



**Breast Center Accreditation &
Certification Comes of Age
Part Three - BICOE and EUSOMA**

*Integrated Oncology Consulting Solutions
And Cancer Care Center Planning*

Breast Center Accreditation & Certification Comes of Age

Part Three - BICOE and EUSOMA

By Eva Huddleston and Marsha Fountain, RN, MSN

In the final installment of the *Breast Center Accreditation & Certification Comes of Age* series, we will discuss Breast Imaging Center of Excellence (BICOE) designation, conferred by the American College of Radiology (ACR) and the European Society of Breast Cancer Specialists (EUSOMA) certification process.

Breast Imaging Center of Excellence (BICOE) Certification

Part of the American College of Radiology's (ACR) mission is to advance the science of radiology and improve the quality of patient care. In support of this mission, the ACR created the Breast Imaging Center of Excellence (BICOE) designation. BICOE recognition is awarded to any breast-imaging center that:

1. Obtains mammography accreditation, either through an FDA-approved state program or the ACR; and
2. Receives ACR accreditation in the following areas:
 - a) Stereotactic Breast Biopsy
 - b) Breast Ultrasound to include the US Guided Breast Biopsy module.

Accreditations necessary for BICOE recognition are voluntary with the exception of Mammography, which is a mandated accreditation for all breast-imaging centers. The ACR has announced that future criteria may include Breast MRI accreditation and audit requirements.

Facilities located at a single physical address who received all accreditations through the ACR will automatically receive a BICOE certificate from the ACR. If the facility receives their mandatory mammography accreditation at the state level and/or has one or more accreditation under a separate address, they must request a certificate from the ACR. The request form is available at www.gm.acr.org/accreditation/bicoe/request_form.aspx.

Benefits of BICOE Designation

Breast Imaging Centers of Excellence (BICOE) will be identified with:

1. A gold seal on the ACR's Accredited Facility Search web page at www.acr.org/accreditation.aspx;
2. Receipt of a BICOE certificate for display in the facility;
3. Participation in the National Mammography Database (NMD) at no cost. The NMD allows participating facilities to compare practice patterns and patient outcomes with other participating breast imaging facilities nationwide.

An additional benefit according to Dr. Suzanne Thigpen from Georgia Health Sciences University is that “BICOE status puts a gold star not just on hospital’s mammography but other modalities as well. Breast ultrasound, ultrasound-guided breast biopsy and stereotactic breast biopsy modalities are all accredited under the center of excellence designation.”

For more information on the ACR’s Breast Imaging Center of Excellence certification process go to www.gm.acr.org/accreditation/bicoe.aspx.

EUSOMA – One European Model

The European Society of Breast Cancer Specialists (EUSOMA) has as its mission to “define gold standards in the management of breast diseases, favouring (sic) a rapid transfer of knowledge from research centres to clinical practice”. One of their four aims is to define standards for patient care in the screening, diagnostic, treatment and support procedures for breast cancer and make them available throughout Europe.

While there are guidelines developed ranging from diagnosis to treatment to complementary therapies, the main accreditation and a cornerstone to the mission of the organization is the development of a certification process for Breast Units. To achieve that, EUSOMA has appointed the European Cancer Care Certification to run the Breast Unit Certification.

In the US, we may think of a unit as a mammography machine. In this model of care, a “Unit” is defined as “clinicians and other professionals specializing in a single anatomical area for diagnosis and treatment”. Therefore, a Breast Unit is where women with breast disease are cared for by specialists in that disease working as a team for diagnosis and treatment.

Requirements

The full requirements for a specialized Breast Unit cover 31 pages and can be found at www.eusoma.org/doc/EusomaBURequirements2010.pdf. In order to qualify, there are a number of mandatory requirements. These include a validated database, 150 newly diagnosed cases of primary breast cancer coming under its care each year and a clinical director.

There are 17 major quality indicators covering diagnosis, surgery, treatment, counseling, follow-up and rehabilitation.

A key component of the Breast Unit is:

The implementation of the suggested structure of Breast Units requires a reorganization of time in each discipline, so that as medical specialists spend more time in breast disease, his or her colleagues no longer treat breast cancer and specialize in other areas. Such a move would coincide with changes that are already occurring within all disciplines; for example, from General Surgery the emergence of specialist surgeons for urology, micro invasive techniques, vascular surgery, upper GI, hepatic and colon. All work must be carried out or directly supervised by specialists specifically trained in breast disease. A service provided by trained specialists is more efficient and more cost effective.

Mandatory Indicators Similar to US

In order to be certified as a Breast Unit, the organizations have selected 10 mandatory quality indicators listed below:

The proportion of:

1. Women who had a pre-operative diagnosis of cancer
2. Invasive cancers with primary cancer for which specific prognostic/predictive parameters have been recorded such as type, grade, ER/PR status
3. Non-invasive cancer cases which have Dominant histological pattern and grade
4. Patients with invasive cancer and axillary clearance performed with at least 10 lymph nodes examined
5. Patients (invasive cancer M0) who received postoperative radiotherapy after surgical resection and axillary staging
6. Patients with invasive breast cancer not greater than 3 cm who underwent BCT
7. Patients with non invasive breast cancer not greater than 2 cm who underwent BCT
8. Patients with DCIS who do not undergo axillary clearance
9. Patients with endocrine sensitive invasive carcinoma who received hormonotherapy
10. Patients with ER/PR negative cancer ≥ 2 cm and/or node+ disease who received adjuvant chemotherapy

Many of these measures correlate with those from the organizations discussed previously.

The methodology for certification includes an application and online questionnaire followed by an onsite audit team including a visit manager, breast surgeon, breast radiologist, breast pathologist and a breast care nurse. If the Unit has some mandatory requirements which are not satisfactory, the Unit can report back in two weeks with a plan to comply. If the corrective action plan is approved, the Unit has six months to fulfill the requirements. A committee reviews all audit information and either certifies the Unit or denies the certification. Once credentialed, there are Surveillance Audits for two years with a full re-audit after that time.

At this time, there are 17 approved units in Austria, Belgium, Germany, Italy and Switzerland.

EUSOMA is not the only certifying agency in Europe. In 2009, a German researcher surveyed European countries for Breast Unit Standards for certification. The conclusions?

Seven of the 9 countries (78%) have a certification process of the breast units. Certification is carried out by public authorities in 4 (57%) countries and by private companies in 3 (43%) countries. Information on frequency of auditing was reported in 4 countries and varied between annual audits (Austria, Ireland and Germany) and audits once every 3 years (United Kingdom).

Conclusions: The current study suggests that the European breast unit landscape is a heterogeneous field. 9 years after the EUSOMA position paper, we do not have any standard European guidelines, neither for the development nor for the mandatory prerequisites of a breast unit. The development and operation of breast units are still country specific.¹

For more information on EUSOMA and the mission and goals, refer to www.eusoma.org.

¹ Taran FA, Eggemann H (2009) Breast Units in Europe – Certification in 9 European Countries 9 Years after the European Society of Mastology Position Paper. Breast Care 4:219-222