



Development of services for symptomatic breast disease: report of the Sub-group to the National Cancer Forum / Bernadette O'Keefe, Niall O'Higgins, Ann O'Doherty.

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**Development of Services
For Symptomatic
Breast Disease**

***Report of the Sub-Group to
The National Cancer Forum***

prepared for the Sub-Group to the National Cancer Forum by
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Foreword

Although, in recent years, advances in diagnosis and treatment have been made, breast cancer remains a major public health issue in Ireland and is responsible for approximately 650 deaths annually.

It is now recognised that patients with breast diseases are best served by a team of specialists working together. Strong evidence exists that women with breast cancer are at lower risk of relapse and have a better opportunity of long-term survival if they are treated in a multidisciplinary setting. Thus, surgeons, radiologists, pathologists, medical oncologists, radiotherapists, plastic surgeons, nurses, counsellors and others all bring expertise together to provide the best care for each patient. Such an arrangement can be achieved only by establishing Specialist Breast Units, strategically placed throughout the country, each treating sufficiently large numbers of patients in order to maintain expertise and to promote best practice. These Units should also be responsive to developments in treatment and should be involved in clinical research and clinical trials in collaboration with each other and with international groups.

Systems of training of breast specialists and guidelines of good care are being laid down by training organisations in Ireland and throughout Europe.

The undoubted high quality of the recently initiated National Breast Screening Programme (Breast Check) for women aged 50-64 years who have no breast symptoms, should be matched by a programme also of the highest quality for women who have breast complaints.

In April 1999, the Minister of Health and Children asked the National Cancer Forum to report and make recommendations on the development of breast services for symptomatic women. The Forum established a subgroup to undertake this exercise, under the Chairmanship of Prof J. Fennelly.

The report has now been approved by the Forum. It is with great pleasure that I acknowledge the efforts of my colleagues on the subgroup in preparing this report. It is also a pleasure to pass the report on to the Minister for Health and Children for consideration and, it is hoped, for implementation.

Niall O'Higgins

March, 2000

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Summary

This is a detailed report. To assist readers in extracting the key information without reading through the full report, the summary has been formulated so that it can stand alone. In order to do this, it has been necessary to repeat some whole sections of the main report in the summary.

Background

Most women with breast symptoms fear that they may have cancer. In the great majority of cases, the breast complaint is not due to cancer. Nonetheless the anxiety generated by the possibility of this fearful diagnosis requires that women with breast symptoms are cared for in an efficient, sympathetic environment by highly trained specialist with access to high quality facilities. These prerequisites are needed in order to provide a firm diagnosis of a benign or innocent condition without delay and thus be in a position to reassure the patient. Equally, when the patient has cancer of the breast, the diagnosis and treatment must be carried out in a systematic fashion and in conformity with the high standards of care expected in a modern society.

Breast cancer causes approximately 650 deaths in women each year in Ireland and thus presents a major public health issue. It is the commonest fatal cancer in women. While it is rare in women under the age of thirty years, it can affect all age groups and is responsible for a high proportion of premature deaths. Despite being the subject of intensive research, causes of breast cancer are still unknown. It is recognised that, in general, the earlier the diagnosis of breast cancer is made, the more likely it is that patients will have a favourable outlook. Although by no means infallible, high quality mammography can lead to the identification of breast cancers when they are very small and when the prospect of cure after treatment is very high. It is for this reason that screening programmes have been established. Breast screening means the investigation of women who have no breast symptoms and who believe that they have no breast disease. The National Breast Screening Programme (NBSP), which commenced in January 2000, is a system where excellence is required in the identification and treatment of small cancers in women without breast symptoms. The purpose of this screening programme is to reduce mortality from breast cancer in women in the fifty to sixty-four year age group.

Because the screening programme will deal only with women in the fifty to sixty-four year old age range and only with those who have no symptoms, the great majority of women with breast cancer will continue to be diagnosed and treated outside of the screening programme. For this reason, and because of the need to investigate and treat the large and increasing number of people with breast symptoms due to benign conditions, it is necessary to ensure that the attention and care provided for these patients is as good as that offered in the screening programme. It is, therefore, essential to put systems in place to achieve this ambition.

Genesis of the report

A number of developments have led to the production of this report:

- There is good evidence that outcomes for women with breast cancer are influenced by the method of care provided and that the use of clinical guidelines can improve the process and outcome of care.
- Evidence demonstrating correlation between workload (volume) and survival exists. In some cases, a 20% improved survival has been noted in patients treated in specialised Breast Units compared to those not treated in such centres.
- Throughout the UK, the USA and Europe there has been a demand for protocols in oncology especially for common cancers and guidelines are being formulated in the area of breast diseases.
- Professional groups such as the Royal Colleges recognise that there is a relationship between longterm survival and the number of patients treated in particular centres and have advocated the establishment of

guidelines for the training of surgeons, radiologist, physicians and radiotherapists involved in breast disease.

- Best practice guidelines have been widely promulgated and continuing medical education (CME) although voluntary at present is likely to become compulsory in the future for all doctors treating patients with breast cancer.
- Establishment of agreed proformas and protocols of management consistent with best modern practice requires an in-built audit system to allow comparison of outcomes from centre to centre within countries. It also allows external benchmarking with centres of excellence in other countries.
- The NBSP will provide an excellent, intensely quality-assured service for screened women who believe that they are healthy and for the treatment of the women who, through screening, are discovered to have breast cancer. It is essential that it be matched by an equally excellent service for those with symptomatic breast disease. It is important to have nationally agreed protocols and guidelines for all services and provision of adequate resources to provide a quality service.
- In the light of the concerns outlined above, the Minister for Health & Children requested that the National Cancer Forum produce recommendations on the provision of services for women with symptomatic breast disease.

The National Cancer Forum established a sub-group to examine the issue. The members of the group are listed in Appendix 1. As part of the work, the Regional Directors of cancer services were asked for information concerning their current service and their views were sought regarding how the service should be developed in their region. In addition, three members of the sub-group visited each region. The consensus view regarding best practice in the management of breast disease was presented to Regional representatives and their views on how this could be achieved in their region were sought. In each region specific issues arose which will need to be dealt with in the process of developing a plan for the breast services. Where possible, difficult issues should be resolved locally. A list of the places that were visited is provided in Appendix 2.

Terms of Reference

To assess the impact on the existing diagnostic services for benign and malignant breast disease in the light of:

- The forthcoming National Breast Cancer Screening Programme;
- The increase in the target population;
- The increased awareness of the importance of breast screening; and
- The current and evolving technologies in the area of breast screening.

To make recommendations to the Minister for Health and Children on:

- The diagnostic services for symptomatic breast disease necessary to meet projected increased needs;
- The need to develop associated services in radiotherapy, medical oncology, counselling and other support services;
- The resources required to develop these services; and
- The principles that should underlie the organisation and delivery of services for breast disease.

Requirements for Good Care

There are some requirements that are necessary to provide good care. There are general requirements, principles for diagnosis and principles for treatment. They are listed below and are based on examination of evidence in the literature, which is described in detail in the body of the report.

General Requirements (1, 2, 3)

- All women with symptomatic breast disease should have prompt access to high quality multidisciplinary care.
- Although services should be delivered as close to the patient's home as is feasible, the overriding priority should be to provide the best, safest and most effective treatment for women and, in so doing, provide the best opportunity for long-term survival to those who are found to have breast cancer.
- Equipment required to provide an excellent service should be available to units dealing with breast diseases.
- All medical and nursing personnel involved should have specific training in breast diseases in designated training centres.
- Standards of care should follow agreed national guidelines and reflect modern advances.
- Medical staff involved in this service must undertake regular audit and technology to allow detailed audit must be put in place.

Diagnostic Principles (1, 3, 4, 5, 6, 7)

All patients with breast disease should have access to high quality care. There are a number of principles that should govern the diagnosis of breast disease for women who have symptoms suggestive of breast disease:

- It is important that women have access to a uniformly high standard of care. Over 90% of women who attend a symptomatic clinic will not require in-patient treatment. It is important that the outpatient service structure can develop to deal efficiently with the increasing number of women who require this service.
- A Breast Team should be in place to diagnose and treat women with breast diseases.
- Because of the crucial role of the general practitioner (GP) in the care of patients with breast diseases, clear referral guidelines should be sent to GPs for their guidance and approval.
- At least one referral breast clinic per week for new patient GP referrals should be held. Such clinics should not be part of the general surgery clinic. Only patients with suspected breast disease should be seen at this clinic.
- All investigations required for diagnosis should be available at this clinic.
- The modern management of breast cancer involves triple assessment, which involves the surgeon (surgical oncologist), radiologist and pathologist working together in the clinic.
- All diagnostic tests should be undertaken at the initial visit in the great majority (90%) of cases. The importance of this principle is emphasised. Such an arrangement allows speedy reassurance for the great majority of patients who do not have cancer but who are anxious (the "worried well"). It also avoids the need for multiple visits to hospital, with their associated inconvenience and economic loss.
- Imaging techniques and expertise (radiographic and radiological) should be subject to the same quality assurance criteria as pertains in the NBSP.
- A pre-operative diagnosis should be made in over 90% of patients with cancer, whether palpable or impalpable.
- For those few patients who require an open surgical operation for diagnostic purposes, the operation should be done within two weeks of the decision that operation is needed.

Treatment Principles (1, 2, 3, 4)

A number of principles should govern the treatment of breast cancer:

- Treatment of breast cancer should be managed by staff with special training and expertise in breast disease.

- Surgeons treating breast cancer should have undergone formal training in breast disease and should work in a Breast Team which has all the necessary facilities and expertise needed for a multidisciplinary approach.
- Consultants in the Breast Team must have dedicated time for attendance at multidisciplinary meetings. In addition Breast Care Nurses and trainees in breast surgery must be in attendance at such meetings.
- In order to collect accurate data preoperatively and to ensure efficiency in administration, data management and administrative clerical staff are required for a Breast Team.
- The ratio of open surgical biopsies that prove benign to the total number of cancers diagnosed should be no more than 1:10 (This does not include operations for nipple discharge and previously diagnosed fibroadenomas).
- More than 90% of patients with cancer should be admitted for operation within 3 weeks of the decision to operate.
- Women with breast cancer should have the support of a Breast Care Nurse.
- The Breast Care Nurse who is a member of the Breast Team should have established links with the ward nurses and the other members of the Breast Team.
- Follow-up arrangements must be defined by protocol and must involve the surgical team.
- The Breast Team should be involved in biopsies, assessment and management of patients with locally recurrent and metastatic breast cancer. Patients with metastatic breast cancer should remain under the care of the Breast Team.
- All women diagnosed with breast cancer should have their management discussed with a surgeon trained in surgical oncology of the breast, a medical oncologist and a radiation oncologist.
- Involvement in international clinical trials should be recommended, fostered and supported.

Reasons for Proposing Specialist Breast Units

There are a number of reasons why breast services should be delivered through a Specialist Breast Unit.

- To develop and maintain the skills to deliver a quality service the professionals providing the service need to be grouped together to form Specialist Breast Care Teams within Specialist Breast Units.
- The improved outcome that is found in Units where there is high caseload is thought to be largely related to the clinical organisation and multidisciplinary care provided by the service rather than due simply to the skill of individual surgeons.
- It is accepted that a multidisciplinary approach to breast cancer affords women the best therapeutic options when diagnosed with breast cancer.
- The important features of a Breast Care Team are the composition of the team, the way the team works and the co-ordination of care that it provides.
- Treatment frequently involves a combination of surgery, adjuvant systemic therapy and radiotherapy.
- The multidisciplinary approach enables the clinician, the radiologist and the pathologist to discuss the findings together and to reach a consensus on the management of each case according to defined protocols.
- The use of triple assessment substantially reduces the number of unnecessary open surgical operations performed both for benign disease and for cancers.
- High quality pre-operative diagnosis will result in a very large reduction in the number of open benign and malignant surgical biopsies.
 - a) This affords great benefit in terms of reduced morbidity associated with open surgical procedures and considerable reduction in the psychological trauma associated with multiple hospital admissions.
 - b) It will also allow good surgical planning, giving an opportunity to counsel patients.
 - c) It leads to cost savings and reduced discomfort and inconvenience to the patient
- Research shows that performance in areas such as mammography and fine needle aspiration (FNA) cytology is related to skills, training and expertise.

- Adequate multidisciplinary discussion and unit audit can lead to the identification of problems and allow for corrective measures to be undertaken.
- Continuing professional development is a requirement of good practice.
- Regional unit and quality assurance raises standards. Breast Units must assess the care they provide in terms of process and outcome.
- Preliminary research conducted by the Women's Health Council on behalf of the National Cancer Forum⁽⁸⁾ indicates that what women want from a breast service is
 - a) to be seen as soon as possible
 - b) to have their tests as soon as possible and preferably in one session
 - c) to have their treatment as soon as possible
 - d) to have their care provided by a Specialist Breast Care Team

Structure of Specialist Breast Unit (1, 2, 3, 4, 5)

The purpose of developing a new organisational structure for the provision of breast services is to improve the quality of care. The majority of women who have a breast cancer usually discover it themselves. When a woman first develops breast symptoms she will usually consult her GP, who will in turn seek to refer her as quickly as possible to a centre that will provide speedy diagnosis and effective management of her complaint. The modern management of breast cancer entails triple assessment, which involves the surgeon, pathologist and radiologist being in the clinic together. It reduces the number of unnecessary operations performed for the benign and malignant breast disease and facilitates rapid diagnosis and better planning of treatment. The proposed structure is based on the guidelines available and the extensive literature on the subject, much of which is referenced throughout the report. The Specialist Unit should be based on a population of 250,000 to 300,000 from which it is expected that there will be at a minimum 100 new primary breast cancers per annum.

The figure of 100 new breast cancer patients per Breast Unit per year is an indicative figure chosen for the following reasons:

- There is evidence of benefit from specialised multidisciplinary care
- There is evidence of benefit from large volume case load
- The figure of 100 applies not merely to the surgeons but to the specialist breast team as a whole. The minimum figure of 100 is necessary to justify the investment of specialist time and other resources to establish and provide ongoing resources for a modern multidisciplinary Breast Unit. A throughput of 100 cases would be expected from a population of 250,000 to 300,000.
- This level of workload is necessary to sustain the collective expertise of the team.
- This level of workload is operationally cost-effective for the deployment of a skilled group of people to function as a multidisciplinary team.
- Grouping a number of hospitals together into a "virtual Breast Unit" would not achieve a functioning multidisciplinary team.
- It is not feasible or cost-effective for a group of specialists to meet weekly and invest time and resources co-ordinating care if the number of new breast cancer patients falls below two cases per week (100 per year).
- A unit seeing 100 cases of breast cancer per year would see at least 1000 new patients with breast symptoms annually. This level of clinical activity (20 new patients per week) would justify the provision of a weekly new patient GP referral clinic, which is essential if women are to be seen without delay.
- Professional consensus in the British Association of Surgical Oncology (BASO) clinical guidelines and other documents state the desirability of such a figure.
- In order to provide the equipment and facilities for an excellent unit, resources are required. It is not feasible to provide this level of resources in many hospitals that do not have the volume to utilise them to optimal efficiency.

- In some places many of the structures are already in place and it will be relatively east to develop the Breast Unit.
- There is a common belief that people are not prepared to travel outside their own area for health services. (9) However, people are prepared to travel for high quality care, particularly where there is recognition that such care is associated with improved survival.
- The vast majority of women with breast symptoms will not have breast cancer. They will only require one visit to the Breast Unit.

The main emphasis of the report is on the core services. It was not possible to deal in as much detail with all aspects of the service. Many important issues such as support services, specialist palliative care services, psychological support and social work support may require further examination at a later date.

The main components of a Specialist Breast Unit include core personnel, other essential personnel, facilities, equipment and organisational elements.

Core Personnel

The core personnel are the people whose presence is considered to be essential for the Breast Team to work effectively in delivering a multidisciplinary service. Some professionals e.g. the radiation oncologist and medical oncologist would not necessarily be based in the hospital where the Breast Unit is located. However, they would need to have sessions at the Breast Unit that would enable them to participate fully as members of the Breast Team. Some of the other professionals such as surgeons with an interest and expertise in breast disease from other hospitals would also require session at the Breast Unit to enable them to participate fully as member of the Breast Team.

The core personnel are as follows:

- Lead Clinician
- Breast Surgeons (lead surgeon normally 6 sessions, each other surgeon 3 sessions each)
- Breast Radiologist (4 sessions)
- Breast Pathologist (4 sessions)
- Breast Care Nurse (2 whole time equivalent (WTE) per 100 cancers)
- Clinic Nurses (1WTE). They will probably be shared with the general outpatient department.
- Medical Oncologist
- Radiation Oncologist
- Radiographers (2 WTE)
- One Administrative Officer (Grade VI or VII)
- Two Clerical Officers (Grade IV or V). Depending on the workload, three may be required.
- One Data Manager

Other essential personnel

This includes other staff that are essential for the delivery of a high quality diagnostic and therapeutic service. Women must have access to the expertise of these professionals. A liaison system, which involves good communication and early involvement in the woman's care, is necessary to ensure that the relevant professionals are brought in at the appropriate time.

- Plastic surgeon
- Clinical psychologist or psychiatrist
- Palliative care specialists
- Physiotherapist/occupational therapist
- Social worker
- Clinical Geneticist

- Pharmacist

One of the key functions of the breast care nurse is to provide support and counselling to women who attend the Breast Unit. The area of support services such as counselling and social work needs to be examined further. The survey of “women’s views and perceptions of the symptomatic breast services” undertaken by the Women’s Health Council which will be submitted to the National Cancer Forum on completion, will provide information regarding what women wish to see provided in this area. (8) Any developments in the provision of support services for patients with cancer should be guided by the national review of support services that was undertaken for patients with cancer. (10)

Facilities

Care for women with breast cancer should be provided in a friendly, comfortable environment with private areas for consultation and counselling. Consideration should be given to the need for changing facilities and the proximity of the various diagnostic and consulting areas. Necessary accommodation will include:

- Reception area
- Waiting room
- Outpatient clinic accommodation which is close to the imaging area
- Radiology, including mammography, ultrasound and imaging guidance for localisation procedures.
- Pathology room or storage of cytology specimens and a microscope
- Nurse counselling area
- Inpatient beds
- Operating time

Equipment

In order to provide high quality multidisciplinary care, basic level of equipment provision is necessary. This includes:

- Stereotactic mammography machine approximately £130,000
- Basic mammography unit approximately £50,000
- Processing equipment approximately £50,000
- Ultrasound Machine approximately £50,000
- Information Technology support and database
- Microscope for Pathologists

The sub-group did not consider it appropriate to attempt to provide detailed costing for the Breast Units. Some locations have some of the necessary facilities and staff in place already. Others would need a large injection of resources in order to establish a Breast Unit. A detailed needs assessment will be required for each proposed centre by the Department of Health and Children and the Health Boards to determine the exact requirements in each location based on what is already available.

