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People in Ireland have a right to expect that medical care be of good quality. They expect that standards of care are consistently high. They expect that access to care is easy, speedy, effective and efficient.

Society expects quality of care to measure up to international norms of good practice. Such assurance can be given by auditing the quality of activity. The word “audit” in clinical medicine means more than the accurate recording of data. It also involves (i) the analysis of data in the context of current good practice; (ii) proposals for improvement arising from the analysis; (iii) the implementation of proposals; and (iv) a repeat of the process in the light of the new developments. Thus, clinical audit represents a continuous process in an upward spiral of improving care towards the goal of excellence.

Demonstration of quality is of supreme importance in cancer care. Cancer patient rights are human rights. Commitment to improvements in care and support for cancer research must be unambiguous, vigorous and sustained.

Inequalities in access to good treatment and variations in outcomes are of deep concern. In response to these troubling issues, many countries have developed guidelines. The primary purpose of cancer guidelines is to reduce morbidity and mortality. They are also helpful to public health officials and to politicians in the planning of health services. Because they are based on clinical evidence, guidelines also reinforce processes of critical appraisal and contribute to professional development.

However, because of improvements in cancer care and the arrival of new technologies and treatments, guidelines soon become outdated, even obsolete, and therefore must be reviewed frequently.

Combining audit with good practice provides a robust and reliable system of cancer care. Such a measurable system provides reassurance to the public, to patients, to relatives and to others. Indices of quality can be selected so that standards in treatment centres can be compared with others nationally and internationally. In this way, standards rise, public confidence is enhanced and research opportunities are promoted.

Breast cancer remains the most common fatal cancer in women and the incidence of the disease is increasing. Such is the anxiety surrounding the disease that all women with breast complaints require rapid expert diagnosis, even though the large majority of breast symptoms are not due to cancer. Prospects for long-term survival and cure, as well as improved quality of life, are increasing. Closer collaboration among clinical doctors, basic science researchers and industry has resulted in shorter times between scientific discovery and clinical application.

Breast cancer is distinctly uncommon in men, but when it occurs it may pose a serious threat to health and requires the same level of expert care as that expected by women with this condition.

Patients are much more likely to survive if they are treated in specialised centres. Thus, specialist breast centres are now recommended worldwide, and were proposed in Ireland in 2000 in the Report on the Development of Services for Symptomatic Breast Disease. In order to maintain expertise and to be able to apply new treatments speedily, such centres must treat a large number of patients.

All personnel involved in breast care should have undergone specific and dedicated training and should attend courses of learning and instruction in order to remain up to date with developments and advances in diagnosis and treatment.

In 2005 the Department of Health and Children established a national quality assurance group for symptomatic breast services. The group represents specialised medical and nursing services involved in the care of women with breast disease. The chairperson of Europa Donna Ireland, the Irish Breast Cancer Campaign, is also a member. The group first developed a series of guidelines for good clinical care for each of the specialty disciplines. The Irish Health Services Accreditation Board supported the function and operation of the development of the standards.
As part of this process, specialists from around the country were consulted and a well-attended and widely supported consultative meeting took place in Dublin in April, 2006. Informed by suggestions and recommendations from a wide range of specialists involved in breast cancer care, data relevant to each specialty were compiled. From such lists, indicators of quality were drawn up.

This report relates to the general requirements for patient care in the setting of the breast centre and the physical and administrative facilities that should be in place to facilitate patients and services. It also defines measures of high quality for each specialty involved in breast cancer care.

The recommendations in this report should be taken in conjunction with the Report on the Development of Services for Symptomatic Breast Disease (2000) in which the specific requirements for a specialist breast centre, in terms of personnel, equipment and facilities, were itemised and explained.

It is recommended that a meeting of representatives from all specialist breast centres be convened regularly, at least annually, so that the performance of each centre can be assessed and compared. The purpose of this exercise is to improve care and drive standards upwards, not to censure institutions or individuals.

We hope that this series of recommendations can be applied soon to all designated specialist breast centres and will have the support of all the political, administrative, medical and nursing groups. We believe that the procedures and standards described here will also be adopted and applied in the private sector This process has had the strong support of patient advocacy groups across all the countries of Western Europe and beyond. We also hope that a similar system of clinical and administrative audit will be found to be helpful and will be applied to other forms of cancer and, possibly, to other types of common illness in the near future.

Niall O’Higgins
October 2006
Chairman
1.0 Prerequisites for a Functioning Specialist Breast Centre
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a) Personnel

1.1 Specialist breast centres shall provide care/services to a population size of approximately 300,000–350,000. They shall have facilities to provide care/service to more than 150 newly diagnosed patients with primary breast cancer per year. All specialist breast centres shall be separate entities, rather than part of a general surgical clinic, and shall have facilities for at least one triple-assessment clinic per week.

1.2 The specialist breast centres shall hold at least one triple-assessment clinic per week for newly referred patients with suspected breast disease.

1.3 A functioning multidisciplinary team must be available at the breast centre. The core personnel required for this team are:
   - Consultant breast surgeon and team
   - Consultant histopathologist
   - Consultant radiologist and radiographer
   - Clinical nurse specialist breast care
   - Consultant radiation oncologists
   - Consultant medical oncologists
   - Consultant plastic and reconstructive surgeons
   - Clinic staff
   - Administrative staff

1.4 In addition to the core personnel as outlined in the Report on the Development of Services for Symptomatic Breast Disease, many other support staff are required to facilitate the functioning of the centre. These should include:
   - Administrative staff
   - Oncology pharmacist
   - Clinical geneticist/Genetics counsellor
   - Data management personnel
   - Research nurse
   - Lymphoedema nurse (or specialist)
   - Palliative care specialist/ team
   - Psychiatrist/ Clinical psychologist
   - Social worker
   - Occupational therapist
   - Plastic surgeon
   - Physiotherapist
   - Nominated orthopaedic surgeon with expertise in the management of bone metastases
   - Access to a neurosurgeon
1.0 Prerequisites for a Functioning Specialist Breast Centre

1.5 There shall be a database in each centre that correlates with the data inputted and can be integrated with other in-house and outside systems.

1.6 The breast centre shall have at least two nominated Consultant surgeons specially trained in the care of patients with breast disease.

1.7 There shall be at least two nominated Consultant radiologists, fully trained and with continuing experience in all aspects of breast disease and associated imaging.

1.8 The breast centre shall have at least two Consultant histopathologists with expertise in breast pathology and designated time for breast work.

1.9 The breast centre should have at least one specialist breast care nurse per 50 breast cancer patients.

1.10 There shall be one whole-time-equivalent Consultant radiation oncologist post dedicated to the specialist breast centre.

1.11 The specialist breast centre shall provide clear and accurate information to patients in verbal, written and other appropriate formats, ensuring that special and minority needs are catered for.

1.12 All staff of the specialist breast centre shall have expertise in communication skills.

1.13 All personnel involved in specialist breast centres shall have allocated, dedicated time for satisfactory conduct of work.

b) Physical facilities and equipment

1.14 Each specialist breast centre shall have dedicated purpose-built physical facilities suitable for the care of patients with breast complaints.

1.15 The administrative and clinical examination areas and the diagnostic areas shall all be in close proximity, preferably in a single dedicated area.

1.16 As outlined in the Report on the Development of Services for Symptomatic Breast Disease, facilities shall include a friendly, comfortable environment with private areas for consultation and counselling.

1.17 Requirements include a reception area, a waiting room, outpatient accommodation close to the radiology and ultrasound area and a pathology room with microscopes and storage facilities.

1.18 Specific mandatory requirements include inpatient beds and dedicated operating time.

1.19 Each specialist breast centre shall be equipped with basic mammography and stereotactic mammography equipment, together with the required processing equipment and ultrasound machine.
2.0 Referral by General Practitioners (GPs) to the Specialist Breast Centre
General Practitioners should have clear information and guidelines on intended referral pathways and on the outcome of the referred patient. The guidelines for referral are not to replace clinical judgement, and a patient deemed to require urgent consultation may need a specific personal contact with the specialist breast centre.

2.1 The patient shall be referred to the specialist breast centre by GPs in accordance with the following written guidelines and written protocols:

2.1.1 Urgent Referrals – to be seen within two weeks

A patient in one or more of the following categories shall be viewed as an urgent referral and shall be seen within two weeks:

1) Patients aged over 35 years with a discrete lump (unilateral, distinct, separate mass)
2) Patients with signs that are highly suggestive of cancer, such as:
   - ulceration
   - skin distortion
   - unilateral nipple eczema
   - recent nipple retraction or distortion
   - discrete lumps
3) Patients whom the GP deems to have a high likelihood of breast cancer at any age
4) Patients with an acute breast abscess. Such patients require immediate referral

2.1.2 Early Referrals – to be seen within six weeks

A patient in one of the following categories shall be viewed as requiring early referral and shall be seen within six weeks:

1) Patients aged under 35 years with a discrete lump (unilateral, distinct, separate mass)
2) Patients with a persistently refilling or recurrent cyst
3) Patients with breast pain not responding to reassurance and simple measures, such as wearing a well supporting bra and simple analgesia
4) Patients with nipple discharge:
   - Aged under 50 with bloodstained discharge
   - Aged over 50 with unilateral nipple discharge

2.1.3 Routine Referrals – to be seen within 12 weeks

Routine referral relates to a patient whom the referring doctor considers to require an opinion or investigation at the specialist breast centre but where there is no clinical concern about breast cancer. These patients shall be seen within 12 weeks.

2.2 A patient in the following categories shall be managed in primary care initially:

- A premenopausal woman or a woman on hormone replacement therapy (HRT) with tender, lumpy breasts
- A postmenopausal woman with symmetrical nodularity
- A patient with minor or moderate degrees of breast pain who does not have a discrete palpable lesion
- A patient with bilateral nipple discharge which is neither blood-stained nor troublesome.
2.3 General Practitioners shall have specific training in carrying out clinical breast examination in patients with breast symptoms.

2.4 An asymptomatic patient with no family history of breast cancer who is at low risk of developing breast cancer should be encouraged to attend the breast screening appointment at BreastCheck if in the appropriate age group.

2.5 All patient referrals shall be dated and sent by letter, fax or secure email and shall contain the relevant clinical information.

2.6 Leaflets detailing referral guidelines to the specialist breast centres shall be available for patients in the GP centre.

2.7 At key points in the patient’s clinical pathway, there shall be coordination and integration of services with the GP and the specialist breast centre.

- Key information shall be provided to GPs in relation to the services provided by the breast centre.
- Information and communication pertinent to the patient shall be provided to the GP in a timely manner.

2.8 An urgent triaged patient referred by the GP shall be offered an appointment in the specialist breast centre within two weeks of receipt of the referral.

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<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure that all urgent referrals are seen promptly</td>
<td>An urgent triaged patient referred by the GP is offered an appointment to attend the specialist breast centre within two weeks of receipt of the referral</td>
<td>More than 95% are offered appointments within two weeks</td>
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</table>

2.9 There shall be monitoring of breast centre capacity and demand to ensure an appropriate balance between urgent and non-urgent referrals. Following triage, the GP shall be informed of the waiting time.

2.10 General Practitioners shall receive information from the specialist breast centre within seven working days of a patient’s attendance at the centre.

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<tr>
<th>Quality Objective</th>
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<tbody>
<tr>
<td>To ensure prompt communication from the breast centre to the GP</td>
<td>GPs receive information from the breast centre within seven working days of a patient’s attendance at the centre</td>
<td>GPs are informed within seven working days in over 95% of cases</td>
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</table>
3.0 Attendance at the Specialist Breast Centre
Attendance at breast clinics is a stressful experience for many patients and information about procedures in the clinic can alleviate patients’ anxieties prior to attendance. It is important that patients meet skilled, experienced staff who can guide them through the process. The confidential nature of the consultation, investigation and treatment is critically important and all staff shall be conscientiously respectful of the patient’s right to confidentiality and privacy.

For patients who use symptomatic breast disease services, the non-clinical aspects of patient care are their introduction to the services and will influence the way in which they access and perceive the clinical aspects. The following aspects of care have been identified in research as being of central importance to patients: the provision of information, the communication skills of the professionals, how visits to the breast centre are organised, how the communication of diagnosis is dealt with and the adequacy and ease of access to support services for patients and their families. Quality-assured non-clinical patient care will ensure that patients are treated with respect and dignity at all times.

It is important that the information given to patients, in whatever format, be timely, sensitive and easy to understand. It should have the effect of explaining the clinical guidelines and helping them to understand that these guidelines (and especially the multidisciplinary approach) will provide them with best quality diagnosis, care and treatment.

**a) Patients’ expectations and requirements**

3.1 The patient shall be offered clear, objective, full and prompt information in verbal, written and other appropriate formats. Special and minority needs shall be catered for.

