9

Organization of Care

"Future of Total Quality Management in Breast Centers"

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9.1 Introduction

Over the last 50 years, advances in computer sciences, software, pharma, screening, and early detection technologies have had a very positive impact on breast cancer survival rates. Along with these technologies, changing service perception and patient-centered approaches have radically changed the known conventional service approach.

Breast centers built in hospitals or separate units facilitated the management of anxiety in women diagnosed with breast cancer with the specially designed examination and waiting areas. They led the spread of patient-oriented design throughout the hospitals.

Van Nuys Breast Center, which was established in 1979, with the name of "breast center" for the first time, has taken its place in history as an excellent example of today's centers with its design and multidisciplinary approach [1].

With its design, multidisciplinary approach, and systematic approach in the treatment planning process, Van Nuys has led the breast centers serving today and changed the quality's meaning in breast care.

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European Academy of Senology, Düsseldorf, Germany From 1979 onward, changing and developing practices will determine how future breast centers will be shaped by centralized "value-based medicine" and "total quality management tools."

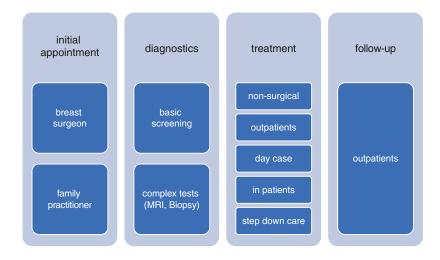
Beginning from the design of a breast center, patient journey auditing, patient-oriented thinking, multidisciplinary approach, data management, certification, and value-based medicine are the main topics of total quality management.

9.2 Breast Center Design

Breast centers should have a multidisciplinary approach and building design to manage a woman's anxiety because every woman who steps into the center comes with the information about the frequency of breast cancer announced by the media. When horror stories about breast cancer diagnosis and treatment from the nearby environment are added to them, the fear of bad news can sometimes lead to an inescapable anxiety disorder. For this reason, the area where screening processes are managed should be designed separately to reduce the woman's anxiety in the design of the building. In large hospital complexes, the door entering the screening area can be provided in the first step by reducing the anxiety by leaving the general hospital entrance. When planning with the architect, a suggestion for basic breast patient flow is given in Fig. 9.1.

In the design of the breast centers, the presence of the screening center and the high-risk

Fig. 9.1 Basic architecture plan recommendation to discuss with the architect



women's clinic on the same floor is significant for accessibility. Reaching multidisciplinary team members' examination rooms from a single entry accelerates the service. In MSKCC Evelyn H. Lauder Breast Center, which is one of the best examples of design and easy access in the world, the entrance of the breast center was designed in a separate area, providing the woman with a modern and relaxing space and easy access to all multidisciplinary team members. Screening tests performed by the breast radiology team and the connection with the breast surgeon on the road to the diagnosis were reflected in the building to reduce the anxiety and provide a safe environment.

Another example is the Luisenkrankenhaus, home to the European Academy of Senology in Düsseldorf, which has an approximate 20.000 m² space; radiology screening center is at the entrance, breast cancer cases that emerged as a result of screening, breast surgery, breast nurse in a separate area, and ISI—International Senology Initiative of survivors who had previously experienced breast cancer experience. This makes it easier to take the first step toward success in diagnosis and treatment.

During the meeting with the architect about the construction of the Breast Center, it is necessary to emphasize that the design should be considered according to "patient journey auditing," which is the diagnosis and treatment adventure in the hospital.

9.3 Patient Journey Auditing

The road map needed during the general design of the clinic is obtained from the patient journey auditing. Patient journey auditing (PJA) is a regular monitoring of the course of the patient's treatment. In the process of continuous innovation and updates, such as breast cancer treatment, control of the flow is vital. From the past to the present, breast cancer is no longer just a disease treated by the general surgeon. Still, it has become a complex treatment chain that requires the breast surgeon, breast plastic surgeon, breast pathologist, breast radiologist, medical oncologist, lymphedema physiotherapist, psychologist, and breast nurse. This process needs to be transformed into algorithms, continuously monitored, updated, and implemented.

As a small example, after targeted treatments like trastuzumab's entrance in the treatment of HER2-positive breast cancer, cardiologists' examination and the design of the center needed to be reshaped. All the algorithms and the needs of the centers changed.