Organisation

The planning of care involves all members of the Breast Team, who must communicate with all other professionals who are involved in the woman’s care. At any particular time in her care there should be a principal clinician with whom she relates. In the early stages this will be the surgeon (surgical oncologist), during adjuvant therapy it will be the medical oncologist and the radiation oncologist, and at a later stage it may be the palliative care physician. There should also be a Lead Clinician for the Breast Unit. The Lead Clinician should generally be the surgeon because

- a) the majority of patients presenting to the Breast Unit do not have cancer and do not require the services of a medical oncologist or radiotherapist, but do need the surgical specialist for clinical assessment and reassurance
- b) it is the surgeon who is the first point of medical specialist contact with the patient in the hospital setting
- c) it is the surgeon who on diagnosis, discusses and undertakes the primary treatment for patients who have cancer in the great majority of cases

The Lead Clinician must have the skills to lead the Unit and promote the development of audit, protocols and quality assurance measures. Important elements of the organisation of the Unit are listed below.

- The range of clinics will include: new patients clinic, results clinic, follow up clinic (general follow up clinic, combined clinic for advanced/metastatic disease with medical oncology and radiation oncology, clinic for women with low risk of recurrence), family history clinic, mastalgia (breast pain) clinic.
- Each team should hold weekly multidisciplinary meetings to discuss the clinical management of patients. All relevant member of the Breast Team should attend the meetings. All patients should be discussed: new cases pre-operatively and post-operatively; patients with recurrent or advanced disease; cases which present difficulties in management; other cases where appropriate.
- Adequate and clear communication between all those involved in the woman's care is important.
- Adequately funded quality assurance is necessary.
- Audit through collection of data using a specially developed proforma. Information is co-ordinated by a data manager and formally presented and evaluated regularly at the Breast Unit and at National level.
- All members of the multidisciplinary team should have the opportunity of specialist training.
- Development of national guidelines and protocols that are agreed nationally should be put in place.
- Research is fundamental to a high quality Breast Unit and Units should be encouraged to
 - a) develop clinical research activity
 - b) liaise with existing academic centres where basic research is conducted
 - c) become involved in clinical trials
- Clinical trials are the basis for the development of the knowledge which leads to the best treatment methods for breast cancer. Breast Units should support clinical research and should participate in a programme of multi centre clinical research and clinical trials aimed at improving the treatment of breast cancer.

The relationship between NBSP and the symptomatic services requires detailed study and analysis. It is essential that any arrangement makes effective use of all resources and ensures equity of access and quality of care for both groups of women. Detailed examination of the various models in place internationally is required with regard to how the two services might be linked.

Current Situation

While good care is currently being provided, there are infrastructural elements, which if developed would lead to an improvement in the quality of care. Based on the information provided by the Regional Cancer Directors and the visits to each region the main findings were:

- Variable practices in the type of surgery being performed
- High rate of open biopsy for benign disease
- High rate of open biopsy for malignant disease
- High rate of benign to malignant biopsies
- Lack of pre-operative diagnosis
- Lack of pre-operative treatment planning
- No surgical training programme for breast disease exists in the country
- Major issues in surgery
 - a) large variations in the type of surgery being carried out on the breast
 - b) lack of accuracy or protocols in assessment of tumour margins

- c) variations in the surgical operations on the axilla.
- Unequal access to pathology services with large variation in the detail of reports by pathologists, for example
 - a) variable accuracy of pathology assessment of tumour margins,
 - b) variation in the detail of reporting numbers of axillary lymph nodes and
 - c) lack of uniform proformas and standard protocols
- Unequal access to ultrasound facilities
- Mammography with no dedicated processing
- Variable and unstructured GP access to mammography
- Variable and unstructured GP referral and follow-up
- Radiotherapy/medical oncology
 - a) access to adjuvant therapy difficult
 - b) where it exists it is sub-optimal
 - c) consultant availability very variable
- Lack of breast clinics; women seen as part of general surgical clinic
- Multidisciplinary meetings are uncommon
- Clinical trials uptake is minimal, and the number of patients recruited into clinical trials is low
- No organisation in management of metastatic breast cancer
- Follow-up variable
- Data not collected to enable evaluation of quality of care

Recommendations

Based on the requirements for good care, the following recommendations are proposed.

- **Specialist Breast Units** should be established throughout the country. These units should be fully staffed and resourced in order to deal with patients with breast cancer.
- The Specialist Breast Unit should be **based on a population of 250,000 to 300,000** from which it is expected that there will be, at a minimum, 100 new primary breast cancers per annum.
- There should be at least two **surgeons** attached to the Breast Unit. The lead surgeon should normally have a minimum of six fixed sessions and other surgeons attending with a special interest in the breast disease should have a minimum of a least three sessions in the Breast Unit, covering GP referral clinics, follow up clinics, breast operating lists, attendance at multidisciplinary meetings and weekly combined breast clinics.
- Requirements for the **training** of a surgeon with a special interest in breast disease and the arrangements needed for a designated training centre have been submitted as recommendations to the Royal College of Surgeons in Ireland.
- Two nominated **radiologists** trained and with continuing experience in breast disease. They must be available for reading mammograms and carrying out ultrasound and stereotactic investigations required at new referral clinics. They must be available to report mammograms on all cases arising from the breast diagnostic work of the unit and to attend the multidisciplinary meetings and audit meetings. In some areas it may not be feasible to have two radiologists based in the hospital and special arrangements may be necessary. Radiologists should have the opportunity to attend specialist training courses similar to training courses available to radiologists working in the UK.
- Two **pathologists** will be responsible for all breast pathology and cytology. They must have dedicated sessions to attend multidisciplinary breast meetings and audit meetings.
- At least two **breast care nurses** available to counsel and offer practical advice and emotional support to newly diagnosed patients, discuss treatment options with them and provide a prosthetic service.
- The **medical oncologist** and **radiotherapist** must arrange the appropriate delivery of radiotherapy and chemotherapy. They should hold joint clinics with other members of the breast care team and must take

part in multidisciplinary and audit meetings. While they may be based at another hospital they should have dedicated sessions at the Breast Unit.

- Breast diagnostic **radiographers** with necessary training and expertise in mammography. They must hold a certificate of competence in mammography.
- **Clerical support** including two full time secretaries of high grade and an administrative officer to organise the clinic and a data manager in each unit.
- Each medical discipline (surgical oncology, medical oncology, radiation oncology, orthopaedic surgery, and specialist palliative care) should have written **protocols of management** of patients with breast cancer.
- Management of all patients with breast cancer should be discussed at a **multidisciplinary meeting**.
- There must be swift effective **communication** between the Specialist Breast Unit and the GP. There should be minimal delay between referral of a woman with a lump from the GP and an outpatient appointment and between first consultation and communication of the diagnosis with the patient and to the GP.
- Patients should be recruited into **clinical trials** where feasible.
- Modern methods of **audit** and monitoring of outcomes must be put in place. This requires effective data management. It requires both routine audit and the basic infrastructure for collection of data concerning patients, their disease, treatment and outcomes, and systematic reporting and recording of pathology data.
- A **Breast Unit Annual Report**, containing data according to protocol from each Breast Unit should be prepared by a designated lead person in each Unit.
- All **Units** should be **interlinked** so that identified information is collected from each centre in such a way as to be amenable to comparison among centres and to external audit.
- All Breast Units should combine **annually** for an **audit/outcome meeting** to monitor and verify that audit standards are being reached and maintained.
- A **National Annual Report** should be produced
- **Annual Quality Assurance** meetings among all Units are necessary in the same way as in screening programme.
- Individual **sub-speciality audit** should be performed. Each group should analyse its own performance indicators and agree protocols.
- A **national executive multidisciplinary committee**, whose function is to analyse the activities of the Breast Units, should meet at least annually.
- A centralised **Quality Assurance Office** should be established and staffed appropriately with a data collection and evaluation manager supported by clerical staff. It should
 - a) collect data from the regional Breast Units,
 - b) co-ordinate and organise the annual audit meeting and
 - c) produce a National Annual Report
- A **Reference Unit** should be established. The function of the Reference Unit would be to
 - a) act as a facilitator and advisor to other Units, particularly in unusual or complex cases
 - b) promote research activity among Units
 - c) be responsible for additional specialist training
 - d) house the Quality Assurance Office
- A **Breast Cancer Multidisciplinary Advisory Group** should be established to
 - a) advise the Minister for Health and Children on the functioning of the Breast Units
 - b) to make recommendations concerning the quality of care in each Unit
 - c) keep under review developments in research in the area of breast cancer
 - d) provide advice on service changes that may be required as a result of research developments
 - e) provide advice on new or unusual interventional procedures such as vacuum assisted biopsy techniques. These techniques are being developed in screening services. Resources should be used in the most efficient manner and they should be centralised as much as possible.

- Organisation of the Breast Unit should include ensuring that **transport arrangements** are in place to facilitate women residing in areas that may pose logistic difficulties in travelling to the Unit. This could include consideration of initiatives such as: (11)
 - a) Van/bus assistance services,
 - b) Taxi services at reduced fares,
 - c) Financial support to individuals who provide informal transportation assistance to patients
 - d) Voluntary transport assistance to women via cancer support groups.
- Each Health Board should examine the geography, road system and population distribution of their own region in order to identify subgroups of women who may have particular difficulties with transport that would deter them from availing of the services provided by the Breast Unit
- While it may be possible for follow-up treatment to be carried out in hospitals other than the Breast Unit, primary surgery and diagnostic procedures must be undertaken at the Breast Unit.
- If difficulties are encountered in implementing these recommendations the National Cancer Forum should be consulted and changes must not be made to the recommendations without approval of the National Cancer Forum.

Location of Units

South Eastern Health Board

The population base justifies one unit. The South Eastern Health Board has ratified the decision to centralise services in Waterford. A significant amount of forward planning at an administrative and organisational level has been carried out within the region. A formal plan for the region has been presented. This plan is in keeping with the guiding principles. It is recognised that other acute hospitals in the area have surgeons and other professionals who have an interest in breast disease who could travel to the centre to carry out breast work there. Such an arrangement would neatly combine the maximum possible use of resources and personnel while maintaining job satisfaction and expert individual attention. Additional posts and sessional commitments will be required to allow for surgical sub-specialisation.

Southern Health Board

The population base in the Southern Health Board is large enough to support two units. Based on the population, it seems appropriate to have two centres in Cork City as no centre outside the city has sufficient population to justify a full unit.

The South Infirmary has the largest number of cancers seen each year. It has a clinical and radiological expertise developed over 15 years. It provides an excellent, integrated, efficient and patient-oriented service, despite the fact that it does not have on-site pathology. This would appear to be the appropriate site to base a Breast Unit. Cork University Hospital (CUH) has established a breast clinic recently, but there is not on-site mammography. One consultant surgeon at the hospital undertakes breast surgery. This is not ideal for full coverage of the service. Radiotherapy will be undertaken there and this needs to be funded adequately in order to provide a good service.

Over the past year, the number of breast cancers seen at CUH has increased. Based on data supplied by the hospitals, it is estimated that CUH and the South Infirmary have seen between 80 and 100 breast cancers per annum. Recently there has also been increased co-operation and collaboration between the two hospitals. Based on the population of the Southern Health Board, a second unit is required. It is recommended that it be based in CUH. It is recommended that the expertise that exists in Tralee should be utilised in the new Breast Unit. Professionals with an avowed and continuing interest from other hospitals should be allowed to participate. This will entail making provisions for their sessions at the base hospital to be covered while they are undertaking sessions at the Breast Unit.

Mid-Western Health Board

The population of the Mid-Western Health Board only justifies one Unit. A large breast clinic has been established in the Limerick Regional Hospital where surgeons from Nenagh, Ennis and St John's Hospital have come together to provide the service. The Health Board population justifies one unit. The unit should be placed in the Limerick Regional Hospital, which has a lot of the activity and ancillary requirements needed. A breast clinic has been operational in Ennis and the surgeons who run the clinic in Ennis should be incorporated into the centre in the Regional Hospital. If such voluntary involvement arises, there should be practical support regarding coverage of their other clinical activities at Ennis Hospital while they are away from base conducting breast work in the Unit. This may mean the appointment of an additional consultant surgeon in the region.

Western Health Board

The population of the Health Board justifies one Unit. The University Hospital in Galway has been delivering a service for a long time under difficult circumstances. They are experiencing large demand relative to resources. The implementation of increased support is an immediate requirement because their workload is already present and the need is immediate. The University Department of Surgery has developed a strong clinical service and supplemented it by enterprising clinical research. There is an immediate need for another breast surgeon and support services.

There is not sufficient population to justify a Unit in Castlebar. The staff at Castlebar Hospital should be encouraged to contribute to the Galway Unit if they wish to do so. As is being proposed for the Mid-Western Health Board and the Southern Health Board, if professionals from Castlebar wish to become involved in the Breast unit in Galway, provision should be made for their sessions at the base hospital to be covered while they are undertaking sessions at the Breast Unit.

North-Eastern Health Board

The population supports only one Unit in the North-Eastern Health Board. Based on the principles discussed in this report, there is no justification for two Units. The most densely populated area is in the southern aspect of the Health Board in Louth and Meath. This is likely to expand over the coming years. Individuals with an expressed interest and expertise in breast services should be incorporated into the Breast Unit. They need to have adequate support in order to cover their regular duties while they are away from their own base hospitals. People should be allowed to become involved, provided they meet with the audit and CME needs. Some facilities already exist in Drogheda and this would appear to be an appropriate location for the Breast Unit.

North-Western Health Board

The population of this Health Board supports only one Unit. Geographical considerations dictate that an innovative approach is required in order to ensure that services are available to patients in acceptable settings as far as possible. In Letterkenny, there is a committed group of people providing a service but they do not have a large enough volume of patients with breast cancer. They will need to link with Altnagelvin Hospital in Derry in order to increase their caseload, experience, expertise and formal cross-cover. If collaboration between Derry and Letterkenny occurs, it should be a true liaison. Scope exist for such a liaison to be formalised. There are strong clinical links between the two hospitals and also between Letterkenny and Belfast City Hospital. These links have been establishes and are being developed further and provide the impetus for a formal arrangement to be established. Northern Ireland population interests in the development of this Unit should be explored with Northern Ireland health authorities. This sort of

decision has to be supported at the highest political level so that the highest standards can be maintained and for the ease of access and administrative efficiency.

Sligo has insufficient population to justify a unit. There is currently little infrastructure in Sligo and considerable resources would be required in order to set up a Breast Unit there. However, the only realistic proposal would be that, in this particular case, crossing Health Board boundaries could be justified. If the population of Sligo, Leitrim, West Cavan and part of Mayo are incorporated, it is estimated that the population would be adequate to provide a sufficient volume of patients. Therefore it is recommended that a Breast Unit be established in Sligo serving those areas. This is an innovative proposal that will require the involvement and agreement of the CEO's and Board of each of the relevant Health Boards. There will need to be agreement that patients cross traditional Health Board boundaries.

Midland Health Board

The population of the Midland Health Board marginally supports one unit. There is a small breast service currently in Mullingar. There is no service in Tullamore. Patients currently travel to Portlaoise where a long established unit with considerable clinical expertise and a great deal of ancillary patient-focused and orientated support at medical and nursing level has been developed over many years. Bearing in mind that the great majority of women attending the clinic will not have cancer, it is not essential to locate the Breast Unit in the designated regional cancer centre. Because the delivery of breast services can largely be delivered in non-emergency settings, it is unlikely to require high dependency support. However, there is concern that the peripheral location of Portlaoise in the Health Board might militate against achieving the critical mass of patients required for the Unit. There would be a case to be made for locating the Breast Unit in Tullamore because of its geographical location in the Health Board and because this would fit in with previous decisions made by the Health Board regarding the organisation of oncology and pathology services. It is essential that the available expertise that already exists within the Health Board should be fully utilised in the new Breast Unit and professionals with an avowed and continuing interest from the other hospitals should be allowed to participate. This will entail making provision for their sessions at the base hospital to be covered while they are undertaking sessions at the Breast Unit. Should the decision be to locate the Breast Unit in Tullamore then the existing and longstanding expertise of those involved in the Portlaoise unit should provide the basis of the service in Tullamore. This will ensure that a highly valued, quality service will be provided to all women in the Midland Health Board region.

Eastern Health Board

In the Dublin region, it is proposed to establish two Breast Units on the north side and three on the south side of the city. One of the Units on the north side should be located in the Mater Hospital. The other Unit, bases at Beaumont Hospital should involve the participation of interested staff from the James Connolly Memorial Hospital in Blanchardstown. On the south side of the city, separate Breast Units should be located in St Vincent's University Hospital, St James' Hospital and the Tallaght Hospital.

The Master Hospital already houses the Eccles Screening Programme and is expected to treat 150 patients per year in the prevalent round. It is appropriate to utilise the expertise at this site for patients in the Breast Unit. It is important to have a Breast Unit in a hospital with a screening unit because follow-up of breast cancer detected by screening takes place in the Breast Unit. Many of the staff and most of the infrastructure required are already in place.

James Connolly Memorial Hospital and Beaumont Hospital each have breast clinics. The catchment population does not support two separate Units. There are committed professionals who have academic links in both hospitals. They are prepared to work together to develop a Breast Unit on one site but availing of the expertise of both hospitals. This initiative should be supported. Neither hospital has adequate facilities or equipment. It is proposed that the Unit be sited at Beaumont Hospital and should involve relevant staff from James Connolly Memorial Hospital. It is proposed that another consultant surgeon with

a special interest in breast disease be appointed. The consultant would have general surgical session in James Connolly Memorial Hospital and specialised breast sessions including theatre sessions in Beaumont Hospital.