3.2 Information provided in leaflets and other formats, both oral and written, shall be in clear and comprehensible language. Patient groups should be involved in their compilation and design.

3.3 Patients, their carers and primary care staff shall be given specific written information about their treatment and its likely side-effects, and contact details for help and advice.

3.4 The extent of detail required at the initial information meeting will vary with the individual and may therefore affect the timing and amount of information provided.

3.5 Patients’ preferences regarding who should accompany them at the time when their diagnosis and treatment are being discussed should be taken into account.

3.6 Patients shall be given the opportunity to discuss their options in relation to future fertility, and shall be given relevant information.

3.7 If they so wish, patients shall be accompanied by a person of their choice at any time seeking information, particularly at critical points of care.

3.8 Patients shall be informed by a social worker about sources of social and practical help and financial entitlements, both verbally and in written form.

3.9 The patients’ records shall include a checklist to show what information has been provided.

3.10 Patients shall be asked to provide feedback on their experience of the treatment, including all side effects, facilities and services. This feedback will be recorded.

3.11 All clinical members of the breast care multidisciplinary team shall be trained in communication and counselling skills and shall maintain such training on a continual basis.
3.12 The multidisciplinary team shall follow recommendations for breaking bad news to a patient.
3.13 The patient shall have a specific time for appointment and be seen within one hour of that time.
3.14 The patient shall be shown to a comfortable waiting area while waiting to be examined.
3.15 The patient shall prepare for the physical examination in a private environment (e.g. a cubicle).
3.16 Patients shall be given clear and detailed information to allow them to make decisions based on evidence.
3.17 Patients receiving information regarding their diagnosis shall be given adequate time to consider options of treatment before decisions are reached.
3.18 Appointment details for the specialist breast centre shall be sent to the patient and to the patient’s referring doctor.
3.19 Before attending, the patient shall receive information regarding procedures that may be undertaken at the specialist breast centre and the length of time they are likely to take.
3.20 Following triple assessment, and when the diagnosis is of breast cancer, the patient shall be given an appointment for a return visit within two weeks so that the definitive diagnosis can be given.
3.21 A patient who is receiving a diagnosis of cancer shall have a clinical nurse specialist present at the time of consultation about the diagnosis. The specialist breast care nurse shall:
   • be present to discuss the implications of treatment and provide advice and emotional support throughout the assessment process; and
   • continue to provide information and support for the patient during the cancer continuum from diagnosis through to follow-up.
3.22 The patient shall be given the option to meet with someone who has undergone similar treatment.
3.23 Before making a decision about breast reconstruction, the patient shall be given the opportunity to meet someone who has undergone similar surgery.
3.24 After operation, the patient shall receive information on wound care. A physiotherapist shall attend and treat the patient after surgery or radiotherapy to the axilla and provide advice about exercise and care of the arm.

b) Clinical requirements at first attendance
3.25 At the outpatient visit, the following information shall be recorded for each patient:
   • Name
   • Address
   • Date of birth
   • Telephone number(s) – including mobile and work numbers
   • Symptoms
   • Details of the patient’s health insurance or medical card status
   • Referring doctor’s name, address and contact details
3.26 A detailed clinical history shall be taken from the patient prior to examination.

3.27 Diagnostic procedures for breast disease requires triple assessment:
   1) clinical examination
   2) imaging by mammography and/or ultrasound
   3) pathology sampling.

3.28 Fine-needle aspiration (FNA) for cytology or core biopsy for histology shall be conducted under image-guidance, which is more precise and accurate than clinical biopsy. Clinical core biopsy may be indicated where imaging fails to identify a suspicious lesion.
4.0 Multidisciplinary Team and Meeting
Patients newly diagnosed with breast cancer should have their care discussed at regular multidisciplinary team meetings. The surgical operation, the options for adjuvant systemic therapy and radiotherapy and how these treatments can best be planned and arranged should all be discussed at the multidisciplinary team meeting. The meeting should have a chairperson to co-ordinate proceedings and decisions from the meeting.

The decisions should be discussed with the patient and the patient’s GP within a defined time period and the recommendation should be carried out, also within a defined period. Any change in the treatment plan that may arise after consultation with the patient should also be documented.

It is recognised that the clinical decision reached at the multidisciplinary team meetings shall be treated as a recommendation and that the clinical decision may be modified due to patient choice and circumstances.

4.1 A multidisciplinary breast team meeting shall be held at least weekly to discuss every patient who has had a core biopsy or FNA and to plan subsequent treatment for the patient.

4.2 A session must be allowed for attendance by representatives from all specialties at weekly team case management and audit meetings.

4.3 Information necessary for effective team functioning and clinical decision-making shall be available at each meeting, including a list of patients to be discussed, imaging and pathology and copies of relevant clinical and diagnostic information and reports.

4.4 The patient shall relate to a specific clinician at each stage of treatment, e.g. the Consultant surgeon in the early stages of the disease, the Consultant medical oncologist during the phase of adjuvant treatment, the Consultant radiation oncologist and, where appropriate, the palliative care physician. These arrangements shall be explicit and understood by the patient.

4.5 A medical Consultant shall be the administrative head of multidisciplinary team meetings.

4.6 Team members shall be prepared for the multidisciplinary team meeting. Preparation for and attendance at meetings shall be recognised as clinical commitments and time shall be allocated accordingly.

4.7 Patients discussed at the multidisciplinary team meeting shall include: 1) all new patients who have clinical or radiological/sonographic abnormalities, 2) all patients who have had triple assessment, 3) all patients following the first therapeutic operation, and 4) those for whom, at any time, discussion at the meeting is deemed appropriate.
4.8 Every patient undergoing core biopsy, surgical biopsy or FNA shall be discussed at the multidisciplinary meeting to ensure concordance of data.

4.9 A definitive diagnosis (cancer or a benign condition) shall be achieved within two weeks of an urgently referred patient’s attendance at the specialist breast centre.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure that patients receive prompt and accurate diagnosis</td>
<td>Definitive diagnosis (cancer or a benign condition) is achieved within two weeks of an urgently referred patient’s attendance at the specialist breast centre</td>
<td>More than 90% of cases</td>
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4.10 A patient receiving a diagnosis of cancer shall be given the diagnosis by the Consultant surgeon in a private environment and with a specialist breast care nurse present.

4.11 A patient shall be offered admission for the first therapeutic operation within three weeks of definitive diagnosis.

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<tbody>
<tr>
<td>To ensure that patients are offered admission for the first therapeutic operation within a prompt timeframe</td>
<td>Patients are admitted for the first therapeutic operation within three weeks of definitive diagnosis</td>
<td>More than 90% of cases</td>
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</table>

4.12 Patients shall be informed that they are entitled to further opinions concerning their clinical management and facilitated in this arrangement if they wish.

4.13 All patients shall be discussed after primary surgical treatment when full histological and other biological information is available. In this way, follow-up adjuvant loco-regional and systemic treatment can best be planned.

4.14 Local protocols shall be in place to ensure patient confidentiality during multidisciplinary meetings.

4.15 A patient with breast cancer shall have the opportunity, and shall be encouraged, to participate in clinical trials in surgery, radiation therapy and systemic therapy.

4.16 Written communication to the general practitioner and/or referring doctor indicating the proposed treatment plan shall occur in a timely fashion.
5.0 Surgery
5.0 Surgery

The Consultant surgeon is usually the first medical specialist to see patients in the specialist breast centre and will be responsible for directing the arrangements for diagnosis and for planning and conducting primary surgical treatment.

The evolution of the discipline of surgical oncology requires all Consultant surgeons who treat patients with breast cancer to have had specific training and expertise in breast cancer surgery and to be familiar with developments and trends in the specialist disciplines concerned, such as radiology, pathology, medical oncology and radiation therapy.

In this way, the multidisciplinary meeting becomes a forum for knowledge, experience and expertise, directed at the specific needs of individual patients.

It is imperative that the Consultant surgeon, as a surgical oncologist, continues to be involved in the follow-up of patients, in the context of the multidisciplinary meeting.

The quality assurance details described below draw attention to the current standard of practice and should be revisited in approximately three years as advances in research and other innovations are applied to patient care.

5.1 Individual Consultant surgeons shall treat a minimum of 50 and a maximum of 150 new patients with breast cancer per year and must attend at least one diagnostic clinic per week.

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<tr>
<td>To treat an appropriate number of new breast cancer cases</td>
<td>Individual Consultant surgeons treat a minimum of 50 and a maximum of 150 new patients with breast cancer per year</td>
</tr>
<tr>
<td>To involve Consultant surgeons in the diagnostic process</td>
<td>Consultant surgeons attend at least one diagnostic clinic per week</td>
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5.2 Patients shall have all treatment options discussed with them by the Consultant surgeon (including breast-conservation, mastectomy and reconstruction), and shall be involved in the decision-making process.

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<th>Target</th>
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<tbody>
<tr>
<td>To keep patients informed of treatment options</td>
<td>All treatment options are discussed with patients before operation by the Consultant surgeon</td>
<td>More than 90% of cases</td>
</tr>
<tr>
<td>To ensure that patients are actively involved in decisions concerning their treatment</td>
<td>Patients are involved in the decision-making process</td>
<td>More than 95% of cases</td>
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5.3 Non-operative diagnosis shall be achieved in over 90% of patients.

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<tr>
<td>To minimise physical and psychological distress and to validate the efficacy of the triple-assessment service</td>
<td>The patient is diagnosed without a surgical operation</td>
<td>More than 90% of cases</td>
</tr>
<tr>
<td>To ensure maximum accuracy</td>
<td>Core biopsies are image-guided</td>
<td>More than 95% of cases</td>
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5.4 For the few patients requiring an open surgical biopsy, the ratio of malignant to benign open surgical operations should be greater than 7:1. This excludes patients with atypical ductal hyperplasia following a core biopsy, patients with fibroadenomas greater than 3cm, papillary lesions, radial scars or phylloides tumours.

5.5 The patient shall be examined before operation by the Consultant surgeon who shall be fully informed of the clinical situation of the patient and of the outcomes of the diagnostic investigations before the operation.

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<tbody>
<tr>
<td>To ensure that the patient receives the highest quality care during surgical procedures</td>
<td>Consultant surgeons are fully informed of the clinical situation of the patient and of the outcomes of the diagnostic investigations before the operation</td>
<td>More than 95% of cases</td>
</tr>
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</table>

a) Pre-treatment

5.6 Before operation, all patients should have a complete medical history and physical examination, a full blood count, biochemical liver function tests, chest radiograph, serum calcium and alkaline phosphatase. Staging investigations with radiology and sonography should be carried out in:

(i) patients with symptoms or signs suggestive of metastatic disease

(ii) patients with abnormal liver or bone biochemistry

(iii) patients with large (T3) tumours or extensive nodal disease

Routine staging investigations are normally specified as requirements in patients undergoing clinical trials of surgery or adjuvant systemic therapy.

5.7 Clinical Tumour Nodes Metastasis (TNM) staging shall be documented (Appendix 2).

5.8 Results of the imaging investigations shall be available in the operating theatre.
5.9 Breast conserving surgery is contra-indicated if:
- the relative size of the tumour to the size of the breast is too large to be compatible with acceptable cosmesis
- there is multicentric disease or extensive malignant microcalcification on mammogram
- there is a contra-indication to local radiotherapy (e.g. previous radiotherapy at this site, connective tissue disease, severe heart and lung disease, pregnancy)

A centrally located tumour is not a contra-indication to conservation, although it may require excision of the nipple and areola, which may compromise cosmesis.

5.10 Patients with clinically occult lesions, or where there are doubts about the location of the tumour, shall have pre-operative localisation guided by ultrasound or by stereotactic mammography equipment / X-ray.

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<tbody>
<tr>
<td>To ensure precise removal of clinically occult lesions without compromising margins or cosmesis</td>
<td>Localisation of clinically occult lesions is image-guided</td>
<td>More than 95% of cases</td>
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5.11 All patients treated with breast-conserving surgery shall have a consultation with a Consultant radiation oncologist.

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<tbody>
<tr>
<td>To ensure that radiotherapy is considered in all patients with breast cancer following breast conservation</td>
<td>The patient shall have a consultation with a Consultant radiation oncologist</td>
<td>More than 95% of cases</td>
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</tbody>
</table>
5.12 A patient with locally advanced breast cancer shall be considered for combined modality treatment including primary chemotherapy, cytoreductive surgery for clinically overt disease and radiation therapy. All such patients shall be discussed at the multidisciplinary meeting before treatment.

