



Eusoma Certification Process for quality in comprehensive and multidisciplinary breast care

1. Background

EUSOMA (The European Society of Breast Cancer Specialists) is the organisation representing Breast Cancer Specialists in all disciplines, covering all aspects of breast cancer from risk and prevention, through diagnosis and treatment of the primary tumour, follow-up, treatment of recurrent and advanced disease, pathology, reconstruction, psychology and audit. EUSOMA has published on several aspects of breast cancer and on service provision as well as giving clinical guidance and providing the basis for audit.

There is evidence that the current Guidelines have influenced practice in several European countries and that specialists in breast care strongly support the concepts of Certification. The Florence and Hamburg statements (1,2) voted on by delegates to the European Breast Cancer Conferences, stressed the importance of working in specialist multidisciplinary units.

EUREF (The European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services) has produced the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (3) supported and printed by the European Commission, which has been influential in member state government planning for screening and has established a European programme: "Voluntary certification of high quality diagnostic breast imaging and breast screening services".

The European Parliament Resolution on Breast Cancer (B6/0528/2006) calls on Member States to ensure nationwide provision of interdisciplinary breast centres by 2016.

In addition to breast specialists (through EUSOMA) demanding specialised Units, the European patient advocacy organisation, EUROPA DONNA, has been supporting and lobbying for the Guidelines for specialist breast units since their publication by EUSOMA in 2000 and considers specialist breast units to be of the utmost importance in enabling women throughout Europe to access the best care and treatment possible. Certification of specialist breast units will be essential in ensuring that units meet guideline requirements, so that women can select appropriate facilities for diagnosis and treatment. This organisation will be influential in demanding that Units ensure their standards by seeking EUSOMA Certification and in widely disseminating knowledge of which units are certified .

EUSOMA has therefore implemented the process of voluntary Certification, with the aim of assuring a high quality breast service across Europe, for the benefit of women in all the member states. The screening component of any Unit or screening service not linked to breast units are separately assessed by EUREF.

2. Need for Certification

A difficulty faced by patients and referring doctors is how to recognise which units have genuine claims to designate themselves specialist units, hence the need for a process of Certification.

Health matters remain the responsibility of individual governments. It is anticipated that it would be extremely difficult to bring about a universal process of Certification, agreed and demanded as mandatory in all countries. However if EUSOMA Certification becomes widely sought then it will become de facto a necessary requirement for a breast unit professionally led and demanded by patients. Hospitals will be eager to claim that they have specialist breast units and specialists will wish to show that they work in recognised units; therefore a process of voluntary Certification by EUSOMA has been established. It should be noted that the present EUREF Certification of screening units is also a voluntary system.

Specialists in breast disease are those who best understand what is needed in a Breast Unit and what is required for efficient and high standard working.

3. EUSOMA Certification Board

Composition

President EUSOMA: M. Rosselli Del Turco

Surgeon : L. Cataliotti

Radiologist: R. Wilson

Radiation Oncologist : H. Bartelink

Medical Oncologist : A. Goldhirsch

Pathologist: : C. Wells

Clinical Geneticist: C. van Asperen

Epidemiologist : A. Ponti

Patient Support - Breast Care Nurse: Y. Wengström

Eusoma Executive Director: L. Marotti

Functions of the Certification Board:

It is the responsibility of the Certification Board to decide on the Certification status of each Unit.

All communications by Certification Board Members must be with the EUSOMA Headquarters.

In considering Certification status the Board must take note of the object of Certification: it is to select the Units capable of delivering a high standard comprehensive and multidisciplinary breast care.

Units which deliver such a service must not be denied Certification because they do not fulfil every single non-mandatory recommendation made by the Board and based on the EUSOMA Guidelines (4). However the Units will take commitment in achieving the missing non-mandatory requirements.

In addition, health care policies vary from one country to another. Although any such considerations must not alter the basic criteria for Certification (see point 4), account is taken of this in considering recommendations on lesser and therefore non-mandatory points.

EUSOMA are inspecting Units for their competence and not whole National Health Care systems.

4. General considerations

The EUSOMA Guidelines “The Requirements of a Specialist Breast Unit”(4) provides auditable recommendations.

The ability of a unit to meet these will be the basis of Initial Certification.

Seven basic criteria underlay the judgement of a Unit:

- A single integrated Unit
- Sufficient cases to allow effective working and continuing expertise
- Care by breast specialists in all the required disciplines
- Working in multidisciplinary fashion in all areas
- Providing all the services necessary – from genetics and prevention, through the treatment of the primary tumour, to care of advanced disease and palliation.
- Patient support
- Data collection and Audit

5. Units

A specialist breast “Unit” is a working entity and does not have to be contained (although preferable) within a single geographical entity, although the constituent buildings must be sufficiently closely sited to allow true multidisciplinary working and all diagnostic procedures to take place at the first consultation; a ‘Unit’ is defined by all aspects of Breast Cancer Care being offered by a multidisciplinary team (MDT) of specialists in breast disease.

