operation of the AEC is important for the production of good-quality images. As well as controlling the exposure duration, some AEC systems select the appropriate kV and target/filter combination.

Short-term reproducibility

Equipment:	Standard PMMA test block (45mm)
Method:	Place the standard test block on the breast support platform. Make a number of exposures at clinical setting using AEC and normal resolution mode. For each exposure, record the mAs and the mean pixel value in an ROI at the centre of the image.
Tolerance:	The maximum deviation of both mAs and pixel value should not exceed 5% of the mean value. Mean pixel value should be within 10% of those recorded at acceptance.
Frequency:	Acceptance, routine QA

AEC thickness compensation

Equipment:	A set of 10mm thickness PMMA plates
Method:	For a range of PMMA thicknesses, make one exposure using clinical AEC settings. Record the mAs delivered and the mean pixel value in an ROI in the centre of the image.
Tolerance:	The maximum deviation of pixel value should not exceed 10% of the mean value.
Frequency:	Acceptance, routine QA

7.10.4 Image quality tests

Limiting spatial resolution

Equipment:	Huttner resolution grating, standard PMMA test block (45mm)
Method:	Image the Huttner phantom on the standard PMMA test block (45mm) and evaluate the RAW images at full resolution on modality display monitor.
Tolerance:	Reference to baseline measurements at acceptance
Frequency:	Acceptance, routine QA

7.10.5 Dosimetry

The MGD for the standard breast can be estimated from measurements with a 45mm thickness of PMMA. The MGD is adjusted for the reduced area of exposure.

Equipment:	Dosimeter standard PMMA test block (45mm)
Method:	Measure the HVL for the clinically used kV, target and filter. Place the dosimeter in the x-ray field. Measure the entrance dose using manual settings to simulate settings observed for the standard test block. Calculate the MGD.
Tolerance:	Consistent with baseline measurement
Frequency:	Acceptance, routine QA

7.10.6 Mobile units

In the event that a mobile is moved, a reduced QA protocol is performed. This includes the following tests:

- Mechanical safety and function
- Alignment of x-ray field/image receptor and missed tissue at chest wall side
- Compression and compression plate alignment
- Short-term AEC reproducibility
- Clinical AEC operation
- Image quality

In addition, detector calibration should be performed and the system should pass the system QA tests according to the manufacturer's specifications.

7.11 References

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Quality assurance
in epidemiology

8. Quality assurance in epidemiology

8.1 Introduction

The aim of BreastCheck – The National Breast Screening Programme is to reduce the number of deaths from breast cancer in Ireland among women aged 50 to 64. In the first 10 years following the introduction of a screening programme, most of the cause-specific mortality is due to breast cancers arising before the screening programme started. After 10 years, the effects of the screening programme may be seen more clearly.

A breast cancer screening programme is, of necessity, a multidisciplinary undertaking. The effectiveness of any programme will be directly related to the quality of the individual parts. Success will be judged not only on the outcome of the programme and its impact on public health but also on the programme's organisation, implementation, execution and acceptability.

Epidemiology is the fundamental guiding and unifying discipline throughout the entire process of a screening programme, from the organisational and administrative aspects, through implementation and execution, to evaluation and assessment of impact. The Programme Evaluation Unit (PEU) has overall responsibility for evaluating BreastCheck and does so using epidemiological and statistical analysis.

8.2 Organisational aspects of a screening programme

The organisational aspects of a screening programme include:

- Identification of the source(s) of data upon which to base decisions regarding the population to be screened
- Access to essential demographic and personal details required for the invitation to screening, administration and scheduling of the process
- Dissemination of promotional information regarding screening
- Attention to the problem of non-compliance

Additional organisational aspects include disseminating the results of screening to participants and appropriate professional staff, maintaining up-to-date administrative records and periodically revising the screening registers as necessary. It is essential to have epidemiological input into decisions made in respect of each of these elements since the evaluation of the outcome and interpretation of the eventual results of the screening endeavour will be intimately affected by organisational aspects of the programme.

8.3 Developing the administrative part of the NBSP database

The components of the administrative part of the NBSP database are as follows:

- Population Register
- Scheduling system
- Invitations and reporting
- Re-call based on screening results

8.3.1.1 Population Register

The Population Register is essential to identify members of the target population.

Sources of demographic data for the Population Register

The Population Register has been compiled from the following data sources:

- Women registered with the General Medical Services (GMS) scheme
- Women registered with the Voluntary Health Insurance (VHI) scheme
- Women registered with the Department of Social Protection (DSP)
- Women registered with Laya Healthcare
- Self-registrants not known to any of the above

Other sources should be evaluated and considered for inclusion as they arise.

Role of external data management provider

The role of the external data management provider in BreastCheck is to maintain a register of women to be called for screening. The external data management provider's main duties in the maintenance of the register are as follows:

- Import data from external sources via the NBSP database. The data may contain details pertaining to new women or amendments relating to women already registered.
- Standardise and input the data.
- Identify duplicates in accordance with BreastCheck criteria.
- Append the appropriate district electoral division (DED) coding to data.
- Process the entered data to ensure that data from all sources merge correctly.
- Export updates to the register to the NBSP database on a monthly basis.