- For locally advanced disease, over 80% of patients shall have combined modality treatment including radiation therapy
- More than 95% of patients shall be discussed and treated accordingly

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<tbody>
<tr>
<td>To ensure that the most effective treatment plan is devised for patients with locally advanced disease</td>
<td>Patients with locally advanced disease have combined modality treatment including radiation therapy</td>
<td>More than 80% of cases</td>
</tr>
<tr>
<td>To ensure the appropriate management of patients with locally advanced disease</td>
<td>The treatment plan for the patient is discussed before operation</td>
<td>More than 95% of cases</td>
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</table>

5.13 The optimal combination of surgery and irradiation shall be determined on an individual basis, considering:

- the extent, nature, and location of the tumour
- the patient’s breast size
- concerns about local recurrence and preservation of cosmetic appearance
- the patient’s general medical condition

5.14 The choice of surgical treatment shall be made jointly by the Consultant surgeon and the patient, who shall be informed of all the options and their potential risks, benefits and implications for further treatment. Surgical treatment shall not be offered or withheld on grounds of age alone. A date for operation, within three weeks of a decision to operate, should be offered.

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<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To minimise psychological distress</td>
<td>A date for surgical operation is offered within three weeks of the decision to operate</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>
b) **Breast-conserving surgery**

5.15 Breast-conserving treatment shall be conducted or supervised directly by a Consultant surgeon.

5.16 The Consultant surgeon shall place incisions to ensure the best cosmetic result and giving consideration to possible subsequent mastectomy.

5.17 The tumour bed cavity shall be marked with metallic clips.

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To facilitate the accuracy of subsequent radiotherapy</td>
<td>The tumour bed cavity is marked with metallic clips</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

5.18 The Consultant surgeon shall aim to obtain a minimum of 0.5cm free circumferential margins from invasive disease and at least 0.5cm to 1cm from in situ disease.

5.19 The Consultant surgeon shall aim to carry out the wide local excision in one complete specimen and orientate the specimen for the pathologist.

- The technique shall involve the placement of sutures or other agreed markers
- The technique shall include the use of radio-opaque clips for impalpable lesions

<table>
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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure proper assessment of histopathological margins</td>
<td>Specimens are oriented according to local protocols</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

5.20 Resection margins shall be assessed by histopathology. Intra-operative specimen radiology shall be used in facilitating this process.

5.21 The Consultant histopathologist shall confirm that the margins of excised tissue are free of tumour cells, and patients who are found to have positive resection margins shall be recommended to have re-excision or mastectomy.

5.22 A patient having conservation surgery shall have no more than two therapeutic operations.

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure accuracy of surgical treatment</td>
<td>A patient has no more than two therapeutic operations</td>
<td>More than 85% of cases</td>
</tr>
</tbody>
</table>
5.23 Patients shall be considered for mastectomy if:
- two or more tumours are present in separate quadrants of the breast
- histologically clear margins cannot be obtained
- radiotherapy is contra-indicated
- mastectomy is the preferred option of the patient
- the tumour size is such that complete excision of the tumour with an acceptable cosmetic result is not possible

5.24 Mastectomy incisions shall be planned and marked.
- Skin puckering and subcutaneous tissue bulging shall be avoided.
- Skin flaps shall be neither excessively thin, such that flap necrosis is likely, nor too thick, such as to leave significant residual breast tissue.

5.25 The patient shall be provided by the specialist breast care nurse with a breast prosthesis and bra which are both comfortable and suitable to the patient’s requirements.
- A temporary prosthesis shall be fitted by the specialist breast care nurse soon after operation (usually within one week) and worn until healing is complete
- Fitting of a permanent breast prosthesis shall be completed approximately six weeks after operation
- The patient shall not be fitted for a permanent prosthesis during radiotherapy, in the presence of a wound infection or when the wound is tender

5.26 The in-breast recurrence rate for invasive cancer after breast-conserving treatment shall be less than 15% at 5 years.

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To minimise in-breast recurrence after breast-conserving treatment</td>
<td>In-breast recurrence shall be recorded after breast conservation</td>
<td>Less than 15% at 5 years</td>
</tr>
</tbody>
</table>

5.27 The chest wall recurrence rate after mastectomy shall be less than 10% after 10 years.

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<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To minimise local recurrence after mastectomy</td>
<td>Local recurrence rate is recorded after mastectomy</td>
<td>Less than 10% at 10 years</td>
</tr>
</tbody>
</table>
d) **Axilla**

5.28 A patient with invasive breast cancer shall have axillary staging.

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure accurate staging of the axilla</td>
<td>Histopathological assessment of axillary lymph node is performed</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

5.29 Image-guided axillary node biopsy (by fine needle aspiration cytology or core biopsy) may be used. If metastases are demonstrated by these means, sentinel node biopsy is unnecessary and formal axillary dissection is recommended.

5.30 The procedure for axillary staging can include:
- Clinical fine-needle aspiration and cytology (FNAC)
- Ultrasound-guided FNAC or core
- Axillary lymph-node dissection (Levels I and II)
- Axillary lymph-node clearance (Levels I, II and III)
- Sentinel lymph-node mapping with blue dye and isotope

5.31 Ultrasound-guided FNA or core biopsy of enlarged or abnormal axillary nodes often provides proof of metastatic lymph-node involvement and is recommended in suitable cases.

5.32 For patients with sonographically normal lymph nodes and where the FNA or core biopsy does not demonstrate metastases, sentinel lymph node biopsy is recommended.

5.33 The most accurate method of identifying the sentinel lymph node(s) is by the combination of blue dye and radio-isotope. Sentinel node biopsy shall involve the combination of blue dye and radio-isotope.

5.34 Sentinel node biopsy shall be carried out only by surgeons who have had formal training in the technique and who have audited their accuracy in at least 30 cases.

5.35 Treatment for the axilla in which lymph nodes are involved by metastatic cancer shall include formal axillary clearance (Levels I and II or Levels I, II and III).

5.36 Where lymphatic mapping demonstrates the sentinel node in the internal mammary chain (IMC), removal of the node shall be considered.

5.37 Elective radiation of IMC is not standard but shall be considered in selected patients.

5.38 Axillary recurrence of invasive cancer shall be less than 5%.
5.0 Surgery

e) Breast reconstruction

5.39 The type and timing of breast reconstruction depend on many biological, technical, psychological and therapeutic variables, each of which shall be discussed between the patient and the surgeon.

5.40 Breast reconstruction shall be provided either by a plastic surgeon or a breast surgeon trained in the appropriate technique. Patients shall have the option of secondary reconstruction if they request it or if their disease profile suggests that it may be more appropriate.

5.41 Oncoplastic surgical procedures shall be available for patients undergoing breast-conserving surgery.

5.42 Assessment of cosmesis is an integral part of breast reconstruction.

5.43 Discussions at multidisciplinary meetings regarding reconstruction/plastic surgery after mastectomy shall be documented.

5.44 The patient shall be provided with written information regarding breast reconstruction.

f) Ductal carcinoma in situ (DCIS) management

5.45 A patient with ductal carcinoma in situ who is a candidate for breast-conserving surgery shall be offered the choice of wide local excision or mastectomy.

5.46 Non-operative guide-wire localisation shall be conducted for all impalpable lesions when breast-conserving surgery is planned.

5.47 Specimen-orientation and specimen radiography shall be carried out.

5.48 A patient with DCIS which is extensive, high-grade or associated with a palpable mass shall have sentinel node evaluation of the axilla.

5.49 Patients who have undergone breast cancer surgery for DCIS shall have a consultation with a Consultant radiation oncologist.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To ensure radiotherapy is considered in patients following breast cancer surgery for DCIS</td>
<td>After surgery for DCIS, the patient is assessed by a Consultant radiation oncologist</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

5.50 Local recurrence of disease following excision alone is approximately 20% at five years and 26% at ten years.

5.51 Current practice indicates that local recurrence of disease following local excision of DCIS and radiotherapy is approximately 10% at five years and 15% at ten years. Follow-up data on patients is essential to ensure that local recurrence rates are not significantly in excess of these percentages.

5.52 The chest wall recurrence rate after mastectomy for ductal carcinoma in situ shall be less than 5% at ten years.
6.0 Radiology
The diagnosis of breast cancer is a multidisciplinary activity requiring input from experienced professionals using state-of-the-art equipment and providing targeted tissue material to the pathologist. The diagnosis shall be made with as little discomfort and anxiety to the patient as possible, maximising non-operative diagnosis of malignancy and minimising open surgery for benign breast conditions.

The quality of the service delivered to the patient is dependent on multidisciplinary interaction and the expertise of the Consultant surgeon, radiologist and pathologist, with input in terms of further management from Consultant medical and radiation oncologists.

The quality assurance pertaining to breast imaging is concerned with physical technical quality assurance, radiographic quality assurance and radiological quality assurance.

6.1 Pre-operative mammography with ultrasound examination shall be regarded as a prerequisite for the assessment of the patient with primary operable breast cancer.

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<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure that an accurate diagnosis is achieved</td>
<td>Pre-operative mammography with ultrasound examination is carried out on patients with primary operable breast cancer</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

6.2 Mammography shall be confined to patients over the age of 35 years unless it is specifically requested by a Consultant surgeon, or to patients in whom there is a strong clinical or sonographic suspicion of malignancy.

6.3 Access to ultrasound will be determined by protocols. Patients under the age of 25 frequently do not require any imaging.

6.4 Patients over the age of 35 presenting with breast symptoms should routinely have a two-view mammogram.

6.5 Any patient over the age of 35 who has a clinically palpable focal abnormality shall have mammography and targeted ultrasound examination.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure early intervention and accurate assessment of a patient with suspected breast disease</td>
<td>A patient over 35 with a clinically palpable focal abnormality has mammography and targeted ultrasound examination</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>
6.6 a) Mammographic equipment:
The equipment used to image the patient shall be capable of producing low-dose, high-contrast images with high spatial resolution. Film screen systems are currently in use in many centres and dedicated processing equipment is essential. Digital mammography is used with increasing frequency and there is evidence that there is no reduction in cancer detection. Detection rates using digital systems may be increased in patients between the ages of 40 and 50. There shall be dedicated equipment designed for mammography with magnification and stereotactic facilities.

b) Ultrasound equipment:
Ultrasound shall be carried out only by specifically trained staff and the ultrasound probe shall operate at greater than 10 MHz. There shall be recording facilities for ultrasound and dedicated equipment shall be available for all breast centres.

6.7 The mammography and ultrasound equipment shall be located in a private area. The breast imaging department shall be located in the specialist breast centre.

6.8 Mammograms shall be carried out by suitably trained radiographic staff who hold an appropriate certificate of competence in mammography and have been trained in a dedicated mammography unit.

6.9 Radiographers shall attend regular update courses.

6.10 The radiographer shall provide optimal images and have good communication skills to facilitate the examination and ensure minimum anxiety to the patient.

6.11 Optimal image quality shall be obtained using minimal radiation dose, and technical repeat and recall rates should be minimised.

6.12 In order to maintain expertise, a radiographer involved in mammography shall perform a minimum of 20 mammographic studies a week.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
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<tbody>
<tr>
<td>To ensure a high-quality radiography service for patients with breast disease</td>
<td>A radiographer performs a minimum of 20 mammographic studies a week</td>
</tr>
</tbody>
</table>
6.13 Consultant radiologists reporting mammograms shall also perform ultrasound and ultrasound-guided biopsies when indicated. They must be trained in these modalities of investigation and shall attend a weekly multidisciplinary team meeting.

- Consultant radiologists shall report at least 1,000 mammograms per year.
- Consultant radiologists shall monitor their reports and their recall and referral notes.
- Consultant radiologists shall report side, size, location and type of any mammographic abnormality.
- All mammograms shall be reported using a standard classification, such as the following radiological code:
  - R1 Normal/benign
  - R2 Benign with some associated nodularity
  - R3 Indeterminate, probably benign
  - R4 Indeterminate, probably malignant
  - R5 Mammographic features of malignancy

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
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<tbody>
<tr>
<td>To ensure a high-quality and efficient radiology service</td>
<td>Consultant radiologists performing mammograms are also trained in ultrasound and ultrasound-guided biopsies</td>
</tr>
<tr>
<td></td>
<td>Consultant radiologists report at least 1,000 mammograms per year</td>
</tr>
<tr>
<td></td>
<td>Consultant radiologists monitor their reports and their recall and referral rates</td>
</tr>
<tr>
<td></td>
<td>Consultant radiologists report side, size, location and type of any mammographic abnormality</td>
</tr>
<tr>
<td></td>
<td>All mammograms are reported using a standard classification</td>
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</table>

6.14 An urgently referred patient should have all imaging in the first visit. A patient requiring early referral (see 2.1.2) shall have imaging within six weeks, and routine imaging shall be done within twelve weeks.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To ensure speed of diagnosis and to minimise anxiety in patients, all imaging shall take place within timeframes in accordance with the patient category.</td>
<td>An urgently referred patient has all imaging done in the first visit</td>
<td>More than 90% of cases</td>
</tr>
<tr>
<td></td>
<td>A patient requiring early referral has all imaging done within six weeks and routine imaging shall be done within twelve weeks</td>
<td>More than 90% of cases</td>
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</tbody>
</table>
6.15 The Consultant radiologist shall decide on the most appropriate method of image-guided biopsy.