Tallaght is a new hospital and is developing its breast services. It is located in an area with a very fast growing catchment population. The expanding population base and catchment would indicate that locating a Unit in Tallaght would be reasonable. Many of the pathology and radiology requirements are available.

St James' Hospital has a newly established well-audited breast clinic. Most of the key personnel are available, as are the back-up facilities. Its catchment area and the service it provides to the inner city population justify a Breast Unit in this hospital.

The first breast clinic in the country was established in St Vincent's University Hospital and it has been providing a symptomatic breast service for twenty years. The hospital currently treats the largest number of breast cancers of any institution in the country. It is to be one of the screening locations for the NBSP and will have approximately 150 extra breast cancers from screening. There is a need for significant investment in infrastructure but many of the requirements are in place.

CHAPTER 1

Breast Cancer

Background

Breast cancer is the most common cancer in women (after non-melanoma skin cancer). The risk to a woman of developing breast cancer before age 75 years is 7.9% and the risk of dying of breast cancer before age 75 is 2.8%. (12) The mortality/incidence ratio is 38%. (12) Approximately 1670 women are diagnosed with breast cancer each year and 650 women die from the disease. (12) Many more women attend the health services with breast symptoms, which require investigation but do not turn out to be breast cancer. These women suffer the same anxieties before diagnosis and deserve to have access to an equally high quality service.

Prevention

Hereditary Breast Cancer

While the causes of breast cancer are not fully understood, some women appear to be at higher risk. A distinction can be made between familial and hereditary breast cancer. Familial breast cancer is where first degree relatives have had breast cancer whereas hereditary breast cancer relates to a genetic aberration giving rise to breast cancer typically occurring at an early age and associated with a high incidence of bilateral breast cancer and other tumours. Genetic factors contribute to approximately 5% of breast cancers and mutations in the BRCA1 and BRCA2 genes are probably accountable for the great majority of genetically determined breast cancers. Many uncertainties exist concerning BRCA mutations. The lack of effective preventive methods for these women complicates recommendations for testing and follow up. (13) Ongoing and future chemoprevention trials might have an important impact upon the use of genetic information. (14) Genetic testing for breast cancer is currently not advisable as a routine until more information is available concerning quantification of the risk factors, possibilities of prevention and specific treatments. Specific guidelines concerning referral of Breast Clinics relating to family history are also difficult to recommend. The general recommendation at present is that when the relative risk of breast cancer is three times that of the general population, Specialist Breast Clinic referral is advisable. People in this category would be suitable to be invited to participate in clinical trials of breast cancer prevention.

Chemoprevention

Tamoxifen, an anti-oestrogen preparation was, in the 1970s found to be valuable in the treatment of patients with advanced breast cancer and later was used in patients with early breast cancer to prevent recurrence. Its role in this situation has been established not only in reducing the incidence of recurrent cancers but also in preventing new cancers in the opposite breast. In recent years three important studies have been reported on the use of Tamoxifen in well women in order to prevent cancer. One of the studies indicated a 45% reduction in breast cancer incidence in people who used Tamoxifen to prevent the disease (15) but two other smaller studies failed to demonstrate a protective effect of Tamoxifen. (16, 17) The issue is unresolved because the follow-up time in these studies is too short to make a definitive statement on the value of this agent. Trials of Tamoxifen prevention are continuing.

Relationship between stage and outcome

A direct relationship exists between the stage at which breast cancer is diagnosed and treated and the long-term survival. The staging of breast cancer is based on the TNM classification i.e the size and extent of the tumour (T), the presence and extent of involvement of the cancer by the axillary lymph nodes (N) and the presence or absence of spread of the cancer to distant sites (M for metastases). Thus for breast cancers of 5 millimetres or less in diameter where the lymph nodes are free of tumour, complete cure after adequate treatment is to be expected in over 95% of cases. For tumours between 5 and 10 millimetres in size, the long term cure rate is around 90%. With increasing size of tumour and with axillary lymph node involvement, the long term survival rates are much lower. However even in patients with relatively large tumours and involved lymph nodes, the long term survival is in the region of 50%. Because of the high probability of cure for patients with small tumours, increasing efforts are being made to identify breast cancers when they are small. Early diagnosis is important.

Breast Screening

Screening for breast cancer aims to reduce premature deaths from breast cancer by identifying and treating the disease effectively when it is in the early stages. High quality mammography can detect cancers before they become apparent and before they have other clinical features. Early and effective treatment of tumours at this stage provides the best chance of long term cure and, in the great majority of cases, allows such cure to be brought about without the need for removal of the breast (mastectomy). The NBSP, recently introduced, is directed at apparently well women between the ages of 50 and 65 years in order to identify and treat small tumours before they become discernible on physical examination. The NBSP is not, at this stage, being extended to younger women because clear proof of the value of population based breast screening has, up to now, been confined to women over the age of 50 years. The NBSP is based on high quality mammography, speedy access to expert care, high quality communications and excellence in record-keeping and audit. It is clearly essential that an excellent programme for women who believe themselves to be free of breast disease must be matched by an equally excellent system for women with symptoms of breast disease.

Screening for breast cancer aims at identifying the disease at an early stage in order to reduce mortality. It is thus based on early detection rather than primary prevention. There have been numerous studies on population based screening mammography. There have been randomised controlled trials and case control studies since 1963. Estimates of mortality reduction have been variable. Not all studies have demonstrated a statistically significant mortality reduction but they have all demonstrated a downward trend in mortality. A meta-analysis of screening mammography published in 1995 indicated a mortality reduction of the order of 25% in women screened between 50 and 74 years. (18) The Department of Health and Children has determined that Phase 1 of the NBSP should commence in the Eastern Health Board, North Eastern Health Board and Midland Health Board areas. Women between 50-64 years will be invited for two-view mammography at two yearly intervals. The Programme will extend to the rest of the country following evaluation of Phase 1. This is a population based screening programme. It is essential that all understand that this service is offered to women without symptoms in the appropriate age group. Eligible women will be identified by compiling a register. Various government departments and statutory bodies are sharing information with the screening programme; these include the VHI, GMS and Department of Social Welfare. Women will be asked to self-register if they are in the appropriate age group. Opportunistic screening outside the NBSP should be discouraged as the NBSP becomes established.

It is imperative that women with symptoms of breast disease are referred to diagnostic breast clinics. This is important, as mammography alone is not appropriate for women who have symptoms. Women with

symptoms must have the benefit of triple assessment, (clinical examination, imaging and pathological assessment). No single test undertaken affords sufficient safeguard against breast cancer being missed. When all three tests are used in the appropriate clinical setting, diagnostic sensitivity and specificity rise. It is important to ensure that women themselves understand that screening is for healthy women without symptoms. They must not self-register when they discover symptoms but rather should attend a diagnostic symptomatic clinic, if their GP thinks appropriate.

CHAPTER 2

Specialist Breast Unit -Outpatient Facility

Diagnostic Principles (1,3,4,5,6,7)

All patients with breast disease should have access to high quality care. There are a number of principles that should govern the diagnosis of breast disease for women who have symptoms suggestive of breast disease:

- It is important that women have access to a uniform high standard of care. Over 90% of women who attend a symptomatic clinic will not require in-patient treatment. It is important that the outpatient service structure can develop to deal efficiently with the increasing number of women who require this service.
- A Breast Team should be in place to diagnose and treat women with breast diseases.
- Because of the crucial role of the general practitioner (GP) in the case of patients with breast diseases, clear referral guidelines should be sent to GPs for their guidance and approval.
- At least one Referral Breast Clinic per week for new patient GP Referral should be held. Such clinics should not be part of the General Surgery Clinic. Only patients with suspected breast diseases are seen at this clinic.
- All investigations required for diagnosis should be available at this clinic.
- The modern management of breast cancer involves triple assessment, which involves the surgeon, radiologist and pathologist working together in the clinic.
- All diagnostic tests should be undertaken at the initial visit in the great majority (>90%) of cases. The importance of this principle is emphasised. Such an arrangement allows speedy reassurance for the great majority of patients who do not have cancer but who are anxious (the “worried well”). It also avoids the need for multiple visits to hospital, with their associated inconvenience and economic loss.
- Imaging techniques and expertise (radiographic and radiological) should be subject to the same quality assurance criteria as pertains in the NBSP.
- A pre-operative diagnosis should be made in over 90% of patients with cancer, whether palpable or impalpable.
- For those few patients who require an open surgical operation for diagnostic purposes, the operation should be done within two weeks of the decision that operation is needed.

Patient Identifies a Problem

The majority of women who have a breast cancer (74%) usually discover it themselves. (19) While regular breast self examination is not advocated as a screening method, it is useful for women to become familiar with their own breasts and how they change at different times of the month. This will enable them to judge any changes that may occur in the breast. Women may notice

- a change in the breast (size or shape, dimpling of the skin, thickening),
- change in the nipple (inverted, thickening, bloodstained discharge, rash) or
- change under the arm (swelling of armpit).

Finding a breast lump can be frightening. The anxiety it causes may lead to inaction and the woman may delay going to her doctor. The Caring for Woman with Cancer (CAWAC) survey found that 24% of women with breast symptoms waited a month or more before presenting to their doctor. (19) With the establishment of the NBSP, it is possible that some worried women with symptoms may register for mammography instead of seeking medical help. Women with breast symptoms should attend their GP. If referral is required they should be referred directly to a breast clinic rather than merely for mammography.

There are substantial personal costs for women who are found to have a breast problem. Such costs are incurred both in women where the breast problem is identified through screening or because of symptoms. (20) Such costs may act as a barrier and disincentive to seeking diagnosis and treatment. This must be borne in mind by any health service provider wishing to provide an equitable service that will be accessible to all women.

Requirements

- Before arriving at the clinic a woman should have an idea of what is ahead of her. This includes information about the various procedures that may be undertaken and the length of time they are likely to take. Such clinic visits can take 2-3 hours if all the diagnostic pathways are required.
- Education is necessary for women in the general population and for professionals.
- Consideration should be given to the format of the information produced and its dissemination to ensure that it can be easily accessed, understood and absorbed by women, including those with disabilities and low literacy levels. The needs of marginalised groups such as travellers, ethnic minorities etc. should be met in any information campaign strategy.
- Guidelines are needed for GPs to improve their knowledge and to facilitate communication with the Breast Unit.

Reasons and Evidence

- Breast disease is common. Women need to be informed as to what breast cancer is and what they need to do once they develop symptoms.
- The majority of women (80%) know little about cancer before their diagnosis. (19)
- Their main source of knowledge appears to be TV, radio, magazines, books and personal contacts. Only 14% of women with cancer identify health professionals and only 3% identify voluntary organisations as a source of information on cancer. (19)
- Women need to understand that the earlier the diagnosis is made the better the outcome.
- Women should be empowered to seek help early when appropriate.
- They should have full knowledge of all investigations and treatment options.

Patient attends GP

When a woman first develops breast symptoms she will usually consult her GP, who will in turn seek to refer her as quickly as possible to a centre that will provide speedy diagnosis and effective management of her complaint.

- The type of symptoms among women who are referred by GPs may vary from breast pain to obvious cancers.
- The role of the GP includes referring women promptly to the most appropriate clinic (deciding where the patient should be referred and also the degree of urgency of such referrals), and providing ongoing care to women with breast cancer including re-referral where necessary.
- The GP requires speedy, direct and focused communication from the Specialist Breast Clinic.

Increased awareness of breast diseases has led to an increased number of women presenting to the GP with breast symptoms to seek advice. There has been a corresponding increase in referrals to surgical clinics and to breast clinics in Ireland. GPs may experience difficulties with regard to the initial diagnosis, referral and long term follow up of the woman. They need clear advice regarding which women need to be referred and which women can be safely dealt with by the GP. Women who can be managed by their GP would include:

- (a) women with minor or moderate degrees of breast pain who do not have a palpable distinct lump
- (b) women under the age of 50 years with multi-ductal nipple discharge which is not troublesome nor blood-stained.

- (c) Asymptomatic women with a minor family history who are at low risk of developing breast cancer and
- (d) Young women with tender nodular breasts and older women with symmetrical nodularity who have no focal lesion demonstrable.

This will only be possible if there are clear guidelines, training and support systems in place for GPs. There should be access to the clinic for these women if the GP requires advice.

Requirements

- GPs require clear guidelines and protocols to assist them in managing women who present to them with breast symptoms and in ensuring that they have rapid access to appropriate care.
- Direct access for GP requested mammography is not recommended and this should not be necessary if access to the breast clinic is adequate. The Breast Unit should have clear and unambiguous arrangements for rapid referral from GPs.
- Clear links must be established with the Breast Units. GPs should be able to ensure that the women who need to be seen urgently (e.g those with a palpable breast lump) are seen within 10 working days at a multidisciplinary clinic and that others (such as with breast pain) are seen within a reasonable time frame.
- This will entail developing in partnership with GPs, agreed protocols for referral and the identification of a contact person within the Breast Unit with whom the GP can liaise.
- The issue of an “urgent” referral is entirely a decision for the GP and should be reserved for those patients whose symptoms and signs are highly suggestive of breast cancer. Guidelines will help the GP decide which patients with breast symptoms warrant referral and which can be managed safely by the GP.
- The term “urgent” should only be used in patients with symptoms highly suggestive of breast cancer. These include
 - (a) discrete lump in a woman over 40 years of age,
 - (b) skin ulceration
 - (c) distortion of the breast or nipple-areolar complex
 - (d) an intradermal nodule
 - (e) blood stained nipple discharge.
- Breast Unit protocols should include provision for communication to the GP of the diagnosis and proposed treatment.
- Reports should be sent to GPs within 1 week. Sufficient support staff are needed to enable this to happen.
- A close working relationship with the Breast Unit will enable the GP to confidently inform the woman regarding what awaits her at the clinic.

Reasons and Evidence

- It is inevitable that the introduction of the NBSP will result in a greatly increased pressure being placed on GPs to provide advice and guidance to women with breast problems.
- The National Health Service Breast Screening Programme, in the UK, in conjunction with the Cancer Research Campaign developed a booklet entitled “Guidelines for Referral of Patients with Breast Problems”. (21) They were designed to assist GPs to make referral of patients with breast symptoms easier, more effective and to make the process more efficient with the ultimate objective of improving the standard of care. There is evidence that they resulted in better referrals to the breast services. (22)
- Avoiding short delays reduces anxiety and avoiding long delays improves survival. During the period between initial suspicion of breast cancer and diagnosis, most women are anxious. Patient surveys show that women are particularly concerned about delay between initial presentation to the GP and diagnosis.

- The CAWAC survey found that while 39% received their diagnosis within one week and 31% received their diagnosis in 2 or 3 weeks, almost one quarter (23%) of breast cancer patients waited one month or more for their diagnosis. (19)
- GPs have a heavy workload. Any assistance that can be provided to aid them in the management of breast cancer will be welcomed.
- Provision of guidelines will make referral decisions easier and provide a higher standard of care for the patient.
- If surgeons receive more appropriately worded referral letters it will be easier to prioritise patients without delaying the diagnosis for women with cancers.

Referral to Specialist Breast Unit

This section outlines what should happen when a woman is referred to a Specialist Breast Unit. On arrival, the clinic secretary welcomes the woman. Details are taken and she is shown into the comfortable waiting room containing information materials. The modern management of breast cancer entails triple assessment, which involves the surgeon, pathologist and radiologist working together in the clinic.

- The clinician takes a good history and conducts a thorough physical examination.
- Most women with a discrete abnormality on clinical examination will require mammography and/or ultrasound. The radiologist gives an immediate report to the clinician.
- If there is a palpable lesion, following imaging, the clinician will take a core biopsy or cytology. Local expertise will dictate which is performed. The pathologist provides an immediate result for cytology but core biopsy results takes 24 hours.
- If the lesion is impalpable the radiologist will undertake the biopsy by stereotactic methods.
- Having had the biopsy, the woman is brought back to the clinician and in the presence of the breast care nurse she is given an explanation of the findings.

Where appropriate, the clinical, radiological and pathological findings should be discussed at the clinic by the consultant surgeon, radiologist, and pathologist. The diagnosis and provisional treatment plan should be agreed. The diagnosis and treatment should be discussed with the patient by the consultant surgeon. The clinician, on reviewing the results may reassure the woman and discharge her back to the care of her GP if she does not require further intervention or she may be asked to return to the results clinic to receive the result of the core biopsy. If a diagnosis of breast cancer is made at the first visit the diagnosis and treatment should be discussed with the patient by the consultant surgeon. A breast care nurse should be present as she has an important role to play in discussing the patient's concerns and providing necessary information. Some clinicians consider it preferable to bring the patient back on a second occasion to receive the diagnosis and to discuss options because they consider this to be less traumatic for the woman.

Requirements

Organisation of Care in the Breast Unit (1,2,3)

All women with breast disease should come to a fully equipped, multidisciplinary Specialist Breast Unit. The majority of women who require assessment for suspected breast cancer do not have cancer and will not require extensive facilities. However, they do require specialist doctors and other professionals so that they can be quickly reassured at a single visit.

- At least one new patient GP referral clinic must be held each week (at which only breast cases are seen)
- Each new GP referral clinic should see approximately 15-20 cases per session. It should be a consultant delivered service. Some Units may require more clinics to cope with the workload.
- Apart from the new patient clinic for GP referrals, other clinics will also be required. They include a results clinic, follow up clinic (general follow up clinic, combined clinic for advanced/metastatic disease

with medical oncology and radiation oncology, clinic for women with low risk of recurrence), family history clinic, mastalgia clinic.

- All necessary investigations should be undertaken at this visit.
- Care should be prompt, multidisciplinary and delivered in a sympathetic manner.
- Each clinic should have appropriate facilities for mammography and ultrasonography with the Specialist Breast Unit Radiologist in attendance.
- The modern management of breast cancer involves triple assessment, which involves the surgeon, radiologist and pathologist working together in the clinic. All facilities and staff needed to carry out the appropriate test should be in close proximity to the diagnostic clinic.
- The clinical, radiology and pathology findings of all new patients with breast cancer should be discussed at a weekly multidisciplinary team meeting.
- The results of the tests should be given to the patient within 5 working days. Women who do not have breast cancer can be reassured and treated if necessary, while those who do may proceed rapidly to treatment.
- Since the majority of women (95%) do not have breast cancer, GPs need to be actively involved in the programme and take care of the women who are diagnosed as having benign lesions. While the specialists at the breast clinic can say that the tests are clear, they cannot guarantee that the woman will not develop cancer in the future. Therefore continuing surveillance is required.