So regular patient journey auditing's necessity was realized by the system naturally.

The need for PJA in breast care was recognized many years ago, and authors concluded their publications "the business of delivering improved care to patients will be down to the efforts of motivated and well-informed clinicians working in a structured manner."

Pittathankal and Davidson from London published in 2010 an example of PJA in breast care. They focused on managing a patient with breast cancer as a complex undertaking, requiring coordination of specialist team members to enable high-quality, individualized care [2]. Also, they based their algorithms on the multidisciplinary approach and board discussions. They described the value of multidisciplinary teamwork as in 1995, the Calman-Hine report emphasized.

These examples can be found in all oncology centers, which are ruled systematically. Below in Fig. 9.2, Istanbul Oncology Hospital's PJA for breast cancer can be reviewed.

To implement the PJA in a breast center, following the path of several patients referred from different sources has to be classified. Central referral points and then the steps of the patients inside the center have to be drawn on a sketch. Also, the jammed aspects of the system must be determined. By actions of lean methodology, the journey of the patient has to be monitored on the

sketch, and the center's points of improvement and system's needs have to be discussed with the patients themselves and the managers of the hospital.

Also, after the first PJA, the center's director, the patients, and survivors together have to focus on where and how to improve the system. A continuous feedback mechanism has to be implemented in the system also.

Since cancer treatments are updated at any time, it should never be forgotten that PJA processes are a process that needs constant monitoring.

9.4 Multidisciplinary Care

In the 1970s, discussing the patients' situation in a simple tumor board with the surgeon, radiologist, pathologist, and oncologist were routinely performed in many centers. However, the methodology and political support of multidisci-

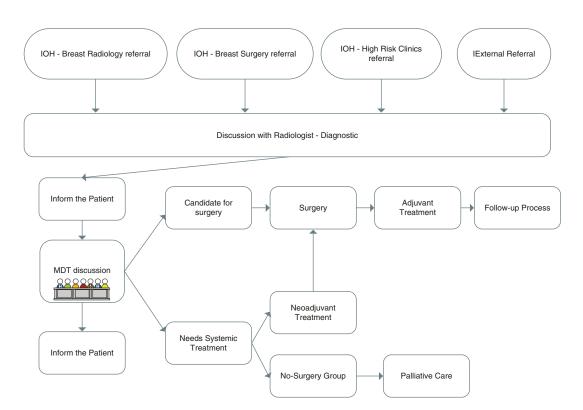


Fig. 9.2 Breast cancer pathway Istanbul Oncology Hospital

plinary teamwork were not well determined. Moreover, there was a lack of data from multidisciplinary collaboration and single, mainly "paternalistic" medicine.

The first supporting mass data was received after a significant reform in the UK in the 1990s.

In 1995, Calman-Hine plan outlined a radical reform of the UK's cancer services to improve outcomes and reduce inequalities in NHS cancer services. The report's main recommendation was to concentrate care into the hands of site specialist and multidisciplinary teams [3].

In the assessment of Calman-Hine, two methods were implemented. The first evaluated the formation of multidisciplinary teams, and the second evaluated the transition from general surgeons to field specialist management.

In 2007, Morris et al. published the first results of the Calman-Hine plan's impacts on breast cancer patients. Although the results were controversial, the policy significantly improved the success and patient satisfaction in the UK [4].

In parallel to the 1990's reforms in the UK, also in Italy and in Germany, there was an irrepressible rise of "senologists." Dr. Umberto Veronesi from Milan and Dr. Mahdi Rezai from Düsseldorf underlined the necessity of multidisciplinary teamwork, led by senologists. Moreover, this initiative gave birth to the European Academy of Senology in 2007.

Also, in parallel to the Calman-Hine report, the efforts of Veronesi and Rezai reshaped breast care forever in Europe. Site-specialist surgeons' rise increased the service delivery speed, quality, satisfaction, and survival rates and decreased complications. However, this way could not have a chance to disseminate in Asia and Africa because of the political obstacles in front of the surgeons.

However, in a way, the need for a multidisciplinary team (MDT) work disseminated throughout the world. Today, in many centers, there are MDT-based services, though there is still old-fashioned single-surgeon practice, which is in some way suitable for "paternalistic service demanding patients."

