



Position Paper

European Breast Cancer Conference manifesto on breast centres/units[☆]



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Abstract

Manifesto—CALL TO ACTION:

- The 2016 deadline for all patients in European Union countries to access specialist, multidisciplinary breast cancer units or centres, will be missed by most countries, despite numerous resolutions and declarations issued since the year 2000 that have called for universal specialist services. This means that many women, and some men, do not receive optimal breast cancer care in Europe.
- **We call on policymakers and politicians to ensure, as soon as possible, that all women and men with breast cancer in Europe are treated in a specialist breast unit.**
To do this, we ask that policymakers and politicians, together with healthcare professionals and patient advocates:
 - Promote, in public and professional settings, the evidence that breast units staffed with specialist multidisciplinary teams deliver superior care and quality of life to women and men with breast cancer.
 - Acknowledge the evidence that treatment in multidisciplinary units lead to overall cost savings as well as higher quality of care.
 - Audit the current national provision of breast cancer care using accredited auditors.

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- Implement mandatory reimbursement and care models that mean treatment can only be carried out in specialist breast units.
- Introduce a breast unit quality certification scheme that is accredited by an accreditation body.
- Join European-wide scientific societies and groups that promote the availability and quality of breast units, and **together commit to providing access to such units for all patients.**

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1. Introduction

In the year 2000, the European Society of Mastology (EUSOMA) published a position paper entitled ‘The requirements of a specialist breast unit’, which set out standards for establishing high-quality breast cancer centres, or units, across Europe [1]. The paper followed a consensus statement drawn up at the first European Breast Cancer Conference in Florence in 1998 [2], which set up a working group tasked with ‘forging the way ahead for more research and better care in breast cancer’, and which highlighted the pivotal role of the dedicated breast cancer unit:

‘This conference demands [our emphasis] that those responsible for organising and funding breast cancer care ensure that all women have access to fully equipped multidisciplinary and multiprofessional breast clinics based on populations of around 250,000.’

By the late 1990s, there was evidence that for optimal care, patients with breast cancer must be treated and cared for by specialist, multidisciplinary teams in dedicated breast units. Reports from the United Kingdom (UK), in particular, and guidelines from the European Society of Surgical Oncology and from the European Union on mammography screening, built on this evidence in recommending specialist units as a priority for breast cancer, as it is a major cancer with many and rapidly changing treatment options, has screening standards, and a wide range of psychosocial impacts.

For example, in 1996 a study comparing survival outcomes by specialist and non-specialist breast cancer surgeons in Scotland revealed that the absolute five year survival rate was 9% higher and the 10 year survival 8% higher for patients cared for by specialist surgeons, with a relative reduction in risk of dying of 16% [3]. A later paper from the United States of America, in 2003, found a similar absolute benefit, of 7% at 5 years, and a relative risk reduction of 33%, of treatment by specialist surgical oncologists [4].

In 2012, an observational cohort study evaluated the effects of multidisciplinary team working on breast cancer survival on nearly 14,000 women in Scotland, and found it was associated with a 18% lower breast cancer mortality at 5 years [5]. By comparing an area where multidisciplinary team working was introduced with areas that had not implemented it, the authors found that such care probably improves patient outcomes by influencing various aspects

of care, such as adherence to guidelines and nurse education, increased surgical volume and experience, and improved interdisciplinary working.

Further research is necessary but it is difficult to compare health systems and there are many variables to consider alongside survival, such as quality of life and patient wellbeing. But the overall conclusion is not in doubt among the vast majority of specialists working in breast cancer. The problem is implementation, as it can require major reorganisation of care. For this reason, policymakers, advocates and breast cancer professionals have had to make repeated calls for universal implementation. In particular,

- European Parliament resolutions of 2003 [6] and 2006 [7] included calls on the member states to ‘establish a network of multidisciplinary breast centres’ and to ‘ensure nationwide provision of interdisciplinary breast centres in accordance with EU [European Union] guidelines by 2016’.
- Written declarations on breast cancer in the EU of 2010 [8] and 2015 [9] called on member states to ensure that all women and men in the European Union have access to treatment in units set up in accordance with the ‘European guidelines for quality assurance in breast cancer screening and diagnosis’, by 2016, including those with advanced breast cancer.
- International consensus conferences for early stage (St Gallen Conference) and metastatic (ABC Conference) breast cancer stress multidisciplinary team working as critical to outcomes.
- The ‘European guidelines for quality assurance in breast cancer and diagnosis’, currently in a fourth edition [10], include a revision of the EUSOMA paper on the requirements of a specialist breast unit, and in 2013, EUSOMA updated these guidelines [11].
- The European Commission Initiative on Breast Cancer (ECIBC) is currently developing a comprehensive quality assurance scheme for breast cancer services underpinned by accreditation [12].

