National Breast Screening Committee
First Report 1998
“By delivering a world class breast screening programme to Irish women, we aim to reduce mortality in women between 50 and 64 years by at least 20% within the decade"
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In presenting this First Report of the National Breast Screening Steering Committee of the National Breast Screening Programme, I am conscious of the significant advance that has been made by the establishment of the Programme and of the strides in cancer detection which are anticipated over the next decade on foot of its introduction.

The work already undertaken by the Steering Committee in identifying the statistical base on which its work will proceed, and in establishing the criteria and the methodology for its execution, conforms with the national cancer strategy and recognises the vital importance of the partners in what will be an integrated, multidisciplinary procedure: the Health Boards, General Practitioners, women's groups both nationally and locally, and voluntary organisations throughout the community. A high level of participation of women in the target age group is essential to the success of the programme, a central feature of the Programme will be a concentration on achieving such an uptake, local access to screening and meticulous follow-up. Thanks to careful preparatory work, once the screening process comes on-line, a quality service is assured which will provide Ireland with a woman-focussed caring environment in which the highest international standards will be observed.

Difficult decisions have had to be made already during the preparatory phase, in order to ensure that the best and most appropriate facilities are put in place. This has meant designating two assessment units for Phase 1 initially, rather than a greater number which had been originally envisaged. The justification for this decision is set out in detail in this Report, as are the steps which have been taken to put together an integrated multidisciplinary team to ensure that the woman is given the best possible treatment from the beginning of the screening process to its eventual outcome. Only in this way can we assure Irish women that our aim - a significant reduction in deaths from breast cancer - is achieved in the designated timescale.

I am pleased to thank the Steering Group and Quality Assurance Committee, for their commitment to the Programme. They have given substantially of their time and their individual and collective expertise and acumen has been invaluable in bringing the preparations to this critical juncture. Their continued advice will be essential to the National Breast Screening Board established by the Minister to give legal status to the Programme. We have been well served and supported by the Department of Health and Children, and to them and to the Minister I express our deepest thanks for their cooperation.

Finally, during the period under review Dr Jane Buttimer, formerly Deputy Chief Medical Officer at the Department of Health and Children, was appointed as Project Director of the National Breast Screening Programme. Her commitment and expertise are already manifest and I am confident that her enthusiasm and drive will lead the Programme into the new millennium bringing hope and a positive outcome for women with early breast cancer.

Dr Sheelagh Ryan,
Chairperson.
Summary & Conclusions

SUMMARY

This report:

• states the background to, and rationale for, the establishment of a national breast screening programme in Ireland;

• describes the work of the National Steering Committee since its appointment in March, 1997, in particular the administrative and medical arrangements which have been put in place;

• analyses the need for, and the role of, a multidisciplinary team of radiologist, surgeon, pathologist, radiographer, medical physicist, nurse, medical oncologist and radiotherapist;

• analyses the role of the primary care team in underpinning the quality of the service, maximising the uptake of invitations to screening, and providing appropriate information;

• details the proposed implementation of Phase 1 of the Programme and the strategies adopted to promote it;

• presents the text of a Women’s Charter stating the service aims of the NBSP.

CONCLUSIONS

The Report concludes that

• Ireland has the fourth highest incidence of breast cancer in the European Union;

• the NBSP has the potential to reduce mortality from breast cancer in women aged 50-64 by at least 20%;

• the NBSP requires a combination of static and mobile units in the three Health Board areas involved in Phase 1;

• the highest standards must be established and maintained in order to provide a screening service which will achieve its objectives of quality assurance.

ESTABLISHMENT

1. Commencement

A Steering Group and a Quality Assurance Committee were established by the Minister for Health and Children to give effect to the National Policy on Breast Cancer.

The period under review commenced in March 1997 and continued until October 1998.

2. Legal Entity

The National Breast Screening Programme has been established as a body corporate under Section 11 of the Health Act 1970. The establishment of the Board as a legal entity is critical in terms of developing a national identity, ensuring that it can be held accountable for its actions and to facilitate the employment of dedicated personnel for the Programme. The National Breast Screening Board (Establishment) Order, 1998 was published on 3 September 1998.

3. Constitution of the Board

The members of the Board are the eight Chief Executive Officers of the Health Boards and not more than four nominees, drawn from the disciplines involved in the early diagnosis and primary treatment of breast cancer. The Project Director is a member ex officio.
i. Background to the policy decision of the Department of Health and Children to introduce a National Breast Screening Programme.

Introduction

The incidence of breast cancer in Ireland is among the highest in Europe, with 1,563 new cases diagnosed in 1995. There are approximately 650 deaths annually in Ireland, representing the most common cause of cancer deaths among Irish women. From the age of 40 onwards, there is an increase in the incidence of breast cancer. Breast cancer is influenced by such factors as family history, reproductive cycle and diet. Many international surveys have confirmed the effectiveness of mammography screening in reducing the mortality of breast cancer.

In Ireland, a Pilot Programme of screening for breast cancer was established in 1989 by the Mater Foundation. It was one of six such pilot programmes, was part of a European initiative and received support from the ‘Europe Against Cancer’ programme. Known as the Eccles Breast Screening programme, its objectives were:

- to evaluate the impact of mammographic screening on morbidity and mortality from breast cancer in Irish women; and
- to address the feasibility and potential value of a national breast screening programme.

The Eccles Programme had a breast cancer detection rate of 7.9 per 1,000 screened in the first round. This indicates that the prevalence of breast cancer in the target population was among the highest in the EU. The Eccles Programme successfully demonstrated that a mammography screening programme is feasible in an Irish setting.

Definition of Screening

Screening for breast cancer means the investigation of women who are apparently well and who believe themselves to be free of serious breast disease, in order to detect those with unrecognised cancer. Screening can be undertaken either on an opportunistic basis or through organised programmes. Opportunistic screening may be of some value to the individual, but may be less efficient in identifying cancers in a given population, than an organised programme directed at a target group. International studies indicate that an organised screening programme could result in a reduction in mortality by 20% - 30% in the target age groups.

The relationship between the screening programme and the well woman is different from the relationship which exists between a symptomatic patient and the medical practitioner. Therefore, a screening programme inviting women for investigation is obliged to establish and maintain the highest possible standards at every stage of the process. Failure to achieve excellence or to audit performance rigorously will damage and seriously undermine the effectiveness of such a Programme.
Aim of an Organised Screening Programme

The primary aim of breast screening is to reduce mortality from breast cancer. A direct relationship exists between early diagnosis and long-term outcome. A reduction in mortality cannot be achieved unless diagnosis is followed by a satisfactory treatment. The Department of Health and Children has therefore decided that the National Breast Screening Programme ends not with the diagnosis of malignant disease, but at the end of adequate primary treatment.

For an organised screening programme to attain its potential, it must adhere to certain criteria regarding specification of objectives and protocols for follow-up of participants. Under the National Cancer Strategy, the following criteria for cancer screening programmes have been identified:

- Aims and objectives of screening programmes must be clearly stated and include targets for compliance and reduction of mortality.
- Steps to ensure a high compliance must be specified, so as to maximise the potential for reducing mortality.
- Protocols for screening, follow-up and referral must be devised and adhered to for quality assurance.
- Results must be fully documented so as to assist evaluation of the effectiveness of the screening programme.
- Design and evaluation of screening programmes must take account of client satisfaction with the programme itself, the communications process surrounding it and the psychological impact of false positive results.

Policy Decision of the Department of Health and Children

Following an independent evaluation of the epidemiological aspects of the pilot programme, in October 1995, the then Minister for Health announced his decision to proceed with a phased introduction of a National Breast Screening Programme (NBSP).

The decision to proceed on a phased basis was guided by the need for:

- the achievement of acceptable compliance levels among the target population;
- ongoing evaluation of the programme from a quality assurance perspective; and
- availability of the necessary clinical expertise to conduct the programme.

Phasing of Programme

Phase 1 of the National Breast Screening Programme will involve screening of women aged 50-64 years in the Eastern Health Board, North Eastern Health Board and the Midland Health Board areas. The target population is approximately 120,000 women and represents approximately 50% of the total national target population. Phases 2 and 3 of the Programme will involve its extension to the rest of the country and the Steering Committee has recommended that Phase 2 should follow Phase 1 as soon as is practicable. The Department of Health and Children will move towards Phase 2 once Phase 1 has proven satisfactory. It is vital that the phased introduction of the Programme should take cognisance of the critical success factors outlined above. Decisions taken in relation to the subsequent phases will be guided by the experience gained in putting in place Phase 1 of the Programme.