Public hospital and private care may be given in two or more different settings but as long as care is provided by the same MDT, to the same protocols and discussed in the Unit’s multidisciplinary case management meetings (MDM’s) and included in Unit audit, Certification may be given of the Unit as a whole. Similarly, teams in two different public hospitals may join together but must be seen to be working as a single Unit producing a single dataset.

There are three ways in which units are organised:

1. Specialist Breast Units providing all services (including diagnosis) except screening: may apply for Certification by EUSOMA.
2. Specialist Breast Units covering all aspects of Breast Care with a Screening Unit Incorporated or Associated. These units may be Certified by EUSOMA but their screening component is separately certified by EUREF.

3. Screening Units (or) Diagnostic Units entirely self contained. It is the EUSOMA view that all screening units and diagnostic units should work within a total integrated breast unit structure and that diagnosis and treatment should not be carried out by separate units (a Unit may work as an integrated structure with a recognised multidisciplinary team but have geographical separation of the diagnostic, treatment or screening facilities: under that circumstance they fall into 1 or 2). Nevertheless it is a fact that separate screening and/or diagnostic units are in place. These Units cannot receive EUSOMA Certification but may apply to EUREF. Units considering Certification, which are unclear into which category they fall, are asked to seek advice from Eusoma before submitting an application.

6. Initial Certification, Full Certification and Re-Certification

6.1. Initial Certification is on the potential (the capacity) of the Unit to meet the recommendations of the EUSOMA Guidelines 'The Requirements of a Specialist Breast Unit (4) i.e. their buildings, hardware, specialist team, protocols, service provision, data base and audit. The results of audit will not be used as a basis for Initial Certification.

6.2. Full Certification (and Re- Certification after every 5-year interval) will depend on Audit of Performance Indicators (such as pre-operative diagnosis rate, percentage of clear margins in breast conserving therapy) and Outcome Measures (such as Local Recurrence rate after breast conserving therapy). These will be measured on the data collected in the years after Initial Certification and transferred to the EUSOMA database (see point 10).

A Unit may apply for Full Certification when it has five years of appropriate data (back data may be suitable for inclusion).

7. EUSOMA Initial Certification : procedure

7.1. EUSOMA Initial Certification is activated on request from the Unit: The information on the procedure and the application form are available on www.eusoma.org. Priority will be given to units situated in Europe.

7.2. The Unit will receive information on Certification process and on the date of the visit. After response to this the Unit will be sent a questionnaire, set out to match the recommendations in the EUSOMA Guidelines Data Collection/Audit.

7.3. The visiting team must include a surgeon , a radiologist, a pathologist and a breast care nurse. One of these will be appointed as visit coordinator. Visitors must be from countries outside of the applicant unit.

7.4. The site-visit has the aim of meeting members of the Unit team in all the core specialities, talking through the replies given on the questionnaires and on arrangements of the working week, ensuring that multidisciplinary working is carried out and talking to some members of the associated services (non-core team).

7.5. Each visit is carried out according to the following schedule:

0.00 hrs: Meeting with the head of Unit, Clinical Director and Members of the Unit Team: at least one representative from each core discipline must be present together with clinical psychologists, clinical geneticist and reconstructive surgeon. Presentation by the Unit with questions discussed during the presentation.

1.30 hrs: Visitors divide to separate tasks

3.30 hrs: MDT meeting observed by visiting team

4.15 hrs: Meeting of the visiting team

7.5.1. Opening session

The presentation by the Unit is discussed as it goes along. Presentations on individual topics must be short and must leave plenty of time for interruptions from the Visitors and be based on the questionnaire. The subjects to be addressed are who are the specialist team in each discipline, their timetables, what are the working arrangements and protocols, case flow, attendance at Multidisciplinary Meetings (MDM's). Outcomes and results of most performance indicators do not form part of Initial Certification and may only be presented briefly. Questions and discussion are continuous throughout. There should be no presentation on techniques (e.g. sentinel node biopsy; use of MRI) nor details of research projects. It is essential that the Head of Unit, the Clinical Director of the Unit and at least one specialist of each core discipline (including data manager and breast care nurse) are present and members of non-core disciplines (clinical psychology, clinical geneticist, associated plastic surgeon).

