



Quality Assurance in Breast Health Care and Requirement for Accreditation in Specialized Units

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ABSTRACT

Breast health is a subject of increasing importance. The statistical increase in the frequency of breast cancer and the consequent increase in death rate increase the importance of quality of services to be provided for breast health. For these reasons, the minimum standards and optimum quality metrics of breast care provided to the community are determined. The quality parameters for breast care service include the results, the structure and the operation of services. Within this group, the results of breast health services are determined according to clinical results, patient satisfaction and financial condition. The structure of quality services should include interdisciplinary meetings, written standards for specific procedures and the existence of standardized reporting systems. Establishing breast centers that adopt integrated multidisciplinary working principles and their cost-effective maintenance are important in terms of operation of breast health services.

The importance of using a “reviewing/auditing” procedure that checks if all of these functions existing in the health system are carried out at the desired level and an “accreditation” system indicating that the working breast units/centers provide minimum quality adequacy in all aspects, is undeniable. Currently, the accreditation system for breast centers is being used in the European Union and the United States for the last 5-10 years. This system is thought to provide standardization in breast care services, and is accepted as one of the important factors that resulted in reduction in mortality associated with breast cancer.

Key words: Breast health, breast center, quality assurance, accreditation

Introduction

Breast health is a subject of increasing importance. The increase in breast cancer incidence and mortality rates affects medical approaches to breast health. Given the innovations in medical technologies and treatment options, the importance of the quality of services for breast health is apparent. That is why the quality of breast health should be improved. The European Society of Breast Cancer Specialists (EUSOMA) and other civil society organizations across Europe and all over the world are determining minimum standards to improve the quality of breast health (1, 2). Two basic approaches are available for breast health services. The first one is the individual approach. Nowadays, a modern and contemporary approach is evolving against this classical type, which is a multi-disciplinary approach (3).

Multi-disciplinary Approach

Multi-disciplinary approach in terms of breast health involves breast surgery, radiology, pathology, medical oncology and radiation oncology (3). Currently, two kinds of applications are available in this type of approach, a. Fragmented and b. Collaborative approach.

Multi-disciplinary approach structuring is being done in two different ways. The first one is “classic multidisciplinary” structuring that includes “horizontal” cooperation, and the other one is in the form of “interdisciplinary” structuring that provides “vertical” and “horizontal” cooperations together (4). In the “horizontal multi-disciplinary” structuring, a team of specialist doctors from multiple branches works together and this is being carried out in some rare centers in our country for the last 10 years. Within this structure, radiology, pathology, breast surgery or general surgery, radiation oncology and medical oncology experts are expected to apply a shared diagnosis, treatment and follow-up process. In contrast, the “interdisciplinary” approach is characterized by including not only the experts of the previously mentioned clinical branches but also the supporting health personnel from each individual branch within the structure with principal duties (5). The mentioned supporting health personnel include chemotherapy, radiotherapy and high-risk nurses, radiology (mammography), nuclear medicine, cytology and laboratory technicians, genetic counselors, social workers, support group members, psychotherapists, clinical psychologists, family counselor and support service officials. Breast health services provided by these different layers

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of health care workers create the “interdisciplinary multi-disciplinary approach”. This collaborative multi-disciplinary approach represents itself best in original “breast unit/breast center” structure where the aforementioned branches serve together (3).

Quality Measures

The quality helix of breast health is in the form of a structure composed of three units; a.monitoring, b. intervention and c. comparison (benchmarking). Breast health assessment tools are important measures of quality of service. These criteria are evaluated in three steps: a. the results of services, b. the structure of services and c. the operation of the service (6) (Table 1).

For the results of health care services, the clinical outcomes are evaluated. Then patient satisfaction and finally the financial condition are taken into consideration. In the evaluation of the financial situation, “profit and loss” situation is analyzed and the results are laid out in detail (7).

