Disease Management Program Breast Cancer – First Experience

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Key Words

Disease management program · Breast cancer

Summary

Background: In the 1990s, Disease Management Programs (DMPs) were developed in the USA as proactive approaches and integrated, continuing care concepts based on guidelines and recommendations and including the points of view of both patients and care providers. The aim was to improve outcome and reduce costs whilst taking into consideration patient risk profiles. Early experiences gained in Germany are reported. **Materials and Methods:** The methods used to implement reliable medical and health-political framework conditions for patients with breast cancer on the basis of the best possible current treatment standards is depicted using the Baden-Württemberg treatment program. **Results:** Of the 130 hospitals in Baden-Württemberg, 41 hospitals and 4 university clinics fulfil the DMP quality criteria. To date, 98 hospital physicians have been licensed as DMP physicians for primary therapy, and in out-patient care, 1,380 DMP physicians have qualified. 44% of the 973 partaking gynecologists, 57% of the 272 general practitioners and 22% of the 131 internists have registered active patients so far. **Conclusions:** At the moment, the quality of results is not covering all factors, because the necessary structural quality has not yet been achieved. Previous experience shows that advantages have been obtained in the sectors of psychosocial care and structured treatment, but that there are still problems. These are found particularly in the flow of data and bureaucracy with the result that physicians have compliance problems. The target must be to eliminate existing weaknesses, for instance in providing the links missing between DMP, quality assurance, breast centers, cancer registers and screening programs. This would, in turn, achieve future feedback for the care providers so that they are fully informed on the quality of results.

Schlüsselwörter

Disease-Management-Programm · Mammakarzinom

Zusammenfassung

Hintergrund: Disease-Management-Programme (DMPs) wurden in den USA in den 1990er Jahren entwickelt als proaktiver Ansatz und integratives kontinuierliches Versorgungskonzept, unter Einschluss sowohl der Patienten- als auch der Anbietersicht, auf der Basis von Leitlinien und Empfehlungen mit dem Ziel, unter Berücksichtigung von Patienten-Risikoprofilen das Ergebnis zu verbessern und Kosten zu mindern. Erste Erfahrungen mit der Umsetzung in Deutschland werden berichtet. **Material und Methoden:** Die Methode für die Umsetzung verlässlicher medizinischer und gesundheitspolitischer Rahmenbedingungen für brustkrebserkrankte Patientinnen auf der Basis des bestmöglichen aktuellen Behandlungsstandards wird anhand des Behandlungsprogramms Baden-Württemberg dargelegt. **Ergebnisse:** Von den 130 baden-württembergischen Krankenhäusern erfüllten 41 Krankenhäuser und 4 Universitätskliniken die DMP-Qualitätskriterien. Für die Primärtherapie wurden bisher 98 Krankenhausärzte als DMP-Ärzte zugelassen. In der ambulanten Versorgung haben sich bisher 1380 DMP-Ärzte qualifiziert. 44% der 973 mitwirkenden Gynäkologen, 57% der 272 Allgemeinärzte und 22% der 131 Internisten haben bisher aktiv Patientinnen eingeschrieben. **Schlussfolgerungen:** Derzeit ist die Ergebnisqualität noch nicht flächendeckend nachzuvollziehen, da die Strukturqualität noch unzureichend umgesetzt ist. Die bisherigen Erfahrungen zeigen Vorteile im Bereich der psychosozialen Versorgung und der strukturierten Behandlung. Probleme bereiten besonders der Datenfluss, die Bürokratie und die daraus resultierenden Compliance-Probleme der Ärzte. Ziel muss es sein, die noch existierenden Schwächen – wie z.B. die fehlende Verknüpfung von DMP, Qualitätssicherung, Brustzentren und Krebsregister und Screening-Programm – zu eliminieren und den Leistungserbringern künftig die Ergebnisqualität zurück zu melden.

Introduction

In the face of the dynamics of medical progress, the medical substance contained in the care of the chronically ill is undergoing a permanent change. Breast cancer is the most frequent malignancy of women in Germany. Although women with breast cancer can, for the most part, be healed here, the fear of relapse or continuation of the illness is a chronic strain on both those directly affected and on their families. With this as a background, the German government decided to legally regulate the methodology of Disease Management Programs (DMPs) which also relates to breast cancer (§ 137 of the V Code of Social Law (Sozialgesetzbuch, SGB V, 1st January 2001) [1]. One of the central targets of this law is the constant improvement of the care process of chronically ill patients by means of integrally structured treatment programs.