Establishment of a National Steering Committee

In March 1997, at the launch of the National Cancer Strategy Action Plan, the then Minister announced the establishment of a National Steering Committee, under the chairmanship of Dr. Sheelagh Ryan, CEO, Western Health Board, to oversee the implementation of Phase 1 of the Programme. The Steering Committee is broadly representative of all key disciplines involved in the screening process. Each of the Health Board areas in Phase 1 is also represented on the Committee (see Appendix A).

The terms of reference of the committee were as follows:

1. to oversee the development of a national Mammographic Screening Service, including recruitment, training and public relations;
2. to evaluate the effectiveness of the Mammographic Screening Service;
3. to develop clinical protocols with respect to mammographic screening;
4. to be responsible for quality assurance and to establish mechanisms to achieve this objective;
5. to report annually to the Minister for Health on the Mammographic Screening Programme;
6. to promote the Mammographic Screening Programme and to undertake research development in screening, especially with regard to emerging technology.

While the terms of reference of the Steering Committee are policy driven, it was necessary initially to make a significant number of executive decisions up to the appointment of the Project Director in May 1998.
Members of the National Breast Screening Steering Committee:
Dr Sheelagh Ryan (Chair), Dr Paddy Barrett, Dr Declan Bedford,
Prof Peter Daly, Prof Peter Dervan, Prof J T Ennis, Ms Angela Fitzgerald,
Mr Tom Gorey, Dr Davida de la Harpe, Ms Anne Marie Hoey (Sec),
Dr Mary Hynes, Ms Orla Laird, Ms Geraldine Luddy, Dr Brian O’Herlihy,
Prof Niall O’Higgins, Prof Philip Walton
(not in picture: Dr Velma Harkins, Prof Donal MacErlaine)
Consultation Process

A sub-group of the Steering Committee held meetings with the Dublin Voluntary Hospitals (see Appendix B for list of those who attended from the hospitals), the North Eastern Health Board, the Midland Health Board, Faculty of Radiology, the Royal College of Surgeons of Ireland and Irish College of General Practitioners, to discuss the model of screening and its implications and to explore how concerns and expectations could be addressed within the Programme.

International Conference

A major conference was held in the Mont Clare Hotel, Dublin on 10 and 11 December 1997, bringing together experts in disciplines involved in breast cancer screening. The conference was aimed at sharing screening experiences, and at providing information on screening for all those who in the future would be involved in the NBSP. Key personnel in the health boards and major voluntary hospitals attended, and feedback from the meeting was extremely positive. The speakers at the conference were experts in the area of breast screening from both Ireland and Europe.

National Cancer Forum

In addition, a series of consultations took place with Professor J Fennelly, Chairperson of the National Cancer Forum and special Advisor on Cancer Services. A meeting between the Steering Committee and the Regional Cancer Directors took place in April 1998. Further links with the National Cancer Forum are now being developed.

Health Boards

The Chief Executive Officers of the three Health Boards involved in Phase 1 are among the members of the National Breast Screening Board. Since the inception of the Programme, the Health Boards have also been represented on the Steering Committee through their Departments of Public Health. The continuous consultation with the Health Boards is an important element in the strategy. Liaising and working effectively with the relevant personnel in each of the Health Boards is critical to the success of the Programme.

With the assistance of the Health Boards’ personnel, a strategy will be developed which will include a plan for the local promotion of the Programme and the timetable for, and location of, the mobile units.

Visitation to Centres of Excellence

In identifying the policy issues and key success factors for an Irish programme, members of the Steering Committee visited centres of excellence in Sweden, the Netherlands and the UK, with established screening programmes. Discussions at these centres with experts in each of the disciplines were comprehensive and forthright and presentations on each study visit were made on return to the full Steering Committee to facilitate comparative debate.
2. Policy issues and parameters for the National Breast Screening Programme

Age Limits

For the introduction of breast cancer screening in Ireland, the Department of Health and Children has determined that the Programme should initially involve women in the 50-64 year age group. Screening for breast cancer will not result immediately in a lower mortality from breast cancer. The impact on mortality will be detectable only after a minimum of 10 years' follow-up of the entire screening cohort. At this stage, the screening age is limited to women between 50 and 64 years, but it is anticipated that, when the Programme is sufficiently developed and it is assured that a quality service can be delivered at a national level, consideration would be given to including older women and continuing the screening of women already in the Programme who have reached 65 years. Screening by mammography under the age of 50 remains unproven in terms of reduction in mortality.

Expected Cancer Detection Rate

Based on the experience of the Eccles Pilot Programme, the number of cancers expected will be approximately 7 - 8 per 1,000 women screened in the prevalent round (first round). This figure is currently being reviewed in the light of the National Cancer Registry data.

The eligible population for screening - women aged 50-64 years - will increase steadily over the coming years:

- by year 2001 - 19% increase
- by year 2006 - 38% increase (cumulative)
- by year 2011 - 56% increase (cumulative)
Screening Parameters

**SCREENING INTERVAL**
When breast screening was introduced in the United Kingdom, it offered mammograms. However, a number of cancers appearing in women between screens (interval cancers) is still possible, even with a two year screening interval. In Ireland, it is proposed to screen women every two years to reduce the occurrence of interval cancers. This is in line with practices in the Netherlands and Sweden.

**DOUBLE READING**
In order to reduce the number of cancers which might go undetected, all screening mammograms will be reviewed independently by two Consultant Radiologists.

**TWO VIEW MAMMOGRAPHY**
It is estimated that two-view mammography, while increasing the overall costs compared with single view mammography, is cost-effective.

**COMPLIANCE LEVELS**
The experience of other screening programmes (UK, Sweden and the Netherlands) indicates that a compliance level of at least 70% attendance must be achieved if the optimal targets for reductions in mortality are to be met.

**RECALL RATES**
A further measure of the quality of the Programme is the recall rate for further investigations should be less than 7.5% in the prevalent screening round and less than 5% in subsequent screening rounds.

**ASSESSMENT BY MULTIDISCIPLINARY TEAM**
Best international practice requires that the assessment of screen-detected abnormalities is carried out by a skilled multidisciplinary team where the volume of work is sufficient to maintain the expertise of all disciplines. The teams should consist of doctors appropriately trained and experienced in the specialties of radiology, surgery and pathology, supported by radiographers and nurses.

**INTERVAL CANCERS**
Even with a two year screening interval, it is still possible for interval cancers to occur, however, and the Programme aims to minimise this.

In order to be comprehensive, it is essential that all such interval cancers are recorded. The methodology of collecting and recording such information will be an integral part of the programme and is currently being developed. Guidelines developed by the Irish Association of Surgical Oncologists state that any woman requiring breast surgery should have a pre-operative mammogram. The Steering Committee has endorsed this recommendation as good practice standard for women who present with symptomatic problems.

**OUTCOMES**
It is a fact that, even with the highest standards and most exacting requirements and audit of equipment and personnel (radiologist, surgeon, histopathologist, radiographer, physicist and nurse), some cancers may not be detected. In addition, even for some apparently early cancers, patients may fail to respond to treatment and the disease may progress. Notwithstanding, screening for breast cancer, if accurately and assiduously carried out, will prevent premature mortality and it is expected to provide a model of excellence in Irish medicine upon which screening, assessment and treatment of other conditions can be based.
3. Epidemiology of Breast Cancer

Introduction

To understand the background and rationale for the introduction of a National Breast Screening Programme in Ireland, it is necessary to examine the epidemiology of breast cancer both in Ireland and in relation to its occurrence in other countries.

Breast cancer mortality:

Examination of the causes of death in Ireland (Fig.1) reveals that in 1995 approximately 24% of all deaths were due to cancer (7,454 / 31,656). Data from the National Cancer Registry (1) indicate that breast cancer accounted for 649 deaths in 1995 or 2% of all deaths. Furthermore, breast cancer accounted for almost 20% of cancer deaths in women (642 / 3,414). Thus it is currently the most common cause of death due to cancer in women in Ireland.

