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Position Paper

The requirements of a specialist breast unit

EUSOMA

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1. Introduction

In October 1998 in Florence the First European Breast Cancer Conference took place, jointly organised by the European Organization for the Research and Treatment of Cancer Breast Cancer Cooperative Group (EORTC-BCCG), the European Society of Mastology (EUSOMA) and Europa Donna. Delegates agreed a consensus statement on research, genetic predisposition, psycho-social status, treatment and quality of care [1].

With the intention of assuring a high quality specialist service Europe-wide, a working party was established to consider what should comprise a specialist service. The formation of a group to draw up guidelines on these issues was an intention of the late Emmanuel van der Schueren, the EUSOMA President. In respect of his wish this was carried out in May 1999 in his home town of Leuven by Professor Cataliotti, President of EUSOMA. The 'Requirements of a Breast Unit' represents the opinion of the European Society of Mastology (EUSOMA) on the standards required for forming high quality Breast Cancer Units across Europe.

2. Objectives

1. To make available for all women in Europe a high quality specialist Breast Service.
2. To define the standards for such a service.
3. To recommend that a means of accreditation and audit of Breast Units be established in order that units providing this service should be recognisable to patients and to purchasers as being of high quality.

3. Background

In the UK the recommendations of the report 'A Policy Framework for Commissioning Cancer Services' [2] are currently being implemented, starting with Breast Cancer services. The recommendation is that specialist breast units be established, staffed by clinicians and other professionals specialising in the single 'anatomical area' of breast disease.

A number of reports from groups concerned in the management of breast disease have been published by the British Breast Group [3]; by the Breast Specialty Group of the British Association of Surgical Oncology (BASO) [4,5] and by the UK NHS Executive [6]. All these reports recommend that breast disease be cared for by specialists in breast disease working as teams in Breast Cancer Units.

The European Society of Surgical Oncology (ESSO) has published similar guidelines [7] to those of BASO and European Guidelines for Quality Assurance in Mammographic Screening have been published [8].

Many hospitals claim to have specialist breast cancer services but it is known that only a few are well organised into multidisciplinary Breast Cancer Units and the quality of each individual service is uncertain. It is the hope of those working in the field that the recommendations in the various reports above will be followed through into clinical practice, to build a breast cancer service of the highest quality throughout Europe.

In order that this may be assured it is necessary that standards are set which any hospital wishing to form a recognised Breast Cancer Unit must meet. The establishment of a high quality specialist service, Europe-wide, is a stated aim of the European Society of Mastology (EUSOMA). A working-party was established by EUSOMA together with EORTC representatives to consider what should comprise a specialist service. This document arose from that meeting and has been reconsidered, modified and approved by the working party.

Further working parties will make recommendations to establish quality standards in the separate aspects of breast cancer care: diagnosis, screening, local treatment of the primary tumour, systemic adjuvant therapies, follow-up, management of risk, management of advanced disease, palliative care, support services, reconstruction, audit and data collection.

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A EUSOMA audit database has been designed for all units to use, which will give immediate outcome measures on the performance of a unit.

4. General recommendations

1. There must be a definition of the mandatory requirements for a Breast Cancer Unit to be recognised.
2. Each country should appoint a National Co-ordinator for the establishment and continuing audit of the Breast Units. He/she must have authority for accreditation of units. It is observed that such an arrangement proved most successful in the implementation of the Breast Cancer Screening Service in the UK and that an extension of this to breast disease in general and pan-European would be a great advantage.
3. (i) A European process of accreditation of Breast Units, based on the fulfilment of mandatory requirements.
   (ii) A European system for quality assurance (QA). A QA database has been accepted by EUSOMA as suitable for audit. This will require a part-time data manager in every Breast Unit.
   (iii) A European structure for the national co-ordinators which will be arranged with the Federation of European Cancer Societies (FECS).
4. (i) Breast Units will most often be established in district hospitals; they should generally cover one-quarter to one-third of a million total population. Some highly specialised units will be larger.
   (ii) National population breast screening programmes should be based within recognised Breast Units and not work as a separate service.
   (iii) There has to be a minimum size for a Breast Unit from the point of view of numbers of specialist staff required, arrangement of frequent clinics, provision of equipment and cost-effectiveness. If two hospitals are close together it is more practical for only one of them to establish a Breast Unit.
   (iv) A Breast Unit should consider holding outreach clinics for symptomatic referred women, screening assessment and follow-up, in the smaller hospitals in their neighbourhood if these are at a distance from the Breast Unit.