DMPs were developed in the 1990s i) as a proactive approach; ii) to integrate services across the spectrum of care; iii) to provide guidelines that include both patient and provider education; iv) with the goal of improving outcome and reducing cost; v) with a view to patient outcome including risk profiling [2, 3]. Therefore, 6 steps are to be considered: 1) identification of important key processes for care services, 2) examination of the present system from the patient's point of view and its modification in a user-friendly manner, 3) inclusion of scientific knowledge in the appropriate care services, 4) comparing of current care service processes with scientific knowledge, 5) modification or renewal of the system when and where necessary, 6) establishment of a higher decision-making committee to accompany the continuing process.

The Federal Joint Committee has appointed a workgroup composed of specialists to examine the above-mentioned principles of the DMPs on the one hand and the generally acknowledged status of medical knowledge on the other. They have also taken into consideration the principles of evidence-based medicine which were applied in the revision of the breast cancer DMP. The workgroup proceeds in the following methodical stages: New scientific knowledge and changes in medical practice are constantly examined, and any needs for changes or additional precision are determined by means of an informal consensus process. Recommendations and statements are compared with current evidence-based guidelines (S 3 Guidelines), nationally and internationally (e.g. Canadian/Australian guidelines). Data are exhaustively adjusted using the results of systematic literature research and taking into consideration original work referring to all stages of the care process. The demands concerning the substance of medical care are restricted to fundamental statements. Beyond this, individual decisions concerning therapy are the responsibility of the attendant medical practitioner who in each case sets up a personal treatment plan in agreement with the patient. The

demands made do not place any restrictions on the leeway necessary for the fulfillment of individual medical treatment.

The methodology of updating described above led to the revision of the breast cancer DMP in the 13th Order to Change the Risk Adjustment Scheme (Risikostruktur-Ausgleichsverordnung, RSAV) in the current version dated 23rd January 2006 [4]. It is the goal of this work to explain current developments and depict future trends in a balancing act between social factors and their consequences for the individual breast cancer patient.

Materials and Methods

Although legal requirements for the breast cancer DMP are, on the one hand, very precise, their implementation in Germany is extremely varied and differs considerably from state to state and from one health insurance fund to another, as well as from service provider to service provider (hospitals and general practitioners). The following treatment program in Baden-Württemberg will serve as an example for the implementation of the medical and health-political set-up conditions:

Contractual Base

The treatment of patients with breast cancer takes place in the out-patient sector with Statutory Health Insurance (SHI) physicians as well as in in-patient institutions (§ 83 SGB V). Contracts are made between the health insurance funds, the Association of SHI physicians and the hospital association, and provide for immediate adjustment to the latest recommendations in terms of content.

Framework Conditions in Baden-Württemberg

Breast cancer is the most frequent malignancy in women. In Baden-Württemberg, each year, more than 2,000 women die of the disease, and at least 2.5 times as many women contract the disease. The diagnosis of breast cancer leads to deep feelings of insecurity in the women affected, which is why the DMP agreements offer orientational assistance by means of i) a gynecological contact person who, at a very early stage, can give advice and coordinate medical matters with the patient's personal circumstances (pilot function); ii) a basis of agreement to give mutual quality assurance for all concerned, including collaborating medical specialists and specially trained general practitioners (this has been included especially for women with metastatic disease in domestic care (out-patient treatment)); iii) observation and care of anxiety and depression taking the psychosocial circumstances into consideration.

In addition to the contracting parties and alongside representatives of significant specialists associations (German Society for Senology, German Cancer Association, County Therapists Chamber, etc.), the Cancer Association and the German Association of Psychooncologists have also worked together on the project. The structural quality of hospitals, participating authorized SHI physicians, the substance matters of care services and training were discussed in detail, and were – following extensive voting processes – agreed upon.

The Physician Responsible for the DMP

The physician responsible for the DMP has, amongst others, to carry out the following tasks: inform the patient of and register her with the DMP; personally perform services under observation of DMP guidelines; participate in extended training events and tumor conferences; refer the patient to a hospital taking part in the DMP; coordinate treatment within the framework of the DMP; draw up the initial as well as the follow-up documentation and transfer it to the data center; keep the patient informed and give advice during treatment.

Participating Hospitals

Participating hospitals must prove that they have achieved certain certification. They must be certified either as a breast cancer center by the Cancer Association/Senology Association or as a tumor center or oncological center, or prove that similar demands have been met for the care of patients with breast cancer. The hospitals must also have a surgeon at their disposal who has been responsible for carrying out at least 50 breast cancer operations since 2005. Hospitals thus integrated will collaborate in quality assurance, bearing in mind that the majority of data is collected in hospitals. It is the responsibility of the German Hospital Federation (Deutsche Krankenhausgesellschaft e.V.) to monitor the parameters mentioned above.