Surgery (3)

- A definite pre-operative diagnosis should be available for 90% of women.
- Women requiring surgery for diagnostic or therapeutic purposes should be given a specific date for this before leaving the assessment clinic.
- All breast surgery for therapeutic or diagnostic purposes should be performed or supervised by a consultant surgeon with a special interest in breast disease.
- Over 90% of diagnostic open surgical biopsies on impalpable lesions which subsequently prove benign should weigh less than 20g.
- Routine pre-operative staging procedures in T1N0 breast cancer is not indicated.
- Surgical procedures should follow agreed guidelines.

Pathology (3,7,23)

- It is essential for pathologists to distinguish cancer from benign conditions.
- Pathologists need to report histological features of prognostic significance in order to ensure that patients are treated appropriately.
- Pathology breast specimens should be reported by a consultant pathologist who has undertaken appropriate nationally recognised training and who participates in comparative audit.
- It is usually necessary to use designated equipment in the pathology laboratory.
- Where such equipment exists, its safety must be monitored.
- A record should be kept of tissue taken from all types of specimens, which may be useful for research purposes.
- It is important to record the histological features of cancers that are of prognostic significance (tumour size, grade, node status, vascular invasion and tumour type). Careful clinical follow up is necessary to correlate the pathological features of tumours with clinical outcome.
- Fine needle aspiration (FNA) cytology and wide bore needle biopsy are complementary techniques. Wide bore needle biopsies are increasingly being used in association with FNA cytology and may be highly effective where cytology is equivocal or where cytological expertise is not well developed.
- When performed for the assessment of microcalcification they can be subjected to specimen radiography to ensure that the microcalcification is present in the core. If benign calcification is found

in the core and this provides a satisfactory explanation of the calcification seen on the mammogram, diagnostic excision biopsy can be avoided

- Evaluation of impalpable lesions and in-situ carcinomas requires specimen radiology to ensure that the specimen contains the radiological abnormality and to select the correct blocks of tissue for histological examination. This technique adds significantly to the length of time required to examine such biopsy specimens. Histological reporting of impalpable lesions should not be undertaken where specimen radiography cannot be performed.
 - If cytology or needle biopsy is negative in the face of strong clinical and radiological evidence of malignancy then they should be repeated and if still negative, an open biopsy performed.
 - Pathologists should not provide FNA cytopathology services unless they have sufficient experience and expertise.
 - A FNA report should be available within 24 hours of receipt of the slides or less, depending on the volume of patients going through the clinic.
 - A report should be available to the clinician within 24 hours of receipt of the core biopsy.
- The report of FNA cytology specimens should follow the following format : -
- C1 = inadequate
 - C2 = benign
 - C3 = atypia probably benign
 - C4 = suspicious of malignancy
 - C5 = malignant

Core biopsy specimens should similarly be classified B1 to B5.

- Frozen section examination should generally be reserved for the unusual circumstances in which a definitive diagnosis cannot be made pre-operatively.
- Frozen sections should not be done on impalpable lesions, as frozen section artefact may render accurate interpretation of atypical ductal hyperplasia or ductal carcinoma in situ difficult to impossible.
- Ductal carcinoma in situ (DCIS) accounts for 5% of cancer in symptomatic women. It may be difficult to distinguish DCIS from ductal hyperplasia and from minimally invasive cancers. These distinctions require a great deal of expertise and experience in addition to extensive tissue sampling.

Histopathology reports should include information on the following factors : -

- The maximum diameter of the carcinoma should be measured in millimetres (mm) and the extent of intraductal and invasive disease recorded in the report.
- The report should comment on the extent of disease and whether the tumour contains an extensive in situ component. This is achieved by giving two measurements for invasive carcinomas where ductal (but no lobular) carcinoma in situ extends to more than 1 mm beyond the invasive component:
 - a) the size of the invasive component:
 - b) the size of the whole tumour.
- Tumours identified as multicentric should be so reported.
- The pathologist must report on the distance of surgical excision margins and this should be discussed at a multidisciplinary meeting. An adequate margin may be defined as that margin which ensures a local recurrence rate in the conserved breast of less than 5% at 5 years.
- Such a report cannot be given unless the surgeon clearly orientates and marks the specimen prior to delivery to the pathologist.
- The Breast Unit must have a clear protocol for the handling of pathological specimens. Subtyping of invasive and in situ cancers must use standard nomenclature as recommended by the European Guidelines for Quality Assurance. (23)
- Histological grading of cancers must be undertaken using the method described by these pathology guidelines. (23) Results must be incorporated into the report.
- Breast pathology specimens should be reported in a standard format.

- All lymph nodes recovered must be submitted for histological examination and the report should state the total number of lymph nodes found and the number of lymph nodes with metastatic disease.
- Frozen sections should not be done on lymph nodes to examine them for metastatic disease because of the high risk of false negative results.
- The presence or absence of lymphovascular invasion must be stated.
- The use of immunohistochemical assay to determine oestrogen receptor status enables more detailed staging and grading of tumours. Tumour receptor status (oestrogen receptor (ER) and progesterone receptor (PgR)) should be determined by using immunohistochemical techniques.

Radiology (3,6,24)

- The radiologist is an integral member of the multidisciplinary breast diagnostic team and has a major role to play in image guided diagnostic procedures.
- These investigations should be performed by a properly trained radiographer, utilising high quality equipment. They should be reported by appropriately trained radiologists with adequate experience.
- Breast imaging should be carried out and reported by a radiologist experienced in breast imaging and who satisfies the agreed standards. Radiologists must have skills in image guided diagnostic procedures as well as image interpretation skills.
- The radiologist should be involved in decisions on the most appropriate imaging investigations.
- Performance in mammography is directly related to expertise. In order to achieve high preoperative diagnosis rates, the radiologist must have sufficient experience and expertise to perform these procedures effectively. The radiologist must be properly trained and continuing medical education is an important requirement.
- Feedback in the multidisciplinary setting is important. Without obtaining outcome at pathology it is possible to make the same mistakes in interpretation despite a large number of mammograms reported.
- A study of diagnostic accuracy found that radiologist who receive feedback on their own practice for all abnormal readings are more likely to recommend immediate workup for cases that turn out to be malignant than radiologists who do not receive regular feedback. (82) Without obtaining feedback on the outcome of mammogram readings it is possible to continue to make the same mistakes in interpretation. (82)
- It is desirable that a sufficient volume of image guided procedures should be undertaken to attain high pre-operative diagnosis rates.
- Increased sensitivity for detection of small cancers has been demonstrated after attending dedicated teaching courses in mammography.
- Reports of imaging examinations should include details of the size, size (mm), extent and nature of any abnormality, a description of any significant associated features with an opinion as to the most likely diagnosis.
- Radiologists in dedicated symptomatic breast imaging must have access to high quality equipment (stereotactic biopsy equipment and ultrasound suitable for breast examination).

Reasons and evidence

- It is accepted that a multidisciplinary approach to breast cancer affords women the best therapeutic options when diagnosed with breast cancer. (3,4,5,25,26)
- The cost of establishing high quality multidisciplinary breast clinics is largely offset by the reduction in bed occupancy and staffed theatre time.
- The use of triple assessment can increase the speed and accuracy and reduce the cost of diagnosis when compared to selective use of component tests. There is evidence and expert consensus that it substantially reduces the number of unnecessary operations performed both for benign disease and for breast cancer. (3,5,7)
- High pre-operative diagnosis rates will

- a) result in a very large reduction in the number of open benign and malignant surgical biopsies
- b) allow good surgical planning, giving an opportunity to counsel patients
- c) afford great benefit in terms of reduced morbidity associated with open surgical procedures and considerable reduction in the psychological trauma associated with multiple hospital admissions
- d) result in cost savings and reduce discomfort and inconvenience to the patient
- There is strong evidence that triple assessment also provides a more accurate diagnosis than a reduced number of tests. (5,27,28,29,30,31,32) If all three tests are positive the probability that the patient has breast cancer is over 99%.(32)
- Definitive surgery for carcinoma can be decided preoperatively allowing treatment for any malignant lesions in a one-stage operation and avoiding the need for frozen sections.

Results Clinic

If a patient has had a core biopsy she will require a further visit to the clinic for results. A patient who has a malignancy should never be given the result over the telephone. The diagnosis and treatment should be discussed with the patient by the consultant surgeon. A breast care nurse should be present as she has an important role to play in discussing the patient's concerns and providing necessary information.

- This visit should be within 5 working days of the diagnostic visit.
- An appointment for the results clinic should be given before the woman leaves the diagnostic clinic.
- The specialist breast care nurse should be available when women return to the results clinic.
- The results should be given in the presence of a breast care nurse.
- Breast care nurses provide advice, support and counselling to patients with breast cancer and their families.
- The information should be given in a quiet area.
- This is a crucial consultation. It takes time for all options to be explained in detail.
- Women who have indeterminate findings after the initial diagnostic clinic should have their cases discussed at a multidisciplinary meeting prior to receiving results.
- At the time of the results clinic, women with a diagnosis of malignancy should be presented with therapeutic options available within an acceptable time frame.
- Women requiring surgery for diagnostic or therapeutic purposes should be given a specific date for this before leaving the assessment clinic.

Reasons and Evidence

- Discussion at the multidisciplinary meeting will enable the clinicians to decide on the optimal treatment for the individual. This will enable a more productive consultation with the woman to occur when the results clinic takes place.
- Women have reduced long term morbidity if they understand the process.
- While it is important for the consultation to take place quickly, the overriding consideration is the thoughtful planning of care for each individual patient.

Chapter 3

Specialist Breast Unit

- *Treatment and Follow up*

Treatment Principles ^{1,2,3,4)}

A number of principles should govern the treatment of breast cancer :

- Treatment of breast cancer should be managed by staff with special training and expertise in breast disease.
- Surgeons treating breast cancer should have undergone formal training in breast disease and should work in a Breast Team which has all the necessary facilities and expertise needed for a multidisciplinary approach.
- Consultants in the Breast Team must have dedicated time for attendance at multidisciplinary meetings. In addition Breast Care Nurses and trainees in breast surgery must be in attendance at such meeting.
- In order to collect accurate data preoperatively and to ensure efficiency in administration, data management and administrative clerical staff are required for a Breast Team.
- The ratio of open surgical biopsies that prove benign to the total number of cancers diagnosed should be no more than 1:10. (This does not include operations for nipple discharge and previously diagnosed fibroadenomas).
- More than 90% of patients with cancer should be admitted for operation within 3 weeks of the decision to operate.
- Women with breast cancer should have the support of a Breast Care Nurse.
- The Breast Care Nurse who is a member of the Breast Team should have established links with the ward nurses and other members of the Breast Team.
- Follow-up arrangements must be defined by protocol and must involve the surgical team.
- The Breast Team should be involved in biopsies, assessment and management of patients with locally recurrent and metastatic breast cancer. Patients with metastatic breast cancer should remain under the care of the Breast Team.
- All women diagnosed with breast cancer should have their management discussed with a surgeon trained in surgical oncology of the breast, a medical oncologist and a radiation oncologist.
- Involvement in international clinical trials should be recommended, fostered and supported.

Provision of Treatment

Once a diagnosis of breast cancer is made, women should receive prompt planned treatment. The CAWAC survey found that 39% of women with breast cancer were treated within one week of diagnosis, 28% were treated within 2 or 3 weeks and 25% waited one month or more after diagnosis for their treatment. The survey found that 89% of the women with breast cancer had surgery, 44% had chemotherapy and 54% had radiotherapy in various combinations.

The GP requires speedy, direct and focused communication from the Specialist Breast Unit.

- Good communication is required both for patients with benign and malignant conditions but, because patients with cancer require a multidisciplinary approach, communication systems are required to be defined and explicit. As the patient with breast cancer often needs the attention of several different speciality groups, it is therefore particularly important that the GP receives accurate, up-to-date and unambiguous information.
- It is desirable that the GP be consulted about the pathway of treatment before it starts.
- The GP should be involved in the physical and psychological rehabilitation of patients with breast cancer and in crucial decisions relating to the management of metastatic disease.

Mode of Treatment

Surgery

Surgery to the breast aims at excising all the disease to maximise chances of cure and local control of the disease together with the provision of accurate pathology staging and a satisfactory cosmetic result. In deciding on which treatment is most suitable for each woman, it is necessary to take into account features of the tumour, and the status of the axillary nodes. Pre-operative diagnosis will enable the clinician to discuss the options with the woman in advance. The range of surgical options includes mastectomy and breast conserving surgery (wide local excision or lumpectomy). Treatment for breast cancer has changed considerably over recent years. An important change has been the shift from mastectomy, which was the standard treatment in the early eighties. The move to breast-conservation surgery occurred when studies revealed that breast conservation followed by radiation therapy was a real alternative without compromising survival.^{25,34}

Breast conserving surgery (followed by radiation therapy to the conserved breast) is the treatment of choice for unifocal invasive breast cancer provided that the disease can be excised with clear margins of at least 5mm around the tumour. Rigorous histopathological assessment of the margins of the excised specimen is required. Some patients who have undergone conservative resection for invasive breast cancer require further excision or completion mastectomy once the full histological report is available as the risk of local recurrence with the breast is unacceptably high if the resection margins are involved by tumour. UK studies have found variation in the rates of breast conservation treatments.^{35,36,37} Not all patients are suitable for breast conservation surgery. Mastectomy is indicated in situations where the disease is multifocal or in situations where radiotherapy is contra-indicated. The possibility of breast reconstruction should be offered to all patients undergoing mastectomy.

Surgery to the axilla is recommended to stage the disease, provide prognostic information. Plan further systemic therapy and to minimise local recurrence in the axilla. Formal axillary dissection (Levels, I,II and III) provides the most accurate staging information on the axilla. A relationship exists between the size of the tumour and the likelihood of the axillary lymph nodes being affected. If a tumour is more than 5 cms in diameter, more than 60% of patients have involved axillary lymph nodes whereas when the tumour is less than 0.5cm the nodes are affected in only 3% of cases. Patients with uninvolved axillary lymph nodes do not benefit from axillary dissection and identification of such patients before the lymph nodes are completely excised would obviously be desirable. Evaluation of the first lymph node that drains the tumour area (sentinel node biopsy) is under investigation in an attempt to avoid extensive surgery on an uninvolved axilla. The ideal technique, the extent of the histopathological examination and the training required for accurate and reproducible results have yet to be determined. For this reason the sentinel node method remains investigational and should be carried out only in the context of a promising method under evaluation. Individual surgeons' results must be audited before the sentinel node assessment becomes the only axillary intervention.

Radiotherapy

Radiotherapy uses high energy x-rays to destroy cancer cells while doing as little harm as possible to normal tissue. Breast irradiation is clearly indicated after breast conserving surgery and, in anticipation of this treatment, the use of metallic clips around the breast cavity following removal of the tumour, is desirable. The tumour bed can then be seen on x-ray films allowing a radiation boost to the area if this is indicated. Radiotherapy to the chest wall following mastectomy is also indicated in patients with a high risk of local recurrence. Post-mastectomy radiation is considered for patients who, in spite of having adequate surgical treatment remain at a high risk of local recurrence e.g. patients with extensive axillary node metastases, lymphovascular permeation or close margins.

Systemic therapy

The aim of systemic treatment is to treat undetectable cancer and improve survival. Systemic therapies are highly cost effective in most women with early breast cancer. 38,39 Substantial reductions in recurrence and mortality in women with early breast cancer up to the age of at least 70 years can be produced by the administration of adjuvant chemotherapy such as Cyclophosphamide, Methotrexate and Fluorouracil (CMF) or Anthracycline-based regimes. Trials of different types, dosages and duration of adjuvant chemotherapy and endocrine therapies are underway and, where feasible, patients should be invited to participate in such studies. Systemic adjuvant therapy should be considered for all patients except for those with a minimal or low risk of recurrent disease. Included in this group would be all node-positive patients and node-negative patients with tumours which are oestrogen-receptor (ER) and progesterone-receptor (PgR) negative and those with other unfavourable histological or biological indices. For node-negative patients at low risk who are also ER or PgR positive, Tamoxifen with or without chemotherapy is appropriate while for high risk node-negative patients who are ER and PgR positive, chemotherapy in addition to Tamoxifen are currently recommended. For patients with involved lymph nodes chemotherapy is recommended with the addition of Tamoxifen in ER or PgR positive women.

Requirements

Surgery 3,23

- All breast surgery for therapeutic or diagnostic purposes should be performed or supervised by a consultant surgeon experienced in and with a special interest in breast disease.
- Surgeons should have the technical skills to support a full range of choices.
- Unless clinical circumstances dictate otherwise, surgery should be carried out within no more than 14 and preferably within 7 working days of confirming the diagnosis.
- Breast surgery, the management of excised specimens and treatment decisions based on pathology and other prognostic information should follow locally written protocols based on the BASO guidelines.
- In order to demonstrate adequacy of excision the entire surface of the biopsy should be painted with India Ink.
- Surgeons should not slice the specimen or sample it before sending it for histopathological examination.
- The pathologist should confirm that the margins of excised tissue are free of tumour cells.
- Patients who are found to have positive margins should be offered re-excision or mastectomy.
- The possible adverse effects and anticipated benefits of axillary sampling or clearance should be discussed with patients.
- Breast reconstruction should be discussed with patients who are to undergo mastectomy and it should be available through either a plastic surgeon or a breast surgeon trained in the appropriate techniques and should be offered to all women in whom it is clinically indicated.
- The breast care nurse should discuss with patients the fitting and supply of breast prostheses and suitable clothing. A patient's discharge should be planned to ensure that the necessary support facilities are available.

Systemic therapies 4,5,41

- Patients with invasive breast cancer should be offered adjuvant systemic therapy (hormone therapy and/or chemotherapy) if appropriate.
- The choice of systemic therapy should be guided by protocols based on up-to-date best evidence.
- Risk and benefits of the different options should be discussed with the patients.
- Chemotherapy should be initiated and supervised by clinicians who are appropriately accredited and experienced and administered only by appropriately trained staff.