   In areas where the population density is low, outreach arrangements are preferable to the establishment of small Breast Units without the clinical volume to maintain expertise. These outreach clinics may be only held perhaps once per month, which may contradict waiting times for appointments but evaluation by an expert team is considered preferable to maintaining the waiting times.

   In these ways women in all countries will have access to specialist breast services.
5. Breast Units should provide care of breast disease at all its stages — from screening through to the care of advanced disease. Occasional attendances might be required of the patient at an associated large oncology centre or radiotherapy hospital, for radiotherapy or possibly certain special chemotherapeutic regimes but the patient must essentially be managed and followed-up at her Breast Cancer Unit.
6. Breast Unit budgets should be separate rather than drawn from a number of budgets within a hospital (radiographical, surgical, oncological, pathological, etc.).

5. Mandatory requirements

5.1. Critical mass

A Unit must be of sufficient size to have more than 150, newly diagnosed cases of primary breast cancer (at all ages and stages) coming under its care each year. (Note: these are newly diagnosed breast cancers. A transfer of a case from another hospital, for example, to receive radiotherapy or at the time of presentation of distant metastases, may be a new referral to that hospital but is NOT a newly diagnosed case and should not be counted as such.)

The reason for recommending a minimum number is to ensure a caseload sufficient to maintain expertise for each team member and to ensure cost-effective working of the Breast Unit: the establishment of a clinic staffed by experts is expensive and must have a high throughput of patients.

5.2. Core team

Each member of the core team must have special training in breast cancer, above that given in general training in his/her discipline and obtained by spending a year in a unit recognised for training. Training and expected standards and the recognition of suitable training units will be laid down in a separate EUSOMA document.

Each member of the breast unit core team must undertake continuing professional education on a regular basis. Breast Unit budgets must include provision for this.

(i) The Breast Unit must have an identified Clinical Director of Breast Surgery.

(ii) Breast Surgeons.

Two or more nominated surgeons specially trained in breast disease, each of whom must

personally carry out the primary surgery on at least 50 newly diagnosed cancers per annum and must attend at least one diagnostic clinic per week.

Between them the surgeons must have at least eight identified $3\frac{1}{2}$–4-h sessions per week in Breast Disease (this is for a unit seeing 150 newly diagnosed breast cancers per year, more sessional time *pro rata* may be required according to the size of the Unit). These sessions will allow for operating time, their participation in diagnostic clinics, a follow-up clinic and, where appropriate, screening assessment clinics. A session must be allowed for attendance at a weekly team case management and audit meeting.

(iii) Breast Radiologist

There must be at least two nominated radiologists, fully trained and with continuing experience in all aspects of breast disease and associated imaging, as laid down in European Guidelines for Quality Assurance in Mammography Screening [8]. They should participate in any national population screening programme and must participate in any national QA scheme for national or regional Breast Radiology. The radiologist must be fully trained in mammography, ultrasound, tissue sampling and localisation procedures under image control. They must have allocated a contracturally defined part of each working week to these procedures and must at the least fulfil volume requirements as laid down in the EUSOMA 'Quality Assurance in the Diagnosis of Breast Cancer' (in preparation), reading a minimum of 5000 mammograms per year. They must attend multidisciplinary meetings for case management and audit purposes. They must be present in diagnostic assessment clinics with the surgeon. Each radiologist must attend at least one diagnostic clinic per week for symptomatic patients or screening assessment.