The Florence statement of 1998 was direct in demanding—not requesting—that patients with breast cancer must have care in specialist breast units. This manifesto is a repeat of that demand in the light of more evidence for the superiority of such specialist care—and the failure over the past 15 years or so to deliver it to all breast cancer patients in Europe.

2. Status of European breast units, and implications

There is a wide variation of breast cancer care among and within European countries, and in particular still a

lack of access to specialist units as set out in the EUSOMA guidelines.

Some countries do not yet have national cancer plans and networking of cancer units, or may have only recently introduced these.

Countries that lack resources such as sufficient radiotherapy equipment for their populations, and certain cancer drugs, notably in Eastern Europe, are currently unable to provide specialist units in most areas.

Wide variations in healthcare systems and professional working can mean that many patients are not treated according to multidisciplinary guidelines, even in high-resource countries that have cancer plans, and even in cancer departments, as there can be national and institutional variability.

Not all specialist breast units are accredited by independent agencies.

As a result, there are wide differences in treatment and outcomes across Europe. In particular, many women are not offered breast conserving surgery despite being good candidates for that procedure, partly due to lack of radiotherapy equipment, and also because of lack of multidisciplinary expertise and adherence to guidelines. There are also variations in the use of adjuvant chemotherapy, hormone therapy and targeted therapy.

Organisation for Economic Co-operation and Development (OECD) health data from 2012 shows that the proportions of mastectomies and breast conserving surgery vary, with the latter being highest in Germany, Austria, France, Belgium and Switzerland, whereas mastectomy rates are highest in Finland, the Netherlands, Belgium, Denmark, Norway and Iceland [13]. The OECD notes that the level of compliance with national clinical guidelines is one way of assessing whether evidence-based care is provided in breast cancer treatment, although there are differences in clinical guidelines across countries.

A current survey for the ECIBC, organised by the Commission's Joint Research Centre, on the implementation of breast units reveals (publication forthcoming) that a) about a third of respondents do not have a breast unit in their geographical area; b) few have breast units mandated by law, and only up to a half have recommendations for breast units; c) few have national or local accreditation; d) mandatory requirements for a certain volume of case, multidisciplinary teams, training and professional development are mostly in place for only a minority of respondents.

Another survey by the Joint Research Centre [14] that received responses from 25 European countries looked at a number of organisational areas, including breast cancer screening, breast cancer services and quality requirements for services, according to the criteria set out in the European guidelines for quality assurance in breast cancer and diagnosis. The service organisation responses show a wide variation in the provision of components that make up the pathway of

breast cancer care in terms of integration and responsibilities (i.e. from screening to diagnosis, treatment, post-treatment management and rehabilitation), and also in quality management regarding accreditation (a separate Joint Research Centre report on external quality assessment of breast cancer services found only eight schemes that were fully amenable to analysis) [15].

A survey of investigators on a large global adjuvant breast cancer trial found that only about half of the respondents (71 of 141) reported that it was mandatory for cancer institutions to have a multidisciplinary team in their country: 65% of respondents in Eastern Europe, 63% in Western Europe, 35% in Asia and 25% in South America [16]. These figures are much lower when it comes to multidisciplinary discussion of advanced breast cancer patients [17].

A study on variations in compliance to quality indicators in more than 41,000 patients treated in breast units across Europe found that treatment compliance with guidelines is often lower in the youngest and oldest patients, with a tendency to overtreat the youngest and undertreat older patients [18].

There are many good breast cancer services in Europe, but also many locations where parts of a multidisciplinary service are not available or carried out according to guidelines, especially but not exclusively in low resource countries and in rural areas. Apart from a lack of vital therapy, in particular radiotherapy and certain drugs, there can be a lack of integrated care for often-complex advanced breast cancer, and lack of ancillary services that add much to quality of life such as specialist breast nurses, psycho-oncologists, patient support groups, physiotherapists, among others.