6.16 A non-operative diagnosis of both benign and malignant conditions shall be obtained in over 90% of cases.

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<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To minimise the number of surgical procedures for the patient</td>
<td>A non-operative diagnosis is achieved in benign and malignant disease</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

6.17 Lesions that are impalpable shall be localised by the radiologist using ultrasound or X-ray guidance and wires shall be placed within 1cm of the impalpable lesion.

6.18 The Consultant radiologist shares the responsibility of ensuring that impalpable lesions are surgically excised successfully. Responsibility for removal of impalpable lesions is shared between the radiologist and the surgeon.

6.19 A patient having breast-conserving surgery shall have specimen mammography.

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To ensure accuracy of excision</td>
<td>A patient undergoing breast-conserving surgery has specimen mammography</td>
<td>More than 99% of cases</td>
</tr>
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</table>

6.20 The Consultant radiologist together with the Consultant surgeon shall be centrally involved in the organisation of the diagnostic breast service. An immediate report shall be available to the Consultant surgeon at the time of triple assessment.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To ensure accurate diagnosis and management</td>
<td>A report is available immediately to the Consultant surgeon at the time of triple assessment</td>
<td>More than 95% of cases</td>
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</table>

6.21 Patients with a diagnosis of invasive breast cancer shall have an ultrasound assessment of their axilla. Ultrasound of the axilla plays a central role in determining patients’ suitability for sentinel node biopsy.

<table>
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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To accurately plan axillary surgery</td>
<td>An ultrasound of the axillary nodes is performed on a patient with a diagnosis of breast cancer</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>
6.22 Indeterminate or abnormal axillary lymph nodes shall either have a fine needle aspiration or core biopsy performed.

6.23 Magnetic resonance imaging (MRI) may be appropriate in the assessment of patients under surveillance because of high-risk family history. The use of MRI in determining suitability for breast-conserving surgery is evolving.
7.0 Histopathology
Breast histopathology quality assurance addresses two subjects. The first relates to reporting of breast histopathology specimens and the second concerns histopathologist competence.

The breast histopathology report provides the information necessary for assessment of patient prognosis and for design of treatment strategies. This information is recorded according to a minimum dataset quality assurance protocol. These data are included in the accompanying guidelines (Appendix 3).

Histopathologist competence and continued medical education are maintained by participation in a recognised educational quality-assurance programme.

7.1 The breast team shall include named Consultant histopathologists with expertise in breast pathology and designated time for breast work, including attendance at the multidisciplinary breast meeting.

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To provide a high-quality Consultant histopathology service for patients with breast disease</td>
<td>Consultant histopathologists have specialist expertise in breast pathology</td>
<td></td>
</tr>
<tr>
<td>To provide good multidisciplinary care for patients with breast disease</td>
<td>Consultant histopathologists attend the weekly multidisciplinary team meeting</td>
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</table>

7.2 Consultant histopathologists involved in the delivery of the symptomatic breast pathology service shall participate in a quality-assurance programme.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To ensure delivery of a high-quality Consultant histopathology service</td>
<td>Consultant histopathologists shall participate in a histopathology quality-assurance programme</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

7.3 Histopathology laboratories shall have access to specimen radiography.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provision of specimen radiography to assist examination of breast specimens</td>
<td>The laboratory has access to specimen radiography</td>
</tr>
</tbody>
</table>

7.4 Non-operative cytology and needle-core biopsy specimens shall be reported in accordance with the NHS BSP UK reporting systems (summarised in Faculty of Pathology, Royal College of Physicians of Ireland (RCPI), minimum dataset for breast cancer histopathology reports).
7.5 The histopathology department shall have clear protocols for the macroscopic examination of specimens in accordance with NHS BSP UK guidelines/Faculty of Pathology, RCPI, minimum dataset for breast cancer histopathology reports.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
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<tbody>
<tr>
<td>To ensure macroscopic examination of breast specimens in accordance with international standards</td>
<td>Up-to-date protocols are available for specimen dissection and macroscopic reporting</td>
</tr>
</tbody>
</table>

7.6 All diagnostic and therapeutic excision specimens shall be weighed and measured.

7.7 Therapeutic breast cancer specimens shall be received orientated with sutures and / or clips and individual resection margins identified.

7.8 Specimen and slice x-rays shall be performed on diagnostic and therapeutic excision specimens containing calcified lesions.

7.9 The sentinel lymph node shall be sliced at no more than 0.2cm intervals and submitted in its entirety for microscopic evaluation. The value of levels and immunohistochemistry remains uncertain and these studies are optional at present.

7.10 In examining axillary lymph node clearance specimens, one representative section shall be taken from macroscopically positive lymph nodes. Macroscopically negative lymph nodes shall be submitted in their entirety for microscopic evaluation.

7.11 Diagnostic frozen section shall be performed only in exceptional circumstances (see 5.3).

7.12 The microscopic reporting of breast cancer specimens and data recording shall be in accordance with NHS BSP UK guidelines / RCPath minimum dataset / Faculty of Pathology, RCPI, minimum dataset for breast cancer histopathology reports.
7.13 Invasive breast carcinoma:

(A) The following data shall be recorded in invasive breast carcinoma:

- Tumour type
- Tumour grade
- Tumour size: invasive tumour size and whole tumour size, including ductal carcinoma in situ (DCIS)
- Lymphovascular invasion
- Radial margin status
- Posterior (deep) margin status
- Skin involvement

Multiple tumours shall be recorded and information relevant to each tumour documented.

The overall number of lymph nodes and the number containing metastases shall be recorded.

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To provide important and relevant data on patients with invasive breast carcinoma</td>
<td>Histological tumour type is recorded</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td></td>
<td>Histological tumour grade is recorded</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td></td>
<td>Invasive tumour size is recorded</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td></td>
<td>The presence or absence of vascular invasion is recorded</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td></td>
<td>Radial margin status in wide local excision specimens is recorded</td>
<td>More than 95% of cases</td>
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<tr>
<td></td>
<td>Posterior (deep) margin status is recorded</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td></td>
<td>Lymph node status is recorded</td>
<td>More than 95% of cases</td>
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</table>
7.13 (B) Hormone receptor status shall be recorded.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To provide hormone receptor status in patients with invasive breast carcinoma</td>
<td>Oestrogen receptor status is available</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td>To provide progesterone receptor status in patients whose invasive breast carcinomas are oestrogen-receptor negative</td>
<td>Progesterone receptor status is available in patients whose tumours are oestrogen-receptor negative</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

7.13 (C) Her-2 status shall be assessed using immunohistochemistry. Borderline positive cases shall be assessed using fluorescent in situ hybridisation (FISH).

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To provide Her-2 receptor status in a patient whose invasive breast carcinomas measure more than 1cm</td>
<td>Her-2 receptor status is available in a patient whose invasive tumour size exceeds 1cm</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>
7.14 Ductal carcinoma in situ (DCIS):  
The following data shall be recorded in ductal carcinoma in situ (DCIS):  
- DCIS grade  
- DCIS size  
- Radial margin status  
- Posterior (deep) margin status  
- Presence or absence of microinvasion/invasion.  
- Hormone receptor status on clinical request.

<table>
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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To provide appropriate data in patients with ductal carcinoma in situ (DCIS)</td>
<td>DCIS grade is recorded</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td></td>
<td>DCIS size is recorded</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td></td>
<td>Radial margin status in wide local excision specimens is recorded</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td></td>
<td>Posterior (deep) margin status is recorded</td>
<td>More than 95% of cases</td>
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</table>

7.15 A written histopathology report containing the prognostic data shall be available within five working days. The results of ancillary studies e.g. hormone receptor, Her-2 studies, may follow in a supplementary report.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To provide histopathology reports in a timely fashion</td>
<td>Histopathology reports containing the prognostic data are available within five working days</td>
<td>More than 80% of cases</td>
</tr>
</tbody>
</table>
7.16 All breast histopathology reports shall be discussed in conjunction with the radiological and clinical findings at a weekly multidisciplinary meeting (see 4.3).

7.17 Information technology (IT) facilities and dedicated staff shall support the recording of all data required for periodic review and for histopathologist participation in quality assurance programmes.

<table>
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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure appropriate data collection</td>
<td>IT facilities and dedicated staff are in place</td>
</tr>
</tbody>
</table>

7.18 Laboratories providing hormone receptor and Her-2 studies shall participate in a quality assurance programme.
8.0 Radiation Oncology
Breast irradiation is the accepted standard of care after breast-conserving surgery for both invasive cancer and ductal carcinoma in situ. Radiotherapy after mastectomy in high-risk patients also significantly reduces the risk of cancer recurrence and improves overall survival.

The goals of adjuvant radiation therapy are to:

(1) eradicate microscopic foci of cancer that may remain after breast surgery;
(2) provide local control and survival rates equivalent to mastectomy; and
(3) maximise quality of life while minimising complications and achieving an acceptable cosmetic result.

Radiation oncology quality indicators include:

a) pre-treatment evaluation, which involves collaboration between radiation oncologists and other members of the multidisciplinary breast cancer team;

b) treatment planning indicators detailing the selection criteria and technical requirements for optimal treatment; and

c) treatment delivery criteria to ensure an optimal clinical outcome.

a) **Before radiation treatment**

8.1 Consultant radiation oncologists shall treat no more than 300 new patients per year.

8.2 The Consultant radiation oncologist shall be a full member of the team and shall participate in the elaboration of the overall treatment of each patient.

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<th>Target</th>
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<tbody>
<tr>
<td>To ensure that the Consultant radiation oncologist is a fully integrated member of the multidisciplinary team</td>
<td>The Consultant radiation oncologist has a dedicated sessional commitment to the specialist breast centre</td>
<td>More than 90% of Consultants</td>
</tr>
</tbody>
</table>

8.3 Radiotherapy centres shall have the staff and capacity to guarantee that patients are treated in line with current international standards.

8.4 The Consultant radiation oncologist shall coordinate patient follow-up with surgery and medical oncology units.

8.5 There shall be adequate facilities such as hospital and hostel beds to accommodate patients travelling for radiation therapy.
b) Therapy planning

8.6 A patient’s suitability for treatment with radiotherapy shall be determined on an individual basis. Patients shall not be excluded on the basis of age alone.

8.7 The patient shall be given information regarding the risks of acute and late complications of radiotherapy.

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure that the patient is fully informed about the benefits and risks of radiation treatment</td>
<td>The complications of radiotherapy are discussed with the patient</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

8.8 Radiotherapy may be given as primary treatment before surgery or it may be used as the sole local treatment modality when surgery is inappropriate (see 9. b2).

8.9 The patient shall sign a consent form prior to starting radiation therapy. The consent form shall be discussed with the patient by the Consultant radiation oncologist and the specialist breast care nurse, ensuring that the patient fully understands the form.

8.10 Radiation therapy shall be considered after mastectomy in a patient with a large tumour (T3, T4), positive margins of excision and those with four or more metastatic axillary lymph nodes.

8.11 The decision regarding radiotherapy after mastectomy for patients with 1 to 3 involved nodes may be individualised and influenced by several biological factors.
8.12 In the selection of patients for breast-conserving treatment with radiation, specific contra-indications include:

- pregnancy
- two or more primary tumours in separate quadrants of the breast or with diffuse malignant-appearing microcalcifications
- a history of previous therapeutic irradiation of the breast region that would require re-treatment to an excessively high total radiation dose level

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
</table>
| To minimise the risk of adverse events | Breast conservation treatments with radiation are avoided in:  
- women who are pregnant  
- women with two or more tumours in separate quadrants of the breast or with diffuse malignant-appearing microcalcifications  
- women with a history of prior therapeutic irradiation in the breast region that would require re-treatment to an excessively high total radiation dose level | More than 95% of cases  
More than 95% of cases  
More than 95% of cases |

8.13 In the selection of patients for breast conservation treatment with radiation, relative contra-indications include a history of collagen vascular disease (excluding rheumatoid disease) and those patients for whom mastectomy is generally considered to be the preferred option (see 5.23).

8.14 The patient’s mammography findings, pathology findings and the surgical procedures shall be evaluated before radiotherapy.

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<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure that the radiation oncologist considers all diagnostic results when planning the patient’s treatment</td>
<td>Mammography findings, pathology findings and the surgical procedures performed on the patient are evaluated before radiotherapy</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>
8.15 A patient not taking adjuvant chemotherapy shall start radiotherapy within eight weeks of surgery.