(iv) Breast Pathologist

A lead pathologist plus usually not more than one other nominated pathologist, specialising in Breast Disease, will be responsible for all breast pathology and cytology. Any pathologist carrying out these roles must have contractual sessions to attend team case management and audit meetings and be specially trained and have continuing experience in breast disease. They must take part in any National or Regional QA schemes.

(v) Breast Care Nurses

Trained Breast Care Nurses must be available to counsel and offer practical advice and emotional and informational support to newly diagnosed patients with breast cancer at the time the diagnosis is given and to discuss treatment plans with them. Similar support should be available in the Primary Breast Cancer Follow-up Clinic and in the Advanced Breast Clinic. At least two Breast Care Nurses will be needed per Breast Cancer Unit and a good ratio for calculation of need is two per 100 newly diagnosed cases for breast cancer.

(vi) Breast Oncologist

(a) A nominated radiation oncologist must arrange the appropriate delivery of radiotherapy and chemotherapy. He/she must hold joint primary breast cancer follow-up and advanced disease clinics with other members of the breast team, at the Breast Unit and must take part in the case management and audit meetings of the Unit.

(b) In some countries, Clinical Oncologists carry out both radiation therapy and prescribe the chemotherapy, in which case a Medical Oncologist (chemotherapy only) is unnecessary as a core team member. In centres where this is not so, a Medical Oncologist must be part of the core team and take a full part in the team activities.

(vii) Breast Diagnostic Radiographers

Radiographers with the necessary expertise and training in mammography are essential members of the team. They must fulfil the training and working practice recommendations as laid down in the European Guidelines for QA in Mammographic Screening [7] and EUSOMA Quality Assurance in the Diagnosis of Breast Disease. They must be responsible for the actual taking of the mammograms, which must not be performed by radiographic or non-radiographic personnel without the above training.

(viii) Data Manager

There must be a National system covering audit. A data manager should maintain the Unit's audit structure. The EUSOMA database is recommended.

(ix) Quality Assurance (QA)

(a) Performance and audit figures must be produced yearly and they must be set alongside defined quality objectives and outcome measures (to be set out in the EUSOMA documents dealing with the various aspects of care). These standards are defined in the EUSOMA database.

(b) Breast Unit budgets must include provision for a trained data manager and filing clerks to be employed to allow the collection of audit data and the compilation of reports.

(c) As part of the audit Units must provide evidence of numbers of patients entered into clinical trials.

5.3. Facilities/Services

(i) All Breast Clinics must be separate and not held as part of a general surgical clinic.

(ii) (a) New patient clinics

At least one clinic per week for newly referred symptomatic women must be held. A Unit diagnosing 150 new cancers per year must expect over 1500 new referrals of symptomatic women (=approximately 30 per week). It is therefore likely that many Breast Units will have to provide two such clinics per week.

(b) Waiting times

Suggested Outcome Measures will be given by the Group drawing up the Diagnostic Guidelines to be published by EUSOMA.

A suggested good practice is that all newly referred patients should be offered an appointment within 10 working days of receipt of the referral.

(c) Arrangements of diagnostic clinics

Clinics to which patients are referred or self-referred must be staffed by a surgeon, a radiologist and radiographers from the breast care team. Multidisciplinary working must allow all standard investigations for triple assessment (clinical examination, all appropriate imaging and tissue diagnostic procedures) to be completed at one visit. Where possible the finding of no abnormality or the diagnosis of a benign lesion should be communicated to the patient at that visit.

(iii) Communication of the Diagnosis

It may not be possible (if core biopsy has been used) or may not be considered appropriate by the unit to give the diagnosis of cancer at the initial visit, but women found to have breast cancer should receive that diagnosis within 5 working days. The diagnosis must be communicated personally by the surgeon at a time free from conflicting duties (or) if given within a designated breast clinic, only when an appointment has been made so that the surgeon has adequate time for discussion. A breast care nurse must be present to discuss further with the patient the options for treatment and to give emotional support. A suitable room with sufficient privacy must be available.