In addition, the BreastCheck population manager monitors the process for automatic and manual duplicate merging and manages the work of the external data management provider accordingly.

Validation of the Population Register

As there is no precedent set in the Republic of Ireland for the range of sources of data used to compile the Population Register, quality standards need to be set for the completeness and accuracy of the register.

The completeness of the Population Register is measured by the extent to which the number of women on the register matches the true target population (as measured by the census). The number of non-duplicate women can be compared with that expected from census data or from the projected population in inter-censal years. This should be reviewed following a census.

The proportion of women who register with the programme, i.e., self-registrants, is also an indicator of completeness, although this number is likely to be an underestimation of the true missing population.

The accuracy of the Population Register is measured by:

- The proportion of duplicates on the register
- The proportion of consent letters returned by An Post
- The proportion of changes made to the register either before or at attendance for mammography

Methods by which the accuracy of the Population Register is maintained

Deduplication

- A deduplication protocol has been developed for the external data company for identifying duplicate records.
- BreastCheck has a protocol to remove exact duplicate records.
- A monthly report of suspected duplicates is produced following each monthly data upload for manual assessment. This is reviewed by the Population Register manager in conjunction with the data team. Positively identified duplicates are removed prior to updating the register.
- The duplicate percentage is to be calculated for each group of DEDs.

Other

- Records of males and deceased women are removed at source. The programme is informed of deaths by the Death Event Publication Service (DEPS) and the National Cancer Registry. Information pertaining to deceased women is now exchanged between the four screening programmes under the National Screening Service (NSS) on a monthly basis to maintain register accuracy in respect of the records of deceased persons across all registers.
- Inaccuracies identified on the register are identified to the data sources by BreastCheck.

Regular meetings will be held with the external data management provider to review the process. Led by the Population Register manager, these meetings will be held quarterly or as needed on an ongoing basis.

Frequency with which the Population Register accuracy is assessed

A weekly audit of returns from An Post duplicates and of changes made to the database is kept. A monthly summary report is prepared. Meetings led by the Population Register manager are held as needed with representatives of the data providers to ensure ongoing co-operation and accuracy of data.

Confidentiality of computerised data

Ensuring that computerised data remain confidential will be the responsibility of the information technology manager. He/She will need to ensure that the screening computer systems have:

- Software and hardware maintenance and support contracts
- Appropriate back-up procedures and records
- A disaster recovery strategy
- Network redundancy features
- IT security policy
- A secure system with appropriate and regularly updated password control

In addition, staff need to be made aware of the principles of the Data Protection Act by the data protection officer or delegate.

8.3.1.2 Scheduling system

Round length is the key measure of the effectiveness of the scheduling system used.

Objective:	To ensure that women are re-called for screening at the appropriate interval
Criteria:	The percentage of eligible women whose first-offered appointment is within 24 months of their previous screen
Minimum standard:	≥90%
Target:	100%

8.3.1.3 Invitations and reportingPotential exclusions

The target population for BreastCheck includes all persons eligible to attend for screening on the basis of age and gender. However, the programme has identified additional criteria on the basis of which women will be excluded from the target population. The remaining group after adjustment will be referred to as the 'eligible population'. In addition, it may be necessary to identify criteria to exclude women from the results of screening. Potential exclusions from both the target population and results of screening are listed in Table 2.

Table 2: Potential exclusions (initial or subsequent screening)

Target population	n =			
Eligible population	n =			
	Excluded from target population		Excluded from results population	
	(no.)	(%)	(no.)	(%)
Deconsent (no reason given)				
Previous breast cancer				
Previous bilateral mastectomy				
Symptomatic women (who notify the programme after receiving initial consent form or invitation)				
Recent mammogram				
Person does not exist				
An Post returns – not known				
– gone away, etc.				
Age >65				
Incapacitated – physical				
– mental				
– other				
Migration – in				
– out				
Deaths				
Terminal illness				
Other, please specify				

Initial versus subsequent screens

Initial screening examinations refer to women who undergo their first screening examination within the screening programme, regardless of the organisational screening round in which they are screened and regardless of previous invitations or reminders.

More than one lesion

For all investigations, the numbers should always reflect numbers of women (not breasts). It is possible that a woman presents with two lesions that are suspect for malignancy. In this situation, data should be recorded with respect to the worst diagnosis or the most invasive diagnostic technique used. If two breast malignancies are diagnosed, the following order of ranking is used:

- distant metastases > positive axillary lymph nodes > size of the tumour
- > invasive carcinoma > ductal carcinoma in situ (DCIS)

All screen-detected lesions will be recorded on the programme database. For individual surgeon workload or detailed audit of activity, the numbers may reflect lesions.

Age

For all epidemiological analysis, age is determined as the age of the woman at the time of the screening examination for that particular screening round. For non-participants, age is determined as the age of the woman at the time of invitation. Women aged 65 at the time of screening are excluded from analysis for the 50–64 age group. It is possible that a small number of women aged under 50 may have been invited, and these women should also be excluded from analysis for the 50–64 age group.