- Cytotoxic chemotherapy should be carried out in facilities that are properly equipped for the purpose.
- Responsibility for the maintenance of safe procedures and standards of practice lies with the consultant concerned.
- Consultant medical oncologists treating patients with breast cancer should be part of a multidisciplinary team and participate in team meetings.
- There should be written protocols for the management of complications and side-effects.
- When clinically appropriate, adjuvant therapy should begin within 15 working days of the decision to give adjuvant chemotherapy.
- Urgent chemotherapy should start within 48 hours and ideally within 24 hours.
- Patients receiving chemotherapy and their GPs should have access to emergency care, information and advice from oncology trained staff on a 24-hour basis.
- They should be given written information on appropriate action for dealing with side-effects of chemotherapy.

Radiotherapy (41)

- There should be pathological confirmation of the diagnosis wherever possible.
- All patients treated with radical intent should have an accurately documented tumour stage according to an internationally (usually TNM) accepted system.
- The treatment intent should be clear: curative, adjuvant or palliative.
- The first outpatient appointment should be within 2 weeks of the receipt of referral.
- Local breast irradiation should be started as soon as possible after surgery¹⁴ usually within 6 weeks except for patients in whom radiotherapy is preceded by chemotherapy.
- Urgent radiotherapy should start within 24 hours.
- Palliative radiotherapy should start within 2 weeks (ideally within 48 hours depending on symptom severity).
- Radical radiotherapy should start within 4 weeks (ideally within 2 weeks).
- Consultant radiotherapists treating patients with breast cancer should be part of a multidisciplinary team and participate in team meetings.
- External beam radiotherapy should conform to the recommendation of the COIN radiotherapy Working Group (42) and where appropriate other European and international advisory bodies.
- Each department must have a standard method of treatment plan normalisation and define a standard for treatment plan acceptability.
- The option of radiotherapy should be discussed with patients before the primary treatment.
- Women who undergo breast conservation should be advised to have postoperative breast irradiation mainly because its omission increases the risk of in-breast recurrence.¹⁴
- Postmastectomy irradiation should be considered for patients who despite proper surgery and adjuvant systemic therapy are at high risk of local recurrence.¹⁴

Reasons and Evidence

Surgery 4,5,14

- Research had revealed that survival is equivalent between breast conserving surgery and radiation and mastectomy alone.
- There is evidence that local recurrence is more probable when cancer cells from tumour margins are left behind after initial surgery, even after radiotherapy.
- There is strong evidence from Randomised Controlled Trials (RCTs) that surgical margin status is a strong predictor of long term local recurrence rates, which can range from 5% to 20% at ten years when

breast conserving surgery is given with radiotherapy (43) and may reach 30% at five years if radiotherapy is not given.(44)

- Individual surgeons must evaluate and audit their local recurrence rates.
- The involvement of the axillary nodes is an important prognostic indicator. Histopathological evaluation of the axilla is a useful tool for estimation of risk of relapse and staging of the axilla by sampling or clearance of lymph nodes allows appropriate management of clinical disease.
- Axillary clearance is the most widely accepted surgical treatment for the axilla.
- Surgical evaluation of the axilla can be performed with sentinel node technology, axillary sampling or axillary clearance. These procedures should follow agreed national guidelines.
- Axillary nodes can be positive even in very small cancers.
- Node positive women should have axillary clearance or radiotherapy.
- Greater morbidity is seen among women treated with radiotherapy.(45)
- Axillary clearance may have therapeutic and prognostic advantages but there is an associated morbidity (lymphoedema and limitation of arm movement) in a small percentage of patients.
- Axillary staging through the pathologic evaluation of the first lymph node that drains the tumour area (sentinel node biopsy) has been tested to avoid extensive surgery on a negative axilla.(46)
- Sentinel node technology is an emerging technique. It has potential advantages over traditional staging but it needs to be assessed in conjunction with standard techniques before being adopted as the only axillary staging. This method remains investigational. Individual surgeons need to carefully collect their data in order to verify results.
- It is unclear whether patients with non-palpable axillary lymph nodes but with microscopic evidence of metastatic involvement benefit from surgical removal of these lymph nodes.

Radiotherapy 4

- Radiotherapy has been shown to reduce recurrence rates after surgery for primary breast cancer.
- Adjuvant radiation therapy reduces isolated local recurrence rates by 67%. (47) The percentage of patients receiving radiation therapy following breast conservation surgery range from 12% to 75% (48, 49) and of adjuvant systemic therapy from 0 to 56% (48,50). These variations may affect survival. (51)
- Complications such as nerve and skin damage may offset the benefits in some women. The complication rate may be minimised by guidelines on good practice.
- Past evidence suggest that addition of radiotherapy to mastectomy does not affect overall mortality.(40) However, recent research indicates that some patients at very high risk of local recurrence might benefit from local and regional post operative radiation therapy. (52,53)
- Radiotherapy to the axilla should not normally be given after surgical clearance of the axilla.
- Radiotherapy has an important role in the management of symptoms associated with metastatic disease.
- In symptomatic metastatic disease, radiotherapy can help to control pain and symptoms and reduce disability.
- There is evidence of beneficial effects of radiotherapy in pain control in bone metastases (5,54,55)
- neurological symptoms and function in brain metastases. (5,56)

Systemic therapy 5,14

- Starting chemotherapy immediately after diagnosis aims to influence tumour growth, avoid the development of resistance, reduce the size of positive axillary nodes an/or the size of the tumour and improve the control of local and systemic disease.(14)
- Preoperative chemotherapy has been shown to be safe, yielding similar results in terms of disease-free survival and overall survival compared to the same regimen used following surgery. (14)
- Patients who receive preoperative chemotherapy are more likely to be candidates for breast conservation surgery.(14,57)

- Clinical and pathological response to primary chemotherapy is associated with prolonged disease-free survival. *.(14)*
- Post-surgical adjuvant therapy for early stage breast cancer is known to improve health outcome.
- The effect is greater in younger women.
- The survival benefit of an initial course of polychemotherapy increases with time. The benefits are greater for node positive women.
- Most trials involve CMF, usually for about 12 months but there is no evidence of differences in survival rates between CMF and other multiple agent regimens. There is no evidence that shorter treatment regimens are less effective than longer courses of treatment. *.(40)*
- Tamoxifen is an important component of treatment for women with tumours that express steroid hormone receptor.
- Treatment with Tamoxifen for 5 years or more has been found to reduce the risk of death by 38% and is more effective than treatment for one year. There is no evidence that higher doses are more effective than the standard dose of 20mg.
- There appears to be no justification for withholding Tamoxifen from older women.
- Combined chemotherapy and Tamoxifen is associated with better outcome compared to Tamoxifen alone.
- The optimal way to administer Tamoxifen (either concomitant with or sequential to chemotherapy) is unsettled.
- Ovarian ablation can have beneficial effects in women with primary breast cancer. *.(5,58)*
- There is evidence that ovarian ablations as effective as chemotherapy for pre-menopausal women. *.(14,40)*
- The occurrence and severity of long-term side-effects are still significant issues when this treatment is given to younger women. *.(14)*

Support Services

Women may need help and support during the difficult time of their diagnosis and treatment. Breast Units should be able to offer specialist advice regarding

- the availability of wigs and prostheses and other supports such as
- social work services,
- psychology etc.

Provision of information is an important element of the care of women with breast cancer. The CAWAC survey found that 40% of women still knew little about cancer after diagnosis and treatment. *.(19)*

The Breast Unit should also liaise with voluntary organisations who have much to offer in recovery programmes and specialist palliative care. The Breast Unit should offer support and continuing advice regarding new medical developments to the voluntary organisations that work so diligently in the field.

Follow up

Arrangements for follow up, at present, are very variable. Many women are called back for frequent follow-up which is demanding on the patient and clinic time and resources. Agreed follow-up procedures that would include the GP should be considered.

Requirements

- Regular mammography is important to detect local recurrence or a second primary cancer in the other breast.

- All women who have been treated with breast conservation for breast cancer should undergo mammography yearly during the first 5 years after surgery and every two years thereafter.
- Some women who have had mastectomy should have biannual mammography on the contralateral breast.
- Most recurrences are symptomatic when detected (5,59) and are most often detected by the woman herself between consultations. Highly intensive follow-up of women who have been treated for primary breast cancer should not be routinely offered by the Breast Unit.
- In view of the lack of evidence of benefit from routine follow up (other than mammography), the intensity and frequency of routine follow up by breast specialists should be re-evaluated. This could only be done in co-operation with GPs and with the facility for speedy access to advice and re-referral where necessary.
- GPs should be involved in developing arrangement for follow-up when routine follow-up at the Breast Unit is to be discontinued or reduced.
- They will require good information on any new arrangements that are put in place, protocols regarding management and clear access to advice and patient review when required.
- The GPs may require training in relevant aspects of breast cancer.
- Individual surgeons must evaluate and audit their local recurrence rates.

Reasons and Evidence

- Patients value continuing relationships with a single provider whether it be a specialist or GP. (14)
- Ongoing care by trained GPs and access to a breast care nurse (61) will be convenient for the patient and will reduce the demand on the time and resources of the Breast Care Unit. (62)
- Women wish to be fully informed and to participate in decisions regarding follow-up care.
- They need to know how to access care when necessary.
- They benefit from access to the breast care nurse for at least a year after surgery. (61)
- Routine tests to detect metastatic disease are not necessary because they do not improve quality of life or survival. (5,59)
- Patients followed up by their GP experience the same quality of life as those cared for by specialist clinics. (63)

Metastatic Disease

Women who have been treated for breast cancer may develop recurrence of the primary cancer or metastatic disease. They are also at higher risk of developing a second primary disease. To a large extent in breast cancer metastatic disease means metastatic bone disease, which is associated with a high level of morbidity and reduced quality of life. The incidence of bone metastases is higher with steroid receptor positive tumours and those that are well-differentiated. (64,65) Patients with bone metastases can present to a number of different specialities. Their successful management requires a co-ordinated approach by clinicians with a special interest in metastatic bone disease. At an appropriate stage in their care, patients with metastatic disease should be followed up at clinics dedicated to this group. Indications for referral to this clinic will be agreed by surgeons, orthopaedic surgeons, oncologists and palliative care physicians.

Most women with bone metastases will present with pain. Initial presentation is often to the GP. The degree of investigation required will depend on the level of clinical suspicion.

- GPs should only undertake initial management if clinical suspicion is minimal (pain has known cause, resolving well at 2-3 weeks from onset) or low (probable cause of pain known, showing good resolution over 4-6 weeks).

- Where clinical suspicion is moderate (pain has no clear cause, persisting but not progressive) or high (pain has no identifiable cause, night pain, severe, and/or progressive, patients with any neurological symptoms or signs), GP should refer back to the breast clinic.
- There is no role for routine skeletal survey or bone scanning of asymptomatic women with a history of breast cancer. (67,68,69)
- Routine CT scanning is not considered to have a role in diagnosis. (26)
- If plain X-ray and skeletal scintigraphy are negative but there continues to be a high level of suspicion then the investigation of choice is MRI scan. (26) If MRI scan is not an option then skeletal scintigraphy should be repeated in 2-3 months. Where there are X-ray abnormalities of uncertain significance bone biopsy should be considered particularly when other metastatic screening tests are negative or equivocal.
- All patients with confirmed solitary or multiple metastases should receive full clinical assessment and full set of staging investigations before treatment is planned.
- Staging investigations to be completed within 10 working days of request and follow up clinic appointment within 1 week of completion.
- Many breast cancer specialists believe that the use of chemotherapy can prolong life in some patients. (5)
- A wide variety of chemotherapeutic and hormonal agents are used in metastatic disease. There is no evidence that any particular regimen is superior. (5)
- In the absence of RCTs it is impossible to estimate the overall effects of treatment on quality and length of life. (5)
- There is evidence that polychemotherapy produces a greater decrease in mortality over three year follow up than single agent therapy without substantial increase in toxicity. (5)

Requirements

- The Breast Unit should make available details of access to the clinic and the Unit should educate GPs in the management of women with skeletal pain and a history of breast cancer.
- 90% of women referred back to the Breast Unit with bone pain to be seen within 10 working days receipt of referral and 90% to have had all their investigations completed within 10 working days.
- All changes in diagnosis and management should be communicated to the GP promptly. The clinic consultant, palliative care nurse, orthopaedic surgeon and consultant surgeon.
- Guidelines are required.
- Dedicated orthopaedic surgeon linked to each Breast Unit with sessional time should attend multidisciplinary meeting where these patients are discussed. Breast care team should have regular participation of an identified orthopaedic surgeon with an interest in metastatic disease and a radiologist with an interest in metastatic disease. (26)
- Orthopaedic surgeon should be responsible for liaising with tertiary specialist colleagues as necessary and ensure that a rota and contact numbers are always available to colleagues on the breast care team. (26)
- Breast care team should provide clear details of rapid access to appropriate assessment to all members of the team, to GPs, to breast care nurses, to patients and to local staff in related disciplines. (26)
- The multidisciplinary team should record the management pathway, which will vary from patient to patient.

Reasons and Evidence

- Improvements in the understanding and management of metastatic bone disease offers the hope of better therapeutic options and it is important that they are referred for expert treatment as early as possible.
- Guidelines will set high standards of care and will bring about a great alleviation of the effects of bone metastases in many women. (26)
- Early detection of metastatic disease in asymptomatic women by imaging and biochemistry does not improve survival. (67,68)

- Tumour markers may be of use for diagnostic purposes as long as the correct cut-off points are used to interpret the results. (26) This is particularly important in confirming the diagnosis of metastatic disease in the presence of suspicious or equivocal imaging investigations. (70)
- It is unusual to have positive findings on CT scan if skeletal scintigraphy is negative. (26)
- A recent review of women with bone metastases in breast cancer found that an orthopaedic surgeon was only consulted in 50% of occasions when their input would have been appropriate. (66)
- Orthopaedic surgeons can make an invaluable contribution to the assessment of patients in whom the distinction between mechanical and non-mechanical pain is difficult. (26) The surgical techniques used in metastatic bone disease differ from those used in routine orthopaedic practice.

Specialist Palliative Care

Women with breast cancer should have access to palliative care at an appropriate time. Depending on the stage of the illness they may require physical, psychological, social or spiritual support. Close liaison between the Breast Unit and the palliative care specialists is essential. Requirements for Specialist Palliative Care are outlined in detail in the report ‘Development of Palliative Care Services’. (71)

Requirements

There should be close links at an early stage between the specialist palliative care team and hospital diagnostic team. The specialist palliative care team prefers to meet the patient at an early stage. Patients should be acquainted at an appropriate stage in their disease with the specialist palliative care team. At various stages in the patient’s illness she may require the support of social services for care and advice.

Reasons and evidence

- There is evidence that pain management is often sub-optimal. (72,73)
- Pain can be controlled through appropriate treatments.
- Multi-professional specialist palliative care teams provide better quality of care.
- Conventional care alone is likely to be inadequate.
- The breast care team should be supported by a specialist palliative care team. Indication for referral to the specialist palliative care team should be agreed by breast surgeons, medical oncologists and the palliative care physician.

CHAPTER 4

Current Service Provision

Introduction

Information regarding the current service provision was gathered through questionnaires completed by the Regional Cancer Directors and visits to hospitals in each Health Board region, which were organised by the Regional Cancer Directors. Appendix 2 shows a list of hospitals visited. Confidential data provided by the National Cancer Registry (NCR) relating to breast cancers diagnosed in each Health Board region was examined. Some patients are diagnosed in hospitals outside their own Health Board. The Regional Cancer Directors also provided some data regarding the number of breast cancers diagnosed in hospitals in their regions. One of the difficulties encountered was the lack of systematic data collection throughout the country. It was difficult to obtain full details of the symptomatic breast disease activity at all hospitals as this information is not always routinely recorded. However, it is estimated that for every one case of breast cancer detected, 17 to 20 patients will require assessment.

It is not possible to obtain a clear picture of the organisation of breast services, detailed throughput for symptomatic breast services, treatments or outcomes. UK data revealed that their cancer survival rates compare unfavourably with those of other countries. They made changes to their services based on best practice and achieved an improvement in outcome. It would be useful if there were data available to judge the performance of breast services in Ireland. From the information obtainable, it appears that the management of breast cancer differs between surgeons and between hospitals as was found in studies from other countries. Few hospitals diagnose 100 cases per year. Surgery for breast cancer is performed in most general hospitals by general surgeons. In some cases particular surgeons have expressed a special interest in breast disease.

In recognition of the evidence available in the literature, there has been a move recently to establish breast clinics. Creative solutions were found for logistic difficulties. For example, clinicians from other hospitals were brought in to provide expertise such as surgery or medical oncology and services such as mammography and pathology were contracted from neighbouring hospitals.

General Findings

The level of service provision varies throughout the country. The main findings are summarised below :

- Variable practices in the type of surgery being performed
- High rate of open biopsy for benign disease
- High rate of open biopsy for malignant disease
- High rate of benign to malignant biopsies
- Lack of pre-operative diagnosis
- Lack of preoperative treatment planning
- No surgical training programme for breast disease exists in the country
- Major issues in surgery
 - a) large variation in the type of surgery being carried out on the breast
 - b) lack of accuracy or protocols in assessment of tumour margins
 - c) variation in the surgical operations on the axilla
- Unequal access to pathology services with large variation in the detail of reports by pathologists for example
 - a) variable accuracy of pathology assessment of tumour margins,
 - b) variation in the detail of reporting numbers of axillary lymph nodes and
 - c) lack of uniform proformas and standard protocols

- Unequal access to ultrasound facilities
- Mammography with no dedicated processing
- Variable and unstructured GP access to mammography
- Variable and unstructured GP referral and follow-up.
- Radiotherapy/oncology
 - d) access to adjuvant therapy difficult
 - e) where it exists it is sub-optimal
 - f) consultant availability very variable
- Lack of Breast Clinics; women seen as part of general surgical clinic
- Multidisciplinary meetings are uncommon.
- Clinical trial uptake minimal; number of patients recruited into clinical trials is low
- No organisation in management of metastatic breast cancer.
- Follow-up variable
- Data not collected to enable evaluation of quality of care.

In examining the structure, a number of disadvantages were noted which might militate against good practice.