The wide range of shortcomings for care of metastatic breast cancer patients is detailed in the largest report so far on this growing number of patients, 'Global status of advanced/metastatic breast cancer: 2005–2015 decade report' [19], which includes several European countries in its surveys.

3. Specialist breast unit requirements

It is not the purpose of this manifesto to describe in detail the requirements for multidisciplinary breast units. But it is important to highlight their scope, as set out in detail in EUSOMA's 2013 'The requirements of a specialist breast centre' [11], as this explains why we are far from their universal provision.

3.1. Definition

EUSOMA's definition of a breast unit or centre is worth quoting in full: *'The place where breast cancer is diagnosed and treated. It has to provide all the services necessary, from genetics and prevention, through the treatment of the primary tumour, to care of advanced*

disease, palliation and survivorship. The breast centre is made up by a cohesive group of dedicated breast cancer specialists working together as a multidisciplinary team with access to all the facilities required to deliver high-quality care throughout the breast cancer pathway.'

The guidelines note that these professionals do not necessarily have to be based in one location, but do need to be in the same geographical area and able to carry out close multidisciplinary work. Further, the guidelines list no fewer than 16 types of professionals that should make up a team, including radiologists, radiographers, pathologists, surgeons, reconstructive surgeons, medical oncologists, radiation oncologists, breast nurses, data managers, geneticists, psychologists and physiotherapists. Note that it is recommended that mammography screening services should be part of or closely located with breast units, partly because of the pivotal role that radiologists play in screening and symptomatic imaging, and also because of the convenience for women of a seamless service.

3.2. Critical mass

A key factor for most specialist cancer work is a minimum number of cases needed to ensure that all team members maintain expertise. It is recommended that at least 150 newly diagnosed cases of primary breast cancer are seen each year from a population of about 250,000.

3.3. Organisation

The guidelines set out the need for protocols, audit, data management and achievement of minimum quality standards. Also specified are multidisciplinary team meetings, and best practice for patient communication.

3.4. Staffing

The core breast cancer services—radiology, surgery, medical oncology, radiotherapy, pathology, nursing—must have at least two professionals in each department, and all staff should comply with EUSOMA's guidelines on standards for training specialised health professionals who deal with breast cancer [20]. Note that in 2013, a manifesto adopted at the Ninth European Breast Cancer Conference identified breast cancer pathology services as needing particular attention [21].

4. Policy, organisational drivers and best practice

In this last section, we summarise European and national initiatives, projects and tools for running a breast cancer service, and give examples of models of care. As there is currently wide variation in the organisation of breast units in Europe, we do not attempt to be comprehensive in listing initiatives in all countries.

We highlight the crucial role of quality and certification for breast units, examples from countries, and key resources and networks.

4.1. Quality and certification

EUSOMA states in its requirements for a specialist breast centre that all units must achieve minimum standards for the mandatory quality indicators defined in EUSOMA's 2013 paper about quality indicators in breast cancer care [22]. The authors note: 'Breast cancer care is complex, onerous and expensive, therefore quality measurements are essential to monitor effectiveness and to guide improvements in healthcare,' and that EUSOMA started a voluntary certification process to assess the clinical performance in breast cancer care in dedicated units in European countries.

In turn, quality indicators are used for benchmarking and certification/accreditation of breast units. The EUSOMA initiative is currently based on the Breast Centres Certification scheme [23]. There is now a new scheme taking shape at European level (see Section 4.2). At present, some countries, such as Germany, Switzerland, Spain, the Netherlands and the UK have their own certification arrangements, which is where a good deal of experience has also been generated.

In a recent paper, EUSOMA has looked at the impact on breast units after certification, using a central data warehouse that collects indicators from a working group of breast units around Europe and now includes more than 80,000 patient cases [24]. Although this shows only a significant improvement for a minority of quality indicators after certification, the authors say that 'dedicated units already provide a high level of care before certification, but continuous monitoring and audit remains of paramount importance as complete adherence to guidelines is difficult to achieve. Adherence to guidelines improves markedly and there are data emerging which show that this results in better outcomes.'

4.2. European Commission Initiative on Breast Cancer

The ECIBC [12] comprises two working groups. The Guideline Development Group is developing a new edition of the European guidelines for quality assurance in breast cancer screening and diagnosis, and the Quality Assurance Scheme Development Group (QASDG) is developing a set of common quality and safety requirements for breast cancer services in Europe.