8.3.1.4 Re-call based on screening results

Refer to the sections on re-call and early re-call rates in Table 1 in chapter 0.

8.4 Implementation aspects of a screening programme

Implementing a breast screening programme from an epidemiological perspective entails more than simply executing the screening process and referring onwards for assessment where required. The particular epidemiological concerns at this phase focus on the complete and accurate recording of all data pertaining to the participant, the screening test, the outcome of that test, the decisions made as a consequence and the eventual outcome in terms of diagnosis. A fundamental concern at each step is the issue of QA. The success of the entire screening programme will be affected by the quality of every element of the process. Stringent quality control is therefore an integral part of each component, from performing the screening test (both operator and machine-dependent aspects), to interpreting the investigation, to classifying the findings and recording the results in a standardised manner.

8.4.1 Developing the clinical part of the NBSP database

To evaluate the effectiveness of the screening programme, it is necessary to have in place a comprehensive system for recording/documenting the activities of the programme throughout the entire process, i.e., screening through assessment, treatment and follow-up; collating relevant data from different sources; analysing and reporting the findings; and determining outcomes.

8.4.2 Components of the clinical part of the database

The components of the clinical part of the database include:

- Client data
- Clinical examination/results of screening
- Further assessments/data on cancers detected
- Outcome of treatments/follow-up data, which may be included after consideration

The sources of data for developing the clinical database are datasheets developed in consultation with specialists in the screening process. (Refer to chapters 4, 5 and 6 for quality standards.)

8.4.3 Organisation of the clinical part of the database

Dedicated screening programme software has been custom-developed for the system. Responsibility for staff training in data input will lie with the unit manager and the dedicated data quality manager. IT support for the clinical database is essential.

8.4.4 Maintenance of the clinical part of the database

The unit manager and data quality manager will be responsible for data collection at unit level and for ensuring the quality of the data. This responsibility will include:

- Training staff in data collection on the screening process
- Using a standard set of definitions relevant to screening
- Developing data collection procedure manuals
- Developing protocols for QA in data collection
- Being responsible for data entry/editing/checking
- Being responsible for QA in data management
- Estimating the completeness of the database at unit level (including types of checks)
- Estimating the accuracy of the database at unit level (including types of checks)
- Maintaining data confidentiality

8.5 Data on treatment and follow-up

8.5.1 Access to data on surgery for screen-detected cancers

(Refer to chapter 6 for acceptable standards and achievable targets.)

Data will be obtained actively from the following sources:

- Standardised data sheets completed by surgeons
- Surgical data on biopsy reports (in cases where women attend another hospital for pathology and/or surgery)

Estimates of the completeness of surgical data will need to be undertaken periodically by the data quality manager.

8.5.2 Access to cytology/pathology data for screen-detected cancers

(Refer to chapter 5 for acceptable standards and achievable targets.)

Data will be obtained actively from the following sources:

- Standardised data forms completed by pathologists
- Biopsy reports/hospital pathology records (in cases where women attend another hospital for pathology and/or surgery)

Estimates of the completeness of pathology data will need to be undertaken periodically by the data quality manager.

8.5.3 Follow-up and ascertaining interval cancers

Cancers diagnosed during the screening interval following a negative result at the previous screening round are known as interval cancers. The aim of this section is to describe the follow-up activities with the target population, including ascertaining interval cancers.

Objective:	To quantify the number of women presenting with cancers between screening episodes
Criteria:	The rate of cancers in screened women in the two years following a normal screening episode
Minimum standard:	Year 1: <0.75 per 1,000 women screened Year 2: <1.25 per 1,000 women screened
Target:	Year 1: ≤0.5 per 1,000 women screened Year 2: ≤0.75 per 1,000 women screened

8.5.3.1 Target population

The target population can be divided into four groups:

- Women who participated in the programme and were considered to have a negative screening test or were deemed not to have breast cancer after further investigation. Following up with this group is key to ascertaining interval cancers.
- Women who participated in the screening programme and were identified as having breast cancer. These women will be followed up for treatment and review, including evidence of recurrence, by their GP or at surgical, radiotherapy or oncology clinics.
- Women who were invited for screening but did not participate
- Members of the target population who were not yet invited for screening (but known to the programme) or who were not invited for screening due to incompleteness or inaccuracies in the Population Register

8.5.3.2 Sources of data for interval cancers

Follow-up for ascertaining interval cancers will require data from the National Cancer Registry, pathology registries and vital statistics. The National Cancer Registry will be the primary source of the data.

8.5.3.3 Collation of data on interval cancers

Women with breast cancer diagnosed in the 24 months following a negative screening episode will be identified as interval cancer cases. The collation of accurate statistics for interval cancers will be carried out at the PEU. The interval cancer rate is expressed as a proportion of the underlying (expected) breast cancer incidence rate in the absence of screening; hence, the rates vary across screening programmes. It is recommended that the interval cancer rate should not exceed 25 per cent of the underlying breast cancer incidence rate during the two-year screening interval. These are demanding targets because most published data from service screening show an interval cancer rate of approximately 2 per 1,000 in two years of follow-up and a proportion close to 40 per cent of underlying incidence during the two-year screening interval. It is usual to report the 12-month and 24-month interval cancer rate of a screening programme per 1,000 women screened. Interval cancers should be reported by five-year age categories, with age being the age at the time of the screening examination (subject to sufficient numbers in five-year age groups for meaningful analysis).