International comparisons of death from breast cancer reveal wide variation in the death rates, varying from approximately 9/100,000 in Japan to more than 40/100,000 in Denmark (Fig.2). Ireland ranks 4th highest in this comparison alongside other Northern European countries such as Denmark, UK, and the Netherlands. The age-standardised rate (note a) in Ireland is higher than that in the United States and Canada and much higher than comparable rates in Southern European countries, in Italy, France, Portugal, Spain and Greece. The Nordic countries (Norway, Sweden and Finland) have a relatively low death rate from breast cancer. Lowest of all are developing countries and Eastern European countries.

Breast cancer incidence:

Data from the National Cancer Registry reveal that there were 1,563 new cases of breast cancer in Ireland in 1995 of which 1,555 were female (1). Fig.3 shows the variation in the rate of new breast cancers by age category (age-specific incidence rate) (note b). This shows that breast cancer occurs infrequently in women under 40 years and that there is a steady increase in incidence through the 40 and 50 year age groups. The largest number of cases (n = 215 or 14% of the total) occurred in women aged 50-54. The age-specific incidence peaked at age 55-59 years and rose again after 70 years to a second maximum in the oldest age group. One-third of all new cases occurred in the age range 50-64 years which is the target age group for the National Breast Screening Programme (1).

The data from the National Cancer Registry for 1995 indicate that just 4% of breast cancers were insitu cancers, i.e. non-invasive cancers. This reflects what would be expected in the absence of screening among breast cancer patients who present with symptoms. This proportion would be
expected to change quite dramatically with the onset of breast cancer screening.

These age-specific incidence data can be used to estimate the risk of developing breast cancer at specified ages. These data are shown in Table 1. The risk increases from approximately 1 in 1,000 at age 30, to 1 in 100 at age 40, to 1 in 25 by age 60, with an accumulated risk of developing breast cancer by the age of 75 (cumulative risk) (note c) of 1 in 12.

Risk factors for breast cancer:

Breast cancer incidence has been shown to be associated with hereditary factors such as: (a) family history of breast cancer, and (b) specific, but rare, genetic abnormalities. It is also associated with aspects of reproductive history such as the duration of uninterrupted reproductive life, i.e. a combination of early onset of reproductive life (early menarche), late menopause and never having been pregnant. The possible association of breast cancer with use of hormones, such as oral contraceptive therapy or hormone replacement therapy has been extensively investigated. There may also be an association with environmental factors such as diet and alcohol intake. In the absence of a known preventable cause or causes for breast cancer, early detection through screening provides the next best opportunity for improved prognosis and outcome.

Effectiveness of mammographic screening:

Mammographic screening for breast cancer has been investigated more thoroughly than screening for any other condition. Systematic evaluations began in 1963 with the Health Insurance Plan randomised controlled trial in New York (2). This was followed by case-control studies in Utrecht (3) and Nijmegen (4) in the Netherlands and further randomised controlled studies in Sweden (5) and the UK (6). Table 2 summarises the estimates of mortality reduction and the levels of

### Notes:

1. Age-standardised rate: age-specific incidence rates from each individual country standardised to a selected population as standard (“New” European 1990)
2. Age-specific incidence rate: number of cases in a specified age group / population in that age group.
3. Cumulative risk: the accumulated risk over a life-time (to 75 years) of developing breast cancer.
More recently, combined data from the randomised controlled trials of mammographic screening that have been carried out (meta-analyses) indicate a significant benefit in terms of mortality reduction of about 25% for screened women aged 50-74 years at entry (12,13). For logistic reasons, however, most screening programmes are set up as service programmes and not as randomised controlled trials or case-control studies of mammography. While it may be tempting to predict that a programme can achieve a reduction in mortality of the order of the highest estimates quoted above, an important recent study examining non-randomised general population screening suggests that the impact of mammography on mortality from breast cancer in the non-randomised situation is of the order of 20%(14). This study also points out, however, that the better organised the population programme, the more reliable will be the estimates of mortality reduction. Based, therefore, on this study, and on the meta-analyses referred to above, a cautious estimate of a 20-25% reduction in mortality from breast cancer in Irish women is advised.

**TABLE 1: Breast Cancer in Ireland**

<table>
<thead>
<tr>
<th>AGE GROUP</th>
<th>Approximate Risk</th>
</tr>
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<tbody>
<tr>
<td>30-34</td>
<td>1 in 1,000</td>
</tr>
<tr>
<td>35-39</td>
<td>1 in 450</td>
</tr>
<tr>
<td>40-44</td>
<td>1 in 100</td>
</tr>
<tr>
<td>45-49</td>
<td>1 in 50</td>
</tr>
<tr>
<td>50-54</td>
<td>1 in 40</td>
</tr>
<tr>
<td>55-59</td>
<td>1 in 30</td>
</tr>
<tr>
<td>60-64</td>
<td>1 in 25</td>
</tr>
<tr>
<td>65-69</td>
<td>1 in 20</td>
</tr>
<tr>
<td>70-74</td>
<td>1 in 14</td>
</tr>
<tr>
<td>75-79</td>
<td>1 in 12</td>
</tr>
</tbody>
</table>

Cumulative Risk at Specific Ages

Statistical significance associated with those estimates. Estimates of reduction in mortality that have been achieved to date in randomised controlled trials vary from 4%(7) to 30% (3). Estimates of benefit from case control studies could be as high as 52% (4) to 70%(3). Thus, several studies, carried out in different countries, over different time periods, using differing epidemiological approaches, have demonstrated a beneficial effect of mammographic screening on mortality from breast cancer screening (2-11). While not all studies achieved a statistically significant reduction in mortality, it is nonetheless noteworthy that the direction of a change in mortality in all studies was downwards.

**TABLE 2: Estimates of Mortality Reduction in Breast Cancer: Evidence from International Studies**

<table>
<thead>
<tr>
<th>STUDY</th>
<th>YEAR</th>
<th>MORTALITY</th>
<th>SIGNIFICANCE</th>
</tr>
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<tbody>
<tr>
<td>HIP</td>
<td>1963</td>
<td>14%</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>BCDDP</td>
<td>1973</td>
<td>12%</td>
<td>NS</td>
</tr>
<tr>
<td>Utrecht</td>
<td>1974</td>
<td>6%</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Nijmegen</td>
<td>1975</td>
<td>7%</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Malmo</td>
<td>1976</td>
<td>5%</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Two Counties</td>
<td>1977</td>
<td>30%</td>
<td>NS</td>
</tr>
<tr>
<td>Canada</td>
<td>1980</td>
<td>18%</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>UK</td>
<td>1981</td>
<td>17%</td>
<td>NS</td>
</tr>
<tr>
<td>Edinburgh</td>
<td>1981</td>
<td>17%</td>
<td>NS</td>
</tr>
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**References:**


4. Progress Report of the National Steering Committee

Introduction
The National Steering Committee had its first meeting on 17 April 1997 and has since met on a monthly basis. The goal and objectives of the Programme were defined as follows:

Goal
By delivering a world class breast screening programme to Irish women, the NBSP aims to reduce mortality in the cohort of screened women (aged 50 to 64 years) by at least 20% within the decade.

Objectives
• to optimise cancer detection;
• to identify and invite eligible women for mammography screening;
• to maximise compliance in the eligible population;
• to ensure that mammography of the highest possible standard is achieved, and that the films are read by personnel with proper training and proven skills;
• to provide prompt and effective further investigation and treatment where indicated;
• to minimise the adverse effects of screening;
• to perform regular audit of the activities of the programme and to provide appropriate feedback;
• to provide a cost-effective service;

Priorities
In order to deliver the goal and objectives, the following issues were identified as priorities by the Steering Committee:

• the development of an appropriate model of delivery for the programme;
• the establishment of protocols and standards for the NBSP;
• the establishment of a Population Register;
• the development of clinical and administrative databases to facilitate call/recall of women and clinical evaluation of the programme;
• the identification of the key resource requirements for the Programme;
• the appointment of the Project Director (May 1998);
• outlining a realistic and effective time frame for the introduction of the NBSP.

Dr Jane Buttimer
Project Director,
National Breast Screening Programme

To provide efficient, sympathetic and effective breast screening to women in the catchment area. It is essential that women find the experience acceptable, so that compliance rates are maximised.
National Quality Assurance Committee

The National Quality Assurance Committee was set up under the Chairmanship of Professor J T Ennis by the then Minister for Health in March 1997. The Committee has been charged with the development of QA guidelines, and is in the process of drawing up detailed guidelines for each discipline. The draft guidelines are nearing completion and will be available to the Steering Committee very shortly.