Registration

Any patient insured by statutory health insurance (Gesetzliche Krankenversicherung, GKV) for whom a diagnosis of breast cancer has been histologically confirmed no longer than 5.5 years ago can be registered. Generally, the diagnosis should be determined by palpation and 1 mammography on 2 levels, and histologically confirmed, before beginning primary therapy. However, in its new version and with a series of additional updated recommendations, the RSAV also considers the registration of patients not later than 5.5 years after surgery and/or conclusion of primary therapy as approved for the best possible care. There is also a possibility of registering a patient with the DMP after the appearance of relapse/recurrence – on condition that the breast cancer, even if dated some time ago, has been histologically confirmed.

Results

In contrast to the many other DMP contracts which are more regional-oriented, the DMP contract for Baden-Württemberg is the only one which includes the entire federal state. Physicians and hospitals are registered in accordance with the quality criteria described above. Of the 130 hospitals in Baden-Württemberg, 41 hospitals and 4 university clinics fulfilled the DMP quality criteria between October 2004 and January 2006. Also, hospital physicians have been licensed as DMP physicians for primary therapy (of these, 98 physicians qualified and were able to be registered: 14 in South Baden, 9 in North Baden, 7 in South Württemberg and 22 in North Württemberg). At the same time, 1,380 DMP physicians have qualified in out-patient care and fulfil the requirements agreed upon. Some 44% of the 973 collaborating gynecologists have actively registered patients which are distributed extremely differently throughout the region. Of 272 general practitioners – with appropriate additional gynecological and psycho-oncological quality criteria – some 57% are actively registered. Of 131 internists, 22% are registered, and in 2 medical care centers (medizinisches Versorgungszentrum, MVZ), 5 physicians and both MVZ have registered.

Regarding treatment of women with metastatic disease who are hence chronically ill, cooperation between general practitioners/general medical/internists in the state of Baden-Württemberg is particularly extensive and carefully regulated. The new RSAV also places considerable emphasis on palliative care, guaranteeing as many women as possible the best possible quality of life in their own surroundings. This applies as

much to the burden of adjunctive treatment (chemotherapy, radiation treatment) as to the lasting systemic-palliative treatment of metastasis. As the above figures show, the consensus regulated by contract by no means covers all needs. Data on the outcome of the continuing care process of patients with breast cancer is only partly available and therefore cannot be presented. The approximately 5,000 new cases in Baden-Württemberg correspond to a period of 2 years with some 10,000 newly affected women. Of these, about one third develop metastasis over time, while the remainder recover, so that figures concerning women who should register remain hypothetical for the time being. With the AOK's (Allgemeine Ortskrankenkasse, General Health Fund) market share of more than 40%, this would, according to internal figures, currently correspond with a registration quota of more than 40% of all new patients [5].

At the moment, the quality of results is not yet fully understood, as structural quality has not been sufficiently implemented. As with every registration process, uniform starting conditions at a comparable level must be set up. Because this process is still at the implementation stage, the first data evaluation was incomplete and should only be assessed with considerable reservation. The figures serve more as examples rather than a source of basic knowledge.

Discussion

Prerequisites for any valid scientific evaluation and assessment, particularly in the DMP process, are the creation and setting up of comparable structural and process qualities. Only on the basis of transparent and comprehensibly implemented framework conditions can data on execution and implementation be gathered and compared, as is demanded in DMPs on behalf of the patient and service supplier. Although the contents have been reliably formulated by the RSAV for all patients, they can often be put into practice in different ways, depending on regional contract regulations in the different federal states. As in every other scientific process of evaluation, the starting conditions must not only be defined but also implemented. Only when the structural and process quality have been firmly established, quality of results can be observed. However, it is possible to give a first evaluation of the experience gained so far:

1. One fundamental positive development of the DMPs is the intention declared in the contract to bring together medical and non-medical professional groups, such as psychotherapists, psycho-oncologists and social services, both interdisciplinary and outcome-oriented, thus placing the breast cancer patient and her needs at the center of attention. Extensive discussions should be held between the patient and the physician in whom she has full confidence, immediately after histological confirmation. She should also help to set up her own treatment program. Quality of life, anxiety and depression,

psychological trauma and other psycho-oncological parameters involving psychosocial care of the patient and her family, should be positioned much more in the center of the care program. This basic care is supplemented at the second stage by offers of low-threshold psychosocial advisory and accompaniment support, set up differently from health fund to health fund. When symptoms require therapy at the third stage, the patient is referred to psycho-oncologically active physicians and psychotherapists.