<table>
<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure optimal outcome after radiotherapy</td>
<td>A patient not taking adjuvant chemotherapy starts radiotherapy within eight weeks of surgery</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

8.16 A patient taking adjuvant chemotherapy treatment shall start radiotherapy treatment within four weeks of the last cycle.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To ensure optimal outcome after radiotherapy</td>
<td>A patient taking adjuvant chemotherapy treatment starts radiotherapy within four weeks of the last cycle</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

8.17 The patient shall start radiation therapy within six months of surgery if receiving chemotherapy prior to radiation therapy.

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<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure continuity of care and minimise waiting time for treatment</td>
<td>The patient starts radiation therapy within six months of surgery if receiving chemotherapy prior to radiation therapy</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

8.18 Administration of anthracyclines/taxanes and radiation therapy concurrently shall be avoided.

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<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To minimise the risk of adverse events</td>
<td>A patient is not administered anthracyclines/taxanes and radiation therapy concurrently</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>
8.19 Axillary radiotherapy is not recommended after level 2 or level 3 dissection, regardless of the extent of nodal involvement, unless there is gross residual axillary disease.

8.20 Patients requiring radiotherapy after breast-conserving surgery shall have radiation to the whole breast.

8.21 A patient with four or more positive axillary nodes shall undergo irradiation to the supraclavicular fossa in addition to chest wall radiation.

8.22 A patient with bone and brain metastases shall be considered for radiotherapy. The opinion of a neurosurgeon should be sought for any patient with isolated intracranial metastases (see 9.b2).

c) Treatment delivery

8.23 Interruptions of treatment shall be avoided. There shall be no more than one week’s difference between actual and planned end of treatment.

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<thead>
<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To ensure optimal clinical outcome and well planned care</td>
<td>There is no more than one week’s difference between actual and planned end of treatment</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

8.24 The dose, fractions and field arrangement of radiotherapy shall be documented.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure maintenance of comprehensive patient records</td>
<td>Dose, fractions and field arrangements of radiotherapy are documented</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

8.25 A patient receiving breast radiation shall be reviewed by a specialist nurse during radiation therapy.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>A patient receiving breast radiation is well-informed</td>
<td>The patient is reviewed by a specialist nurse</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

8.26 The Consultant radiation oncologist shall use measures to assure reproducibility of patient set-up, during treatment and at simulation, by the use of a rigid immobilisation device.
8.27 To ensure irradiation to the lung and heart is minimised, central lung distance shall be less than 3cm and maximum heart distance shall be less than 1cm on tangential radiation simulator films.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To ensure that the volume of lung exposure to radiotherapy treatment is minimised</td>
<td>Central lung distance is less than 3cm on tangential radiation simulator films</td>
<td>More than 95% of cases</td>
</tr>
<tr>
<td>To ensure that the amount of heart exposure to radiotherapy treatment is minimised</td>
<td>Maximum heart distance is less than 1cm on tangential radiation simulator films</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

8.28 Use of sophisticated planning techniques, including three-dimensional treatment planning, may facilitate avoidance of cardiac and lung irradiation and shall be mandatory for internal mammary nodal irradiation.

8.29 Boosts to the tumour bed should be administered in patients under 50 years of age. Patients aged over 50 years with close/positive margins should also receive a boost.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To minimise local recurrence</td>
<td>Patients under 50 years of age receive a boost</td>
<td>More than 95% of cases</td>
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<tr>
<td></td>
<td>Patients over 50 years of age with close or positive margins receive a boost</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

8.30 Selection of the boost dose and volume shall be based on knowledge of the surgical clips in the tumour bed cavity and the pathologic findings. Boost irradiation shall be delivered using electron or photon beam or by interstitial implantation.
9.0 Medical Oncology
The specialty of medical oncology is dedicated exclusively to the study of cancer and how it is best treated, particularly with systemic therapy. Breast medical oncologists have experience and expertise in treating breast cancer at all stages: early, locally-advanced and metastatic disease.

a) Early breast cancer (Stage I, IIa, II b, and T3N1)

Most patients with early breast cancer are cured with surgery alone. However, many patients relapse with either local or distant recurrence and may die of the disease. Adjuvant systemic therapy has the potential to eradicate micro-metastatic disease at the time of surgery, thereby preventing relapse and death.

The selection of appropriate adjuvant therapy depends on factors related to:

(i) the treatment (toxicity, schedule);
(ii) the tumour (type, size, grade, lymph node status, receptor status); and
(iii) the patient (age, willingness to accept hair loss and other toxicity; fertility issues, co-morbidities, social supports; geographical factors etc).

Adjuvant chemotherapy shall be considered for all patients under 70 years of age with node-positive breast cancers and for patients with node-negative cancers who have poor prognostic features (young age, high-grade, lymphovascular invasion, hormone-receptor negativity, Her-2 positivity, size greater than 2cm). Adjuvant chemotherapy shall be considered in a fit patient over 70 years of age.

It is important to ensure that potential candidates for adjuvant systemic treatment have these therapies available to them, have the opportunity to discuss the advantages and disadvantages of treatments in detail with a breast medical oncologist, and are monitored closely for toxicity.

Adjuvant systemic therapy (general)

9.1 Every patient with invasive breast cancer measuring more than 1cm shall be referred to a medical oncologist for consideration of adjuvant systemic therapy.

9.2 Adjuvant systemic therapy shall start within six weeks of surgery and written protocols shall be in place.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure maximal benefit from treatment</td>
<td>A patient requiring adjuvant chemotherapy starts adjuvant systemic therapy within six weeks of surgery</td>
<td>More than 90% of cases</td>
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</table>
9.3 The decision regarding adjuvant systemic therapy will be made by the Consultant medical oncologist after consultation with the patient. Staging and predictive biological factors shall be documented in the medical oncology consultation.

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<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure the decision to treat is based on biological evidence</td>
<td>Biological data is recorded at medical oncology consultation</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

9.4 The risks and benefits of therapy shall be discussed with the patient, who will have access to written information, support from a nurse specialist and time for reflection and discussion before making a treatment decision. The Consultant medical oncologist and the patient shall decide the best treatment pathway.

9.5 Written treatment protocols shall be available to all staff in each specialist breast centre and shall include a copy of the original publication upon which the treatment regimen is based. These protocols shall also include a description of common toxicities and required parameters for treatment.

9.6 Adjuvant chemotherapy shall be prescribed only by a Consultant medical oncologist, and administered by a trained medical oncologist or nursing staff in a properly resourced, specialist oncology unit.

9.7 All healthcare professionals administering chemotherapy shall attend a training course at least once every two years.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure maintenance of standards of safety</td>
<td>All staff administering chemotherapy attend a training course every two years</td>
<td>More than 90% of staff</td>
</tr>
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</table>

9.8 Detailed written information on side-effects of therapy and on support services and access to such services shall be provided to the patient before treatment.

9.9 Adjuvant chemotherapy shall begin within six weeks of surgery unless there are specific medical contraindications.
9.10 If a patient is treated with chemotherapy, the planned regimen schedule and dose (dose per cycle x number of cycles) shall be documented in the medical oncology record.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure that the planned treatment programme is clear to all concerned</td>
<td>The precise schedule and dose of treatment are recorded</td>
<td>More than 95% of cases</td>
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</tbody>
</table>

9.11 Details of chemotherapy treatment shall be recorded by administering staff.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To maximise safety and good communication</td>
<td>Details of cycles of chemotherapy are recorded</td>
<td>100%</td>
</tr>
</tbody>
</table>

9.12 Specialist oncology medical and nursing staff, with inpatient facilities, must be available at all times to support patients who develop treatment-associated toxicities. Toxicities shall be recorded and graded prior to each cycle of chemotherapy.

9.13 A single optimal chemotherapy regimen has not been defined.

- In general, four to eight courses of an anthracycline- and/or taxane-containing regimen is appropriate for most patients.
- A patient with Her-2 positive tumours shall be considered for trastuzumab therapy. Trastuzumab shall not be administered concomitantly with anthracycline therapy. A patient receiving trastuzumab shall have serial assessment of cardiac function.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure maximum benefit to a Her-2 positive patient</td>
<td>A Her-2 positive patient receives trastuzumab after completing the course of chemotherapy</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

9.14 Dose adjustment, delay, and reasons for same shall be recorded.

9.15 Dose intensity shall be maintained unless significant toxicity occurs. Recombinant stem cell haematopoietic growth factors shall be used to obviate haematological toxicity if necessary.
9.16 Adjuvant hormonal therapy shall be considered in over 90% of patients with hormone-receptor positive tumours.

- If a patient is to receive both chemotherapy and hormonal therapy, the treatment should be administered in that sequence and not concomitantly.
- Adjuvant hormonal therapy can consist of tamoxifen with or without ovarian ablation in premenopausal women, and aromatase inhibitor or tamoxifen in post menopausal women. The optimal regimen or duration of therapy has yet to be defined.
- The patient shall be attended for the duration of adjuvant hormonal therapy by a breast care specialist.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure maximal benefit from sequential treatment</td>
<td>Hormone-receptor positive patients receive adjuvant hormonal therapy</td>
<td>More than 90% of cases</td>
</tr>
<tr>
<td>To ensure maximal benefit for hormone receptor positive patients</td>
<td>When the course of chemotherapy has been completed, hormone receptor positive patients receive adjuvant hormonal therapy</td>
<td>More than 90% of cases</td>
</tr>
</tbody>
</table>

b) Advanced, recurrent or metastatic disease

9.17 Multidisciplinary care for a patient with advanced, recurrent or metastatic disease shall be directed by a Consultant medical oncologist.

b1) Locally advanced breast cancer (Stage IIIA-C, except T3N1)

A patient with inoperable locally advanced breast cancer shall receive primary chemotherapy with an anthracycline-based regimen, unless contra-indicated. Taxanes may also be used in combination, either concomitantly or sequentially. After primary systemic therapy, the choice of appropriate local treatment shall be discussed at multidisciplinary meetings.

9.18 A patient with locally advanced (stage IIIB or IIIC) disease shall have full staging performed, including isotope bone scan, imaging of liver and pelvis and chest computerised tomography (CT).

9.19 Core biopsy and receptor analysis of the tumour shall be performed before treatment.

9.20 Systemic therapy (hormonal or chemotherapy) shall precede local treatment and shall be individualised, based on clinical parameters.

9.21 Optimal local therapy may consist of surgery and/or radiation therapy.
b2) Metastatic breast cancer

A patient who relapses with distant metastases is rarely cured and in such cases the goal of treatment is palliation. The treatment of metastatic breast cancer shall be directed by a Consultant medical oncologist who has access to the full range of ancillary services likely to be required, including: general surgery, orthopaedic surgery, radiotherapy, pain control team, palliative care, social worker, counsellor etc. As the goal is palliation, treatments associated with least toxicity are preferred.

Local symptoms may best be relieved with local therapy such as radiation or surgery. Orthopaedic surgery has an important role to play not only in the treatment of established pathological fracture or cord compression, but also in the prevention of these complications. Orthopaedic intervention and/or radiotherapy shall therefore be considered early in patients with known metastatic disease to bones.

Systemic therapy for metastatic breast cancer improves survival and quality of life. The decision-making process regarding optimal systemic therapy is complex, but some general principles apply:

1. Less toxic treatment (endocrine or other targeted therapy) is preferable to more toxic treatment (chemotherapy).
2. A patient with hormone-receptor positive disease shall be first treated with hormonal therapy unless there is compelling reason to use chemotherapy (for example in impending organ failure).
3. Intravenous bisphosphonates shall be used in cases of metastatic bone disease unless a contra-indication exists.
4. Sequential single-agent chemotherapy is preferable to combination treatment in most patients.
5. Trastuzumab shall be used in a patient whose tumours over-express Her-2.

A patient receiving systemic therapy for metastatic disease shall be monitored by the medical oncology service for evidence of treatment toxicity as well as disease response or progression.

9.22 Hormonal therapy shall be considered as first-line therapy except in any patient with hormone-refractory or hormone-receptor negative tumours, or with immediately life-threatening disease.

- For premenopausal patients a combination of hormonal therapy with an LHRH antagonist and tamoxifen is recommended
- For postmenopausal patients first-line therapy should be with a third-generation aromatase inhibitor
- Hormonal therapy shall be continued, if tolerated, until progression of disease
- Second-line hormonal therapy shall be considered in patients who have derived benefit from first-line treatment

9.23 Chemotherapy shall be considered for patients with hormone-insensitive disease.

9.24 Guidelines for the administration of systemic therapy are the same for patients receiving treatment for metastatic breast cancer as have been outlined for those being treated in the adjuvant setting.

9.25 Objective assessment of disease response to treatment should occur regularly, every three to four months.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To evaluate the efficacy of therapy</td>
<td>Objective evaluation of response to treatment is undertaken every three months</td>
<td>More than 90% of cases</td>
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</table>
9.26 Chemotherapy shall be continued until progression of disease or significant toxicity occurs.