Model of Screening

In the initial deliberations of the Steering Committee, a number of options were considered as to the best model of screening to apply in the Irish context. These options ranged from having a single national assessment and administration centre supported by mobile outreach, to having several locally based units. The final decision recommended to the Department of Health and Children was two units for Phase 1. This emerged after much consultation with experts in the field and visits to centres of excellence in the UK, the Netherlands and Sweden where National Programmes are well established. The Steering Committee also reviewed the literature and had regard to enquiries into those screening programmes which encountered difficulties and problems, mainly from a Quality Assurance perspective, and also having regard to the experience in the Eccles Programme. All advice pointed to the need for:

- the concentration of expertise in centres of excellence;
- achievement of a minimum throughput to maintain expertise;
- multidisciplinary assessment of screen-detected lesions.

These factors, coupled with the recognition that screening and the management of the screen-detected lesions in a 'healthy' group was different to symptomatic disease, meant that quality assurance had to be the guiding principle.

The decision of the Steering Committee was unanimous in this recommendation.

Location

Following this, in November 1997, the Committee decided that the two units should be located in publicly accessible sites on or near the campuses of the Mater Misericordiae Hospital (Eccles Unit) and St. Vincent's Hospital (Merrion Unit).

Each unit will comprise a screening facility which will also serve as the centre for multidisciplinary assessment of screen-detected lesions, and its mobile unit to bring the screening services as near as possible to women throughout the three health boards. Each mobile unit will be linked with one of the central units.

The decision of the Committee in relation to the precise locations for the two units was based on the established reputations and expertise of the two hospitals in the diagnosis and treatment of symptomatic breast disease. Arising from its involvement in the Pilot Screening Programme, the Mater Misericordiae Hospital has been identified by EUREF (European Network of Reference Centres) as a centre of excellence. Similarly, St. Vincent's Hospital has the largest established symptomatic breast clinic in the country, where approximately 180 new cases are diagnosed each year. The epidemiological evidence available shows that these two centres have the highest throughput levels in the early detection and treatment of symptomatic breast disease.

Radiological Criteria

MINIMUM THROUGHPUT LEVELS

In the original 1986 Forrest Report (which laid the basis for policy on breast screening in the UK), the reading of a minimum of 5,000 mammograms per radiologist was suggested, to ensure quality and maintain expertise. Best practice now recommended by EUREF (European Network of Reference Centres) is up to 10,000 mammograms per radiologist (one mammographic examination is equivalent to one screened patient). The Steering Committee took note of this best practice. While the preferred model of screening was initially to establish as many local/regional units as possible, when the quality assurance parameters were applied to the screening population in Phase 1, only 2 units could be justified.

The rational for this is as follows: with two units, the actual number of women to be screened (based on 75% uptake in target population) would be 23,000 women per unit per year. In line with this, each unit...
would require two Whole Time Equivalent (WTE) radiologists. The preferred configuration is three people to meet the minimum throughput requirements and to allow for double reading at all times and multidisciplinary assessment on a continuous basis. With 6 sessions from each radiologist, this provides for 7,500-8,000 primary readings; double readings bring this to 15,000 -16,000 per radiologist per year.

The competence of the radiologist is crucial in the detection of screened cancers. The more mammograms one reads, the more proficient one becomes at detecting small cancers. Furthermore, this also results in a lower recall rate of women, which in itself is a further quality standard. Accordingly, the Steering Committee decided to set up its standards in line with international best practice.

Specialisation in Breast Imaging has long been a major specialty for radiologists in Sweden and the United States where one-year Fellowship Programmes are available. The Faculty of Radiologists in RCSI has recognised the importance of specialisation in Breast Imaging. More recently, the Education Sub-Committee of the Royal College of Radiologists (London) has recommended a minimum of one-year training in Breast Imaging for those radiologists interested in being involved in screening mammography.

The importance of ancillary diagnostic techniques such as ultrasound, colour doppler, scintimammography, magnetic resonance imaging and image guided biopsy has created a sub-specialty interest of considerable importance. There is substantial evidence that this challenging specialty attracts highly trained diagnostic radiologists, who are immensely challenged by the goal of diagnosing lesions less than 5mm in diameter. The scope for research is very significant, given developments in digital mammography.

**Surgical Criteria**

The Steering Committee accepts in principle the British Association of Surgical Oncologists (BASO) recommendations.

In line with these, the Steering Committee examined the international standards regarding the minimum throughput levels in surgery. For symptomatic breast disease, it is recommended that breast surgeons perform a minimum of between 30-50 procedures per annum.

In relation to breast surgery for screen-detected lesions, the BASO recommendations for minimum throughput levels have been applied. For surgical centres with training and quality assurance functions, minimum throughput levels of 100 procedures per annum are required.

**Assessment**

The essential aspect of assessment is the expertise and experience of the multidisciplinary team being available to each woman. The Steering Committee considers that it is vital to:

- ensure that a high quality service is established and maintained;
- ensure that the number of recalls and invasive procedures are kept to a minimum
- ensure that a consistent approach to assessment is provided;
- ensure that cancer detection is maximised. The assessment of screen-detected abnormalities in the breast is a specialised field. Most of the abnormalities detected on the mammogram are impalpable. This means that specialised techniques are required to locate the abnormalities in the breast. The aim of the assessment is to either make or exclude the diagnosis of breast cancer, using techniques that are the least invasive possible;

- allow comprehensive evaluation of the programme and ensure that, as far as possible, interval cancers are included in the evaluation;
- ensure constant improvement of the quality of the programme.

This policy is supported by the research evidence on improving outcomes in breast cancer, which shows that multidisciplinary assessment following strict protocols gives a better outcome.

The individual circumstances and preferences of women should always be facilitated, in the context of an informed choice.

**Quality Management**

Quality management will apply to all aspects of the programme. Quality assurance (QA - i.e. the prevention of quality problems through planned and systematic activities including documentation, training, and reviewing the process) and quality control (i.e. controlling and monitoring the process to produce quality products and services) are an integral part of this. All elements of the programme must be an integral part of the quality dimension. These include:

- Population Register
- Administration of the Programme
- Radiology
- Radiography
- Medical Physics
- Surgery
- Pathology
- Nursing
- Epidemiology
In order to invite women between the ages of 50 and 64 years for breast screening an accurate and comprehensive population register is required. The Health (Provision of Information) Act, 1997 facilitated the compilation of a National Population Register from a number of sources for the purpose of screening programmes. Four key agencies were identified for this purpose - General Medical Services, Voluntary Health Insurance, British Provident United Association (BUPA) and the Department of Social, Community and Family Affairs - and they have all confirmed their co-operation and support in the compilation and on-going maintenance of the register. The data received required further work, e.g. standardising the addresses, deduplicating the data and adding District Electoral Division codes to the data. A register is now in place (September 1998), which is being validated against the census data. Initial assessment indicates a high level of identification of eligible women, and this may minimise the need to seek other sources of data. However, as it is unlikely to include 100% of the population, self-registration will be an important element of the Programme.

A comprehensive information system is fundamental to the quality management, quality assurance and quality control of the breast screening programme. A systems analyst, a business analyst and an epidemiologist have been employed on a short-term consultancy basis to specify or ‘tailor-make’ the IT system appropriate for use in the Programme. Extensive consultation took place with key representatives of potential users of the system, in the overall design of the best model. The development of a custom made system was deemed to be essential and in recognition that this could take some time, due to complexity and EU procurement requirements, it was decided to proceed with an interim IT system.

The interim system will allow the bulk scheduling of appointments, the recording of attenders and non-attenders, the processing of test results and the production of result letters for the client and the General Practitioner. However, it does not allow the recording of any further quality assurance data including the follow-up treatment. It supports only the administrative aspects of the programme. This system is now in place. The data required for the quality components will be collected manually during the life of the interim system, and incorporated into the longer term solution in due course. The specification for this went to tender in October 1998.

During 1997, an ad-hoc Manpower Planning Group (a sub-group of the National Steering Committee) was set up to identify the key manpower requirements for Phase 1 of the Programme. Its recommendations are based on European Quality Assurance guidelines for mammography (i.e. minimum throughput levels, requirements for cross-over, double-reading, etcetera) and also draw on the experience of the Eccles Pilot Programme. A review of the manpower infrastructure is currently taking place and being benchmarked against Breast Test Wales.