Multidisciplinary teamwork in breast care has plenty of advantages (Fig. 9.3). The treatment strategy planned at MDT is comparably different in many ways from single-surgeon practice. The radiologists' opinion on tumor size and neighborhood can change the surgery type from breast conserving to mastectomy. The view of a pathologist and a geneticist on a high-risk lesion can end with a surgery or a chemo prevention. The discussion with a medical oncologist can save the breast with neoadjuvant treatment opportunities.

The multidisciplinary breast team members are:

- Breast surgeons
- Oncoplastic/reconstructive surgeons
- Breast physicians
- Breast nurse navigators

Fig. 9.3 MDT benefits

The benefits of the periodical meetings Breast unit Joint decision on treatment audit/clinical recommendations management Facilitate **Improve** Adherence to Risk Assessing quick interservice clinical management patient specialist delivery guidelines of in difficult eligibility for referral and targets and good practice clinical trials cases opinion waiting times

- Clinical and medical oncologists
- · Breast radiologists and radiographers
- Nuclear medicine radiologists
- · Pathologists
- · Clinical geneticists
- Prosthetists
- · Clinical psychologists
- · Palliative care nurses
- · Research coordinators
- Database team manager
- · Administrative staff

In most of the breast centers, breast surgeons are conductors. They are the first medical professional to adopt the problems of the patient, but breast nurse navigators are an essential role holder in patients' journeys, "More than a nurse, as a sister." All the patients' anxiety and social and medical problems are met by the breast nurse firstly. The system has to focus on breast nurse navigators.

The formation of MDT is not enough in a center. There must be an authority or an accreditation/certification rule to let the system run MDT meetings periodically at least once a week.

9.5 Data Management

It is vital to follow up on the clinical applications and to record the data produced in the service process for the planning of the future. The patient's demographic information, morphological and biological characteristics of the tumor, and the treatments should be recorded systematically.

Today's hospital information systems do not have enough equipment to evaluate the outcome. Mostly, they are used to record financial and patient identification data.

Systematically recorded data should be easy to report. There is much software available to serve these purposes. In the European market, there are TuDoc, Alcedis, and dataBreast software. Alternatively, with the excel software that is arranged according to the clinic's road map, data can be easily tracked.

When selecting the software for clinical use or creating a database, it is essential to evaluate

whether the software's reporting capability is appropriate for benchmarking. If the purpose of data collection is not planned correctly from the beginning, the effort spent during data entry may be wasted in the future.

Also, financial metrics are essential for breast center management. Value-based breast care metrics can be defined in a well-combined hospital information system and tumor registry software. Value-based medicine metrics enable the center to reshape itself according to its own region's needs.

9.6 Organizing Logistics and Controlling the System

In all strategic publications, organizing logistics, system maintenance, and lean management tools are not well described. However, to restrain the system, the center director and breast nurse must be keen on logistics management and lean management capabilities. All the protocols of the working place must be written; all the cascade of the system must be part of an employee's orientation training.

The protocols of the working place are:

- Hierarchy of the system
- Meeting schedules (MDT, administrative, etc.)
- Patient hospitality protocol
- Medical devices' user guides and maintenance protocol
- Medical consumables storage and expiry date control protocols
- 5S and Kaizen lean management tools

The hierarchy of the system on the organization chart determines the staff's responsibilities. All the team must understand they are a part of an existing system that has duties of a human being and their families.

Meeting schedules must be determined and well running. It must be planned according to operating theater schedules. All team members of the MDT must understand the seriousness of meetings.

Patient hospitality protocol, by other means first impression protocol, must be determined as the first law of the system. Welcoming and filling out anamnesis forms procedures are first impressions on the patient, which can increase or decrease the anxiety of the patient. To manage the stress of the patient at the first entry, it is highly recommended to train the staff with mindfulness-based stress reduction or other anxiety managing psychological techniques.

Medical devices' user guides and maintenance protocols must be stated clearly to protect the system from running safely. Also, they must be aware of medical consumables storage, and expiry date controls must be a part of daily routine. The staff that is responsible for their workplace must control the critical storage limits and primary storage limits to let the system flow in order.