7.5.2. Visitors split to separate tasks

The Visiting Radiologist visits the imaging unit for breast disease and meets the breast radiologists and radiographers (technicians); inspects the location of the diagnostic unit (within the breast unit, in campus, outside campus and distance); the dedicated rooms; the examinations performed and whether these are available on the day the woman first attends for consultation and clinical examination; the equipment; is given the numbers of mammograms, breast ultrasounds and MRI's performed each year and who reads MRI's and CT scans (breast radiologists or general radiologists); the number of radiographers (technicians) and whether they are trained in and are dedicated to breast disease; who assess imaging for diagnosis and response of distant metastases.

The Visitor must check whether the physico-technical quality control of the radiologic equipment is performed according to the European Guidelines.

The Visiting Pathologist visits the Pathology laboratory and meets with the pathologists reporting breast disease.

The Visitor checks the equipment for routine diagnostic work and for specimen radiography; the staffing levels of secretarial and technical staff; checks that the pathologists are not under undue workload pressures, as this will invariably affect the time available for accurate grading and typing of tumours, the turn around time and ability for multidisciplinary working and intra-laboratory conference (one pathologist should gross and report approximately 4000 histological specimens of average complexity per year).

The Visitor must check whether the laboratory participates in technical and diagnostic external quality assurance (EQA) schemes and whether the laboratory is accredited by any National laboratory scheme. If the laboratory is producing receptor results and Her-2 testing by immuno-histochemistry or FISH, then the laboratory should participate in technical assessment of competence in these, such as that provided by NEQAS in the UK.

The existence of adequate transport systems between the laboratory and the clinical facility and operating theatre and adequate communication channels with the clinicians.

It is expected that the lead breast pathologist has a major interest in breast pathology, reports to the standard of national or international guidelines and is able to attend conferences or update courses in breast disease.

The Visiting Breast Care Nurse meets with those on the team primarily responsible for patient support (psycho-oncologists, clinical psychologists, breast care and/or psycho-oncology nurses, social workers); a representative of any patient volunteer group which is active in helping with support; clinical psychologist and/or psychiatrist who provides back-up on request from the support staff; the person giving support for genetics; the contact person on the Unit for women in long-term follow-up.

The Visitor has to check the role of Breast Care Nurses, their tasks and activities within the Unit.

The Visitor must have explained by one of the surgeons and one of the support staff the arrangements for support when the initial diagnosis of cancer is given, later the pathological findings and adjuvant treatment and the staff who give support if and when the diagnosis of advanced disease is given.

The Visitor must be shown the information literature provided to patients and have someone present who can both translate and explain how the literature is given out i.e. whether it is individualised so that only certain leaflets are given to a patient dependant on the features of the breast cancer.

The Visitor should inspect some of the facilities – the out-patient (ambulatory) clinic, the imaging facilities, the chemotherapy suite and accommodation for patients admitted for surgery.

The support given to patients with learning, visual hearing or language difficulties must be explained to the Visitor. Enquire whether there are formal assessments of quality of life (QoL) aspects e.g. general QoL questionnaire, of cosmetic outcome (again may be by questionnaire) (5) of side effects such as lymphoedema.

The Visit Coordinator meets with the surgeons, the reconstruction team, the clinical geneticist, the radiation oncologist, the medical oncologist and the Audit officer. Particularly the arrangements are assessed for counselling, investigation and intervention for women asking for advice on their family history; for reconstruction; for follow-up and (unless clear from the preceding session) for the involvement of the Oncologists in the team; how advice on reconstruction is given; the post-operative physiotherapy. If time permits, the surgeon is also given a brief overview of the teaching and research.

7.5.3. Multidisciplinary meeting

Units are asked to arrange for one of their regular multidisciplinary case management meetings to be held, which the visiting surgeon, radiologist, pathologist and breast care nurse observe. The meeting must be a real case

discussion meeting and not a demonstration. The relevant x-rays, cytological slides and the post-operative histology should preferably be demonstrated by the radiologists and the pathologist using a projection device. Treatment options should be presented by surgeon, medical oncologist and radiation oncologist. All members of the core team should be present (including the staff responsible for patient support). Those members of the Unit who do not regularly attend these meetings, should not be invited. The visiting team are not present to discuss individual case management nor unit policies and should make no comment during the meeting.

MDT meeting has to be hold in English. It is the style of the MDT meeting, the participation of all staff, the method of presentation etc rather than the actual decisions made which the visitors need to see.

7.5.4. Meeting of visitors

After the MDT meeting the visiting team meets briefly in confidence to exchange information and views on the Unit and making sure all important issues have been taken into consideration during the visit. Following this, visitors may feel to ask additional information to the Unit team.

7.6. Reaching Decisions on EUSOMA Initial Certification

7.6.1. Following the visit the visitors send their reports to Eusoma within two weeks to draw them up in the Preliminary Report format.