The radiology manpower requirements for Phase 1 are four whole time equivalents (WTE). These are determined primarily by the minimum throughput of reading to maintain expertise, to allow for double-reading and follow-up assessment and to facilitate multidisciplinary assessment of screen-detected lesions. These quality parameters have been established in screening programmes elsewhere (UK, Sweden and the Netherlands). The following is the consultant Radiology manpower approved by An Comhairle for Phase 1:

**ECCLES UNIT**

Post A: 8/3 sessions - NBSP/ Mater Misericordiae Hospital
Post B: 6/5 sessions - NBSP/ Mater Misericordiae Hospital
Post C: 6/5 sessions - NBSP/ Mater Misericordiae Hospital

**MERRION UNIT**

Post A: 8/3 sessions - NBSP/ St. Vincent’s Hospital
Post B: 6/5 sessions - NBSP/ St. Colmcille’s Hospital
Post C: 6/5 sessions - NBSP/ St. Michael’s Hospital
The manpower requirements to perform surgical follow-up of screen-detected lesions for Phase 1 of the Programme have been assessed as 1 WTE per unit, involving 2 surgeons (for continuity of triple assessment and to ensure that suspicious lesions are investigated within specified times, as determined by quality assurance protocols). The surgical workload is based on the following data:

- Recall rate 5 out of 1000 recalls per year: 144 cancers per unit per year.
- Recall rate 7.5 out of 1000 recalls per year: 180 cancers per unit per year.
- Cancer detection rate: 7 cancers per 1000 screened.
- 8 cancers per 1000 screened.
- Biopsy ratio (benign/malignant): 1:1 = 288-360 biopsies per unit per year; 2:1 = 432-540 biopsies per unit per year.

As with radiology, the surgical requirements for Phase 1 are based on the need to maintain expertise in the management of screen-detected lesions, to facilitate multidisciplinary assessment/case conferencing and ensure a consultant delivered service. The surgical sessions dedicated to the Programme are for this purpose only. The other sessions, i.e. to each hospital, are for general surgical work which may or may not include surgery associated with symptomatic breast disease.

The structuring of the surgical sessions with the majority commitment to the programme is deemed essential for the success of the National Programme. These sessions of course will apply at the base hospitals, i.e. Mater Misericordiae Hospital and St. Vincent’s Hospital.

The following is the Consultant Surgical manpower approved by An Comhairle for Phase 1:

**ECCLES UNIT**

Post A: 6/5 sessions - NBSP Mater Misericordiae Hospital

**MERRION UNIT**

Post A: 6/3/2 sessions - NBSP St. Vincent’s Hospital/UCD

* Currently being reviewed in the light of the National Cancer Registry data.

**PATHOLOGY REQUIREMENTS**

The pathology requirements are based on the expected number of specimens to emerge from the screening population. It is estimated that for Phase 1 the equivalent of one WTE Histopathologist is required for each unit. It is recommended that these would be on a phased basis commencing with 6 Histopathologist sessions per unit.

The following is the Consultant Pathologist manpower approved by An Comhairle for Phase 1:

**ECCLES UNIT**

Post A: 6/5 sessions - NBSP Mater Misericordiae Hospital

**MERRION UNIT**

Post A: 6/3/2 sessions - NBSP St. Vincent’s Hospital

The Consultant requirements at each unit for Phase 1 are generally consistent; however, some variation on sessional input in the posts is explained by the existing skills base, the re-structuring of posts in the hospitals and the geographic catchment area to be served by each unit/hospital.

The idea of having a lead consultant in each specialty - and at each unit - is for him/her to take overall responsibility for Quality Assurance in that discipline for each unit. The structuring of the posts, with a major commitment to the Programme and a general commitment to designated hospitals, is designed to attract the best candidate.

In relation to the lead Radiologist post, the Committee is satisfied that the minimum commitment should not fall below 8 sessions, to allow for the Quality Assurance and management functions to be carried out at each site.

Finally, while consultants will be working in assessment centres which are ‘high street’ locations (Eccles Unit and Merrion Unit), these units will be on the campuses of major teaching hospitals to which consultants will have joint appointments and the back-up of collegiate support.
Equipment Requirements

During 1997, the dedicated equipment requirements for Phase 1 were identified by the Steering Committee and a sum of £810,000 from the 1997 allocation for the NBSP was used to procure a number of key items for the two units at Eccles and Merrion. The specifications for the two sites are identical, thus ensuring that an equivalent standard will be available at both units. The mobile unit from the Eccles Pilot Programme has been refurbished. An additional mobile for the Merrion Unit has been requested. An assessment of need for other equipment is currently being undertaken.

Accommodation

Proposals have been received from the Mater Misericordiae and St. Vincent’s Hospitals for the development of suitable accommodation for the Screening Programme. Having regard to the fact that the Programme is inviting apparently well women for screening, every effort is being made to create a non-clinical ‘high-street’ type environment in the screening/assessment units. The screening and assessment will be done in the static units in the first instance. The funding arrangements for the two refurbishment programmes have been finalised with the respective hospitals, and it is expected that the necessary works for the temporary accommodation will be completed in January 1999, to facilitate the commencement of Phase 1. The permanent accommodation for the Eccles Unit should be complete in Autumn 1999 and that for the Merrion Unit in March 2000.

Other Resource Issues

To facilitate timely treatment of screen-detected lesions, the operating theatre requirements will be at least one all-day operating theatre per week per static unit. A number of inpatient hospital beds (4 to 6) per static unit will be required for the treatment of these patients. These beds will range from one-day to seven-day beds.
5. Role of the Multidisciplinary Team

Role of Radiologist

Mammographic screening for breast cancer is a radiological procedure, and the success of the programme depends upon the expertise and commitment of the radiologists employed within the service. The radiologists' judgement, in association with the Quality Assurance Scheme, is the ultimate criterion for the delivery of mammographic quality.

The Steering Committee endorses the recommendations with regard to the minimum professionally accepted standards for training, as detailed by the Royal College of Radiologists, and will expect all radiologists to be able to provide evidence that such training has been satisfactorily undertaken, and adhere to the professionally set standards.

Radiologists involved within the screening programme will be additionally expected to:

- participate at all levels within the Quality Assurance Programme;
- be a constituent part of the assessment team;
- discharge where appropriate, in conjunction with the Project Director of the Screening Service, delegated management responsibilities;
- take part in medical and clinical audit with professional colleagues;
- maintain minimum standards and progress towards excellence;
- be aware of developments in breast screening and the diagnosis of symptomatic breast disease.

Role of the Surgeon

The Steering Committee accepted in principle the BASO recommendations concerning the role of surgeons in breast cancer screening, subsequently supported by the Irish Association of Surgical Oncologists. In the light of these principles the following has been adopted:

- specified surgeons should be involved in the screening process, rather than having all surgeons within a district playing such a role;
- the lead surgeon should have a special interest in breast surgery as prescribed by An Comhairle;
- other selected surgeons should be formally trained in practices relating to breast cancer screening;
- attendance at assessment sessions, to take part in the decisions regarding the management of these women and to discuss issues with the women involved, would be required;
- the same surgeon should, whenever possible, be involved in each case through to diagnosis including, where appropriate, open excision biopsy/surgical treatment;
- the surgeon should participate at all levels within the Quality Assurance Programme.
Role of the Pathologist

The role of the pathologist in the breast screening programme requires a close working relationship with the surgeon and radiologist. The amount and frequency with which one needs to consult the other make it desirable that they are based at the same hospital.

The Steering Committee accepted the many compelling reasons why a lead pathologist should be responsible for the results produced by each screening unit:

- the highest quality of specimen examination, reporting and recording of results is required;
- specimens sent as a result of the breast screening service require meticulous examination technique;
- the lesions detected by the screening service are different from the normal range of breast pathology, with a much larger number of difficult and 'borderline' lesions;
- a high level of expertise in breast fine needle aspiration cytology is desirable.

The Steering Committee concluded that the pathologist should be based at the same hospital as the screening surgeon and radiologist for regular contact, and that sessions should be allocated to a single pathologist in each unit where practicable.