Lean management tools are getting more popular in the last 20 years. Kaizen lean methodology was first described in the 1970s by Masaaki Imai. He is known as the leader of the Japanese industrial miracle. His lean methodology, called Kaizen, is focusing on working area management. The word "Kaizen" means "change for better" in Japanese. It was first described for automobile production, but today, it is getting popular in healthcare. Kaizen is a daily process, and its purpose goes beyond simply improving productivity. At the same time, when done correctly, it is a process that humanizes the workplace, eliminates excessive hard work, and teaches people how to experiment with their work using the scientific method and learn how to assign and eliminate waste in business processes [5].

The way of Kaizen in daily healthcare practice is getting popular because it is effortless to learn. The Kaizen Cycle "Plan \rightarrow Do \rightarrow Check \rightarrow Act" enables breast center team members to prevent complications, with the basic concept, that is, to identify and quickly remove waste.

Another example of lean management in healthcare services that can be useful for breast centers is 5S management. 5S is a workplace organization method that focuses on a list of five Japanese words, seiri, seiton, seisō, seiketsu, and shitsuke, which means "Sort," "Set In order," "Shine," "Standardize," and "Sustain." 5S

describes how to organize a hospital for efficiency and effectiveness by identifying and storing the items used, maintaining the area and articles, and sustaining the new flow. The decision-making process arises from a dialogue about standardization, which builds understanding among partners how they should do the work and take action. Once practiced in a cancer center, it helps maintain cleanliness and orderliness in the workplace, reduces waste in the processes of care, and improves patient flow. 5S is famous for its ability to establish the necessary prerequisites of mindset, workplace, and patient flows, which are the foundations needed for an effective quality improvement program. Many trainings for Kaizen and 5S are available both online and on hands-on courses.

Both Kaizen and 5S lean methodologies are running in many cancer centers in Japan. The complicated management and maintenance of huge Japanese Cancer Centers are excellent examples of Japanese lean methods.

9.7 Accreditation and Certification

As the need for a specialized breast center emerged in the 1980s, several centers and units were established both in Europe and North America. However, some of these centers or units were not following the regular path of multidisciplinary teamwork and specialization in breast cancer treatments. Parallel to the increasing numbers of "Breast Units," a legal definition was needed.

In 1998, in Florence, the European Organization for the Research and Treatment of Cancer Breast Cancer Cooperative Group (EORTC-BCCG), European Society of Mastology (EUSOMA), and Europa Donna delegates agreed on a consensus statement on research, genetic predisposition, psychosocial status, treatment, and quality of care [6].

Following this meeting, in 1999, the EUSOMA task force focused on "Requirements of a Breast Unit" opinion on the standards required for forming high-quality breast cancer units across Europe. It was first published in 2000 and updated in 2013, the basic requirements of "European Breast Units" were established [7].

This publication is the initial criteria book for the European Certified Breast Centers. It is a guide for the centers to shape multidisciplinary team, screening techniques, standardizing operations, pathology specimen preparation, psychosocial support, lymphedema management, data management, etc. There are mandatory requirements of the critical mass of at least 150 cases per year, MDT meeting schedules, and essential technologies for breast care.

In parallel to these efforts in early 2004, in Germany, the German Cancer Society DKG started a voluntary program for the certification of cancer centers [8]. Foundation for each of the current 18 tumor-specific certification modules is the evidence-based guidelines developed and updated by the German Guideline Programme in Oncology. As of March 2019, there are 243 certified breast cancer centers including 17 centers outside of Germany in Austria, Switzerland, and Italy according to the requirements of the certification program of the German Cancer Society.

There are plenty of publications about the effect of certification in a civil manner. Most of them are reporting; quality control through internal and external audit and benchmarking lead to better cancer care and betterspecific breast cancer care [9–11]. However, many of the world's leading and reputable rule-setting university hospitals and institutes do not need certification systems. This behavior stems from the power of their system accrediting and steering. In themselves, there are already monitoring mechanisms and flows that do not require certification. Certification is not a must, but it is a useful tool to monitor the system that is currently running.

They proved using guidelines routes the center to a better outcome.