9.27 A patient shall continue on trastuzumab until progression of disease or significant toxicity occurs.

9.28 A patient with progressive disease or poor tolerance of initial therapy shall be considered for second-line chemotherapy.

9.29 Patients with bony metastases shall have consultation with an orthopaedic surgeon if there is a significant risk of pathological fracture or spinal cord compression.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>To reduce the incidence of pathological fracture and spinal</td>
<td>Patients with skeletal metastases</td>
<td>More than 90% of cases</td>
</tr>
<tr>
<td>cord compression</td>
<td>have a consultation with an orthopaedic surgeon if they are at risk of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>pathological fracture or spinal cord compression</td>
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</tbody>
</table>
10.0 Clinical Nurse Specialist in Breast Care
In recent years the value of the breast care nurse has been recognised increasingly worldwide and the specialty of breast care nursing is now an essential component in the multidisciplinary management of patients with breast disease.

The specialist breast care nurse shall be involved in direct patient care, communication and explanation and also in facilitating patient transition between the various medical specialties (e.g. surgery, medical oncology and radiation oncology), thereby providing a critical link for patients in what is often a complex pathway of care.

10.1 The specialist breast care nurse (SBCN) (or clinical nurse specialist in breast care) shall work exclusively in breast care and shall be an integrated part of the breast care team.

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<tr>
<th>Quality Objective</th>
<th>Outcome Measure</th>
<th>Target</th>
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<tbody>
<tr>
<td>To ensure that a patient with breast cancer receives appropriate nursing care</td>
<td>A patient with breast cancer is cared for by a specialist breast care nurse throughout the illness</td>
<td>More than 95% of cases</td>
</tr>
</tbody>
</table>

10.2 The SBCN shall have undergone specific training and have officially recognised qualifications in oncology and breast care. The training in Ireland currently involves the acquisition of an officially approved higher diploma in oncology and breast care.

10.3 The SBCN shall be involved in the assessment, planning, delivery and evaluation of care given to patients with breast disease in hospital, in the community and in the outpatient setting.

10.4 The SBCN shall provide advice, support and guidance to nursing colleagues in clinical management related to breast care nursing.

10.5 The SBCN shall be an active participant in clinical research that contributes to improvements in breast care.

10.6 The SBCN shall become actively involved in clinical audit and in proposals for implementing change.

10.7 The SBCN shall be able to recognise physical and psychological morbidity and the need to refer appropriately.
11.0 Patient Support Services and Follow-Up
All patients with early breast cancer shall have their follow-up care co-ordinated through the multidisciplinary team involving the breast surgeon, medical oncologist and radiation oncologist.

11.1 Appropriate psychosocial support shall be available to patients and their family at each stage during the treatment, and shall continue to be available after treatment has finished. Such support shall include access to a social worker, clinical psychologist and psychiatrist.

11.2 Every patient shall have access to a Reach to Recovery or similar volunteer following breast cancer surgery.

11.3 Close linkages and partnerships between the hospitals and community-based services shall be developed.

11.4 Patients and their families shall have ongoing access to psychosocial support.

11.5 Patients shall have access to a named person in the specialist breast centre with whom they can communicate at any time, usually the specialist breast care nurse.

11.6 Patients shall be given written information about local cancer support centres, patient support groups and advocacy groups.

11.7 Patients shall be given written information about entitlements and benefits, or referred to sources of advice.

11.8 Patient follow-up after primary therapy for early breast cancer shall be co-ordinated by one medical Consultant skilled in the surveillance of cancer patients and breast examination. Rapid access to another member of the multidisciplinary team shall be facilitated as specific issues arise. A surgical oncologist is the most appropriate co-ordinating doctor for those patients who have been treated with surgery alone. For those patients who have received adjuvant chemotherapy, the co-ordinating physician should be a medical oncologist.

11.9 Ideally, frequency of follow-up should be every 3–6 months for the first three years after primary therapy and every 6–12 months thereafter.

11.10 A dedicated telephone service for advice and arrangements for appointments at the specialist breast centre shall be available throughout the working week.

11.11 A specialist breast care nurse shall be available to offer support and arrange counselling for the patient and facilitate ongoing appropriate referrals.

11.12 Patients shall be encouraged to report new symptoms promptly, without waiting for the next scheduled appointment.

11.13 Mammography and a clinical examination shall be offered to patients yearly.

11.14 Routine diagnostic tests to screen for distant metastases in asymptomatic patients shall not be performed.

11.15 Every patient who has undergone treatment for breast cancer shall have continuing access to the specialist breast centre for an indefinite period.

11.16 There shall be an open access policy to enable GPs or other healthcare professionals to refer patients back to the breast care team without delay if they suspect recurrent cancer or problems related to treatment for breast cancer.

11.17 Megestrol acetate or depot intramuscular medroxyprogesterone acetate shall be considered to control the severity of hot flushes in a patient with breast cancer.
11.18 Non-hormonal therapies for hot flushes shall be discussed with the patient.
11.19 Identification and management of lymphoedema shall be guided by written protocols.
11.20 Every patient who experiences arm swelling or discomfort, shall have access to a lymphoedema service, staffed by nurses and physiotherapists who have experience in dealing with this problem.
11.21 Patients shall be given information regarding lymphoedema and how they can make contact with the lymphoedema service.
11.22 Patients with a strong family history of breast cancer, and their families, should have access to genetic breast cancer services, including counselling.
12.0 Training and Continuous Professional Development
It is impossible to ignore the universal call for specialised training for all those involved in breast care. The extensive scientific and educational publications on this theme consistently emphasise that high-quality care can be delivered only by trained specialists working together. The possibility for error in diagnosis or treatment is much reduced when each patient’s condition is discussed by a multidisciplinary team staffed by trained individuals who are up to date and fully informed.

Each specialist breast centre has a team of people who come from various disciplines and who have had specific specialised training in breast diseases beyond that provided in their general professional training. In order to keep pace with developments, it is also necessary that each person involved in breast care takes part regularly in accredited courses. Continuing professional development (CPD) is more important than ever because of the rapid clinical application of new technologies and new treatments. Demonstration of satisfactory CPD will become essential for doctors in order to remain on the specialist register of medical practitioners.

A position paper entitled Guidelines on the Standards for the Training of Specialised Health Professionals Dealing with Breast Cancer (EUSOMA), specifies training requirements that can be applied to accredit specialists in breast radiology, breast diagnostic radiography, breast care nursing, breast surgery, breast pathology, breast medical oncology, breast radiotherapy and breast medical physics.

The EUSOMA document specifies minimal theoretical and practical knowledge requirements and identifies a strategy needed to evaluate competence in each of the disciplines mentioned.

A paper from the World Federation for Medical Education (WFME) on CPD states that doctors must ensure that the CPD activities they undertake are adequate to maintain and develop competencies required to respond to the needs of their patients and of society. Furthermore, it notes, doctors should define the competencies expected to be gained from CPD activities and should share such learning with their peers.

All personnel involved in the specialist breast centre must be provided with sufficient dedicated time and encouragement to maintain their knowledge and skills, a point emphasised in the Association of Breast Surgery publication Guidelines for the management of symptomatic breast disease.

The Report on the Development of Services for Symptomatic Breast Disease indicates that CPD for breast disease should be mandatory for all specialists and should be funded. The report also specifies the extent of training that should be expected of all Consultant surgeons who treat patients with breast complaints.

Each relevant training body should be encouraged to formulate a training programme for doctors, nurses, radiographers and other health professionals coming under its authority, along the lines of the EUSOMA suggestions or those proposed for surgeons by the Royal College of Surgeons in Ireland and in Appendix 4 of the Report on the Development of Services for Symptomatic Breast Disease.

12.1 All specialists involved in the care of patients with breast disease shall have undergone specific training in a specialist breast centre.

12.2 All members of the team shall undertake regular continuing professional education.

12.3 All disciplines shall be encouraged and have the opportunity to attend at least one national and one international conference annually.
13.0 Implementation
13.0 Implementation

13.1 The Report on the Development of Services for Symptomatic Breast Disease (2000) and, more recently, the National Cancer Forum (2006) have recommended that a certain number of specialist breast centres be developed in Ireland and supported by staffing and physical structure to allow each centre to operate to a high standard of care delivered with skill, compassion and efficiency to all patients with breast complaints.

13.2 The requirements for each centre have been set out and justified in previous documents and supported by publications from the international scientific and medical literature. Justification for specialised centres derives from the convincing evidence of improved outcomes, both in survival and quality of life, for patients treated by specialists in the context of a multidisciplinary team approach to care.

13.3 The nomination and designation of centres should be announced without further delay and resources allocated immediately to support each centre. Public support for and confidence in these centres can come only when they are active and measure up to the standards defined in this document.

13.4 An implementation group, provided with the authority and the funding to ensure that the designated centres can be developed as envisaged, should be established. The members of the group should be people with knowledge and experience of specialist breast centres and should include a non-medical patient advocate with experience of breast cancer.

13.5 The programme for the development of specialist breast centres requires that the implementation group be provided with specific, clearly defined funding so that it can proceed purposefully and with a degree of certainty which would not be possible unless financial arrangements are “ring-fenced”.

13.6 It should be expected that detailed documentation of activity be recorded in each centre so that administrative and clinical audit can be undertaken. An identical and comprehensive dataset of information should be in place in each centre so that the activity centres can be compared with each other regularly, probably once a year.

13.7 In order that the quality of administrative and clinical care can be assessed, it was deemed necessary to draw up a series of markers or measures of good care, based on current national and international models of good practice. This task has been undertaken by the National Quality Assurance Group as evidenced in this report. Quality measurements for each of the disciplines involved in breast care were proposed and targets set. In this way, high-quality and realistic standards can be assured.

13.8 Each centre must have a dedicated data manager and a minimum of two administrative assistants to enter the data.

13.9 It is of the utmost importance that the information collected in each centre be accurate and unambiguous and that it be validated regularly from outside each centre. A full-time validation officer, with experience in cancer data management, should be appointed to validate the information from each centre on a continual basis.

13.10 A central office with a full-time IT project director, a data manager and administrative staff should be established forthwith so that the process of establishing the common dataset can be initiated without delay.

13.11 An annual meeting during which the performance indicators of each centre are presented formally should take place, allowing the strengths and deficiencies of centres to be compared with each other and allowing external quality review to occur from time to time.

13.12 Periodic meetings between the implementation group and the relevant training bodies (e.g. the Royal Colleges of Surgeons, the Royal College of Physicians, An Bord Altranais) should take place to ensure a flow of advice and information concerning developments in training and CPD.
14.0 Data Collection, Validation and Monitoring
a) Data collection

14.1 Data regarding the patient’s waiting times between referral and first appointment, between first appointment and receipt of diagnosis, and between diagnosis and surgery shall be collected.

14.2 Audit and other issues of relevance to data monitoring and management shall be discussed at the multidisciplinary team meetings.

14.3 There shall be agreed standardised data forms and definitions used to collect data in each unit. An IT system shall be in place to facilitate data collection.

14.4 There shall be a national quality assurance office with a data manager who receives regular data input from individual specialist breast centres.

14.5 Each specialist breast centre shall employ a dedicated data manager and a data entry clerk for the collection and validation of the data required.

14.6 A dataset definitions document will be required to outline clearly how each data field should be completed. This will ensure that no data field is open to interpretation and will speed up the data collection at each centre.

b) Data validation

14.7 The data received from each centre will require validation to ensure that they are correctly recorded at each breast centre. This process will involve employing a validation officer to visit each centre and randomly choose patient cases for review. The patient’s medical chart will be cross checked with the data submitted to ensure that all fields match correctly.

14.8 The data will be sent to a central office after the patient identifiers have been removed. At the central office, a unique dummy number will be assigned to each record and these numbers sent back to the hospital involved. Following this, the validation officer will request charts for review using this dummy number prior to organising a hospital visit.

14.9 A minimum of 10% of the data should be validated and all data fields should be assigned a critical or a non-critical status. Guidelines listing the corrective actions to be taken will be required in cases where errors are found.

14.10 A project manager should be employed to implement and develop this data collection and validation. The project manager will also organise regular meetings with all breast centres to review the data submitted.

14.11 The unique dummy number will allow for tracking patients whose care takes place at more than one centre, e.g. a patient who is diagnosed at one hospital and has surgery with follow-up at a second hospital. The same number will be applied to this patient at both hospitals.
14.0 Data Collection, Validation and Monitoring

c) Data monitoring and audit

14.12 The specialist breast centres shall produce annual performance and audit information which shall be set alongside defined quality objectives and outcome measures.

14.13 Each specialist breast centre shall participate annually in a national meeting to review and compare data and performance.