In units in which preoperative irradiation or primary medical therapies are used, cases which might be suitable for these must be seen jointly by a surgeon and radiation or medical oncologist before treatment commences.

(iv) Imaging equipment

(a) **Imaging equipment**

The unit must be in possession of all necessary imaging equipment for complete and adequate breast diagnosis as defined in the EUSOMA 'Guidelines for Diagnosis of Breast Disease'.

(b) **Sampling, Guidance and Imaging equipment**

A faxitron or similar device for specimen radiography must be available in the operating theatre or very close by in order to confirm adequate excision of impalpable lesions prior to skin closure. It is useful to have a similar device in or very near to the pathology laboratory to assist adequate pathological examination of such specimens.

(v) Primary breast cancer follow-up clinic

(a) **Adjuvant Therapies**

The surgeon and radiation oncologist (±medical oncologist—see above) must decide on the appropriate adjuvant therapies in light of the pathology of the surgical specimen. A multidisciplinary case review meeting must be held each week, attended by the team surgeons, oncologists and presented by the pathologist.

(i) Radiotherapy may be delivered within the Breast Unit or patients may have to travel to a Radiotherapy Hospital.

The minimum equipment in a department giving radiotherapy must be two megavoltage units, a brachytherapy unit, a simulator and a computerised planning system. The department must have a radiotherapeutic quality control programme for the breast cases.

(ii) The administration of cytotoxic therapy as adjuvant therapy or for advanced disease must be by an accredited oncologist with proper facilities (Clinical or Medical Oncologist).

(iii) Although the patient may have to visit a separate Hospital to receive radiotherapy, or specialised chemotherapy the subsequent follow-up should be by the team members of her Breast Unit.

Follow-up at the Breast Unit has the advantage of convenience for the patient and their relatives. The skills of the diagnostic breast team are also available for the detection and investigation of a possible recurrence.

(b) All patients with primary breast cancer must be followed-up in a combined Breast Clinic with the attendance of a nominated surgeon and the nominated radiation (clinical) oncologist at the Breast Unit. Any imaging or other investigations necessary, should be able to be carried out at the same visit.

(vi) Advanced and Recurrent Breast Cancer

(a) There must be one Advanced Breast Cancer Clinic at least every 2 weeks at the Cancer Unit attended by the Clinical Oncologist±

Medical Oncologist and with the surgeon available for consultation. Patients with distant metastases, locally advanced primary breast cancer and local or regional recurrence, must be managed in this clinic.

(b) Patients who have received radiotherapy or complex chemotherapy at a Cancer Centre should normally be referred back to the Breast Team at their Breast Unit for further follow-up.

Chemotherapy

(c) The nominated Oncologist (Clinical or Medical) must supervise chemotherapy in line with protocols drawn up by the Unit Team.

There must be facilities and suitably trained staff for the safe delivery of standard chemotherapy regimens (both for adjuvant treatment and for advanced disease) and for dealing with complications.

(vii) Benign clinic

The Breast Unit must hold a clinic to advise women with benign disease both for confirmation that a lump managed without excisional surgery is benign and for treatment of mastalgia or inflammatory conditions, e.g. mammillary fistula.

5.4. Associated services and non-core personnel

(i) **Psychological Support**

If the patient is experiencing psychological morbidity that can not be dealt with effectively by members of the Unit team, she should be referred to a psychiatrist or a clinical psychologist who is nominated as the liaison psychiatrist/psychologist for the Breast Unit (non-core team member).

(ii) **Reconstruction**

A Unit team must provide breast surgical reconstruction when required for: (1) those patients not suitable for breast conserving therapy (2) patients with extensive local disease. The breast surgeons in the team should be able to undertake basic reconstruction and there should be a standard arrangement or joint reconstruction clinic with a nominated Plastic Surgeon (non-core team member) who takes a special interest in breast reconstructive techniques.