8.5.3.4 Radiological review of interval cancers

(Refer to chapter 4.)

Records of the radiological review need to be retained by the QA radiologist and epidemiologist to quantify the programme's false negative rate.

8.5.3.5 Radiological classification of interval cancers

(Refer to chapter 4.)

8.5.3.6 Ascertaining cancers in the non-screened population

The National Cancer Registry is the data source for cancers in the non-screened population (i.e., in non-participants and women not invited). A summary report of the number of women invited to screening by BreastCheck who did not attend and who have had cancers recorded subsequent to their invitation will be sought periodically. Individual case matching cannot be carried out because of the absence of informed consent in the non-screened population. Therefore, analysis will be undertaken at the macro level.

8.5.3.7 Comparability of data in interval and other cancers

An annual review will need to be carried out to compare surgical and pathology data items for interval cancers and cancers in non-screened women with data on screen-detected cancers.

8.5.3.8 Proposed links to the National Cancer Registry

Breast screening data and National Cancer Registry data need to be combined to determine the screening status of the women at the time of diagnosis.

Information is required on the following:

- Screen-detected cancers
- Interval cancers
- Cancers in non-attenders
- Cancers in lapsed attenders
- Cancers diagnosed before first invitation
- Cancers in the uninvited

The National Cancer Registry Tumour Registration officers should be able to track BreastCheck-detected cancers through the units. To complement this, BreastCheck will, as required, download a file to the National Cancer Registry. This file will contain demographic data pertaining to:

- All women invited for screening
- All women who did not attend
- Women with a normal mammogram result
- Women with breast cancer detected by BreastCheck

The National Cancer Registry will periodically download to BreastCheck a file containing:

- Death information in the invited population (cause of death, breast cancer, other)
- Individual cancers in the screen-attended population
- The number of cancers in non-participants
- Previous breast cancer information on the screen-attended population

8.5.3.9 Issues for quality control

The following issues may affect quality control:

- Lag period for availability of National Cancer Registry data
- National Cancer Registry unable to provide individual information to BreastCheck on women who did not attend for screening
- Data on recurrence not currently sought by the National Cancer Registry

The accessibility of information on screened cases treated in other hospitals will need to be examined carefully.

8.6 Evaluation and screening outcome

Evaluating a breast screening programme is an epidemiological undertaking of paramount importance to the programme. Parameters of performance that describe the screening process and early outcomes are measures of programme quality, which become available early in the lifetime of a screening programme (i.e., before the programme is fully operating in all geographical areas for at least 10 years). However, it will not be possible to calculate these endpoints unless adequate provision has been made in the planning process for the complete and accurate recording of the data required.

A key component of the evaluation of screening is the ascertainment of interval cancers, a process that requires forward planning and formal links with data sources other than those required for screening. The ultimate decision regarding the effectiveness of screening, i.e., the impact of screening on mortality and life years gained, demands that (i) follow-up of the screened population be continued over an extended period of time, (ii) information regarding vital status and disease-free status be ascertained and recorded at defined intervals and (iii) the determination of programme impact be based on sound epidemiological evidence.

Evaluating the outcome of screening requires considerable input from epidemiology and statistics. The performance indicators are specified below.

Process evaluation	Participation rate Additional imaging rate Re-call rate Cancer detection rate Specificity Positive predictive value (PPV)
Early outcomes	Surgical procedures performed Benign open biopsy rate Invasive cancers $\leq 10\text{mm}$ and $< 15\text{mm}$ in diameter Ascertainment of interval cancers Sensitivity
Late outcomes	Case-fatality rate Mortality rates (relative and absolute)
Programme impact	Deaths prevented Life years gained Quality of life* Side effects* Cost effectiveness*

*Require data not routinely collected

The results of a screening programme become available throughout the screening process and afterwards. Information on participation, re-call and cancer detection rates will be available at the end of each screening round. If one accepts certain assumptions, estimates of specificity and PPV can be derived at the end of a screening round. If surgical and pathological data are complete, information on surgical procedures and size and types of cancers will also be available.

The ascertainment of interval cancers and, consequently, estimates of sensitivity and negative predictive value (NPV) will not be complete until a specified interval since the last women screened in that round has passed.

Participation is the key indicator when evaluating a breast screening programme. Participation predicts the overall capacity of the programme to ultimately reduce breast cancer mortality. However, in addition to evaluating overall participation, adherence to the programme shown by women in later screening rounds should be evaluated. Adherence to the screening programme can be expressed as the percentage of women in the current screening round who also attended the previous screening round.

Background information on breast cancer in the target population is required in order to be able to interpret outcome measures of the screening programme.