- Lack of resources
- Inability to provide Triple Assessment in many places because the structure is not there.
- Lack of radiotherapy, oncology services etc.
- Insufficient theatre capacity in some hospital to ensure protected time for breast cancer patients
- Geographic difficulties
- Transport difficulties
- Political difficulties
- Currently many centres do not have the volume of patients to maintain optimum expertise.
- May be recruitment difficulties in some areas e.g. radiologists, cytotechnicians
- Will take time to establish specialist Breast Units and regional oncology services.

However, there are many strengths within the system. There have been infrastructural developments that if improved will provide a better service.

- Commitment, skills
- Some degree of sub-specialisation has developed
- Dedicated breast clinics in some hospitals
- Multidisciplinary meeting in some hospitals
- Triple Assessment in some hospitals
- Many have already started to move towards a quality service and identified some of the difficulties.
- Not starting from scratch but building on strong foundation

Mammography

- There is an enormous amount of opportunistic screening taking place that is not being formally evaluated. It may not be beneficial.
- Some hospitals provide screening mammography for GPs; others channel all referrals through the surgeon who will decide on the management.
- Hospitals have seen an increase in the referrals from GPs, some of who believe that a national breast screening programme is already available nationwide.
- Women are increasingly presenting to GPs requesting mammography and GPs in turn are referring them to the hospital for the service.
- Part of the increase is due to an increasing awareness among women and also a mistaken impression that the NBSP is already in operation on a countrywide basis.

- Due to a lack of access to diagnostic breast clinics in many areas many GPs find themselves with no option other than to send women for mammography.
- Public concern about breast cancer has led charitable organisations to raise funds to purchase mammography equipment in the belief that this is the only requirement for diagnosis of breast cancer.

Surgery

- Many surgeons throughout the country undertake breast surgery. The number of breast cancer patients seen by them varies.
- Based on figures provided by the NCR, only one hospital diagnosed more than 100 new cases of breast cancer per year and seven public hospitals diagnosed more than 50 cases in 1996.
- There are a considerable number of open diagnostic malignant and benign biopsies.

Pathology

- Facilities for pathology are variable.
- Some centres have access to histology and analysis of core biopsies.
- There were a few centres providing FNA cytology but this is relatively rare.
- There is a shortage of cytotechnicians.

Oncology

- Information regarding adjuvant chemotherapy was scanty.
- There have been a lot of new appointments made recently.
- It is vital that protocols and guidelines should dictate management.

From the review, it was clearly apparent that change is required. Women throughout the country should have access to a uniform standard of care. It would not be possible to provide high quality services in every hospital but the aim would be that all women would have access to a Specialised Breast Unit.

CHAPTER 5

The Recommendations

Recommendations

Based on the requirements for good care, the following recommendations are proposed.

- Specialist Breast Units should be established throughout the country. These units should be fully staffed and resourced in order to deal with patients with breast disease.
- The Specialist Breast Unit should be based on a population of 250,000 to 300,000 from which it is expected that there will be, at a minimum, 100 new primary breast cancers per annum.
- There should be at least two surgeons attached to the Breast Unit. The lead surgeon should normally have a minimum of six fixed sessions and other surgeons attending with a special interest in breast disease should have a minimum of at least three sessions in the Breast Unit, covering GP referral clinics, follow up clinics, breast operating lists, attendance at multidisciplinary meetings and weekly combined breast clinics.
- Requirements for the training of a surgeon with a special interest in breast disease and the arrangements needed or a designated training centre have been submitted as recommendations to the Royal College of Surgeons in Ireland.
- Two nominated radiologists trained and with continuing experience in breast disease. They must be available for reading mammograms and carrying out ultrasound and stereotactic investigations required at new referral clinics. They must be available to report mammograms on all cases arising from the breast diagnostic work of the unit and to attend the multidisciplinary meetings and audit meetings. In some areas it may not be feasible to have two radiologists based in the hospital and special arrangements may be necessary. Radiologists should have the opportunity to attend specialist training courses similar to training courses available to radiologists working in the UK.
- Two pathologists will be responsible for all breast pathology and cytology. They must have dedicated sessions to attend multidisciplinary breast meetings and audit meetings.
- At least two breast care nurses available per 100 cancer patients to counsel and offer practical advice and emotional support to newly diagnosed patients, discuss treatment options with them and provide a prosthetic service.
- The medical oncologist and radiotherapist must arrange the appropriate delivery of radiotherapy and chemotherapy. They should hold joint clinics with other members of the breast care team and must take part in multidisciplinary and audit meetings. While they may be based at another hospital they should have dedicated sessions at the Breast Unit.
- Breast diagnostic radiographers with necessary training and expertise in mammography. They must hold a certificate of competence in mammography.
- Clerical support including two full-time secretaries of high grade and an administrative office to organise the clinic and a data manager in each unit.
- Each medical discipline (surgery, medical oncology, radiation oncology, orthopaedic surgery, and specialist palliative care) should have written protocols of management of patients with breast cancer.
- Management of all patients with breast cancer should be discussed at a multidisciplinary meeting.
- There must be swift effective communication between the Specialist Breast Unit and the GP. There should be minimal delay between referral of a woman with a lump from the GP and an outpatient appointment and between first consultation and communication of the diagnosis with the patient and the GP.
- Patients should be recruited into clinical trials where feasible.
- Modern methods of audit and monitoring of outcomes must be put in place. This requires effective data management. It requires both routine audit and the basic infrastructure for collection of data concerning patients, their disease, treatment and outcomes, and systematic reporting and recording of pathology data.

- A Breast Unit Annual Report, containing data according to protocol from each Breast Unit should be prepared by a designated lead person in each Unit.
- All Units should be interlinked so that identified information is collected from each centre in such a way as to be amenable to comparison among centres and to external audit.
- All Breast Units should combine annually for an audit/outcome meeting to monitor and verify that audit standards are being reached and maintained.
- A national Annual Report should be produced.
- Annual Quality Assurance meetings among all Units are necessary in the same way as in screening programme.
- Individual sub-speciality audit should be performed. Each group should analyse its own performance indicators and agree protocols.
- A national executive multidisciplinary committee, whose function is to analyse the activities of the Breast Units, should meet at least annually.
- A centralised Quality Assurance Office should be established and staffed appropriately with a data collection and evaluation manager supported by clerical staff. It should
 - a) collect data from the regional Breast Units,
 - b) co-ordinate and organise the annual audit meetings and
 - c) produce a National Annual Report.
- A Reference Unit should be established. The function of the Reference Unit would
 - a) act as a facilitator and advisor to other Units, particularly in unusual or complex cases and
 - b) promote research activity among Units
 - c) be responsible for additional specialist training
 - d) house the Quality Assurance Office
- A Breast Cancer Multidisciplinary Advisory Group should be established to
 - a) advise the Minister for Health and Children on the functioning of the Breast Units
 - b) make recommendations concerning the quality of care in each unit
 - c) keep under review developments in research in the area of breast cancer
 - d) provide advice on service changes that may be required as a result of research developments
 - e) provide advice on new or unusual interventional procedures such as vacuum-assisted biopsy techniques. These techniques are being developed in screening services. Resources should be used in the most efficient manner and they should be centralised as much as possible.
- Organisation of the Breast Unit should include ensuring that transport arrangements are in place to facilitate women residing in areas that may pose logistic difficulties in travelling to the Unit. This could include consideration of initiatives such as (11)
 - a) van/bus assistance services,
 - b) taxi services at reduced fares,
 - c) financial support to individuals who provide informal transportation assistance to patients
 - d) voluntary transport assistance to women via Cancer support groups.
- Each health board should examine the geography, road system and population distribution of their own region in order to identify subgroups of women who may have particular difficulties with transport that would deter them from availing of the services provided by the Breast Unit.
- While it may be possible for follow-up treatment to be carried out in hospitals other than the Breast Unit, all surgery and diagnostic procedures must be undertaken at the Breast Unit.
- If difficulties are encountered in implementing these recommendations the National Cancer Forum should be consulted and changes must not be made to the recommendations without approval of the National Cancer Forum.

Introduction

There are some long-established breast clinics throughout the country and over the last few years a significant number of new clinics have been established. Many do not have the population base to enable sufficient volume of patients and concentration of expertise. During the visits, staff in many of the newly established smaller clinics expressed concern about the lack of volume and the medico-legal consequences. In formulating the recommendations note was taken of the breast clinics that were long established. Equipment has to be used to the maximum in order to be cost effective. No professional should be expected to provide treatment without state of the art equipment and facilities. However, it is important to keep in mind the efficient use of taxpayers' money in the provision of a cost-effective service in a health service that has a limited budget. Each Unit will need to be fully funded. In many of the places the facilities are already in place and will not need to be set up from scratch. A needs assessment should be undertaken in each location. This formal assessment should be undertaken in each centre by the health board in the first instance and agreed with the Department of Health & Children. Issues that need to be considered include ensuring that each professional has enough sessions to undertake the work in the Unit, that they have sufficient cover when they are on holiday, and ensuring that their routine work is covered at their base hospital when the particular professionals are working at the Breast Unit.

The Issues

- The decision regarding where to locate the Breast Unit in each Health Board is difficult.
- The factors to be considered include geography, population, custom and established pattern of health service use, plans for development under the National Cancer Strategy and skills and expertise and the facilities that are already in place.
- It is the view of the sub-group that professionals with an expressed interest in breast disease should be accommodated in their wish to continue to provide a service through the Specialist Breast Units.
- Creative solutions may be required to enable professionals from hospitals that are not part of the Breast Unit to participate in the service provision.
- Breast cancer does not usually require high dependency care and so can be sited in Specialist Breast Units that may not necessarily have high dependency facilities.
- Some women may require treatment in a dedicated oncology centre.
- Specialist staff can travel to designated Breast Units to deliver the service and so utilise their expertise.
- Given the infrastructure required and the number of new breast cancer cases per year in each health board, the number of hospitals where Specialist Breast Units can be established is limited.
- As can be seen from the map of Ireland Appendix 3, apart from the larger SHB and EHB, each health board has a population that would be expected to produce 100 new cases of breast cancer per year. A case could be made for siting one specialist Breast Unit in each of these health boards.
- However, this is an overestimate of the breast cancers that would be seen at a Breast Unit, as some patients will attend a private facilities or attend centres outside their own health board area. In the case of health board that are included in the screening programme, those cancers that are diagnosed by the NBSP will be treated by the NBSP rather than the Specialist Breast Unit.
- Despite limiting it to one Breast Unit per health board, the desired throughput for the Units will still only be marginally achieved.
- A large number of women are treated outside the public health service in the private sector. It is essential that providers of private health insurance are aware of the evidence supporting the establishment of Specialist Breast Units. The private sector should be encouraged to follow the same guidelines and principles to ensure the same standard of care for all women.

Geography/Population

In some Health Board areas there are regions with large geographical distances but with small population bases. In some areas, women may have difficulties in getting from home to a particular hospital because of the distances that need to be travelled or because of the time it takes to get there due to public transport arrangements. Travelling to clinics may be a source of great expense. There is a fear that difficulties in travelling to the Breast Unit may result in some women (particularly in those with additional social and economic barriers) failing to attend for appointments. There has not been in depth examination of this issue in the literature. Most studies focus on the transportation barriers to screening mammography and prevention services. For example:

- In the Canadian National Breast Screening study only 5% of subjects listed excessive distance and travelling time as disincentives for screening. (74)
- In Northern Ireland no relation was found between screening compliance and distance from mobile screening units, and few (4%) women expressed a preference for more accessible clinics. (75)

With any study, it is important that the distance the women surveyed had to travel be taken into account. Those that have short distances to travel will not perceive transport and distance to be a barrier. Also, many studies conduct their surveys on people who are attending the clinic. The people who do not attend due to transport difficulties may not form part of the survey and their views are therefore not represented. For example:

- In the USA, a study in Northern Michigan, where only 26% of woman lived 20 miles or more from a mammography unit, found that most women did not consider lack of transport or distance to travel to be a problem in obtaining a mammogram
- But in Southern Michigan, where 64% of the women lived 20 miles or more from a mammography unit, 24% of women surveyed found transportation and distance to be a difficulty. (76)

International studies indicate that few women use public transport to attend breast services (screening or symptomatic) or cancer treatment services. (11,20) The preliminary findings of Women's Health Council study indicate that only a small percentage of women attending symptomatic breast services use public transport. This may be partly because many of them see public transportation as a difficulty. (8) The completed study may shed some more light in this issue.

The majority of women who have benign breast disease will only require one visit to the Breast Unit but transportation is an important issue for patients with cancer who have to make many journeys for chemotherapy and/or radiotherapy. (11) The longer distances travelled result in higher personal costs to the patient and minority groups are more likely to be in need of assistance. (11)

Currently in Ireland, 60% of women can get to their treatment centre within one hour, 23% are between one and three hours away and 7% travel over three hours for treatment. (19) It would not be feasible to provide a full Specialist Breast Unit to cater for a small number of women who have transport difficulties. It would be more cost-effective to put in place suitable method to bring them to the Breast Unit and the literature shows improved survival for women who attend a high volume Specialist Breast Unit.

Implementation of the report must include transport provision. This may entail an organised transport service to the Breast Unit from the more inaccessible areas. Careful deliberation will be required to ensure that the difficulty some women may have with travel is dealt with effectively. Transport could be provided through the health board. This could entail (11)

- Van/bus assistance services
- Taxi services at reduced fares
- Financial support to individuals who provide informal transportation assistance to patients, or
- Voluntary transport assistance to women via cancer support groups.

Each Health Board should examine the geography, road system and population distribution of its own region in order to identify subgroups of women who may have particular difficulties with transport that would deter them from availing of the services provided by the Breast Unit. It is worth noting that:

- The majority of people either have their own cars or have access to a car.
- Most women will only require one diagnostic visit so they will have to travel only on one occasion.
- If they have triple assessment, then the majority of women will have only one visit. Even if they have a core biopsy, an appropriate professional from the Unit can telephone the women with benign result and inform them that they do not need to return.
- The vast majority will not have breast cancer and will not be required to return to the clinic.
- While it may be possible for follow-up treatment to be carried out in hospitals other than the Breast Unit, all surgery and diagnostic procedures must be undertaken at the Breast Unit.
- A difficulty will occur with the provision of radiotherapy and possibly chemotherapy. This problem will arise no matter where the diagnosis is made. Provision of radiotherapy and chemotherapy does not necessarily need to take place in the Breast Unit but may be provided in a hospital closer to the patient's home if the facility is available there and the consultant providing the treatment is part of the Breast Care Team.
- Women are willing to travel if there is a better outcome.

Network-one unit on two sites

The option of providing a network encompassing "one virtual Unit" on a number of sites has been suggested by some people. However, it would lead to a dilution of expertise and expensive equipment would be underutilised. If there is an insufficient volume of patients, multidisciplinary meetings do not happen. A sufficient volume of patients is needed to justify multidisciplinary meetings and clinics. There is great benefit to be derived from a team of people working together routinely.

Planning of services

Service planning has tended to be ad hoc in the past. This has led to charitable organisations around the country purchasing equipment in the belief that it will be of benefit to women. This equipment is often purchased without revenue support and frequently without the required numbers of patients to guarantee the maintenance of expertise. It does not always fit with the health board's broad plan for services in the region. The reality is that management of breast disease is multidisciplinary and requires co-ordinated planning and implementation. Purchasing individual items of equipment is inadvisable and does not contribute to good quality care.

Location of units

Locating Breast Units within Health Boards has the following advantages:

- It is the established administrative structure of the health services.
- There are administrative and financial arrangements in place.
- Tradition and practice.
- Health Boards, broadly speaking, largely conform to the population base required to establish Breast Units.
- Referral linkages are already established with primary care and between hospitals on a Health Board basis.
- There is the option of transcending Health Boards where necessary. Transgressing Health Board boundaries would be administratively difficult but it may be necessary in some situations. This would be in keeping with the principles of the National Cancer Strategy, which recognises that it is necessary for some specialist services such as radiotherapy to be provided on a Regional basis.

Location of Units

South Eastern Health Board

The population base justifies one unit. The South Eastern Health Board has ratified the decision to centralise services in Waterford. A significant amount of forward planning at an administrative and organisational level has been carried out within the region. A formal plan for the region has been presented. This plan is in keeping with the guiding principles. It is recognised that other acute hospitals in the area have surgeons and other professionals who have an interest in breast disease who could travel to the centre to carry out breast work there. Such an arrangement would neatly combine the maximum possible use of resources and personnel while maintaining job satisfaction and expert individual attention. Additional posts and sessional commitments will be required to allow for surgical sub-specialisation.

Southern Health Board

The population in the Southern Health Board is large enough to support two units. Based on the population, it seems appropriate to have two centres in Cork City as no centre outside the city has sufficient population to justify a full unit.

The South Infirmary has the largest number of cancers seen each year. It has clinical and radiological expertise developed over 15 years. It provides an excellent, integrated, efficient and patient-oriented service, despite the fact that it does not have on-site pathology. This would appear to be the appropriate site to base a Breast Unit. Cork University Hospital (CUH) has established a breast clinic recently. They do not have on-site mammography. One consultant surgeon at the hospital undertakes breast surgery. This is not ideal for full coverage of the service. Radiotherapy will be undertaken there and this needs to be funded adequately in order to provide a good service.

Over the past year, the number of breast cancers seen at CUH has increased. Based on data supplied by the hospitals. It is estimated that CUH and the South Infirmary have seen between 80 and 100 breast cancers per annum. Recently there has also been increased co-operation and collaboration between the two hospitals. Based on the population of the Southern Health Board, a second unit is required. It is recommended that it be based in CUH. It is recommended that the expertise that exists in Tralee should be utilised in the new Breast Unit. Professionals with an avowed interest from other hospitals should be allowed to participate. This will entail making provision for their sessions at the base hospital to be covered while they are undertaking sessions at the Breast Unit.

Mid-Western Health Board

The population of the Mid-Western Health Board only justifies one Unit. A large breast clinic has been established in the Limerick Regional Hospital where surgeons from Nenagh, Ennis and St John's Hospital have come together to provide the service. The Health Board population justifies one unit. The unit should be placed in Limerick Regional Hospital, which has a lot of the activity and ancillary requirements already. A breast clinic has been operational in Ennis and the surgeons who run the clinic in Ennis should be incorporated into the centre in the Regional Hospital. If such voluntary involvement arises, there should be practical support regarding coverage of their other clinical activities at Ennis Hospital while they are away from base conducting breast work in the Unit. This may mean the appointment of an additional consultant surgeon in the region.