14.14 Breast centres shall be encouraged to support clinical research and shall be expected to participate in multicentre studies aimed at improving treatments for breast cancer. The specialist breast centres shall produce annual information regarding the numbers of patients entered into clinical trials.

14.15 Clinical trials and other issues of relevance to research shall be discussed at the multidisciplinary team meetings.

14.16 Patient satisfaction with care and treatment received at every stage throughout the disease continuum shall be measured.
List of Abbreviations
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>BASO</td>
<td>British Association of Surgical Oncologists</td>
</tr>
<tr>
<td>BC Guidelines</td>
<td>Irish Breast Care Nurses Association</td>
</tr>
<tr>
<td>CSBS</td>
<td>Clinical Standards Board for Scotland</td>
</tr>
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<td>CPD</td>
<td>Continuing Professional Development</td>
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<td>(CT)</td>
<td>Computerised Tomography</td>
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<td>DCIS</td>
<td>Ductal Carcinoma in Situ</td>
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<td>ECAHB</td>
<td>East Coast Area Health Board</td>
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<tr>
<td>EUSOMA</td>
<td>European Journal of Cancer, EUSOMA Position Paper</td>
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<td>FISH</td>
<td>Fluorescent in Situ Hybridisation</td>
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<td>FNAC</td>
<td>Fine-Needle Aspiration and Cytology</td>
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<tr>
<td>IHSAB</td>
<td>Irish Health Services Accreditation Board</td>
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<td>IMC</td>
<td>Internal Mammary Chain</td>
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<td>NBCCA</td>
<td>National Breast Cancer Centre Australia</td>
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<td>MRI</td>
<td>Magnetic resonance imaging</td>
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<td>NCNM</td>
<td>National Council for the professional development of Nursing &amp; Midwifery</td>
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<td>QA Guidelines for Nurses in Breast Cancer Screening</td>
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<td>NICE:</td>
<td>National Institute for Clinical Excellence</td>
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<td>RCPI</td>
<td>Royal College of Physicians of Ireland</td>
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<td>RCSI:</td>
<td>Royal College of Surgeons in Ireland</td>
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<td>SIGN:</td>
<td>Scottish Intercollegiate Guidelines Network</td>
</tr>
<tr>
<td>TNM</td>
<td>Nodes Metastasis</td>
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Bibliography
Bibliography

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Appendix 1
Membership and
Terms of Reference
National Quality Assurance Group Membership

- Prof. Niall O’Higgins (Chair), Consultant Surgeon with a special interest in breast disease, St. Vincent’s University Hospital, Dublin
- Prof. Paul Redmond, Consultant Surgeon, Cork University Hospital and Head of Department of Surgery, UCC
- Prof. Des Carney, Consultant Medical Oncologist, Mater Misericordiae Hospital
- Mr. James Geraghty, Consultant Surgeon, the Adelaide & Meath Hospital incorporating the National Children’s Hospital (AMNCH)
- Dr. Ann O’Doherty, Consultant Radiologist, St. Vincent’s University Hospital and Clinical Director, BreastCheck Merrion Unit
- Dr. Patricia Fitzsimons, Consultant Radiologist, Sligo General Hospital
- Dr. Cecily Quinn, Consultant Histopathologist, St. Vincent’s University Hospital
- Prof. Peter Dervan, Consultant Pathologist, Mater Misericordiae Hospital
- Dr. Paul Donnellan, Consultant Medical Oncologist, University College Hospital Galway
- Dr. Clare Faul, Consultant Radiation Oncologist, St. Luke’s Hospital, Dublin
- Dr. Ailis Ni Riain, Irish College of General Practitioners
- Dr. Aine McNamara, Specialist Registrar in Public Health Medicine
- Dr. John Kennedy, Consultant Medical Oncologist, St. James’s Hospital, Dublin
- Ms. Terry Hannan, CNM3, the Adelaide & Meath Hospital incorporating the National Children’s Hospital (AMNCH)
- Ms. Deirdre O’Connell, Europa Donna Ireland
- Tony Holohan, Deputy Chief Medical Officer, Department of Health and Children
- Ms. Roisin Boland, Chief Executive Officer, Irish Health Services Accreditation Board
Terms of Reference

Having regard to international best practice and best available evidence and the requirements regarding quality assurance as set out in the Report to the National Cancer Forum on the Development of Services for Symptomatic Breast Disease, to

1. develop an agreed set of guidance for the interdisciplinary management of breast cancer
2. convene relevant subspecialty groups to develop sub-specialty specific guidance for surgery, pathology, radiology, medical oncology and radiation oncology
3. develop an agreed set of interdisciplinary performance indicators for the management of symptomatic breast cancer
4. convene relevant subspecialty groups to agree on sub-specialty specific performance indicators for surgery, pathology, radiology, medical oncology and radiation oncology
5. agree a minimum dataset of information to be collected in each unit which would enable performance indicators to be generated
6. establish information technology requirements to gather the agreed minimum dataset
7. set out a plan to enable the implementation of these guidelines and performance indicators, having regard to the existing service planning process
8. continually update guidance and performance indicators for the management of symptomatic breast cancer
9. produce an annual report based on the agreed performance indicators.
Appendix 2
TNM Classification
The most widely used classification for breast carcinomas is the TNM classification. T, N and M categories are assessed by the combination of physical examination and imaging such as mammography.

**T Categories**

**Primary Tumour (T)**

Definitions for classifying the primary tumour (T) are the same for clinical and for pathologic classification. The telescoping method classification can be applied. If the measurement is made by physical examination, the examiner will use the major headings (T1, T2 or T3). If other measurements, such as mammographic or pathologic, are used, the examiner can use the telescoped subsets of T1.

- **TX** – Primary tumour cannot be assessed
- **T0** – No evidence of primary tumour
- **Tis** – Carcinoma in situ; intraductal carcinoma or lobular carcinoma in situ; or Paget’s disease of the nipple with no tumour
- **T1** – Tumour ≤ 2cm in greatest dimension
  - **T1a** ≤ 0.5cm in greatest dimension
  - **T1b** > 0.5cm to 1cm in greatest dimension
  - **T1c** >1cm to 2cm in greatest dimension
- **T2** – Tumour > 2cm and ≤ 5cm in greatest dimension
- **T3** – Tumour > 5cm in greatest dimension
- **T4** – Tumour of any size with direct extension to chest wall or skin
  - **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 T4a and T4b above
  - **T4d** Inflammatory carcinoma

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1. The NSW BCI does not use the telescoped sub-classification for pN, but we clearly document the number of nodes dissected, number of positive nodes, the extent of nodal involvement and the extent of any extracapsular extension.

2. Paget’s disease associated with a tumour is classified according to the size of the tumour.
Appendix 2 - TNM Classification

**N Categories**

NX – Regional lymph nodes cannot be assessed
N0 – No regional lymph nodes metastasis
N1 – Metastasis to movable ipsilateral axillary lymph node(s)
N2 – Metastasis to ipsilateral axillary lymph node/s fixed to one another or to other structures
N3 – Metastasis to ipsilateral internal mammary lymph node(s)

**Pathologic Classification (pN)**

pNX – Regional lymph nodes cannot be assessed (e.g. previously removed, or not removed for pathologic study)
pNO – No regional lymph node metastasis
pN1 – Metastasis to moveable ipsilateral axillary lymph node(s)
pN2 – Metastasis to ipsilateral axillary lymph nodes that are fixed to one another or to other structures
pN3 – Metastasis to ipsilateral internal mammary lymph node(s)

**M Categories**

MX – Presence of distant metastasis cannot be assessed
M0 – No distant metastasis
M1 (scf) – Metastasis only to ipsilateral supraclavicular lymph nodes
M1 – Distant metastasis
Pathological staging is preferable because:
– it is more accurate for tumour size,
– it is especially relevant for N stage, and
– it relates better to treatment strategies.

Avoid a mixture of clinical and pathologic staging.
Appendix 3
Minimum Dataset for Breast Cancer Histopathology Reports

The Faculty of Pathology
Royal College of Physicians of Ireland
Introduction

This minimum dataset for breast cancer reports is intended to provide guidelines for and to promote consistency in histopathology reporting of non-operative and operative breast cancer specimens. It has been developed from Essential Parameters in Breast Cancer – Histopathology Reporting Guidelines, produced by the All-Ireland Breast Cancer Group and endorsed by the Faculty of Pathology, Royal College of Physicians of Ireland. The dataset is based on international best practice and takes account of the breast minimum dataset developed by the UK Royal College of Pathologists. The importance of triple assessment in non-operative diagnosis is emphasised and quality assurance measures are outlined. The document specifies the evidence-based critical predictive and prognostic parameters that constitute an informative histopathology report for ductal carcinoma in situ and invasive carcinoma of breast. The data in the proforma reports may be provided as, or supplemented by, free text but the use of a proforma approach is recommended to ensure provision of the necessary histopathology data for treatment planning and assessment of prognosis. Details of the recently revised pTNM classification are also included. Inclusion of this information in the histopathology report is particularly useful for local and national statistics.

Working party

Dr. Cecily Quinn (co-ordinator), Consultant Histopathologist, Irish National Breast Screening Programme & Department of Histopathology, St. Vincent’s University Hospital, Dublin 4.

Dr. Conor O’Keane, Consultant Histopathologist, Mater Misericordiae Hospital, Dublin 7.

Professor Peter Dervan, Univeristy College, Dublin & Consultant Histopathologist, Mater Misericordiae Hospital, Dublin 7.

Professor Charles Eugene Connolly, University College Galway & Consultant Histopathologist, University College Hospital, Galway.

Dr. Michael Jeffers, Consultant Histopathologist, Meath, Adelaide & National Children’s Hospital, Tallaght, Dublin.

1. Non-Operative Diagnosis

Triple assessment aims to achieve a diagnosis by combining the results of imaging with clinical examination and the use of fine-needle aspiration cytology (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. Non-operative diagnosis requires good communication between the clinician, radiologist and pathologist. In particular, the results of FNAC/NCB must be interpreted in conjunction with the radiological and clinical findings, and never in isolation.

Fine-needle aspiration cytology

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

Interpretation and reporting

FNAC specimens are assigned to one of the following five categories as defined by the UK NHS BSP Guidelines.
C1: Non diagnostic/Inadequate
The specimen is poorly cellular (fewer 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 which does not contain epithelial cells may be reported as C2, e.g. cyst fluid and aspirates from lesions suggestive of fat necrosis or abscess.

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 are present, e.g. increased cellularity, loss of cell cohesion, nuclear pleomorphism or nucleoli. 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 differentiate accurately 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.

Needle core biopsy
NCB is image-guided by the use of ultrasound or stereotaxis. Sensitivity is related to needle size and to the number of samples taken. NCBs for evaluation of microcalcification are x-rayed to ensure that the sample is representative. Specimens are formalin-fixed, paraffin-embedded and sections are cut and stained with H&E. It is usual to examine three levels and to retain parallel spare sections for immunohistochemistry. Further levels may be necessary to detect microcalcification. Cam 5.2 is useful in the investigation of paucicellular lobular carcinoma. Smooth muscle actin stains assist the distinction of radial scar from tubular carcinoma and sclerosing adenosis from invasive carcinoma.
Interpretation and reporting

NCB specimens are reported according to the UK NHS BSP system that is similar but not identical to that used for FNAC.

**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 or intramammary lymph node. The B1 category is also used for specimens that are considered to be unsatisfactory for histological assessment.

**B2: Benign**

There is evidence of a benign process or lesion, e.g. cystic change, duct ectasia, 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. 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% of cases, and apparently benign papillary lesions on core biopsy may harbour foci of DCIS when the entire lesion is examined. Atypical lobular hyperplasia (ALH) is a risk factor for malignancy and does not in itself present a mammographic abnormality. The presence of ALH on NCB may signify a tumour in the vicinity. 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 ADH. Up to 50% of lesions diagnosed as ADH on NCB prove to be malignant on subsequent excision. Depending on the degree of change, ADH may be assigned to either the B3 or B4 category.

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.

B3 lesions require further evaluation, usually surgical excision for complete histological examination.

**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 repeat NCB or open surgical excision.

**B5: Malignant**

There is unequivocal evidence of malignancy, in situ or invasive. Due to sampling error, approximately 20% of lesions reported as in situ carcinoma on NCB will have accompanying invasion in the resected specimen.

The B5 category is also appropriate for other malignant lesions, e.g. malignant phyllodes tumour, lymphoma, 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 smooth-muscle actin stains. Misdiagnosis of radiotherapy change can be avoided by obtaining an adequate clinical history. Spindle cell lesions are difficult to assess on NCB and, if in doubt, an excision biopsy is advisable.

Hormone receptor studies

Hormone receptor status, oestrogen receptor (ER) +/- progesterone receptor (PR) PR, and Her-2-Neu status 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, hormone receptor studies are repeated on tumour tissue from that specimen.