8.6.1 Parameters for assessing programme performance

(Refer to Table 1 in chapter 4 for acceptable standards and achievable targets.)

Parameters by which the performance of a breast screening programme is assessed include:

- Participation/uptake rate
- Additional imaging rate
 - at the time of screening
 - total
- Re-call rate
- Cytology/biopsy procedures with an inadequate result (%)
- Total cancer detection rate (per 1,000 women screened)
- Invasive cancer detection rate
- DCIS detection rate
- Invasive cancers, ≤ 10 mm diameter (% of invasive cancers detected)
- Invasive cancers, < 15 mm diameter (% of invasive cancers detected)
- Benign open biopsy rate (per 1,000 women screened)
- Standardised detection ratio (SDR)
- Interval cancer rate

8.6.2 Explanation of terms relevant to performance parameters

Cancer

Invasive, DCIS and cancers of unknown invasive status

Uptake rate

The percentage of invitations that resulted in technically adequate screens

Additional imaging rate

The number of women who have an additional imaging investigation as a proportion of all women who have a screening test

Re-call rate

The number of women re-called for further assessment after a screen, expressed as a proportion of women with technically adequate screens

Early re-call rate from assessment

The number of women with a final outcome of assessment placed on early re-call, expressed as a percentage of women with technically adequate screens

Pre-operative diagnosis by cytology and/or core biopsy

The number of women diagnosed by C5 cytology or B5 core biopsy expressed as a percentage of the total number of women diagnosed with cancer

Benign open biopsy rate

The number of women who underwent an open biopsy, the outcome of which was benign, expressed as a rate per 1,000 women screened

Non-invasive cancer rate

The number of women with non-invasive cancer (DCIS), expressed as a rate per 1,000 women screened.

Standardised detection ratio (SDR)

The SDR was developed as an alternative to the invasive cancer detection rate. The SDR is an age-standardised measure in which the observed number of invasive breast cancers detected is compared with the number that would have been expected if the age-specific detection rates achieved by the Swedish two-county trial¹ applied. The SDR adjusts the observed cancer detection rates according to the age structure of the screened population. An SDR of 1.0 indicates parity with the Swedish two-county trial and would suggest that the mortality reduction achieved in the Swedish study should be achievable by BreastCheck.

All screening units should aim to achieve the target SDR of ≥ 1.0 . An SDR of < 0.75 indicates that a unit is detecting insufficient cancers and that a mortality drop similar to that in the Swedish two-county trial is unlikely to result. Where an SDR of < 0.75 is achieved, this should be investigated by the QA team.

When calculating the SDR for the prevalent screen, account should be taken of the level of mammographic screening in the five years prior to screening under the BreastCheck programme.

Sensitivity

The sensitivity of a screening test refers to the ability of the test to designate women with early malignant disease as 'positive'. An acceptable way of estimating the sensitivity is to follow up the negative screenees for the development of cancer within a defined time interval. If these interval cancer cases are assumed to be falsely negative, the sensitivity can be assessed by relating the interval cancers to the number of cancers detected (i.e., true positives/true positives + false negatives).

Specificity

The specificity of a screening test refers to the ability of the test to designate women without malignant disease as 'negative'. The specificity refers to the ratio of truly negative screening examinations to those that are truly negative and falsely positive (i.e., true negatives/true negatives + false positives).

Positive predictive values (PPVs)

The ratio of lesions that are truly positive to those that test positive

8.6.3 Estimating the impact of the programme

The ultimate objective of every breast cancer screening programme is to reduce mortality from the disease without adversely affecting the health status of those who participate in the programme. Studies that have been carried out in different countries, over different time periods and with differing epidemiological approaches have demonstrated that mammographic screening reduces mortality from breast cancer.

Estimates of reductions in breast cancer mortality that have been achieved to date in randomised controlled trials of mammographic screening vary from 4 per cent to 30 per cent. Estimates of benefit from case control studies could be as high as 54 per cent to 70 per cent. However, data from recent studies that examined non-randomised general population screening suggest that the impact in the non-randomised situation is somewhat reduced. Having said that, the better organised the population programme, the more reliable will be the estimate of mortality reduction.

8.6.3.1 Predicting mortality reduction

Studies on the mortality reduction achieved by screening have shown that it is possible to predict the level of reduction by reference to a number of factors specific to individual programmes. These factors include the age-specific incidence and mortality rates from breast cancer, estimates of rates of disease progression, the sensitivity and specificity of the screening test employed, the therapeutic efficacy of treatment, the age groups chosen for screening and the expected compliance rate.

