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SPECIAL ARTICLE

Term and Role of Tumor Centres in Oncology Healthcare in Germany

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Summary

Breast cancer is the most common malignant disease among women in Germany. There are more than 50,000 new cases of breast cancer diagnosed each year in the country. As breast cancer is a complex disease it necessitates an interdisciplinary treatment, therefore it is very likely that patients with breast cancer will benefit from treatment in special centers, either a "breast cancer centre" or "tumor centre". In recent years certifying programs for the above mentioned centers have been introduced, which guarantee standards of the quality of treatment for breast cancer all over the country.

In this article we report on the development and role of tumor centers in oncology healthcare in Germany, which nowadays have a very good international reputation. Moreover, they may be a good example to other countries to found similar centers in order to improve standards of the management in oncology healthcare.

Key words: breast cancer, disease management, Germany

The trend in modern oncology develops towards more and more sophisticated diagnostics and multimodal treatment concepts based on increasingly expensive novel technical equipment as well as high-prized pharmaceutics. It is obvious that with a non-expanding budget in the health sector and increasing costs for cancer treatments –due to higher expenses in the individual patient and the overall increasing number of cancer patients based on the demographic development– cancer diagnostic and therapeutic procedures demand a concentration process. The interdisciplinary collaboration in diagnosis and treatment is more and more a matter of teamwork, and therefore the term "tumor centre" is frequently applied for. This expression basically does not mean more than an existing interaction between different specialties in oncology. As known from sports, team efforts do not necessarily mean good quality. There are teams that are sliding down in the ranks with others climbing up although both have the same number and position-representatives in their teams. There is no guarantee for good quality if it is not to be proven by separate mechanisms. Therefore, a group of gynaecologists from several departments of obstetrics and gynaecology in Northrhein-Westfalia has tested and improved a pre-existing draft version of a data system of breast cancer patients for its practical applicability. The above mentioned data system follows a patient through the complete diagnostic and therapeutic course during a primary phase of disease and adds all follow up results and doctor's contacts regardless of additional therapeutic measures or mere follow up data – may it be out-patient or in-patient. With all data being in a single file, the complete history of the individual patient is always available. Furthermore, the data of all patients of one particular centre as well as of all patients from all centres can be evaluated according to stage or treatment, application of adequate treatment components etc, and can be subjected to a benchmarking process between different participating centres.

With this approach, we are getting close to what really matters for a patient when hearing or seeing the term "breast cancer centre" or "tumor centre". Special breast units have been built since 2002 to optimize health care for breast cancer. Both, the Certification Procedure by

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the German Oncology Society and the German Society of Mastology as well as the Disease Management Program (DMP) for Breast Cancer have been fundamentals for building breast units in Germany. Based on the situation analyzed by the advisory council in 2000, treatment for breast cancer was republic-wide presented in a DMP in 2002 along with DMP for diabetes mellitus type II. DMPs for widespread diseases were recommended in Germany by Prof. Dr. K. Lauterbach [1], one of the economical advisors of the German Ministry of Health. In the first place, the aim of DMPs was to link programs for chronic diseases with the risk structure adjustment of the health insurance companies to enhance these adjustments. DMPs provide an incentive for insurance companies to see about patients with the so-called "bad risks", since insurance companies obtain a certain amount of money for each patient who is enrolled in a DMP. By then, only age and female gender were taken into account for the risk structure adjustment [2].

DMPs claim to improve general care of patients. Guideline-based therapy is aimed at following a cross-sector concept [3]. Besides improving the quality of care by using evidence-based standards, patients shall be guided throughout the different parts of therapy by one coordinating doctor based on "structured care programs for chronic diseases".

The Federal Coordination Committee-since 2004 named Conserted Federal Committee (GBA)-of the self government defined criteria of adequate, guideline-based therapy within a DMP. In the beginning, DMPs were set up for 3 years and should be evaluated afterwards.

These programs are administered by health insurance companies. Therefore, the federal insurance authority is responsible for accreditation of the programs - each insurance company has to apply directly for accreditation. Accreditation will be granted for a certain federal state each, and is not available nationwide. Until October 2005 more than 1500 programs for breast cancer had been authorized by the federal insurance authority. This authority is also responsible for a terminator evaluation of the programs [4]. Meanwhile, in each federal state the results of the DMPs are collected. The clinical and outpatient doctors have to fill in questionnaires which are sent to DMP-data centres, which were built up in each federal state. Data is deleted for data protection after 5 years. For patients, the participation in a DMP is voluntary [3].

The implementation of DMP Breast Cancer is accompanied - but has been independently developed - by the establishment of certificated Breast Centres through the respective professional oncology associations DKG (German Society for Oncology) and DGS (German Society for Mastology). Certificates are given if certain quality features are fulfilled. The quality criteria have been defined by an expert commission of the two societies (with 16 members) according to evidence-based knowledge.