(iii) **Palliative Care**

A specialist palliative care service must be available for the referral of patients with advanced breast cancer. A close working relationship must be established between members of the Breast Unit and the palliative care service to ensure that breakdowns in continuity of care do not occur.

(iv) **Prosthesis**

There must be provision for a Prosthesis fitting service within the unit.

(v) **Lymphoedema**

An identified Physiotherapist or a Breast Care Nurse must have an interest in the treatment of lymphoedema.

(vi) **Risk**

Women seeking advice with regard to risk, e.g., family history, must be able to receive this from the Breast Surgeons who must acquire the requisite knowledge.

Gene probing must be available when required and those patients considered suitable should be seen jointly by the Breast Surgeon and a nominated Clinical Geneticist (non-core team member).

5.5. Case management meetings

There must be at least one prospective weekly case management meeting attended by the members of the Core team. All must have allocated time for this meeting which must consider cases under diagnosis and the forward planning of patients who have received surgery.

5.6. Management protocols

The Unit must have written protocols for diagnosis and for the management at all stages (primary and advanced cancer). All protocols must be agreed upon by the core team members.

5.7. Information to patients

Women must be offered written information and this must be available with regard to their diagnosis and/or treatment options. This should be in addition to receiving counselling from the Breast Care Nurse.

6. Research

Research is one of the essential parts of training of specialists. Units should be encouraged to provide research opportunities and this must be taken into account when assessing units for their suitability for accepting trainees.

7. Additional points

The implementation of the suggested structure of Breast Units requires a reorganisation of time in each discipline, so that as a consultant spends more time in breast disease, his or her colleagues no longer treat breast cancer and specialise in other areas. Rationalisation of

work patterns, in this way would provide sufficient staff for the Breast Units. Such a move would coincide with changes that are already occurring within, for example, General Surgery in the emergence of specialist surgeons for urology, for microinvasive techniques, for vascular surgery, for colon surgery, etc.

All work must be carried out by specialists specifically trained in breast disease rather than by junior staff. A service provided by a trained specialist is more efficient and more cost effective — decisions are made earlier whereas junior staff are more likely to call a patient back several times unnecessarily and to carry out unnecessary investigations; operating by consultants is more efficient for technical reasons; the interpretation of imaging techniques and the reading of histology is much more likely to produce definitive opinions if carried out by trained specialists.

We estimate that for a 20 million population base, the provision of cost-effective Breast Units, each diagnosing more than 150 new cancers per year, requires approximately 60 Breast Units.

8. List of attendees

8.1. EUSOMA Working Party

Professor Roger Blamey, Surgeon, Nottingham (Chairman).
Professor Mogens Blichert-Toft, Surgeon, Copenhagen.
Professor Luigi Cataliotti, Surgeon, Firenze (President EUSOMA).
Dr Alberto Costa, Surgeon, Milano.
Dr Marco Greco, Surgeon, Milano.
Dr Roland Holland, Pathologist, Nijmegen.
Professor Manfred Kaufmann, Gynaecologist, Frankfurt.
Dr Nicholas Perry, Radiologist, London.
Dr Antonio Ponti, Epidemiologist, Torino.
Ms Katy Redmond, Nurse, Dublin.
Mr Richard Sainsbury, Surgeon, Huddersfield.

8.2. EORTC attendees

Professor Cornelius van de Velde, Surgeon, Leiden (President EORTC Breast Group).
Dr Marie Christiaens, Surgeon, Leuven.
Professor Jacek Jassem, Radiation Oncologist, Gdansk.
Dr Jean Pierre Julien, Surgeon, Rouen.
Professor Robert Paridaens, Medical Oncologist, Leuven.
Dr Emile Rutgers, Surgeon, Amsterdam.

8.3. Leuven attendees

Professor EF van Limbergen, Radiation Oncologist, Leuven.
Dr W Van den Bogaert, Radiologist, Leuven.
Professor I Vergote, Gynaecologist, Leuven.
Dr J Wildiers, Medical Oncologist, Leuven.

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