2. Although the subject of lowest quantities has always been a controversial one, it wins in complex surgical procedures when favorable restorative surgery, for instance, clearly improves the quality of life. This has, in fact, gained in significance over the last few years. Killeen's summarizing article on oncological procedures makes a clear statement especially on the subject of breast cancer operations: hospitals with low volume are those with some 10 to a maximum of 30, those with high volume from 49 operations per year [6]. As shown in all the latest wider studies, large centers have proved to have the advantage – on the one hand, through organizational processes in the hospital, but also through the surgeon as a quality factor [7–12].

3. The flow of data is unsatisfactory, not only in DMPs, but in Germany as a whole, and the availability of individually gathered data leaves much to be desired. The legislative, predetermined data flow is unnecessarily complicated and extravagant and, for a variety of reasons, a link-up with other code systems is not possible. DMP physicians transmit data to a central office, but, at the moment, cannot make any direct use of the data collection. The present legal situation provides for DMP data to be destroyed after 5 or 7 years for reasons of data protection. In their current version, DMP forms have been clearly simplified and adapted to clinical procedures. Whether this will reduce the physician's compliance problems, remains to be seen. In the future, electronic data collection should increasingly replace written correspondence in all sectors, so that the complex linking of performance data will become more realistic. Because interfaces with other documentation procedures do not yet exist, they must be created quickly, so that the course of each disease and the treatment success in particular can be followed more clearly and easily.

4. Additional critical points are the demands inflicted on service providers by bureaucracy, especially where the introduction of breast cancer centers, the Federal Office for Quality Assurance (Bundesgeschäftsstelle Qualitätssicherung, BQS), the Cancer Register and not least the DMP is concerned. Tests have proved that 1 physician and 1 documentalist are needed to deal with the entire documentation required for certification, BQS, cancer registration and DMP participation in breast cancer centers where 200 diseases are newly diagnosed each year. The funds used for bureaucracy reduce the financial means available for medical care.

5. Politicians and their advisors point out the 10 years of experience of DMPs in the USA, but do not consider that these

programs were introduced at the beginning of the 1990s primarily for cost control. In spite of intensive literature research, it was not possible to find any publications positively evaluating the benefits of DMPs for treating breast cancer in the USA. The well-known Institute of Medicine confirmed the non-success of this attempt to treat breast cancer a few years ago [13].

6. The data of the Munich Cancer Registry prove that the 'deterioration', as it has been publicly depicted, of healing rates in Germany when compared with other countries is solely due to the lack of screening [14]. Karsa [15] calculated that 3,000 deaths caused by breast cancer per year in Germany could be avoided by a functioning mammography screening. As the DMP is presently not connected with a system for early recognition of breast cancer, this benefit of the DMP system cannot be taken advantage of.

7. Linkage to the RSAV is one of the main points of criticism of the breast cancer DMP. Until now, compensation payments between the health insurance funds have been determined by means of each patient's profile (age, gender). This profile will be extended by the registration quota in the DMP. When registration quotas are low, funds will flow from the RSAV into those regions with better recruitment into the DMPs. In this way, practically all cost bearers and service suppliers are compelled to sign a DMP contract [16].

Conclusions

It is the aim of this work to describe to-date developments on the above mentioned basis and depict future trends in the balancing act between social factors and their consequences for the individual fate of women with breast cancer. Mere assumptions and speculations should not form the foundation of comprehensive integrative care of women who are frequently confronted with the grave diagnosis of breast cancer for the rest of their lives. For this reason, the care services contained in the complex treatment of breast cancer have, for the first time, been approved, consented and reliably structured for the persons affected in the new 13th RSAV and put on a legally binding basis following countless voting processes with medical experts and patients' representatives. Outcome standards gathered on the life quality of the persons affected and on medical parameters serve not only to protect those affected, as in every modern management, but also to give an overall view of the costs and performance processes. A flow of information should be set up by increasing communication between partners in the process of medical care, which is rather unusual in this sector but all the more necessary.

The mutual contractually agreed care structures provide the opportunity to use currently available medical services more effectively and to recreate the subject of health of affected women holistically and interdisciplinarily with a high level of care quality. At the moment, no data are available in Ger-

many concerning the quality of results. The first imperfections in the structure of the DMPs have been eliminated in the current version (13th RSAV). The ideas and/or ideals of the DMPs can, however, only succeed with breast cancer when all mentioned weaknesses are overcome. Essentially, a modern,

EDP (electronic data processing)-supported, user friendly link-up of code systems is necessary for breast cancer (BQS, breast cancer centers, cancer registers and DMP), and a fast and qualitatively good feedback to the service supplier.

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