A required condition for certification is that the department has performed general quality assurance assessments (so called ISO or KTQ certification). The special certification for a breast unit is added. Both professional societies founded a corporation [5] which conducts certification performance by sending out experts into the units. The experts work out a report concerning structure and performance of the inspected breast unit based on a defined plan. Preliminary certification is given for one year each; final certification can be acquired after 3 consecutive years of certification. The first breast unit in Germany was certified in 2002.

Quality indicators for breast units in DMP and Certification, respectively, are minimum workload per centre and minimal workload per surgeons. The minimum workload per centre is the first and most crucial structural requirement for the health care system in Germany. The experts of DKG/DGS, as well as the responsible advisors of DMP consider a minimum of 150 first diagnosed breast cancer cases per operating centre per year as essential structural criteria of quality, similar like the European level the European Society of Mastology (EUSOMA) [6], following the results of a retrospective study of Roohan et al. [7] (level of evidence III). This study showed that survival of breast cancer is the best in hospitals with a workload of 150 or more breast cancer cases a year. EUSOMA also considers that treating less than 150 cases a year is not economical [6]. There are critical voices in Germany concerning the evidence for minimum figures for breast operations [8], as well as construction of special breast units resulting in a clear concentration of patient amounts at certain locations.

The next quality indicator is the minimum workload per surgeon. In addition to the limitation of locations for breast units there is also a limitation for surgeons as a result of the retrospective study of Sainsbury et al. [9]. 5-year survival was better for patients treated from 17 surgeons with 30 or more operations per year than for patients treated from 120 surgeons with less than 29 operations. In Germany, 50 operations per surgeon have been assessed. Consequently, a breast unit needs 3 surgeons up to a combined workload of 200 cases per year, which means that breast surgery is only done by a few experts in gynaecological departments. Thus, recruitment of specialists is limited to a few persons.

After positive experiences with this system in the treatment of breast cancer the Northrhein-Westfalian Cancer Society has developed a stepwise concept for most of the frequent tumor entities. The primary empha-

sis is to ensure that modern and established components of diagnostic work up and a multimodal treatment concept is accessible for each patient. This means, under practical aspects, that a list of structural requirements and a catalogue of documentation necessities have been developed according to the breast cancer documentation system. Currently there are about 200 hospital units applying the Oncology Data System (ODS), an easy system for breast cancer documentation - many of them have undergone a certification process that has been nationally established by the German Cancer Society and the German Society for Senology and Europe-wide by EUSOMA.

Based on the material for breast cancer patients, expert groups under the auspices of the Northrhein-Westfalian Cancer Society have also developed comparable requirements for colorectal cancer, prostate cancer, malignant melanoma, and are currently working on similar concepts for lung cancer, gynaecological tumors, as well as for lymphomas and leukaemias.

For an initial phase the so-called quality indicators have been selected, which can be considered as surrogate markers for good quality as long as long-term stage-dependent survival and morbidity data are not available. Of course, later on, 5- and 10-year survival and morbidity data are the important endpoints, but as the terms express, it takes a couple of years to arrive at this stage.

There are also potential disadvantages in an interdisciplinary setting for cancer diagnosis and treatment: the group can only be as good as the weakest member in the chain. Besides the endless discussions and lacking courage to come to a final mutual decision, it may inadequately prolong processes for the individual patient. Moreover, the individual cancer patient may feel that he/she has lost his personal counterpart in an extremely difficult situation for her or him. One of the basic requirements is that an experienced physician has to take the responsibility of guiding a patient through the, sometimes, labyrinthine pathways of diagnosis and treatment under extreme psychic tension and stress.

With the enthusiasm about the perspectives and achievements pointed out before, one must not forget statistical and biometrical cautions: with the variability of primary stages and consecutive treatment modalities one needs relatively high patient numbers in the different subgroups to come to reliable statistically proven endpoints in results. It might be that, based on the numbers of patients in the individual institution, there may be no discrimination possible between 90% and 95% cure rates. For this reason it might be appropriate to define a range for results that – in case it would be met by the team of a "centre" - this may be evaluated as adequate. The same caution has to be focussed on the fact that all 46-50,000 women affected by breast cancer in Germany per year can not be treated by the centre that appears to have the best results in comparison to the other ones. What we can achieve is to increase treatment results to an adequate level in all accredited centres so that high quality care can be offered to all patients not far away from their homes.

Another aspect has also been proposed for general discussion: how much effort can and should be attributed to the documentation process. There are calculations that approximately 10% of the DMP fees are used up by the manpower and other resources for breast cancer patients' documentation. This means that costs for documentation are in an immediate competition with the costs for adequate primary service to the patients. The worst case scenario would be spending all money for an excellent documentation of what therefore has to be an extremely poor treatment quality for which no money was available.

Under these changes in society and with the dynamic alterations and improvements in cancer diagnosis and treatment there has to be a constant change within the service patterns in oncology. What has to be our primary interests are at the changes made along quality perspectives which can not be debated by anyone rather than along political decisions or questionable developments due to economic restrictions. For this reason, it is extremely important to collect data and draw the pertinent conclusions.

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