Western Health Board

The population of the Health Board justifies one Unit. The University Hospital in Galway has been delivering a service for along time under difficult circumstances. They are experiencing large demand

relative to resources. The implementation of increased support is an immediate requirement because their workload is already present and the need is immediate. The University Department of Surgery has developed a strong clinical service and supplemented it by enterprising clinical research. There is an immediate need for another breast surgeon and support services.

There is not sufficient population to justify a Unit in Castlebar. The staff at Castlebar Hospital should be encouraged to contribute to the Galway Unit if they wish to do so. As is being proposed for the Mid-Western Health Board and the Southern Health Board, if professionals from Castlebar wish to become involved in the Breast Unit in Galway, provision should be made for their sessions at the base hospital to be covered while they are undertaking sessions at the Breast Unit.

North-Eastern Health Board

The population supports only one Unit the North-Eastern Health Board. Based on the principles already discussed in this report, there is no justification for two Units. The most densely populated area is in the southern aspect of the Health Board in Louth and Meath. This is likely to expand over the coming years. Individuals with an expressed interest and expertise in breast services should be incorporated in the Breast Unit. They need to have adequate support in order to cover their regular duties while they are away from their own base hospital. People should be allowed to become involved, provided they meet with the audit and CME needs. Some facilities already exist in Drogheda and this would appear to be an appropriate location for the Breast Unit.

North-Western Health Board

The population of this Health Board supports only one unit. Geographical considerations dictate that an innovative approach is required in order to ensure that services are available to patients in acceptable settings as far as possible. In Letterkenny, there is a committed group of people providing a service but they do not have a large enough volume of patients with breast cancer. They will need to link with Altnagelvin Hospital in Derry in order to increase their caseload, experience, expertise and formal cross-cover. If collaboration between Derry and Letterkenny occurs, it should be a true liaison. Scope exists for such a liaison to be formalised. There are strong clinical links between the two hospitals and also between Letterkenny and Belfast City Hospital. These links have been established and are being developed further and provide the impetus for a formal arrangement to be established. Northern Ireland population interest in the development of this Unit should be explored with Northern Ireland health authorities. This sort of decision has to be supported at the highest political level so that the highest standards can be maintained and for the ease of access and administrative efficiency.

Sligo has insufficient population to justify a unit. There is currently little infrastructure in Sligo and considerable resources would be required in order to set up a Breast Unit there. However, the only realistic proposal would be that, in this particular case, crossing Health Board boundaries could be justified. If the population of Sligo, Leitrim, West Cavan and part of Mayo are incorporated, it is estimated that the population would be adequate to provide sufficient volume of patients. Therefore it is recommended that a Breast Unit be established in Sligo serving those areas. This is an innovative proposal that will require the involvement and agreement of the CEO's and Board of each of the relevant Health Boards. There will need to be agreement that patients cross traditional health board boundaries.

Midland Health Board

The population of the Midland Health Board marginally supports one unit. There is a small breast service currently in Mullingar. There is no service in Tullamore. Patients currently travel to Portlaoise where a long-established unit with considerable clinical expertise and a great deal of ancillary patient- focused and oriented support at medical and nursing level has been developed over many years. Bearing in mind the

great majority of women attending the clinic will not have cancer, it is not essential to locate the Breast Unit in the designated regional cancer centre. Because of the delivery of breast services can largely be delivered in non-emergency settings, it is unlikely to require high dependency support. However, there is concern that the peripheral location of Portlaoise in the Health Board might militate against achieving the critical mass of patients required for the Unit. There would be a case to be made for locating the Breast Unit in Tullamore because of its geographical location in the Health Board and because this would fit in with previous decisions made by the Health Board regarding the organisation of oncology and pathology services. It is essential that the available expertise that already exist within the Health Board should be fully utilised in the new Breast Unit and professionals with an avowed and continuing interest from the other hospitals should be allowed to participate. This will entail making provision for their sessions at the base hospitals to be covered while they are undertaking sessions at the Breast Unit. Should the decision be to locate the Breast Unit in Tullamore then the existing and longstanding expertise of those involved in the Portlaoise unit should provide the basis of the service in Tullamore. This will ensure that a highly valued, quality service will be provided to all women in the Midland Health Board region.

Eastern Health Board

In the Dublin region, it is proposed to establish two Breast units on the north side and three on the south side of the city. One of the Units on the north side should be located in the Mater Hospital. The other Unit, based at Beaumont Hospital should involve the participation of interested staff from the James Connolly Memorial Hospital in Blanchardstown. On the south side of the city, separate Breast Units should be located in St Vincent's University Hospital, St James' Hospital and in Tallaght Hospital.

The Mater Hospital already houses the Eccles Screening Programme and is expected to treat 150 patients per year in the prevalent round. It is appropriate to utilise the expertise at this site for patients in a Breast Unit. It is important to have the Breast Unit in a hospital with a screening unit because follow-up of breast cancer detected by screening take place in the Breast Unit. Many of the staff and most of the infrastructure required are already in place.

James Connolly Memorial Hospital and Beaumont Hospital each have breast clinics. The catchment population does not support two separate Units. There are committed professionals who have academic links in both hospitals. They are prepared to work together to develop a Breast Unit on one site but availing of the expertise of both hospitals. This initiative should be supported. Neither hospital has adequate facilities or equipment. It is proposed that the Unit be sited at Beaumont hospital and should involve relevant staff from James Connolly Memorial Hospital. It is proposed that another consultant surgeon with a special interest in breast disease be appointed. The consultant would have general surgical sessions in James Connolly Memorial Hospital and specialised breast session including theatre sessions in Beaumont Hospital.

Tallaght is a new hospital and is developing its breast services. It is located in an area with a very fast growing catchment population. The expanding population base and catchment would indicate that locating a unit in Tallaght would be reasonable. Many of the pathology and radiology requirements are available.

St James' hospital has a newly established well-audited breast clinic. Most of the key personnel are available, as are the back up facilities. Its catchment area and the service it provides to the inner city population justify a Breast Unit in this hospital.

The first breast clinic in the country was established in St Vincent's University Hospital and it has been providing a symptomatic breast service for twenty years. The hospital currently treats the largest number of breast cancers of any institution in the country. It is to be one of the screening locations for NBSP and will have approximately 150 extra breast cancers from screening. There is a need for significant investment in infrastructure but many of the requirements are in place.

Reasons and Evidence for Specialist Breast Unit

Survival Outcomes

There have been many reports in the literature of variations in the standards of care and also variations in the outcome of breast cancer patients between and within countries. Caution is always necessary when interpreting such variations. The survival of a cancer patient depends on the characteristics of the patient, on the biology of the disease, and on the quality of the medical services. Some part of the variation will be due to random variation. Apparent variations may be due to differences in ascertainment of cases and the quality and detail of information available in various regions. Variation in medical care may be due to many factors including differences in health care systems, differences in physicians' practice and styles and patient characteristics that may influence how they use the medical services. (77) Variations in outcome may be due to variation in case mix, with sicker patients attending particular hospitals with special expertise. Other factors include stage at presentation, treatments administered, and cultural, behavioural and environmental factors.

- Studies have demonstrated important variations in practice among surgeons and among hospitals in the management of breast cancer. (48-51, 79,80)
- Some studies have found better outcome among patients treated by specialists.
- One Scottish study found that patients with breast cancer have 9% better survival at five years and 8% better survival at 10 years when cared for by specialist surgeons. (78) The maximum survival benefit was seen in those aged 50 to 64 years and applied across all socio-economic groups. (78)
- Some studies have found a higher mortality among women who were treated in hospitals that had a low volume of breast cancer cases.
- The increase in mortality can range from 19% in moderate volume hospitals, 30% in low volume hospitals and 60% in very low volume hospitals, compared to those who had their surgery at high volume hospitals. (78)
- While variations in technical surgical practice may not have a large impact on survival, differences in the use of systemic adjuvant treatment may influence outcome. (50, 79,80)
- Variations in practice, in particular under-use of efficacious treatments represent opportunities to improve health and longevity in women with breast cancer. (81)
- While in Ireland we do not have evidence of poor outcome for women treated at low volume hospitals, we do not have the data to determine many aspects of the quality of their care.

Volume

- Radiologists can differ widely in their interpretation of mammograms and their recommendations for management. (83) It is important that radiologists report a sufficient volume of mammograms to attain and maintain a high level of performance. A significant association has been demonstrated between recommendations for immediate work-up in cancer cases and the total number of lifetime mammograms read. In one study, radiologists with the highest frequency of recommending immediate work-up in cases that proved to be malignant had read more than 15,000 mammograms over their lifetime. (82) If a radiologist only reads 500 mammograms per year it would take 30 years to achieve this level of expertise to maximise sensitivity. Thus, radiologist reporting mammograms need a significant volume to achieve optimum cancer detection.
- It is desirable that a sufficient volume of image guided procedures should be performed to attain high pre-operative diagnosis rates.
- Women managed by individual surgeons treating more than 30 to 50 cases of breast cancer each year appear to have better survival, probably because they are more likely to receive adjuvant therapy (79, 50) and consultants who treat more patients are also more likely to work in a multidisciplinary team and make more use of the full range of therapeutic options for their patients. (50)

- The better outcome for patients where there is a high caseload may not be a function of the skill of the surgical team but a function of the clinical organisation. (50, 80)
- Patients of high volume surgeons are more likely to get adjuvant treatments and are 15% more likely to be alive at 5 years compared to patients of low volume surgeons. (51)

Where did the figures for the Breast Unit come from? (1,2,3, 4, 5)

Experience in other countries has led to the view that breast disease should be treated in Specialised Breast Units with high standards of care (4) through management by surgeons, radiologist, pathologists, clinical and medical oncologists and nurse specialists, each of whom specialises in breast cancer, working as a team and providing services from early detection through to care of advanced disease. (3) Studies abroad have demonstrated important variations in practice between surgeons and between hospitals in the management of breast cancer. While variations in technical surgical practice may not have a large impact on survival, differences in the use of systemic adjuvant treatment may influence outcome. It is suggested that a viable unit would deal with a minimum of 100 breast cancers per year and also deal with the worried well for assessment and advice.

The figure of 100 new breast cancer patients per Breast Unit per year is an indicative figure chosen for the following reasons:

- There is evidence of benefit from specialised multidisciplinary care
- There is evidence of benefit from large volume case load
- The figure of 100 applies not merely to the surgeons but to the specialist breast team as a whole. The figure of 100 is necessary to justify the investment of specialist time and other resources to establish and provide ongoing resources for a modern multidisciplinary Breast Unit. A throughput of 100 cases would be expected from a population of 250,000 to 300,000.
- The level of workload is necessary to sustain the collective expertise of the team.
- This level of workload is operationally cost-effective for the deployment of a skilled group of people to function as a multidisciplinary team.
- Grouping a number of hospitals together into a ‘‘virtual Breast Unit’’ would not achieve a functioning multidisciplinary team.
- It is not feasible or cost-effective for a group of specialists to meet weekly and invest time and resources co-ordinating care if the number of new breast cancer patients falls below two cases per week.
- A unit seeing 100 cases of breast cancer per year would see at least 1000 new patients with breast symptoms annually. This level of clinical activity (20 new patients per week) would justify the provision of a weekly new patient GP referral clinic, which is essential if women are to be seen without delay.
- Professional consensus in the BASO clinical guidelines and other documents of the desirability of such a figure.
- In order to provide the equipment and facilities for an excellent unit resources are required. It is not feasible to provide this level of resources in many hospitals that do not have the volume to utilise them to optimal efficiency.
- In some places a lot of structures are in place and it will be relatively easy to develop the Breast Care Unit.
- There is a common belief that people are not prepared to travel outside their own area for health services. However, there is evidence that when people discover that their outcome will be better in terms of improved survival, they are prepared to travel.

The multidisciplinary approach

- It is accepted that a multidisciplinary approach to breast cancer affords women the best therapeutic options when diagnosed with breast cancer.

- Women attending breast clinics have a high level of anxiety. A multidisciplinary clinic will result in most women only having to make a single diagnostic visit to the breast clinic. There is considerable lessening of anxiety if the one diagnostic visit is required.
- There is a definite cost saving to the health service; multiple visits are demanding on resources.
- There is also financial saving to the patient and her family. Most women attending a breast clinic are accompanied, frequently by their partner. This results in absence from work and so reduction in visits can result in hidden cost savings to the economy.
- The cost of establishing high quality multidisciplinary breast clinics is largely offset by the reduction in bed occupancy and staffed theatre time.

CHAPTER 6

Structure of a Unit

Introduction

Patients with symptomatic breast disease who present to their GP should be referred directly to a specialist breast service. Direct and early referral will reduce the time to diagnosis, avoid duplication of investigations and will ensure that the patient is managed from the outset by multidisciplinary teams with specialist skills. The modern management of breast cancer entails triple assessment, which involves the surgeon, pathologist and radiologist being in the clinic together. It reduces the number of unnecessary operations performed for benign and malignant breast disease and facilitates rapid diagnosis and better planning of treatment. The proposed structure is based on the guidelines available and the extensive literature on the subject. The Specialist Breast Unit should be based on a population of 250,000 to 300,000 from which it is expected that there will be a minimum of 100 new primary breast cancers per annum.

The main components of a Specialist Breast Unit include core personnel, other essential personnel, facilities, equipment and organisational elements.

Core Personnel

The core personnel are the people whose presence is considered to be essential for the Breast Team to work effectively in delivering a multidisciplinary service. Some professionals e.g. the radiation oncologist and medical oncologist, would not necessarily be based in the hospital where the Breast Unit is located. However, they would need to have sessions at the Breast Unit that would enable them to participate fully as members of the Breast Team. Some of the other professionals such as surgeons with an interest and expertise in breast disease from other hospitals would also require sessions at the Breast Unit to enable them to participate fully as members of the Breast Team.

The core personnel are as follows:

- Lead Clinician
- Breast Surgeons (lead surgeon normally 6 sessions, each other surgeon 3 sessions each)
- Breast Radiologist (4 sessions)
- Breast Pathologist (4 sessions)
- Breast Care Nurse (2 WTE per 100 cancers)
- Clinic Nurses (1WTE). They will probably be shared with the general outpatient department.
- Medical Oncologist
- Radiation Oncologist
- Radiographers (2 WTE)
- One Administrative Officer (Grade VI or VII)
- Two Clerical Officers (Grade IV or V). Depending on the workload, three may be required.
- One Data Manager.

Other essential personnel

This includes other staff that are essential for the delivery of a high quality diagnostic and therapeutic service. Women must have access to the expertise of these professionals. A liaison system, which involves good communication and early involvement in woman's care, is necessary to ensure that the relevant professionals are brought in at the appropriate time.

- Plastic surgeon
- Clinical psychologist or psychiatrist

- Palliative care specialists
- Physiotherapist/occupational therapist
- Social worker
- Clinical Geneticist
- Pharmacist

The breast care nurse provides a valuable service and the supportive care and skills in counselling of specialist nurses are most important. A specific training programme for such nurse specialists is a requirement. One whole time equivalent breast care nurse is required per 50 new cases of breast cancer per year. This implies that three breast care nurses are needed for Units treating 150 patients and four nurses required for Units treating 200 patients. One of the key functions of the breast care nurse is to provide support and counselling to women who attend at the Breast Unit.

The area of support services such as counselling and social work needs to be examined further. The survey of ‘women’s views and perceptions of the symptomatic breast services’ undertaken by the Women’s Health Council which will be submitted to the National Cancer Forum on completion, will provide information regarding what women wish to see provided in this area. (8) Any developments in the provision of support services for patients with cancer should be guided by the national review that was undertaken of support services for patients with cancer. (10)

Facilities

Care for women with breast cancer should be provided in a friendly, comfortable environment with private areas for consultation and counselling. Consideration should be given to the need for changing facilities and the proximity of the various diagnostic and consulting areas. Necessary accommodation will include:

- Reception area
- Waiting room
- Outpatient clinic accommodation which is close to the imaging area
- Radiology, including mammography, ultrasound and imaging guidance for localisation procedures
- Pathology room for storage of cytology specimens and a microscope
- Nurse counselling area
- Inpatient beds
- Operating time

It is important that there is adequate space for the clinic. In some centres the accommodation is already available. The clinical rooms should be in close proximity to the breast imaging area (mammography and breast ultrasound). This is important as women will change for clinical examination and ideally should be able to proceed to imaging without dressing and undressing. There should be the facility for a pathology room for storing cytology specimens and a microscope. The nurse counselling area should be placed in close proximity to the clinic so that distressed women do not have to walk far.

The requirements for beds and theatre are unlikely to increase. High pre-operative diagnosis will result in fewer requirements for surgical beds and theatre time. Some local reorganisation may be required to ensure admission and treatment within acceptable time scales.

Equipment

In order to provide high quality multidisciplinary care, a basic level of equipment provision is necessary. This includes:

- Stereotactic mammography machine – approximately £130,000
- Basic mammography unit approximately £50,000

- Processing equipment approximately £50,000
- Ultrasound machine approximately £50,000
- IT support and database
- Microscope for Pathologists

Organisation

The planning of care involves all members of the Breast Care Team, who must communicate with all other professionals who are involved in the woman's care. At any particular time in her care there should be a principal clinician with whom she relates. In the early stages this will be the surgical oncologist, during adjuvant therapy it will be the medical oncologist and the radiation oncologist, and at a late stage it may be the palliative care physician. There should also be a Lead Clinician for the Breast Unit. The Lead Clinician should generally be the surgeon because

- a) the majority of patients presenting to the Breast Unit do not have cancer and do not require the services of a medical oncologist or radiotherapist, but do need the surgical specialist for clinical assessment and reassurance
- b) it is the surgeon who is the first point of medical specialist contact with the patient in the hospital setting
- c) it is the surgeon who, on diagnosis, discusses and undertakes the primary treatment for patients who have cancer in the great majority of cases.

The Lead Clinician must have the skills to lead the Unit and promote the development of audit, protocols and quality assurance measures. Important elements of the organisation of the Unit are listed below.