Role of the Radiographer

The role of the radiographer is central to the success of the screening programme. A woman’s first contact with the screening service is likely to be with a radiographer and for ninety five percent of the women attending, the radiographer may be the only contact. The Steering Committee endorses the recommendations of the College of Radiographers with regard to the training and role of the radiographers in breast screening. All radiographers employed in the Programme must attain their Certificate of Competence in Mammography. Training for this is provided by the NBSP primarily utilising resources available to the Programme within Ireland, but also using centres in other countries.

Radiographers working in the breast screening programme must possess an exceptional ability to take on responsibilities without direct supervision. Working on the mobile unit demands flexibility and the ability to carry through the complete examination at one visit and necessitates an unusual degree of dedication.

In addition it is expected that radiographers will:

- maintain consistently high standards of mammography at all times as laid down in the Quality Assurance Manual and be an active member of the quality control team;
- be able to reassure, advise and provide proper care and attention for all women who are being examined during both the preliminary screening and the assessment activities;
- carry out the film processing to the required standard and display the films for reading;
- contribute to the management of the screening service where appropriate and liaise with all other staff of the screening service and with members of the community so as to achieve the standards set;
- contribute to clinical audit and peer review.

Role of the Medical Physicist

A very important requirement for a breast screening programme is that quality be always maintained to a very high standard. This is one of the roles of the physicist who, together with the radiographer, ensures that all the many parameters are correct initially and are consistently maintained. Total image quality is dependent on exposure conditions, film processing chemistry and film viewing facilities. The Medical Physicist must establish the quality control programme and make sure that it is maintained.

Other duties of the Medical Physicist include:

- consultation on equipment purchases;
- design of facilities to ensure good radiation safety practices;
- instruction of staff on radiation safety;
- liaising with the Radiological Protection Institute of Ireland on licensing matters;
- acting as Radiation Protection Officer for the Programme;
- undertaking and assisting in research programmes;
- purchasing, maintaining and ensuring the calibration of monitoring equipment.
Role of Nurse

The Steering Group also discussed the role of the nurse in assessment. The Breast Care Nurse has a vital role to play as part of the multidisciplinary approach to the management of Breast Cancer, supporting women from recall to assessment, through to diagnosis and recovery. Her role encompasses:

- the Clinical dimension, Counselling, Patient Advocacy, Education, Pre- and Post-operative Care and Research.

The nurse is a member of the multidisciplinary team in the assessment/screening clinic. Her primary role is to provide information and support for the women attending. When women are recalled for assessment they are usually very worried or frightened, they often have no symptoms and their disbelief is frequently obvious. The Breast Care Nurse working in a screening situation is available to answer the woman's questions and gives the woman the opportunity to express her anxieties and feelings. She is also available on telephone if the woman wishes to seek further information and is ever supportive during this anxious time.

Depending on the outcome of assessment, the woman may be referred for treatment and care to the General Hosptial. It is important that there is consistency of counselling and advice in both the assessment centre and the acute treatment centre, even though the emphasis will be different. To ensure continuity of support to the woman, a sound working relationship should be established between the nurse specialists in both areas.

Other Professions

The Cancer Strategy emphasises the multidisciplinary approach for quality standards of care of cancer patients. While the radiotherapist and oncologist are not part of the multidisciplinary team in the screening centre, they have an important role to play in the ongoing care of cancer patients. The following outlines this role:

ROLE OF RADIOThERAPISt

Application of screening mammography, and the wider use of diagnostic mammography, will inevitably lead to an increase in the number of breast cancer cases diagnosed. Caring for such women will also add to the workload of the radiotherapist/clinical oncologist. With earlier detection of smaller cancers and wider use of breast conservation surgery, there will be a requirement for post-operative radiation treatment to the conserved breast and in some cases of total mastectomy. The need for radiation therapy will almost equate with the level of surgical care in the context of screen-detected invasive cancer. The treatment of invasive and pre-invasive cancer detected by screening mammography and the additional needs of these patients, will need to be considered carefully in the Planning of radiation therapy services.

ROLE OF THE MEDICAL ONCOLOGIST

On first inspection, it would appear that the role of the medical oncologist should lessen with the application of screening methodologies. This is not the case, however. In the prevalent round of screening it is likely that a significant number of the invasive cancers detected will require adjuvant medical therapies. In subsequent screening rounds, other issues are likely to arise such as the use and benefits of chemo-prevention. In randomised trials of adjuvant therapy, tamoxifen was shown to produce a 40% reduction in the risk of contralateral breast cancer and, based on this, a recent preliminary report on the use of this agent in women deemed to be at high risk of developing breast cancer has given positive results. Provided this is confirmed and a satisfactory risk/benefit ratio exists, a greater use of this approach will become the norm in clinical practice. Patient follow-up after cancer diagnosis is an area of some controversy in terms of need, appropriateness, protocols and resource application. It is unlikely that women who have entered a screening programme and who have had a cancer diagnosis will be content with less than a structured programme of follow-up. The surgeon, radiotherapist and medical oncologist will be central to meeting this need.
Care Team

The Primary Care Team

GENERAL PRACTITIONERS AND PRACTICE NURSES
The NBSP is an important new challenge for the Primary Care Team. For the programme to be successful, the commitment of the general practitioner and the practice nurses is vital. The general practitioner and his or her team can improve the quality of the programme, increase uptake and provide information, support and counselling for women screened. It would also be very helpful if the primary care team were to provide feedback to the programme.

Information and advice will be needed, not only by those attending for screening but also by those who choose not to participate. The uptake of mammography among the target population may be the single most important determinant in the effectiveness of the Programme, and the role of the GP in this cannot be overestimated. In the USA it has been shown that the doctor can have the greatest effect on lower socio-economic groups, while letters from GPs in the UK have been crucial in persuading first-time non-attenders to comply.

ADMINISTRATIVE PROBLEMS
Nevertheless, there are inbuilt administrative problems in Ireland which militate against the effectiveness of the GP. In many other countries each citizen has a national identity number. General practitioners have comprehensive age:sex registers which can be used to identify and invite eligible persons for screening. At the present time this is not possible in Ireland. Other limitations also exist and these can be summarised as follows:

• there is no personal national identity number;
• General Practitioners do not have comprehensive patient lists;
• many women do not have a general practitioner;
• women may choose a different general practitioner for ‘women’s health issues’.

The NBSP is currently exploring the possibility of facilitating the compilation of a General Practitioner Register with the relevant bodies.

QUALITY, UPTAKE AND INFORMATION/COUNSELLING
The Role of the Primary Care Team in the screening process has three primary dimensions:

QUALITY
• Improve acceptability of the programme
• Encourage appropriate referral arrangements
• at the end of the first round of screening, evaluate primary care team involvement

UPTAKE
• Encourage self-registration
• Encourage attendance
• Provide practical advice
• Allay fears
• Discuss screening with non-attenders.
INFORMATION AND COUNSELLING

- Answer general queries
- Advise ineligible women
- Discuss the implications of recall for further investigation
- Discuss the implications of a biopsy
- Discuss the treatment options

To facilitate good communication between GP practices and the screening office, practices will be provided with information on all aspects of the programme so that they will understand the procedures and know the time schedule of the screening process.

ACHIEVING A HIGH ATTENDANCE RATE

The attendance rate can be maximised via the Primary Care Team by:

- understanding the organisation of the programme in order to provide accurate information;
- actively publicising the programme using posters, leaflets and verbal encouragement;
- understanding the procedure for changing appointments;
- understanding the procedure if an appointment is missed;
- being aware of the beliefs, fears and anxieties about breast cancer and breast cancer screening;
- encourage non-attenders to attend for screening.

COUNSELLING WOMEN RECALLED FOR FURTHER INVESTIGATION

The General Practitioner and the woman will be notified at the same time regarding the need for recall. The woman will be given a definitive appointment within a few days of receiving the notification. Most often the anxiety and fears of the woman will be dealt with by trained staff at the unit but some women will wish to consult their GPs. They will wish to know what the implications of the result are, and to have an explanation of the next steps. General Practitioners therefore need to be informed about the complexity and limitations of mammography. Most women who are recalled will be found to be normal on assessment and will join the routine recall system.

In spite of the constraints in involving the primary care teams in the recruitment process, it is essential that ‘bridges’ are developed with the GP and the practice nurses. This will be done through:

- the Irish College of General Practitioners and the Practice Nurses Representative Body;
- the Tutors and Continuing Medical Education network;
- the development of an Information Pack for the General Practitioner;
- visits to practices.