8.6.3.2 Ascertaining the impact of BreastCheck on mortality

Ascertaining the impact of the programme on mortality requires that:

- Follow-up of the screened cohorts continue over extended periods of time via the National Cancer Registry
- Despite the problems of follow-up, data on vital status and disease-free interval be vigorously sought and recorded through the National Cancer Registry and other methods
- Adequate links exist between programme data and other relevant data sources, such as the National Cancer Registry, medical records, pathology registers and vital statistics
- Data required to estimate the effectiveness of screening be available, such as:
 - Pre-screening age-specific incidence and mortality data
 - Information on stage at diagnosis prior to screening

Parameters to be measured may include:

- Case-fatality rate
- Deaths prevented
- Life years gained
- Quality of life
- Cost effectiveness

8.7 References

1. Tabar L, Fagerberg G, Duffy SW, et al. The Swedish two county trial of mammographic screening for breast cancer: recent results and calculation of benefit. *J Epidemiol Community Health*. 1989; 43(2):107-14.

Quality assurance in
breast care nursing

9. Quality assurance in breast care nursing

9.1 Introduction

Quality assurance in breast care nursing within BreastCheck – The National Breast Screening Programme operates at two levels: unit and national. At unit level, the breast care nurse (BCN) will regularly audit her own performance against the standards of practice described in section 9.6 and will participate in the audit of nursing roles described in section 9.7. The operational policy for breast care nursing (screening) outlined in section 9.5 should be followed by the BCN in conjunction with the standards outlined in sections 9.6 and 9.7. At national level, a co-ordination group for nurses in breast cancer screening will co-ordinate QA activities.

9.2 Unit level

The unit-level BCN is part of a multidisciplinary team that provides services within the breast screening centre. The minimum standard required is that the nurse will:

- Actively participate in the multidisciplinary team meetings and the decision-making process¹
- Be present at the assessment clinic and, where possible, see all women attending for assessment
- Be available to support and provide information to the woman throughout the assessment process
- Be present to support and provide information when diagnosis is given
- Inform and support the woman in the discussion of treatment options
- Inform and support the woman throughout her hospital admission and initial treatment
- Keep appropriate and accurate nursing records
- Participate in clinical audit
- Ensure accurate arrangements for cover are in place when the post holder is not available
- Develop nursing practice in accordance with evidence-based findings on patient requirements

9.3 National level

A co-ordination group for nurses in breast cancer screening – the breast care nurse group – will represent nursing within BreastCheck. A QA nurse will be appointed to represent the group at the QA Committee. The group will set and review standards to be achieved by BCNs within the screening process and throughout the primary treatment of patients. The group will also identify the educational and professional needs of nurses within BreastCheck.

9.4 External review

An external QA nursing review will be undertaken by, for example, a member of the UK NHSBSP Co-ordination Group for Nurses. In the future, it is envisaged that the QA nurse representative on the QA Committee will participate in regional QA visits. The QA nurse will act as a co-ordinator for other BCNs in the screening service, will represent their interests at both local and national levels and will keep them informed about regional and national QA issues.

9.5 Operational policy for breast care nursing (screening)

9.5.1 Philosophy

As a member of the multidisciplinary team, the BCN will be committed to ensuring that a woman receives support and information throughout and, when appropriate, beyond the screening process (such as, for example, when a woman needs to be admitted to hospital). The provision of comprehensive nursing support and care is dependent on BCNs whose knowledge and skills are continually being updated. To provide the required levels of support, the BCN will need resources such as clerical support, appropriate equipment and relief staff.¹

As specified in the sections below, the operational policy for breast care nursing within the screening programme outlines boundaries and lines of communication so that repetition and overlap is avoided. The policy should be followed in conjunction with the standards and protocols outlined in sections 9.6 and 9.7.

9.5.2 The BCN's role

As a member of the multidisciplinary team within the screening programme, the BCN will provide specialist nursing advice, education and support to women and their families.² She will be a resource for colleagues and other members of the multidisciplinary team. She will be accountable for her own professional practice in accordance with An Bord Altranais Cnámhseachais na hÉireann (Nursing and Midwifery Board of Ireland [NMBI]).³ The BCN is responsible for auditing her clinical practice.¹

The BCN will be present during the assessment clinic and will have access to dedicated facilities (e.g., a room) that provide privacy.

Through agreed referral pathways, the programme BCN will have access to a BCN in the hospital sector and will be able to contact professionals in other healthcare settings when necessary.¹

9.5.3 Communication

All members of the breast care team will be expected to establish channels of communication within the screening programme. Existing networks will be used to ensure that liaison between the screening programme as a whole and other healthcare providers is effective.¹

9.5.4 Accountability

The BCN will report to the unit clinical director and will be professionally accountable to NMBI.¹

9.5.5 Documentation

Systems of documentation will be agreed and established to ensure that accurate records are available for audit and research. The BCN will be responsible for ensuring that women's records are confidential. Documentation includes data recorded for the NBSF database.

9.5.6 Education and research

The BCN will have achieved qualifications relevant to the role (see Table 3 below). She will have access to and support for ongoing professional development.^{1,2} The BCN will be given the opportunity to complete an annual personal development plan. To support this, time and development funding will be made available.

9.6 Standards of practice

This section outlines the standards of practice expected of BCNs working within the screening programme.¹ Standard 1 sets out the criteria that must be met before a nurse can function at BCN level. Standard 2 sets out the standard of care expected of the BCN in the assessment and results process. Standard 3 sets out the role of the BCN in co-ordinating primary treatment.