Validated guidelines that have previously been recognized at the national or international levels are used for clinical assessment of results. For example, the European Union (EU) member countries use the fourth edition of the European Quality Assurance in Breast Cancer Screening and Diagnosis Guideline that was published in 2006 for

this assessment. Performance indicators are needed for the assessment of clinical outcomes (8) (Table 2). The performance of the clinic is established by each performance marker, and it is re-assessed if they comply with the minimum requirements. If desired, inter-institutional

Table 1. Quality parameters for breast health service

- 1. Outcome
 - a. Clinical outcomes
 - b. Patient satisfaction
 - c. Financial situation (Profit/cost)
- 2. Structure
 - a. Inter-disciplinary meetings
 - i. Diagnostic meetings
 - ii. Therapeutic meetings
 - b. Operational standard procedures
 - c. Standardized reporting system
- 3. Functioning

Table 2. Performance criteria for evaluation of the clinical outcomes in breast health according to the 2006 European Guidelines for Quality Assurance in Breast Cancer Screening and Treatment

Performance Criteria for evaluation of breast health clinical outcomes

- In over 95% of the patients with palpable breast cancer triple assessment (PE, Mammography, FNA/Core biopsy) is performed.
- The delay between mammography and result should be less than 5 working days.
- The delay between mammography and further investigations should be less than 5 working days.
- The delay between the decision to operate and the operation day should be less than 15 working days. Ideally, it should be less than 10 working days.
- More than 90% of patients proven to have breast cancer should have a pre-operative FNA or core biopsy at the diagnosis of cancer.
- More than 70% of patients subsequently proven to have clinically occult breast cancer should have a pre-operative FNA/core biopsy that is diagnostic for cancer.
- Every patient with an invasive cancer considered to be suitable for breast conservation must have information about the possibility of BCT.
- Over 90% of women having conservation surgery should have 3 or less therapeutic operations.
- Patients with invasive breast cancer of less than 2 mm or tubular cancer of less than 10 mm do not need lymphatic mapping or elective axillary dissection (or only RT application).
- For patients with an invasive cancer, information on the nodal status should be obtained (eg. lymph node sampling >4 nodes, or ALND more than 10 nodes, or sentinel lymph node biopsy).
- More than 90% of the patients with invasive cancer and proven lymph node metastasis should have axillary treatment (ALND, radiotherapy to the axilla or combined in extensive nodal involvement).
- The breast relapse rate for invasive cancer after BCS should not exceed (1-2%/year) 15% at 10 years.
- Excellent or good cosmetic result from a patient’s point of view should be at least 80% at 3 years.
- The chest wall relapse rate after mastectomy for invasive breast cancer should be less than 10% after 10 years.
- BCS after preoperative CT (for histologically-confirmed) patients should result in a breast relapse rate of less than 15% after 10 years.
- Over 80% of the patients with a locally advanced breast cancer should have combined modality treatment (preoperative CT, cytoreductive surgery, radiotherapy).
- The breast relapse rate (invasive cancer) after BCS for DCIS should be less than 10% at 10 years.
- The chest wall relapse rate after mastectomy for DCIS should be less than 5% at 10 years.

PE: Physical examination; FNA: Fine needle aspiration biopsy; BCS: Breast conserving surgery; ALND: Axillary lymph node dissection; CT: Chemotherapy; Preop: Preoperative; DCIS: Ductal carcinoma in situ

comparisons can also be made. If there is no local guideline that is suitable for local characteristics, a national or regional guide appropriate for this purpose should be created (9). Another step in evaluating the results of services is to determine patient satisfaction. "Patient questionnaires" are used for this purpose. In these forms, questions regarding both patient satisfaction at various service levels and demographic information are included. Within this survey, patients are asked question about the approach of doctors and other medical staff to patients, the appointment process, the appointment method, the information about the medical situation and investigations. In a study regarding this area, it has been demonstrated that multidisciplinary breast centers offer the patient a highly satisfactory service within a short time for the diagnosis of breast diseases (10). The final step in the evaluation of the results of services is the organization's financial situation. The profit and loss during the services provided are calculated and it is revealed if the institution's operation is efficient within this structure (4, 7).

Another factor among quality of service criteria is the nature of the services provided. The structure of breast health services must be arranged by considering patient safety. In this context, interdisciplinary meetings should be held to ensure maximal diagnosis and treatment safety, written instructions should be prepared stating standard criteria for various processes and initiatives and standardized synoptic reporting systems should be implemented (6, 11).