INFORMATION PACK FOR IRISH GENERAL PRACTITIONERS

A book with the following chapter headings will be prepared:

- cancer of the breast;
- early diagnosis of breast cancer: the case for mammographic screening;
- organisation and management of the National Breast Screening Programme;
- communicating effectively with women about breast screening: the role of the primary care team;
- guidelines for the management of patients with breast problems including benign breast disease.

A grant has been sanctioned to the Irish College of General Practitioners to develop and administer a comprehensive education and information programme for General Practitioners. The components of the programme are:

- priming phase;
- information pack;
- information meetings;
- access to resource personnel.

The General Practitioners’ support of the Programme will be even more important in the low uptake areas where the Programme and the General Practitioners will need to work synergistically together.
an Integrated Approach

The Steps in the Screening Process

CONSENT AND INVITATIONS
Women will be invited for screening from the Population Register in accordance with District Electoral Division areas. Women will be screened within two years of becoming eligible. Women aged between 50 and 64 living in the Eastern Health Board, North Eastern Health Board and Midland Health Board regions and registered in the population register will receive a consent letter with an information leaflet about the programme. This enables a woman to 'opt out' of the Programme if she wishes and to convey her decision in writing.

The letter of invitation for mammographic screening will outline the advantages of screening in a truthful fashion. The purpose of the letter is to ensure an informed choice and to 'enlighten not frighten'. Procedures for changing appointments will be in place. Women who fail to attend for screening will be issued with one further invitation.

THE SCREENING PROCEDURE
The screening unit will be woman-focussed, and every effort will be made by staff to ensure that the experience for the woman throughout the process is as pleasant as possible. A short questionnaire will be filled by the woman or radiographer and the woman will then receive her two-view mammography examination. Sometimes additional views will be required but these are kept to a minimum.

Two radiologists will report on each film and all results must be posted within three weeks. Results will be sent to the woman and to the General Practitioner if the woman has nominated one.

ASSESSMENT CLINIC
Each assessment unit will take referrals from its static unit and mobile units within its geographic area. Women who are being recalled for assessment will receive an appointment within two weeks of being notified. In order to minimise anxiety, the Programme aims to issue recall invitations to arrive one or two days before the clinic. Women will be invited to bring a family member or friend for support.

Women recalled may require ultrasonography or more sophisticated mammography before reassurance. For women in whom an abnormality is still suspected, a full assessment will then proceed, involving a surgeon, screening radiologist, a specialist nurse and pathology support. At multidisciplinary assessment, a decision will be made as to whether biopsy is required; if so, this will be carried out at the clinic, using core needle biopsy or fine needle aspirate. (If a lesion is palpable, the surgeon may carry out this procedure; for impalpable lesions, the biopsy will be carried out by the radiologist under the control of ultrasound or stereotactic technique.) The quality assurance standards require that more than 70% of screen-detected cancers should be diagnosed in this way without the need for open surgical biopsy. It is important that this assessment and the diagnosis be carried out and reported within a short time span.

Women for assessment will be provided with counselling by the breast care nurse and given all appropriate information. At the clinic there will also be access to the multidisciplinary team. Women will be sufficiently informed to enable them to fully participate in the decision-making process and be assured of consistent advice and opinion.
Women with biopsies will be invited back to a results clinic held not more than one week after assessment.

Women requiring hospital admission will have their diagnosis fully explained by the clinician and will be offered a hospital bed within 2 weeks: bookings will be made before they leave the unit. A contact telephone number will also be provided for further support.

A Women's Charter (Appendix C) will be provided so that women will be informed about what to expect from the programme. It will also encourage women to provide feedback to the programme in order that continuous quality improvement can take place.

SURGERY AND FOLLOW-UP

TREATMENT

Breast-conserving surgery is the treatment of choice for the majority of small-size screen-detected cancers, followed by radiation therapy to the conserved breast. Therefore, it is imperative that the radiation therapist works closely with the breast surgeon. The surgeon must also work very closely with the histopathologist, not only in the orientation of the excised specimen to ensure that an adequate clear margin around the lesion has been obtained, but also for the most accurate information about the axillary lymph nodes. Systemic treatment will be considered for all patients with factors indicating poor prognosis and this requires the involvement of a medical oncologist.

ENVIRONMENT

The quality of the service is a vital factor in influencing women to participate in a screening programme. For this reason, the physical environment of the units should be attractive and offer a calm, reassuring and welcoming atmosphere with cheerful colours and comfortable furnishings. Units should also ensure privacy and confidentiality.

CENTRAL AND LOCAL ORGANISATION

The headquarters for the programme will initially be based in Corrigan House and ultimately in the Eccles Unit. Each of the units will operate as independent management units, responsible for the day-to-day work including:

- ensuring that the Quality Assurance guidelines and operator manuals are implemented and that timely reports are given to the Project Director;
- co-ordination of the local services;
- managing the assessment clinic;
- ensuring that women recalled to the assessment unit are followed up;
- ensuring that results from the recall/assessment clinics and treatment are given/sent to the General Practitioners in a timely manner;
- ensuring that the processes and time frames in the Women's Charter are adhered to;
- ensuring timely access to treatment facilities;
- fostering and maintaining links with local hospital(s), General Practitioners and other relevant bodies.

The Project Director will establish a management team representing key groups from both units initially and ultimately from all national units. With the input from this team the following will be managed from headquarters:

- the co-ordination of the units including the management of the quality assurance of all aspects of the programme;
- the development and implementation of operator quality control manuals;
- the population register;
- the issuing of consent letters, invitations to screening and result letters to women and General Practitioners;
- monitoring compliance / non-compliance and developing strategies to improve it;
- the budget strategy plan and its implementation;
- purchasing terms;
- development and implementation of the promotional strategy;
- recruitment and human resource management;
- planning implementation of phases 2 and 3;
- Board support;
- evaluation of the Programme;
- immediate responses to the public, media, parliamentary questions, and Minister and Department of Health and Children and Health Boards enquiries.

As far as possible, aspects of the above will be delegated from headquarters to the screening units.

Ultimately the effectiveness of a screening programme is measured by its effect on mortality and life-years gained. This requires follow-up of the screened population over an extended period of time and the collection and recording of information regarding vital status and disease-free status at defined intervals. Close links with the National Cancer Registry will facilitate this process. The epidemiological dimension is thus an integral part of the Programme.

In addition, the overall effectiveness of the Programme will be both independently assessed and benchmarked against the performance of other national programmes particularly in the UK and Europe.
8. Promotion of the Programme to maximise compliance

A major success factor for the Programme is to maximise the number of women who attend for screening. In the current absence of a fully comprehensive population register, every effort needs to be made to encourage women to participate in the screening Programme and if not on the register to ‘self-register’. To accomplish this, a promotional strategy is essential.

The strategy is woman-centred, aiming to ‘give women what they want’. However, in the initial stages women may not know or fully anticipate what they want but the programme will facilitate them over time. The corporate identity therefore needs to reflect the goals of the service and the links between identity and goals can be created and nurtured over time. Deep understanding of women’s needs is required.

In order to optimise the service there is a need for the following:

- to initiate a dialogue with the women;
- to continually draw on new ideas to improve the service;
- to build a strong relationship with all those using the service.

The Programme Identity

The first step in the strategy was to employ a design company to create an identity for the programme, which would accurately reflect its nature and provide the foundation on which a communication plan can be built. An identity is more than just a mark, it involves a whole-hearted approach to all aspects of communication. The creation of an identity needs to take consideration of how and where it will be used. The identity must have the ability to arrest and inform its specific target audience. The principal elements of the brief and discussions with the design companies were:

- the service is a proactive programme;
- the service must be professional, efficient and caring;
- the service must provide a confident yet sensitive image;
- the information provided must be open and honest, so that women can make informed choices;
- experience in international programmes should be taken into account (e.g. the Northern Ireland experience highlighted reluctance to participate in screening due to fear and the need for positive communication and reassurance of the benefits of testing).

A positive and effective way of communicating these messages was identified through the proposed identity, which will be launched in early 1999.
Promotion of the Programme

The promotion of the programme requires that the publicity and education should be directed at:

- the women in the target age group;
- the public as a whole;
- health professionals, women's groups and voluntary organisations which might have an opportunity to inform and influence women.