9.6.1 Standard 1: Criteria to practise as a BCN

Rationale: A nurse must be adequately prepared to practise as a BCN. The level of study required to achieve a specialist qualification (as specified by the HSE) is given in Table 3 below.

Table 3: Standard 1: Criteria to practise

Standard	Outcome measure
Registered with NMBI on the general division of the live register. Ideally, the nurse should have:* <ul style="list-style-type: none"> • Five years' post-registration experience • Experience of working within breast/ oncology 	Evidence of relevant qualifications (certificates available)
Post-registration qualifications should ideally include: <ul style="list-style-type: none"> • Higher diploma in oncology with breast care modules or equivalent (or willing to enter into a contractual undertaking to obtain a higher diploma) • Relevant counselling/communication skills • Evidence of further education/ appropriate expertise in the specialty • Evidence of commitment to professional development, training and research 	The BCN is appropriately graded.

*Recommendations

9.6.2 Standard 2: BCN role in assessment and results process

Rationale: The role of the BCN (screening) is to inform and support the woman throughout the assessment and results process. Re-call for breast assessment has been found to increase anxiety. A difficult assessment experience may deter a woman from attending subsequent screening. The BCN can help to make breast screening more acceptable to a woman by providing her with information and psychological support. Each assessment clinic should have a BCN present throughout the assessment and results process. Research has shown that giving adequate information in accordance with the needs of the woman can decrease anxiety and enhance the woman's ability to cope.⁴ The BCN will also be involved in discussions with the woman regarding all treatment options and will provide information and support during the decision-making process.

Standard 2 covers two BCN roles:

- Clinical
- Managerial/educational/research

Table 4: Standard 2: Clinical role

Standard	Outcome measure
The BCN is present throughout the assessment clinic to provide information and psychological support. Women re-called for assessment are made aware of the availability of BCNs and are given contact details.	All re-called women have access to the BCN. BCN contact details are available to women.
Women requiring further investigations (biopsy or further treatment) are seen by the BCN.	Records reflect the involvement of the BCN.
Facilities are available for private consultation with the BCN.	There is evidence of the availability of private facilities.
The BCN evaluates and supports all women who require interventions at the assessment/results clinic and ensures relevant interventions are made. The BCN has appropriate knowledge and skills to recognise psychological distress.	There is evidence of assessment.
The BCN assesses the woman's requirement for information and offers appropriate verbal and written information. Information includes details of support groups.	The records reflect the information offered.
The BCN has relevant qualifications and knowledge to enable her to provide required specialist information and support to the woman throughout the decision-making process and hospital admission.	Women have access to a BCN with suitable qualifications.

Table 5: Standard 2: Managerial/educational/research role

Standard	Outcome measure
The BCN is a recognised core member of the multidisciplinary team and contributes to the discussions regarding ongoing care.	The minutes of the multidisciplinary meetings record the presence of the BCN.
The documentation system on the programme database records details of information and support given to the woman. This information is made available to the BCN in the symptomatic service when the woman's primary treatment is completed.	The documentation records the information and support given by the BCN. The BCN within the symptomatic service has access to all the information required for the woman's ongoing care.
The BCN contributes to the overall development and promotion of the programme through her involvement in teaching and research.	There is evidence of formal and informal teaching.

9.6.3 Standard 3: BCN role in co-ordinating primary treatment

Rationale: To ensure that women who have been identified as requiring surgery are referred to the hospital service and that their admission is organised by appropriate personnel. Women are provided with follow-up appointments as deemed necessary. The BCN liaises with the relevant personnel to provide this service.

Table 6: Standard 3: Role in co-ordinating primary treatment

Standard	Outcome measure
The BCN provides information and details for the woman's admission.	There is evidence of an effective referral system.

9.7 Protocol for assessing the performance of the BCN

To achieve a high standard of care for women, it is important that the written standards of care published in this guidelines document be regularly applied and monitored by the BCN. An external QA process will be followed to review and audit the role of the BCN within the assessment unit.¹ With the support of the QA Committee, the QA Committee's BCN representative will organise an external QA visit approximately every five years.

9.7.1 Questionnaire

To ensure that there is uniformity in the nursing role and responsibilities and to highlight any difficulties or areas of concern, a standard 'visit questionnaire' is completed for the BCN being reviewed during the external QA visit. The results of the questionnaire are collated and analysed with a view to identifying recommendations for improvement. During the QA visit, the questionnaire should be completed with reference to the standards specified in section 9.6.