Interdisciplinary meetings are organized as either multi- or interdisciplinary manner. These meetings are organized in two ways: a. for diagnostic purposes and b. for treatment (3, 4). Diagnostic meetings require the presence of specialist physicians from surgery, radiology and pathology clinics (12). The goal in these meetings is to make diagnosis correctly and quickly, provide interdisciplinary communication and support training in each discipline. Standard schemes have been developed to make the correct diagnosis quickly and to improve early application in primary care (13). Making the correct diagnosis in a timely manner is also one of the priority targets in Turkey. In a study conducted in Turkey, the average length of time between when the patient first noticed signs of breast cancer and when she contacted a health care provider was reported as 10 days. In this same study, the mean period between referral to a health care provider and biopsy was found to be 10 days, while the mean elapsed time from biopsy to surgery was reported as another 10 days. The mean time between surgery and systemic treatment was found as 31 days. Based on the data from this study, the interval from referral to biopsy, biopsy to surgery and surgery to postoperative systemic therapy is much longer in Turkey, despite marked regional differences, as compared to developed countries (14). These results reveal the requirement for interdisciplinary diagnostic and therapeutic meetings in Turkey in order to improve the quality of breast health services and provide faster diagnosis and treatment. The primary purpose of multi-disciplinary meetings for treatment is to determine if all prospectively conducted diagnostic initiatives were performed properly and accurately, if the surgical treatment was sufficient and to ensure the implementation of the most appropriate treatment for the patient after deciding on the correct adjuvant treatment options. Providing the environment for continuing medical education, developing cancer registries, evaluating health care quality improvement programs and quality practices, contributing to the implementation of standard clinical protocols, and creating an environment and an opportunity for clinical study, research and innovation are among secondary objectives of therapeutic meetings (4, 12, 15). With the multi-disciplinary meeting for treatment purpose, adequate and accurate data is collected, adequate pathology report is

prepared, and adjuvant treatment is started in a timely and accurate manner. It has been shown that by conducting these meetings; more breast conserving surgery is done, adjuvant radiotherapy is given more frequently if required, the rate of neoadjuvant therapy application increase, the interval between treatments is shortened, and both patient and physician satisfaction (in terms of communication and cooperation) increase (16-18). A coordinator is responsible for the organization and execution of these multidisciplinary meetings that aim to improve the quality of breast health services. These meetings must be regularly held in a certain place, at a fixed day and time of the week. It is recommended that these meetings should continue for at least 1 hour. Each meeting is supported by pathology and radiology imaging technologies and all meetings are recorded (11).

Another parameter that is taken into consideration during the assessment of breast health services is the presence of written, standard criteria for particular procedures. For example, sentinel lymph node biopsy in clinical N0 patients, and diagnosis and treatment protocols in patients with locally advanced breast cancer can be listed among such procedures. The required standard criteria for sentinel lymph node biopsy are adapted according to previously prepared standard protocols for indications, methods and evaluation that have been by surgery, nuclear medicine and pathology units (3).

Quality standards for breast health services also include the use of standard templates for reporting of procedures. The use of standard forms, in reports that are being used by breast health services such as radiological imaging, pathology and surgery reports, is recommended. The data being reported in such forms should be concise, standard, electronic, related to the aim, suitable for data protection, not time consuming, and easily accessible. In this way, assistance in internal and external correspondence and archiving can be provided (19).

The last parameter used in the evaluation of the quality of service is the way service is functioning. The easiest and most functional way of projecting all the above quality improving methods in combination to service, is to provide this service within breast centers (units). The mentioned breast center is a concept created in order to provide multidisciplinary service (20, 21). The main goal of breast centers is providing coordinated, rapid and high quality breast health services for breast cancer, which is the most common cancer in women. It is intended to both using labor efficiently, and providing savings in health care in general by this means. Diagnostic and comprehensive treatment services are targeted through breast units. Breast units can be either centers for both diagnostic and treatment purposes or specific centers acting only for the diagnostic process. In diagnostic breast units, surgeons, radiologists and pathologists work together. Indications for biopsy are given together, suspicious cases that are identified during routine scanning are quickly consulted with the surgeon (22). Mammograms of women presenting with symptoms are performed within the same day, and if necessary, additional investigations such as ultrasound and breast biopsy are carried out to provide a rapid diagnosis. In more comprehensive breast units, therapeutic services are offered as well as diagnostic procedures. Reconstructive surgeons, medical oncologists and radiation oncologists are also included in patient care in addition to the above-mentioned experts from three departments in these units. In even more comprehensive units, psychiatrists, gynecologists, physical therapy and rehabilitation specialists are involved (5, 23).