Quality assurance for non-operative diagnosis

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 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 aspirated.

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 case that turns out (within a period of 2 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 case that was given a C5 or B5 result and which turns out at open surgery to be a benign lesion (including atypical hyperplasia).

False negative rate
The number of false negative results expressed as a percentage of the total number of carcinoma sampled.

False positive rate
The number of false positive results expressed as a percentage of the total number of carcinoma sampled.

Inadequate rate for FNAC
The number of inadequate FNAC specimens expressed as a percentage of the total number of cases aspirated.
United Kingdom National Health Service Breast Screening Programme (UKNHSBSP) – Suggested Thresholds

**Fine-needle aspiration cytology**

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<tr>
<td>Absolute sensitivity (AS)</td>
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<td>Complete sensitivity (CS)</td>
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<td>Specificity (full) (SPEC) (including non–biopsied cases)</td>
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<td>Positive predictive value (+PV)</td>
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**Needle core biopsy**

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<td>&lt;15</td>
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<tr>
<td>Suspicious rate</td>
<td>&lt;10</td>
<td>&lt;5</td>
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* These tables of suggested thresholds have been developed by the UK Breast Screening Programme based on experience and expected standards and are included in this document as a guide. Within screening and symptomatic practice, these figures will vary depending on sampling techniques, indications for FNAC, and the experience of the aspirator.
2. Operative Specimens

Macroscopic Examination

**General Points:**
Specimen details
Specimens should be received 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, axillary lymph nodes, are recorded at the beginning of the macroscopic description.

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 30gm. It is not necessary to weigh mastectomy or axillary lymph node specimens.

Specimen radiography
Specimens containing mammographically detected abnormalities are x-rayed following surgery to ensure that the abnormality has been removed. The x-ray should be sent to the laboratory with the specimen to enable the pathologist to correlate the radiological and macroscopic findings. 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 to assessment of lesion size and margin identification. Block selection is directed by the macroscopic and x-ray findings.

Margin marking
The specimen margins are inked prior to dissection to facilitate microscopic assessment of excision status. A variety of marking compounds is available, with India ink and Alcian Blue most commonly used. 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.

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

The presence and extent of ductal carcinoma in situ (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 4–5 mm intervals, usually perpendicular to the long axis of the specimen. The slices are placed sequentially on an x-ray plate, taking care to maintain 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.
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 free and posterior margins and to identify the free margins individually (i.e. medial, lateral, superior, inferior). A positive free margin is usually amenable to surgical treatment in the first instance and the surgeon may opt to confine re-excision to the compromised margin. 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.

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.

Sentinel lymph node

Sentinel lymph node (SLN) biopsy as an alternative to full axillary node surgery as a staging procedure for breast cancer is under evaluation. The hypothesis underlying the SLN concept is that tumour cells drain into one or more “sentinel” lymph nodes 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. There is no common protocol for SLN examination. At a minimum, the SLN is processed in its entirety for histological examination, divided into multiple pieces at right angles to the long axis if greater than 5mm, and examined at one level. The role of intraoperative assessment and immunohistochemistry in SLN biopsy remains to be defined.

Microscopic Examination

Predictive and prognostic parameters in malignant disease

Ductal carcinoma in situ

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

Grade

Cytological grade has replaced the assessment of architecture as the basis of DCIS classification. 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.

Size

DCIS lesions which measure in excess of 4cm are associated with a greater incidence of microinvasion, early invasion, positive margins following attempted conservation surgery, and local recurrence. 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.
Margins

The distance of DCIS from the nearest margins is recorded. The location of these margins is also specified, differentiating, in particular, between the posterior and free margins. Margin width is rapidly emerging as the most significant factor in determining the likelihood of local recurrence following conservation surgery for DCIS.

Other

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

Microinvasion

The UK NHSBSP Guidelines propose that microinvasive carcinoma is a tumour in which the dominant lesion is DCIS but in which there are one or more clearly separate foci of invasion involving non-specialised interlobular stroma, none measuring more than 1mm in maximum dimension. Applying these strict criteria, microinvasive carcinoma is a rare condition. A similar restrictive definition is being promoted for international usage (TNM). At the present time, the prognosis of microinvasion is considered to be comparable to high-grade DCIS.

Invasive carcinoma

The following parameters have been shown to be associated with clinical outcome, and together 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, mucinous and medullary. Tubular, cribriform and mucinous carry an improved prognosis compared with ductal NOS. The prognosis of tubular mixed is determined by the grade of the accompanying ductal NOS component. Medullary carcinoma may have an improved prognosis if strict diagnostic criteria are utilised. Lobular carcinoma is associated with an increased incidence of multifocality.

Grade

Tumour grade is a powerful predictor of prognosis and is assessed on all types of invasive breast carcinoma. 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:

<table>
<thead>
<tr>
<th>Tubule formation</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Majority of tumour (&gt;75%)</td>
<td>1</td>
</tr>
<tr>
<td>10% – 75%</td>
<td>2</td>
</tr>
<tr>
<td>Little or none (&lt;10%)</td>
<td>3</td>
</tr>
<tr>
<td>Nuclear pleomorphism Small, regular, nuclei</td>
<td>1</td>
</tr>
<tr>
<td>Larger nuclei with visible nucleoli and moderate variability in size and shape</td>
<td>2</td>
</tr>
<tr>
<td>Marked variation in nuclear size and shape</td>
<td>3</td>
</tr>
<tr>
<td>Mitotic count (per 10 high-power fields)</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>1</td>
</tr>
<tr>
<td>Intermediate</td>
<td>2</td>
</tr>
<tr>
<td>High</td>
<td>3</td>
</tr>
</tbody>
</table>
• The size of a high-power field varies between microscopes and it is necessary to standardise the mitotic count for individual microscopes. 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 (Reference: National Co-ordinating Group for breast screening pathology. Pathology reporting in breast cancer screening. NHSBSP Publication no. 3. 1997). Mitoses are counted at the periphery of the tumour.

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 a quarter of the mass lesion together with the presence of DCIS in adjacent breast tissue constitutes extensive intraduct component. 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 as macroscopic assessment may overestimate the size of the invasive element due to the presence of streaky fibrosis and/or DCIS. The size of the invasive tumour only is recorded, unless DCIS extends more than 1mm beyond the invasive component, when the size of the combined DCIS and invasive tumour is also recorded.

The size of the invasive component rather than overall tumour size relates to axillary nodal metastases and survival. 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. To avoid misinterpreting tumour retraction artefact, the tissue surrounding the tumour rather than the tumour itself should be examined for LVI.

**Margin status**

The risk of local recurrence following conservation surgery is significantly reduced by adequate clearance of invasive carcinoma and any associated DCIS. 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. The number of involved lymph nodes and the total number of lymph nodes examined are recorded, and specified per level if appropriate. The sentinel lymph node is included in the overall count, with its status individually recorded. The presence of extranodal extension is also documented.

**Biological markers**

Oestrogen receptor (ER) status, used to select patients for hormonal therapy, is routinely evaluated immunohistochemically on paraffin tissue sections. Progesterone receptor (PR) status is also determined on ER-negative tumours as a small percentage of this group are PR-positive and may be hormone sensitive. Her-2-neu status is evaluated to assess patient suitability for herceptin therapy.
pTNM Pathological Classification

pT – Primary Tumour

- The pathological classification requires the examination of the primary carcinoma with no gross tumour at the margins of the resection. A case can be classified pT if there is only microscopic tumour in a margin.
- The pT categories correspond to the T categories.
- When classifying pT the tumour size is a measurement of the invasive component. If there is a large in situ component (e.g. 4cm) and a small invasive component (e.g. 0.5cm), the tumour is coded pT1a.

pTX Primary tumour cannot be assessed

pT0 No evidence of primary tumour

pTis Carcinoma in situ

- pTis (DCIS) Ductal carcinoma in situ
- pTis (LCIS) Lobular carcinoma in situ
- pTis (Paget) Paget’s disease of the nipple with no tumour

pT1 Tumour 2cm or less in greatest dimension

- pT1mic Microinvasion 0.1cm or less in greatest dimension
- pT1a > 0.1cm and < 0.5cm in greatest dimension
- pT1b > 0.5cm and < 1cm in greatest dimension
- pT1c > 1cm and < 2cm in greatest dimension

pT2 Tumour more than 2cm but not more than 5cm in greatest dimension

pT3 Tumour more than 5cm in greatest dimension

pT4 Tumour of any size with direct extension to chest wall or skin only as described in T4a to T4d

- pT4a Extension to chest wall
- pT4b Oedema or ulceration of the skin of the breast, or satellite skin nodules confined to the same breast
- pT4c Both 4a and 4b
- pT4d Inflammatory carcinoma

pN – Regional Lymph Nodes

- The pathological classification requires the resection and examination of at least the low axillary lymph nodes (level 1) that will ordinarily include six or more lymph nodes. If the lymph nodes are negative, but the number ordinarily examined is not met, classify as pN0.
- Examination of one of more sentinel lymph nodes may be used for pathological classification. If the classification is based solely on sentinel node biopsy without subsequent axillary lymph node dissection, it should be designated (sn) for sentinel node, e.g. pN1 (sn).
- Cases with only isolated tumour cells (ITC) in regional lymph nodes are classified as pN0. ITC are single-tumour cells or small clusters of cells, not more than 0.2mm in greatest dimension, which are usually detected by immunohistochemistry but which may be verified on H&E stains. ITCs do not typically show evidence of metastatic activity, e.g. proliferation or stromal reaction.
pNX  Regional lymph nodes cannot be assessed
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 in ipsilateral internal mammary nodes with micrometastases detected by sentinel lymph node 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 Internal mammary lymph nodes with micrometastases detected by sentinel lymph node dissection but not clinically apparent
pN1c Metastasis in 1–3 axillary lymph nodes and internal mammary lymph nodes with micrometastases detected by sentinel lymph node 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 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 one or more positive axillary lymph nodes; or in more than three 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 three axillary lymph nodes and in internal mammary lymph nodes with microscopic metastasis detected by sentinel lymph node dissection but not clinically apparent
pN3c Metastasis in supraclavicular lymph node(s)
pM  Distant Metastasis
The pM categories correspond to the M categories.
pMx  Distant metastasis cannot be assessed
pM0  No distant metastasis
pM1  Distant metastasis
Sample Proforma Report

Ductal carcinoma in situ
Therapeutic 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 DCIS is / is not associated with calcification.

- The maximum dimension of the area involved by DCIS is ...... mm.

- 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 ..... mm and is grade 1 / 2 / 3.
  Lymphovascular invasion is / is not seen.

- MARGINS (if less than 10mms)
  Superior DCIS ..... mm; Invasion ..... mm
  Inferior DCIS ..... mm; Invasion ..... mm
  Medial DCIS ..... mm; Invasion ..... mm
  Lateral DCIS ..... mm; Invasion ..... mm
  Free anterior DCIS ..... mm; Invasion ..... mm
  Posterior DCIS ..... mm; Invasion ..... mm

- Additional information:
- pT N M
Sample Proforma Report
Invasive Breast Carcinoma
Therapeutic excision specimen

Microscopy
- Invasive ductal / lobular / mucinous / tubular / other carcinoma.
- Grade 1 / 2 / 3 (little / moderate / marked tubule formation; mild / moderate / severe nuclear pleomorphism; low / intermediate / high mitotic count).

There is associated / no associated DCIS.

Low / intermediate / high grade with a solid / cribriform / micropapillary / papillary / mixed growth pattern and no / focal/ marked necrosis.
- Invasive carcinoma measures ..... mm.
- In situ and invasive carcinoma measure ..... mm.
- Lymphovascular invasion is / is not seen.
- Margins (if less than 10mms)
  Superior DCIS ..... mm; Invasion ..... mm
  Inferior DCIS ..... mm; Invasion ..... mm
  Medial DCIS ..... mm; Invasion ..... mm
  Lateral DCIS ..... mm; Invasion ..... mm
  Free anterior DCIS ..... mm; Invasion ..... mm
  Posterior DCIS ..... mm; Invasion ..... mm
- Additional information:
- Axillary lymph nodes
  ..... / .... axillary lymph nodes contain metastatic carcinoma
  (Level 1 = .../ ... Level 2 = ... / ... Level 3 = ... / ...).
  The sentinel lymph node is positive / negative.
- Biological markers
  ER pos / neg
  PR pos / neg
  Her-2-neu pos / neg
- pT N M
References
References


• Seidman JD, Schnaper LA, Aisner SC. Relationship of the size of the invasive component of the primary breast carcinoma to axillary lymph node metastasis. Cancer 1995;75:65-71.


National Quality Assurance Standards for Symptomatic Breast Disease Services

Developing Quality Care for Breast Services in Ireland

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