The latter group, QASDG, is building on EUSOMA and national initiatives, and its subgroups are working on all aspects of testing (such as imaging and pathology), competence (training and continuous education), quality concepts, organisation and scope, indicators, certification processes and clinical research. It aims to set out accreditation according to international standards for certification bodies to assess the whole care

pathway for breast units, as well as for parts of the service such as pathology, and will fill in gaps such as metastatic disease not yet covered by EUSOMA.

Importantly, it has a modular approach so that it can adapt to different breast services in Europe, as some have the entire pathway from screening to end of life under one ‘house’ but others have separate organisations for screening, treatment and end of life care. One of the key outputs will be a requirements manual covering domains such as clinical effectiveness and facilities, cross-referenced to an indicators library.

The quality assurance scheme will be launched as a voluntary tool for Europe following the completion of reference documents and a pilot run at a sample of breast cancer services. It is expected to be available in member states by 2018/19 and the development group is welcoming feedback via the European Commission’s Joint Research Centre.

See also an ECIBC presentation on ‘the quality of quality metrics’ in healthcare, illustrated by breast cancer surgery, where outcomes that are harder to measure—but need to be, such as patient satisfaction—are outlined [25].

4.3. Country case study—Germany

The certification system launched in Germany in 2003 is of wide interest as it is a voluntary initiative that has been subject to evaluation in several papers (published in English) and because it also covers breast cancer centres in Austria, Switzerland and Northern Italy. The certification system is part of Germany’s cancer plan, as are breast units, which were the first specialist cancer centres in the country established by the German Cancer Society.

Benchmarking of certified breast centres (of which there are now more than 210 at some 270 operating sites) using quality indicators (QIs) showed ‘a very high level of fulfilment of the QIs’ [26], and that since the certification was introduced after unsatisfactory results had been noted in the pan-European Eurocare survival study [27], there has been a substantial increase in 5 year survival rates. Although this cannot be seen as causation, the authors say there has been a high degree of satisfaction by patients and hospital management with the measures, along with improvement of compliance with guidelines.

Most hospitals treating breast cancer in Germany have joined the programme, demonstrating what can be achieved with a voluntary certification system. Of particular importance is that the quality indicators are audited by an independent certification institute (in Germany this is a private company called OnkoZert).

4.4. Other health system models and initiatives

The following are examples of initiatives in a selection of other countries and do not represent the complete

picture in these countries. The breast units survey by the ECIBC gives a guide to organisational factors (publication forthcoming), with the following topics:

- Breast units present in a respondent’s geographical area
- Breast units required by law
- Breast units recommended as policy
- National accreditation/certification of breast units
- Regional/local accreditation/certification of breast units
- Mandatory accreditation/certification of breast units.

As noted in the status section of this manifesto, unpublished results show few countries have legal requirements and also few have regulated accreditation/certification systems for breast units; most initiatives in Europe are voluntary. The ECIBC has also collected other information on quality schemes for breast cancer in Europe, including screening, as also noted in the status section above (see Section 2). More details are available in a presentation [28].

4.4.1. Peer review and quality statements

One of the first European countries to recognise the role of breast units was the UK. After reports from the mid-1990s showing the advantages of specialist units and the ways that cancer services could be organised at regional level, the National Health Service (NHS) in England moved quickly to establish multidisciplinary teams and networks that covered the breast cancer pathway and those of other cancers, across hundreds of hospitals. Today the NHS operates National Cancer Peer Review, a quality assurance programme for NHS cancer services, including breast cancer [29]. It involves both self-assessment by cancer service teams and external reviews of teams conducted by professional peers, against nationally agreed quality measures. See the quality standard for breast cancer published by the National Institute for Health and Care Excellence, which details 13 quality statements for services [30].

4.4.2. Audit

Few countries operate a systematic audit of breast cancer services. The Netherlands is one—since 2011 the NABON Breast Cancer Audit started collecting data from all Dutch hospitals with the aims of nationwide evaluation of quality parameters, evaluation of guideline adherence, and weekly feedback to participating institutions. Within 3 years, several quality assessments improved, such as guideline compliance for preoperative and postoperative multidisciplinary team meetings, and percentage of patients starting surgery within 5 weeks [31]. Although there is not currently a certification system, nearly all hospitals run multidisciplinary breast units with dedicated teams with case volumes ranging from 60 to 600 a year. The ministry of health has also insisted that all breast cancer indicators for hospitals are published.