9.8 Value-Based Care and Patient Outcome Measurement

In 2010, Michael Porter from Harvard Business School asked the question: "What is value in healthcare?" This publication was not questioning the revenue of healthcare services, but to criticize our focus. Because he realized that the teams that are managing the system were mainly focused on finance, patient-centeredness, safety, convenience, satisfaction, high-quality, access to services, and profitability, however, this type of management has led to slow progress in performance improvement [12].

Value in healthcare was described as: "patient-centered outcomes achieved per healthcare Money spent." Also, Porter defined The Outcome Measures Hierarchy in three tiers: the first tier, health status achieved or retained, the second process of recovery, and the third sustainability of health. Comparing with today's managers' point of view, Porter showed us to re-describe the way of managing our diseases with "a real way that patient feels."

In conventional ways, the hospitals are serving and, in a way, advertising how they are helping with highly skilled doctors, beautiful facilities, modern hotel room designs, and high technologies. However, Porter asked whether our patients are interested in these services?

In the first tier, he tried to measure the health status between survival and degree of health and recovery. In some cases, we can help the patient survive, but how? Did the patient benefit from survival?

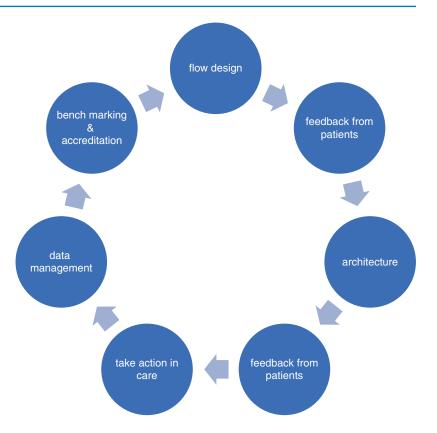
In the second tier, time to recovery and time to return to normal activities were measured, including the disutility of care or treatment process (e.g., diagnostic errors, ineffective care, treatment-related discomfort, complications, adverse effects) and also how the patients were affected by treatment and diagnostic procedures.

In the third tier, sustainability of health was measured with the true faith of recurrences and the cost of treatment-induced illnesses.

This model defined quality and achieving performance improvement in health services. There are few publications about value-based care in breast cancer management, but all are promising a new way to rearrange our focus of treatments.

In a publication from Fayanju et al. from MD Anderson, they measured their service. They reached a conclusion as healthcare costs continue to rise around the world, an electronic health record integrated, a value-based framework for

Fig. 9.4 Action plan recommendations for a center of excellence



healthcare delivery with explicit, transparently reported patient outcomes will not only create opportunities for performance improvement across the breast cancer care continuum. Still, they will also enable internal and external benchmarking across providers, systems, and even countries [13].

A well-running example of a value-based care running system is a prostate center in Hamburg. Martini Klinik is a center for prostate cancer run by ten urologists. Their single focus is prostate cancer treatment for nearly 20 years. The system's different target was focusing on real patient satisfaction from the first day Martini Klinik was established. From the first day of their practice, the managing team determined their goal on increasing patients' after-discharge happiness and satisfaction. They have a reliable follow-up infrastructure to audit their patients' quality of life in daily life. Their value-based care criteria are similar to Porter's principles. With this way of thinking, Martini Klinik today takes care of more than 5000 prostate cancer patients every year.

Tips and Tricks

To establish a system designed and which operates in universal standards, first, there is the need to listen to our patients, the end user of the system. The feedback from patients at every stage during design planning and operation of the method according to the current diagnosis and treatment requirements is precious. The tips that must be taken into consideration during flow design are given in Fig. 9.4.

Future Trends

In 2013, OnkoZert, the independent certification institute of the German Society of Cancer, announced its project "oncomap. de." This project aimed to make patient outcomes visible and lets the patients

choose the center for treatment according to certification and real-time quality map. Oncomap.de enables the patient to see which clinic can provide "the service they need" firsthand. The map shows all the contacts of certified centers for each cancer situation such as breast cancer, prostate cancer, lung cancer, etc. It is based on the cancer center certification program of DKG. For any center who does no longer fulfill the requirements laid out in the catalogues of requirements, the certificate will be revoked, and it will no longer be listed on oncomap.

In the future, governments and service providers will focus more on total quality management. The aim will be to increase the quality of outcome and patient satisfaction.

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