Although the 50-64 year age group is being offered screening, sharing of knowledge and attitudes with others is important in developing acceptance of the service and ensuring its continued uptake. The following methods will be used to reach these audiences.

Media

The Programme identity and its variations will be the format in which all communication is made e.g. in all the relevant materials emanating from the programme, communications with media and public. The national and local networks will be used in promoting the programme. This will include the issue of general press statements on the progress of implementing the service as well as the provision of interviews and articles on different aspects of breast disorders. Key journalists at national, regional and local levels who have a particular interest in health issues will be approached to include items in their press articles and in programmes on both television and radio.

Direct communication with women

Issuing of the consent and invitation letters is a key promotional opportunity. A comprehensive range of information leaflets is being developed. Every opportunity will be used to distribute the leaflets and promote the programme. The letters are an important medium for conveying information and education about the Programme. Information will be presented so that a woman can make an informed decision to participate.

Communication with the Primary Care Team

The Primary Care Team has a major contribution to make to the promotion of the Programme, primarily in three distinct areas.

Initially it is planned to provide the information pack to the General Practitioners well in advance of the commencement of the Programme. As the screening process moves from area to area, practices in each target area will receive information on the service available locally. Consideration is currently being given as to the best methods of doing this. The Programme will endeavour to communicate with all practices and is seeking the assistance of the ICGP on the methodology and facilitation of the process.

Communication with women's groups and voluntary bodies and through the workplace

Every effort will be made to work in partnership with women's groups and the voluntary organisations and employers. Many of these groups have an excellent track record in promoting cancer prevention programmes.

Communication through other bodies and professionals

There are a significant number of other groups which can be used to promote the Programme. The Health Promotion Unit of the Department of Health and Children, the Health Boards and their staff, the National Cancer Forum and the Regional Directors of Cancer, the Irish Cancer Society, the Voluntary and other Hospitals have much experience in this area. Every effort will be made to work synergistically with these groups.

Diagnostic Services

Allowing for the incidence of breast cancer in Ireland, it follows that the majority of cancers will continue to present symptomatically and be treated in the therapeutic/symptomatic services. If a woman in the screening age group seeks an appointment with the screening service outside of the standard call/recall invitation system, because she is symptomatic, she will be directed to the therapeutic services in her own area. It will be essential that this data is subsequently linked with the programme for evaluation purposes. The experience of other countries has shown that the establishment of organised screening programmes has resulted in an increase in the demand on the diagnostic services due to increased awareness among the non-screened population, with increased self-referral. The Steering Committee recommends strongly that high quality mammography and other facilities be provided in the Breast Clinics which have been and will be developed throughout the country, so that a high standard of care can be guaranteed to every woman with breast cancer (symptomatic as well as screen-detected).
Membership of Steering Committee for
National Breast Screening Programme

Dr. Sheetagh Ryan,
(Chairperson),
CEO,
Western Health Board

Ms. Angela Fitzgerald,
Assistant Principal,
Department of Health
and Children

Dr. Paddy Barrett,
Consultant Radiologist,
South Infirmary/Royal
Victoria Hospital Cork

Dr. Declan Bedford,
Specialist in Public Health,
North Eastern Health Board.

Professor Peter Daly,
Consultant Medical Oncologist,
St. James's Hospital, Dublin

Professor Peter Dervan,
Consultant Pathologist,
MaterMisericordiae Hospital, Dublin

Professor J.T. Ennis,
Consultant Radiologist,
Eccles Breast Screening Programme

Mr. Tom Garey,
Consultant Surgeon,
MaterMisericordiae Hospital, Dublin

Dr. Vetma Harkins,
General Practitioner,
Banagher, Co. Offaly

Dr. Davida de la Harpe,
Specialist in Public Health,
Midland Health Board

Dr. Mary Hynes,
Director of Public Health,
Western Health Board

Ms. Orla Laird,
Superintendent Radiographer,
Eccles Breast Screening Programme

Ms. Geraldine Luddy,
Chief Executive, Women’s Health
Council. Consumer Representative

Dr. Brian O’Herrlihy,
Director of Public Health,
Eastern Health Board

Professor Niall O’Higgins,
Professor of Surgery and
Consultant Surgeon,
St. Vincent’s Hospital, Dublin

Professor Donal MacErlaine,
Consultant Radiologist,
St. Vincent’s Hospital, Dublin

Professor Philip Walton,
Professor of Applied Physics,
University College, Galway

Dr. Jane Buttimer,
Project Director (ex officio)

Ms. Anne Marie Hoey,
(Secretary)
Appendix B - National Screening Programme

Consultation Process with the Agencies-Attendees

29 OCTOBER 1997

• Beaumont Hospital
  Mr. H. Osbourne,
  Consultant Surgeon
  Dr. F. McGrath,
  Consultant Radiologist

• MANCH Group
  Dr. Arthur Tanner,
  Consultant Surgeon

• St. James's Hospital
  Dr. John Reynolds,
  Consultant Surgeon
  Mr. Ian Carter,
  Deputy Chief Executive Officer

• Mater Misericordiae Hospital
  Mr. Brian Conlon, Financial Controller
  attended on behalf of
  Mr. Martin Cowley, CEO

• Faculty of Radiology
  Dr. David McInerney
  Honorary Secretary

• R.C.S.I.
  Professor Kevin O'Malley, Registrar
Appendix C - NBSP Women’s Charter

SCREENING COMMITMENT

• All staff will respect the woman’s privacy, dignity, religion, race and cultural beliefs.

• Services and facilities will be arranged so that everyone, including people with special needs, can use the services.

• Your screening records will be treated in the strictest confidence and you will be assured of privacy during your appointment.

• Information will be available for relatives and friends relevant to the woman’s care in accordance with the patient’s wishes.

• You will always have the opportunity to make your views known and to have them taken into account.

• You will receive your first appointment within 2 years of becoming known to the Programme.

• Once you become known to the Programme you will be invited for screening every two years while you are aged 50 to 64 years.

• You will be screened using high quality modern equipment which complies with National Breast Screening Guidelines.

WE AIM:

• to give you at least 7 days notice of your appointment;

• to send you information about screening before your appointment;

• to see you as promptly as possible to your appointment time;

• to keep you informed about any unavoidable delays which occasionally occur;

• to provide pleasant, comfortable surroundings during screening;

• to ensure that we send results of your mammogram to you within 3 weeks;

IF RECALL IS REQUIRED WE AIM:

• to ensure that women will be offered an appointment for an Assessment Clinic within 2 weeks of being notified of an abnormal result;

• to ensure that you will be seen by a Consultant doctor who specialises in breast care;

• to provide support from a Breast Care Nurse;

• to ensure you get your results from the Assessment Clinic within one week;

• to keep you informed of any delays regarding your results.
IF BREAST CANCER IS DIAGNOSED
WE AIM

• to tell you sensitively and with honesty;

• to fully explain the treatment available to you;

• to encourage you to share in decision-making about your treatment

• to include your partner, friend or relative in any discussions if you wish;

• to give you the right to refuse treatment, obtain a second opinion or choose alternative treatment, without prejudice to your beliefs or chosen treatment;

• to arrange for you to be admitted for treatment by specialised trained staff within 3 weeks of diagnosis;

• to provide support from a Breast Care Nurse before, and during treatment;

• to provide you with information about local and national cancer support services and self help groups.

TELL US WHAT YOU THINK

Your views are important to us in monitoring the effectiveness of our services and in identifying areas where we can improve.

You have a right to make your opinion known about the care you have received.

If you feel we have not met the standards of the Women's Charter, let us know by telling the people providing your care or in writing to the programme.

We would also like to hear from you if you feel you have received a good service. It helps us to know that we are providing the right kind of service - one that satisfies you.

Finally, if you have any suggestions on how our services can be improved, we would be pleased to see whether we can adopt them to further improve the way we care for you.

You Can Help By

• Keeping your appointment time

• Giving at least 3 days notice if you wish to change your appointment

• Reading any information we send you

• Being considerate to others using the service and the staff

Please try to be well informed about your health.

Let us know

• if you change your address

• if you already have an appointment

TELL US WHAT YOU THINK.

YOUR VIEWS ARE IMPORTANT.
Breast
The National Breast Screening Programme

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