7.6.2. The Preliminary Report will be sent to the visiting team for their approval and the to the Certification Board for their evaluation and to the Unit, which may be asked to answer additional questions or to send some clarifications.

7.6.3. Comments from these individuals (and replies to extra questions posed) have to be received by EUSOMA within 4 weeks.

7.6.4. Once all necessary information and Board comments have been received these will be included in the Amended Report with a recommendation on Initial Certification status and sent to the Certification Board for their final evaluation on the Unit .

7.6.5. The members of the Certification Board have 28 days to approve or disagree with the recommendation. Failure to register an objection will be taken as assent.

7.6.6. Once the Certification Board has reached the agreement on the Certification status of the Unit the final report will be prepared and sent to them, to the Visiting team and to the Unit informing on the status of their Certification: Initial Certification granted or Conditional Certification granted or failed.

7.6.7. Any objection must have a reason clearly stated, which should cross a basic criterion and be evidence based or supported by a published consensus statement. Such an objection is forwarded to the Board.

If objections from more than one member remain then a teleconference of the Board will be arranged. If the Board fails to reach unanimity then the decision has to be taken by a majority vote: if more than 25% of the Board are against Certification then it will be denied.

7.6.8. If a Unit wishes to appeal against an adverse decision then a letter must be sent to EUSOMA stating the reason for appeal. This will be passed onto the EUSOMA Executive, whose decision will be final (applicant Units should note that Certification is Voluntary and not a legal requirement).

8. Levels of Initial Certification

8.1. Initial Certification

8.2. Conditional Initial Certification, defined standards to be met within a set time period (from 3 to a maximum of 12 months) and once met, Initial Certification will be accorded by Eusoma automatically.

8.3. Fail

9. Full Certification and Re-Certification

9.1. This will be largely electronic and based on the outcome measures for case management stipulated in the various EUSOMA Guidelines, recorded continuously onto the data base designed for the EUSOMA Network.

9.2. Full Certification (see point 6.2) may be applied for when a Unit has 5 years of Audit Data, which may include cases treated in years prior to Initial Certification.

9.3. Re- Certification is applied every 5 years after Full Certification and will again be based on performance indicators and upon long-term outcome measures.

9.4. The data required to be recorded at initial diagnosis and treatment and of the follow-up data, will be available on www.eusoma.org. It is important to note that one of the absolute requirements to be met for Initial Certification is on the ability to submit Audit data to EUSOMA: this data is used for Full and Re- Certification.

The Unit must have an electronic database in place. If the database is not one already approved by EUSOMA (approved databases will be listed on the EUSOMA web site) the procedure for validation will be arranged. Then a transfer of raw (i.e. individual patient) anonymised data to the QT EUSOMA Model Data Set (6) must be made. Assessment by EUSOMA at Initial Certification will depend on the following: transfer can be satisfactorily performed, correct data items are being recorded with the appropriate definitions, if a data analysis system is used to calculate outcomes then the accuracy of that procedure will be assessed.

10. EUSOMA network of certified units

On receipt of Initial Certification the Unit will become a partner in the EUSOMA Network of Certified Units.

All Eusoma Certified Units will be listed in Eusoma web-site. Eusoma is not responsible for Units declaring to be certified by Eusoma, if not listed in this web-site.

The list of Certified Units may be published in any other publications authorised by Eusoma and the certified Units, in order to inform the general public.

Partners in the EUSOMA network will own the collected data submitted to the EUSOMA Database to be used for Full and for Re- Certification. They will therefore be empowered to decide on which data may be analysed collectively and used for research and standard setting. The constituents of Eusoma Network are the General Assembly the Council and the Network Chairman .

The Unit will be asked to fill in a questionnaire and provide data transfer to Eusoma Network Database on an annual basis.

The Unit loses the right to be part of the network and therefore the certification status if:

- The Unit does not arrange a satisfactory yearly data transfer
- The Unit does not pay the yearly administrative contribution
- The Unit does not fill in the yearly questionnaire
- The Unit on the basis of the results of performance indicators analysis and on the basis of the capacity to take the appropriate measures, no longer complies with the Eusoma requirements.

11. EUREF certification (see point 5)

EUREF has already defined its own processes for the certification of screening units (see EUREF Certification Protocol) and has its own Certifying Groups. EUREF Certifying Groups have a different composition from EUSOMA Certifying Groups and include specialists from additional disciplines, e.g. a medical physicist, a diagnostic radiographer (technician) and an epidemiologist. Requests for EUREF certification should be sent direct to EUREF (www.euref.org).

*This document is a revised version of the original Eusoma position paper, R.W. Blamey, L. Cataliotti, **Eusoma Accreditation of a Breast Unit**, published in the European Journal of Cancer 2006;42(10):1331-1337*

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