- The range of clinics will include: new patient clinic, result clinic, follow up (general follow up clinic, combined clinic for advanced/metastatic disease with medical oncology and radiation oncology, clinic for women with low risk of recurrence), family history clinic, mastalgia clinic.
- Each team should hold weekly multidisciplinary meeting to discuss the clinical management of patients. All relevant members of the Breast Care Team should attend the meetings. All patients should be discussed: new cases pre-operatively and post-operatively; patients with recurrent or advanced disease; cases which present difficulties in management; other cases where appropriate.
- During the meeting the team should agree and document the treatment plan for each patient, agree further investigation, agree which patient should be offered entry to approved clinical trials and refer patients for treatment such as oncology where necessary.
- A record of meetings should be documented.
- Adequate and clear communication between all those involved in the woman's care is important.
- Adequately funded quality assurance is necessary.
- Audit through collection of data using a specially developed proforma. Information is co-ordinated by a data manager and formally presented and evaluated regularly at a Breast Unit and at national level.
- All members of the multidisciplinary team should have the opportunity of specialist training.
- Development of national guidelines and protocols that are agreed nationally.
- Research is fundamental to a high quality Breast Unit and Units should be encouraged to
 - a) develop clinical research activity
 - b) liaise with existing academic centres where basic research is conducted
 - c) become involved in clinical trials

Clinical trials

Clinical trials are the basis for the development of the knowledge, which leads to the best treatment methods for breast cancer.

- Breast Units should support clinical research and should participate in a programme of multi-centre clinical research and clinical trials aimed at improving the treatment of breast cancer. (3)
- While it is the right of any individual patient to decide whether she wishes to take part in a clinical trial, participation in clinical trials must be encouraged.
- Clinical trials need to become more acceptable to the public as well as to the medical community for much more to be achieved that increases knowledge about breast cancer and its management. (14)
- This can be achieved through involving patients more fully in the design and conduct of the trials.
- Excessive extrapolation of results from existing clinical trials are reliance upon indirect evidence might be detrimental to the development and validation of effective treatments. (14)
- Those involved in trials should co-ordinate their efforts to avoid unnecessary duplication and to provide added value through pooling data. (2)

Quality Assurance Office

A centralised Quality Assurance Office should be established and staffed appropriately with a data collection and evaluation manager supported by clerical staff. It should

- collect data from the regional Breast Units,
- co-ordinate and organise the annual audit/outcome meetings and
- produce a National Annual Report.
- be located in the Reference Unit

Reference Units

A Reference Unit should be established to provide support and advice to Breast Units throughout the country. This Reference Unit could provide second opinions if appropriate for more complex or unusual cases. This would be in the form of advice and where possible returning the patient to the referring Breast Unit for appropriate treatment. The Reference Unit should be encouraged to establish a teaching and training/continuing education programme. This should be multidisciplinary and involve both formal and informal training facilities. The Reference Unit should facilitate the other Units with research and other academic activity.

The main function of the Reference Unit would be to

- co-ordinate all the Units
- act as a facilitator and advisor to other Units, particularly in unusual or complex cases,
- promote research activity among Units and co-ordinate clinical research
- be responsible for additional specialist training
- house the Quality Assurance Office

Communication

The diagnosis and treatment of breast cancer involves many professionals within the Breast Unit, across hospital departments, between hospitals, between the hospital and the GP and with voluntary organisations. Difficulties with communication will militate against high quality care and may also promote complaints and litigation. The CAWAC survey found that although 94% of women with breast cancer were satisfied with the overall care they received, only 62% were satisfied with the level of communication between their GP and the hospital and only 67% were satisfied with the co-ordination of their treatment across hospital departments. (19) It is recommended that the role of cancer co-ordinators be explored to help facilitate communication and co-ordination of cancer services. This is important not only to aid communication with GPs but also to help link women with support systems and services located in the community.

When the new Breast Units are established, all professionals especially GPs should be informed of the new arrangements. They should understand how to access the appropriate service for their patients. Adequate and clear communication between all those involved in the woman's care is important. Administrative structures are necessary to ensure:

- Communications with GP, family, other team members
- Rapid access for appointments and efficient processing of data
- Accuracy of data
- Adequate recording of all relevant clinical, radiology, pathology, chemotherapy, radiotherapy, biological and other data
- Consistency of records within elements of the Unit and among the Units

Family History Clinics

A number of dedicated family history clinics should be established. The Reference Unit would be an appropriate location for such a clinic. When a woman has a relative risk of breast cancer that is three times that of the general population, referral to a Specialist Breast Unit is advisable. Women with less than three times increased risk probably do not require extra surveillance. There are charts available that aid in the assessment of increased risk for women with relatives with breast cancer. They should be kept under surveillance with regular examination and/or mammography at an appropriate age. These data should be collected and correlated nationally. There are approximately 3000 to 4000 such women per million population. These women should attend family history clinics based at breast clinics. Women with ten times increased risk should be referred to a dedicated genetic family history clinic. There are approximately 10-15 such families per million population (based on UK data). These women will require counselling and perhaps genetic testing.

The role of family history in the aetiology of cancer is an important area that is not confined to breast cancer. It is an issue that requires detailed examination, with the view to providing centralised genetic services for all cancers. It was not the remit of the sub-group to examine this subject in detail. The recommendations apply only to the immediate needs for women with breast cancer and are not intended to go beyond that. The issue of inherited predisposition to cancer in general needs to be fully evaluated by experts in the field.

Financial Implications of Establishing Breast Units

There is significant cost associated with the establishment of a unit. There will however be savings due to the increased efficiency particularly if 80% of women make only one diagnostic visit. The review appointments utilise valuable clinic time and there is a significant potential cost saving to the patient and the economy due to reduction in clinic visits.

The sub-group did not consider it appropriate to attempt to provide detailed costing for the Breast Units. Some locations have some of the necessary facilities and staff in place already. Others would need a large injection of resources in order to establish a Breast Unit. A detailed needs assessment will be required for each proposed centre by the Department of Health & Children and the Health Boards to determine the exact requirements in each location based on what is already available.

CHAPTER 7

Quality Assurance Structure

Introduction

It is important that quality assurance structures are put in place to ensure that women receive the highest standard of care. Clinicians involved in the service must be prepared to perform regular audit. Audit is the systematic and critical analysis of the quality of care including the procedures for diagnosis and treatment, the use of resources and the resulting outcome and quality of life of the patient. It is an essential part of clinical care. This is vital not only to ensure standard but also to enable clinicians to monitor their own performance. Most clinicians work to very high standards but work in the field of breast cancer diagnosis and treatment has become increasingly difficult due to medico-legal challenges. Participation in quality assurance is usually reassuring to clinicians and enables them to realise that they are performing similarly to their other colleagues in the field in other Units. Quality assurance must be the sharing of experience and must not be threatening to the individual professional. There will be a requirement for each sub-speciality group to perform their own quality assurance. It will be important that this is done confidentially within the relevant professional group. Inter-disciplinary audit will be required to monitor the performance of the Unit as a whole.

- All members of the Breast care team should participate in the audit of the structure, process and outcomes relating to the breast service.
- Team members should participate in relevant sub-specialist regional meetings.
- Regional forums should be established among all professional groups to enable them to share experiences, promote audit and continuing professional development.
- A range of guidelines should be developed nationally to promote a consistent evidence-based approach to the management of breast disease.
- Close liaison between the pathology laboratory and the National Cancer Registry is necessary.
- A standard set of data is necessary using the same diagnostic criteria.
- People appointed need to have special interest and specific training in breast disease and undertake to attend CME. This must be funded.
- The monitoring of CME is based on the acquisition of credits granted.
- Regular meetings of all Units are necessary.
- External visits to each Unit.

There are a number of components to a Quality Assurance programme:

- Training, both initial and continuing medical education
- Unit audit
- Subspecialty Audit (National)
- Multidisciplinary Audit (National)
- Guidelines

Training

All members of the multidisciplinary team should have the opportunity of specialist training. Many people already working in the field will have been appointed prior to the establishment of formal training programmes. Some clinicians would value the opportunity of a refresher-training course. This facility should be available if required. Future Consultant appointments in surgery, radiology and pathology with a formal sub-speciality interest should have acceptable sub-speciality training. There should be funding available for staff to attend continuing medical education. This should be mandatory as agreed by each sub-speciality group. A suggested guide for training and recruitment of consultant breast surgeons is shown in Appendix 4.

Unit Audit

Breast Units must assess the care they provide (care process and outcome) and there should be an environment of critical self-appraisal. Audit should assess the quality of care using objective criteria. The Units should keep accurate records of diagnostic, staging, treatment and follow-up data. There should be a nationally agreed minimum database for all Breast Units. A Data Manager should collect relevant data. Each Unit should meet regularly (probably 6 monthly) to formally present and evaluate the Unit statistics. The lead clinician in the Unit should be responsible for and have the ownership of the Unit data. The Unit will be required to have close links with the National Cancer Registry.

Sub-Speciality Audit (National)

Breast cancer is diagnosed and treated by a number of sub-speciality groups. There are performance review indicators that are specific to each sub-speciality group. It is important that these sub-speciality groups should meet regularly to provide professional support and formal audit. The sub-speciality groups should establish professional standards and guidelines. Regular national sub-speciality meetings will benefit individuals working in the field and will help raise and maintain standards. Each group should elect a chairperson for an agreed term of office. The chairperson would collect relevant data on each sub-speciality. This chairperson would represent the group on a national executive multidisciplinary committee. Sub-speciality audit must be the result of equal participation of all individuals in the group. Confidentiality should be respected but if there is a potentially serious deviation from the standard the chairperson should be enabled to take remedial action.

Multidisciplinary Audit (National)

It is important that national data are collected and analysed. An executive multidisciplinary committee should be established with membership from each sub-speciality group. An annual meeting of professionals involved in the diagnosis and treatment of breast diseases should review key performance and outcome indicators i.e. clinic wait time, percentage patients diagnosed at single visit, bed wait times, benign biopsy rates, pre-operative cancer detection rates, percentage tumours less than 15mm undergoing conservation surgery, re-excision rates, lymph node status, etc. Audit should be an integral part of the service just as in breast screening. The annual meeting will result in the sharing of information and should help develop a collegiate atmosphere amongst those delivering the service. It would be appropriate to have an academic session at the time of the presentation of the annual report. An interested speaker would be of considerable value.

A national Quality Assurance Office should be developed. The national Quality Assurance Office should be centrally funded and could be located in the Reference Unit. It should be staffed by a data manager with clerical support and should receive regular downloads from the Units. The chairperson of the multidisciplinary committee should with the support of the Quality Assurance Office produce an annual report with evaluation of key performance indicators. This report would include wait times for initial diagnostic visit, number of diagnostic visits, wait time for diagnostic and therapeutic surgery. Information on adjuvant treatment should be collected including details of radiotherapy and chemotherapy regimes.

An Irish Breast Group should be established to facilitate quality assurance, development of protocols and the sharing of information and expertise. A sub-group should be appointed and designated to promote and co-ordinate research into the field of breast cancer.

National Guidelines

Each sub-speciality group should issue guidelines on patient management. These guidelines should include acceptable professional standards. These guidelines should be agreed nationally, implemented locally and reviewed nationally. Only clinicians who agree to practice guidelines and perform audit should provide the service.

Written guidelines and protocols should be available for each component of care; GP, surgeon, radiologist, pathologist, medical oncologist, radiation oncologist, breast care nurse, physicist, management, and secretarial staff. With the introduction of guidelines and protocols there is likely to be an increase in the use of systemic adjuvant therapy in early breast cancer. The additional costs that result are likely to be balanced by a reduction in treatment costs for recurrence and for advanced disease. Guidelines should be continually evolving. Effective implementation is essential.

Reasons why Quality Assurance is needed

Knowledge and skills relevant to clinical practice must be kept up to date throughout working life. Regular audit and quality assurance raises standards. Departments must assess the care they provide (both care processes and outcome). There should be an environment of critical self-appraisal.

- The quality of care should be evaluated using objective criteria.
- The diagnosis and treatment of breast disease has many key processes that can be subjected to objective standard analysis. It is imperative that each individual part of the process is audited but the overall outcome is important.
- It is important that the clinician and radiologist locate the lesion accurately and that the pathologist can make a definite diagnosis. All aspects of the process must be monitored.
- Performance in mammography is directly related to expertise. There is evidence of improvement in radiologists' interpretation after dedicated teaching courses. (89) There is also evidence of improvement in small cancer detection when the number of radiologists involved in reporting is restricted. (90)
- Because of the demanding nature of the mammographic technique, rigorous attention to the use of appropriate equipment and performance of quality assurance by the radiologist, the radiographer and medical physicist is required.
- Quality assurance of physical and technical aspects of mammography must include equipment specification, acceptance testing and routine quality control. The importance of high quality standards in mammography imaging has been recognised by many organisations and countries world wide most notably the EU (91, 92,93,94) and the United States which has legislated through the Mammography Quality Standards Act.
- The image quality must be stable with respect to information content an optical density and the radiation dose to the breast must be as low as reasonably achievable for the diagnostic information required. The demands on image quality hold for every mammogram produced and the quality assurance program must ensure that high quality images are achieved consistently.
- The need for quality assurance has been recognised by the Royal Colleges and guidelines have been developed.
- The importance of reviewing guidelines has been demonstrated by the UK NHS BSP Pritchard Guidelines, which were issued prior to the establishment of the Programme. These have been reissued and the standards raised twice over the last 10 years.
- It is important that the Republic of Ireland collects data in the future that will allow comparison with survival patterns stage by stage in other countries. The collection and analysis of data and performance will lead to a uniformly high quality assurance service for women attending clinics with breast symptoms throughout the country.

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Appendix 1

Membership of Sub-Group on Symptomatic Breast Cancer Services

Prof James Fennelly*, Chairperson National Cancer Forum, 21 Alma Road, Monkstown, CO Dublin.

Dr Jane Buttimer, Director, National Breast Screening Programme, Corrigan House, Fenian Street, Dublin 2

Ms Sioghan Carroll, Breast Care Nurse, c/o Prof Paul Redmond, Cork University Hospital, Cork.

Prof Eugene Connolly*, Consultant Pathologist, University College Hospital Galway.

Prof Peter Daly*, Consultant Medical Oncologist, St James's Hospital, James's St, Dublin 8.

Prof Donal Hollywood*, Regional Director of Cancer Services, Midland Health Board, and Consultant Radiotherapist, St Luke's Hospital, Highfiels Road, Rahgar, Dublin 6.

Mr John Kelly, Consultant Surgeon, South Infirmary-Victoria Hospital, Old Blackrock Road, Cork.

Mr Michael Lyons*, Principal Officer, Secondary Care Division, Department of Health and Children, Hawkins House, Dublin 2.

Ms Geraldine Luddy, Chief Executive, Womens Health Council, Irish Life Centre, Abbey St., Dublin 1

Mr Peter Naughton, Consultant Surgeon, Portlaoise General Hospital, Portlaoise, Co. Laois.

Prof Niall O'Higgins*, Prof of Surgery, University College Dublin (St Vincent's University Hospital, Elm Park, Dublin 2).

Dr Bernadette O'Keefe*, Deputy Chief Medical Officer, Department of Health and Children, Hawkins House, Dublin 2.

Dr Orlaith O'Reilly*, Director of Public Health, South Eastern Health Board, Lacken, Dublin Road, Kilkenny.

Mr John Reynolds, Regional Director of Cancer Services and Consultant Surgeon, Waterford Regional Hospital, Ardkeen, Waterford.

Dr Greg Kelly*, General Practitioner, Knockrae, Castlerea, Co Roscommon.

* = Member of National Cancer Forum

Appendix 2

List of Hospitals Visited

Health Board	Regional Director	Hospital Visited *
SEHB	Mr. Gordon Watson	Waterford Regional Hospital
SHB	Prof. W.O. Kirwan	Cork University Hospital
		South Infirmary, Cork
		Tralee General Hospital
WHB	Mr. Oliver McAnena	University Hospital Galway
		Castlebar General Hospital
MWHB	Dr. Tom Peirce	Limmerick Regional Hospital
NEHB	Mr. Finbar Lennon	Our Lady of Lourdes Hospital, Dorgheda
	Dr. Deborah Condell	Cavan/Monaghan Hospital, Cavan
NWHB	Mr. Kevin Moran	Sligo General Hospital
		Beaumont Hospital
EHB	Prof. David Bouchier-Hayes	Mater Misericordiae Hospital
		St Vincent's University Hospital
	Mr. John Hyland	Meath, Adelaide, NCH, Tallaght
	Mr. John Reynolds	St James' Hospital
		Mullingar General Hospital
MHB	Prof. Donal Hollywood	Tullamore General Hospital
		Portlaoise General Hospital

* Representation from other relevant hospitals in the Health Board was arranged through the Regional Directors of Cancer Services.

Appendix 3

Appendix 4

Training of General Surgeon with Special Interest in Breast Disease

Programme 1

The level of training which a general surgeon with sub-speciality interest will be expected to have achieved by the end of Higher Surgical Training

- General Surgeon with special interest in breast disease should spend one year in higher training working 50% of the time for a consultant with special interest in breast disease in a Breast Unit.
- Should spend additional 6 months full-time in a Reference Breast Unit.
- Should spend one month in a Medical Oncology service and one month in a Radiotherapy Unit.
- Should spend a period of one month in a specialist Palliative Care Unit.

Programme 2

That level of subspeciality training that will be required of a consultant who might practice almost exclusively in breast diseases.

- One year of training spending 50% of time with a consultant with a special interest in breast disease in a Breast Unit.
- One year of training in a Reference Breast Unit.
- Flexible year of research related to breast disease.
- At least one month each in Medical Oncology and Radiotherapy Unit.
- Time spent in Palliative Care also desirable.
- Should spend a period of one month in a specialist Palliative Care Unit.

Requirements for a Post Advertised for Consultant General Surgeon with a Special Interest in Breast Diseases

- Dedicated Breast Unit with full secretarial support.
- Two Breast Care Nurses
- Expert on-site breast radiology/ultrasound
- Expert on-site breast cytology/histopathology
- Radiation Oncologist and Medical Oncologist with special interest in breast cancer on-site or visiting at least twice a week
- Specialist palliative care service on site or attending the Unit at least twice a week
- Adequate access to breast reconstruction
- Counselling and psychological support systems in place
- Computer database with adequate secretarial and data management input
- Adequate inpatient beds and operating time to meet the clinical guidelines
- External Assessor should be a surgeon who specialises in breast disease