4.4.3. Reimbursement

In the Netherlands, a driving force for change has been the government's healthcare inspectorate and insurance companies, as the latter now only reimburse care in hospitals that conform to the audited quality indicators (as above). A similar reimbursement approach has now also been adopted in Italy—payments will only be made in centres with certain minimum caseloads, which will be come into force by the end of 2016.

4.4.4. Legal measures

In December 2014, the Italian ministry of health issued a rule, since approved by regional administrations, that all regional health services must organise breast units according to a minimum case load of 150 new breast cancer cases a year, the first cancer type to be managed in this way in the country. Further, a non-profit organisation (Senonetwork Italia) [32] has been set up to network breast cancer services and promote treatment in dedicated centres, and also training, with universities as partners. So far, it has signed up more than 100 centres in Italy.

There is mixed news from Belgium, a country with Europe's highest breast cancer incidence. In the early 2000s, an audit of breast cancer services found that many hospitals fell far below the minimum case load recommended by EUSOMA, and that 5 year survival was 77% at low volume centres compared with 84% at high volume centres, and that less than 60% of women underwent breast conserving surgery. In 2007 a royal decree defined standards for specialist breast units, largely based on EUSOMA requirements, and owing to pressure from Europa Donna Belgium and politicians. But no auditing has since been carried out, and in 2013 the law was amended to downgrade the volume requirement (to 125 cases a year), and quality indicator monitoring is currently voluntary.

4.4.5. Ringfenced budget

After many years of lobbying and presenting European guidelines advocates, in 2015 Cyprus has gained government support to set up the country's first certified breast unit. Importantly, it is a specific item in the country's healthcare budget and implementation is currently being monitored by advocates as a model for rolling out to other hospitals.

4.4.6. Telemedicine

Despite access to many standard therapies for breast cancer, patients in Romania have worse outcomes than patients in high-resource countries who receive the same treatments. There are plans to implement a telemedicine web-based platform that will enable an experienced multidisciplinary breast tumour board at the Ion Chiricuta institute in Cluj-Napoca to review cases and improve treatment decisions for patients in small, remote centres. This is through a grant from the

American Society for Clinical Oncology [33]. The use of telemedicine is growing around Europe, such as for networking remote units in Sweden.

4.5. Advocacy and charitable organisations

It is no exaggeration to say that advocacy organisations have played a pivotal role in raising standards for breast cancer care. Europa Donna, the European Breast Cancer Coalition, has member groups in 47 countries and campaigns at European and country level to improve breast cancer services, and specifically for the implementation of specialist breast units in all countries. It was instrumental in drafting and advocating for the European Union resolutions and declarations described in the introduction to this manifesto paper.

Europa Donna has developed a range of materials, including a short guide to the European guidelines for quality assurance in breast cancer screening and diagnosis that has been translated into 17 languages [34,35].

At national level, advocates in various countries have been successful in changing policy about breast cancer. A good example is lobbying by UK charity, Breast Cancer Care, for better data on metastatic breast cancer, resulting in a data collection project and moves to routinely record more information in registries [36]. In Italy, Europa Donna Parlamento is a group that comprises the Italian forum of Europa Donna and women members of parliament that has lobbied for setting up regional committees that address the regionalisation of health services in Italy.

4.6. Other European/international initiatives and resources

The mission of the Breast Centres Network is to promote synergy among breast units by connecting specialists and personnel working in the field, and to help breast cancer patients find the right place for care or for a second opinion [37]. It is run by the European School of Oncology and currently lists more than 220 breast units globally.

The American College of Surgeons runs the National Accreditation Program for Breast Centers, and its 2014 standards manual is available for download [38].

5. Conclusion

We hope this manifesto and supporting evidence will encourage policymakers, health professionals and advocates to investigate their own national and local provision of specialist breast units and the tools and criteria currently in use for developing consistent, high-quality breast cancer care.

Apart from the imperative to care for all breast cancer patients in specialist units, according to our call to action, it is important that thorough European-wide

research is carried out to quantify and qualify the exact provision of breast cancer services in each country so that better comparisons of health systems policy can be made, and more examples of best practice generated.

Conflict of interest statement

None declared.

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