A breast center is defined as a group of experts who essentially work only on breast cancer in one building; however, it is not necessary to

be under a single building in terms of physical conditions. These services can be offered under the concept of breast unit, in all cases where multi-disciplinary practice within reasonable distance of each other is possible, despite being in separate buildings. The standard breast unit (center) requirement is 30-40 units per every ten million population. The location of these units in large or medium-sized hospitals is more appropriate in terms of efficiency. It is expected that at least 150 newly diagnosed breast cancer patients (regardless of stage, or surgical treatment) is treated annually to ensure that the treatment services work effectively and the specialists gain adequate experience. Patients who were diagnosed in other centers are included in this figure but those who had been treated elsewhere and were referred only for systemic therapy or radiotherapy should not be included. In these centers, at least 50 breast cancer surgery must be done per surgeon. In addition, specialist physicians working in the breast center are expected to fulfill certain criteria. The physicians should spend half of their çalışma süresi in the breast cancer clinic, surgery, pathology or image reading, multi-disciplinary meetings, and outpatient treatment. For example, a breast radiologist should evaluate at least 1000 diagnostic mammograms annually, and if they are working in a screening center they should assess at least 5,000 mammograms annually (1, 8, 24). The indispensable core staffs of breast centers are the breast (maintenance) nurses. These are qualified nurses who are trained to provide psychological support to breast cancer patients (especially during diagnosis) and forming a bridge between patients and clinicians during follow-up (1, 5, 8, 24).

Breast center performance results are recorded on an annual basis and these data are compared according to the criteria in the manuals. Therefore, breast centers must have appropriate standards. The expected standards include execution of services by a team of experts from breast health-related disciplines, presence of written and easily accessible clinic specific or regional/national diagnostic and treatment guidelines, implementation of weekly interdisciplinary meetings, creation of an on-going cancer database and above all a structured leadership policy for breast health programs. Another expected standard is the participation of at least 4% of patients who are treated in that institution, in a clinical trial that the institution is included in (25).

The quality spiral of the services offered for breast cancer is evaluated in five steps, as in all health care practices. The first step includes preparation of the institution's building/ device/equipment infrastructure and elemental. In the second step, the established institution is primarily evaluated for essential criteria. The third step is offering the service for a certain period, according to the initial directives. In the fourth step, clinical applications are monitored and services are assessed according to specified performance criteria (auditing). In the last step, the action plan of the clinic is revised according to the evaluation results and the vision and targets are developed in the field of application. During these steps, data collection and appropriate recording are crucial tasks. In this way, institutions and their activities can be kept under annual periodic control in terms of quality assurance. Also the efficiency of the institution and also whether it acts in accordance with its aims can be demonstrated (26).

Accreditation of Breast Health Services

Currently, in light of the principles mentioned above, accreditation has become a necessity to improve the quality of service in breast health services. The European Society of Breast Cancer Specialists was founded as an organization that gathers experts from each discipline that deal with breast cancer under one roof. Within this organization, experts who deal with breast cancer in terms of risk and protection, diagnosis and treatment, follow-up, treatment of recurrence and ad-

vanced disease, pathology, reconstruction, and psychological support are included. This organization also prepares comprehensive guidelines to create a standard approach to breast cancer patients in various areas (1). This institution has defined quality assurance parameters that have been implemented by the European Union (EU), which in turn has led to the accreditation of institutions within the Union (27). The breast center accreditation program, which is implemented as the official EU policy since 2002, has led to the accreditation of only four hospitals or units until now (28). Likewise, a national accreditation program is being implemented in the United States since December 2008. In this program, 27 standard criteria within 17 main components are taken into account. Nonetheless, three standard components are essential.

These are: 1. The breast center organizational structure should give the program leader the opportunity to take initiatives, 2. Patients should be discussed in interdisciplinary meetings, and diagnosis and treatment services should be given at the previously agreed national standards, and 3. An interdisciplinary team should manage the patient after cancer diagnosis. Following accreditation, the efficiency of the clinic is reviewed and the validity of the accreditation is approved by on-site evaluations in every three years. With this program, 270 breast centers from 41 states have received national accreditation in the United States as of February 2011 (29).

The preparation of national guidelines in Turkey was first initiated in Breast Cancer Consensus held in 2006. This conference call was then repeated in 2008 and 2010, in order to establish national standards for breast cancer (30). However, it is not known how much of these standards included within the guide are being applied during practice. In a study conducted in our country, it was identified that there was not a homogeneous application in the diagnosis and treatment of patients with breast cancer, and there was implementation differences by geographic region. It was reported that the standards accepted by national and international institutions were not widely practiced in our country. Insufficient infrastructure and the absence of multidisciplinary approach in diagnosis/treatment were determined as the most important shortcomings (31).

With the applications that are performed in the framework of breast health service, quick, clinical and cost-effective service is delivered. Similarly, with the development of cooperation in education, more skilled manpower is created. By the development of common clinical and research projects, development of rational authentic health policies that are supported by regional evidence is provided (23).

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