The aims of the questionnaire are:

- To review the performance of the BCN against the guidelines specified in this document
- To determine whether the BCN in the assessment unit is appropriately graded (see section 9.6) and has undertaken or is currently undertaking training
- To assess the workload of the BCN (against contracted hours)
- To ensure that a high standard of care is achieved by regularly auditing and monitoring the practice of the BCN according to the standards of care specified in section 9.6
- To ensure that the BCN participates as a member of the multidisciplinary team
- To provide an opportunity to the BCN to demonstrate working practices and to raise specific QA issues that the QA Committee may need to address
- To provide a tool to facilitate discussion about issues that affect quality, to disseminate good nursing practice and to discuss and agree actions to address BreastCheck standards of nursing care that are not being achieved

9.7.2 Action

The external reviewer will clearly identify areas of concern and instances where the standards of care as published in this guidelines document are not being achieved. The reviewer will inform the QA Committee's chair and BCN representative of the concerns and, together with the BCN and local management, as appropriate, will plan a course of action to address the identified issues. The proposed plan of action will be clearly documented in the QA visit report, and a specific timescale will be set. Confidentiality should be maintained. It is anticipated that areas of concern could be addressed at local level in most cases. Unresolved issues should be reported to the chair of the QA Committee.

9.7.3 Reports

Following each QA visit and completion of the visit questionnaire, the reviewer will submit a written nursing report to the QA director within the specified time. The reviewer must ensure that all QA visit questionnaires are retained by the NSS and available on request.

9.8 Quality assurance visit questionnaire

Breast Screening Unit:			
Name of BCN (Screening):			
Please complete one questionnaire per nurse working in screening.			
Grade:	PT (hours):		
FT:			
Relevant qualifications: (Please provide photocopies.)			
Name of visitor:	Date of visit:		
Recommendations			
1. To whom are you accountable? Professionally: Managerially:			
2. Which of the following facilities do you have?			
Contact card	Yes/No	Private room	Yes/No
Bleep	Yes/No	Answer phone	Yes/No
Secretary	Yes/No	Office	Yes/No
Computer	Yes/No		

	<p>3. a) How many assessment clinics are held each week? b) How many assessment clinics are attended by you each week? c) Is your post a combined breast screening and symptomatic role? d) For how many nursing hours per week are you contracted to BreastCheck?</p>	
	<p>4. Do women have your name and contact number before they attend the assessment clinic?</p>	<p>Yes/No</p>
	<p>5. If you are not present at the assessment clinic, a) Who contacts you? b) How are you contacted? c) When are you contacted? d) What are the criteria for contacting you?</p>	
	<p>6. a) Is a BCN available to all women attending the assessment clinic? b) Are you able to see women in private if necessary?</p>	<p>Yes/No Yes/No</p>
	<p>7. Do you refer women to the BCN in the symptomatic clinic? (Please provide evidence of the referral mechanism.)</p>	<p>Yes/No</p>
	<p>8. a) Are you involved with the woman: b) At the time of her assessment? c) At the time of her diagnosis? d) During her ongoing care?</p>	<p>Yes/No Yes/No Yes/No</p>

<p>9. Please specify the literature/information that is available for women in the assessment clinic:</p>	
<p>10. Record keeping:</p> <p>a) Please specify for which women you keep records:</p> <p>b) What do you document?</p> <p>Contact card given Yes/No</p> <p>Clinical details Yes/No</p> <p>Information offered Verbal: Yes/No Written: Yes/No</p> <p>Psychological assessment Yes/No</p> <p>Referral to other health professionals Yes/No</p> <p>Others (please specify)</p>	
<p>11. Do women have options within the following areas?</p> <p>a) Hospital? Yes/No</p> <p>b) Consultant? Yes/No</p> <p>c) Treatment? Yes/No</p>	
<p>12. How many women did you see last year in the assessment clinic?</p>	

<p>13. How often do you attend the multidisciplinary meeting?</p> <p>a) Weekly</p> <p>b) Monthly</p> <p>c) Less frequently than monthly</p> <p>d) Never</p>	
<p>14. Are you auditing your own clinical practice?</p> <p>(Please provide evidence.)</p>	<p>Yes/No</p>
<p>15. Are you involved in any research related to screening?</p> <p>Please specify/give examples of evidence-based practice:</p>	<p>Yes/No</p>
<p>16. Do you feel you have the opportunity to participate in ongoing education? Yes/No</p> <p>If not, are there any courses that you would like to take?</p>	
<p>17. How many relevant courses/study days have you taken in the last year?</p>	

18. Do you have cover for sick/study days/annual leave?	Yes/No	
19. What support do you have?		
20. Do you have an annual Individual Performance Review (IPR)? Date of last IPR	Yes/No	
21. Are you involved in teaching formally/informally? (Please provide evidence.)	Yes/No	
22. Are there any initiatives, suggestions or problems you wish to highlight? Please specify:	Yes/No	
23. If there is anything you wish to discuss before the visit, please contact the named QA visiting nurse.		

9.9 References

1. NHS National Cancer Screening Programmes. Interim quality assurance guidelines for clinical nurse specialists in breast cancer screening, 5th ed. NHSBSP Publication no. 29 [online], 2012, available: <http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp29.html> [accessed 11 Dec 2014].
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5. National Council for the Professional Development of Nursing and Midwifery. Framework for the establishment of clinical nurse/midwife specialist posts, 4th ed. Dublin: National Council for the Professional Development of Nursing and Midwifery; 2008.



An tSeirbhís Náisiúnta Scagthástála
National Screening Service



BreastCheck

An Clár Náisiúnta Scagthástála Cíoch
The National Breast Screening Programme