
Cancer Care: New Value Chains Challenge German Hospital Structures—A Comprehensive Cancer Center Perspective

Florian Kron, Andreas Bernschein, Anna Kostenko, Jürgen Wolf, Michael Hallek, and Jan-Peter Glossmann

Abstract

The medical and economic impact of cancer is a major challenge for hospitals in every country. Comprehensive cancer centers (CCC) are at the forefront to fight cancer. From an organizational perspective these large centers are highly complex. They combine patient-oriented cancer care with basic, translational and population-based cancer research. These centers cannot operate as stand-alone organizations but rely on cooperation in a network of hospitals and office-based physicians. The medical progress in recent years—which is often referred to as *personalized* or *precision* medicine—comes with hope for patients but also with diagnostic, organizational and financial challenges. Especially clinical trials are time-consuming and costly but indispensable being the backbone of treatment progress. A growing economic pressure results from a policy of increased competition on the one hand and a strict separation of ambulatory and inpatient care on the other hand. In this article we discuss the challenges and opportunities from the perspective of the Center for Integrated Oncology (CIO) Köln Bonn which is one of the largest CCCs in Germany. The political, scientific and economic challenges and opportunities are described as well as possible solutions including practical experience.

Keywords

Comprehensive cancer center • CCC • Cancer genomics • Sectorization • Economic challenges • Networks of cancer care • Germany • Oncology

F. Kron • A. Bernschein • A. Kostenko • J. Wolf, M.D. • M. Hallek • J.-P. Glossmann, M.D., M.P.H. (✉)

First Department of Internal Medicine, Cologne University Hospital, Kerpener Straße 62, 50937 Cologne, Germany

Center for Integrated Oncology Köln Bonn, CIO Köln Bonn, Cologne University Hospital, 50924 Cologne, Germany

e-mail: jan-peter.glossmann@uk-koeln.de

1 Introduction: Challenges and Opportunities

In the near future more people in Germany will die of cancer than of cardiovascular disease. Parts of Europe are already reaching a ‘tipping point’ where cardiovascular disease is no longer the leading cause of death (Nichols et al. 2014). There are new and promising developments of diagnostics and treatment leading to personalized cancer medicine. The prerequisites for good cancer care are complex and they especially challenge large comprehensive cancer centers (CCC). In the following we describe current medical and political developments as well as economic challenges from the perspective of the Center for Integrated Oncology (CIO) Köln Bonn.

1.1 Barriers in the German Health Care System

With the new millennium the Advisory Council for the Concerted Action in Health Care in Germany published the report *Appropriateness and Efficiency* and identified the overuse, underuse and misuse of diagnostics and treatment in the German health care system (Schwartz et al. 2000). Various deficits especially apply to cancer care. Most importantly there still is the strict separation of the ambulatory and inpatient care. This fragmentation of the in- and outpatient sector, sometimes referred to as sectorization, results in a lack of coordination in patient care and contributes to overuse (e.g. unnecessary referrals and repetition of diagnostic tests) and underuse (e.g. exclusion from medical services). The consequences are loss of information, inconsistent documentation, suboptimal therapies, avoidable harm and last but not least psychological stress for the patient. Recent health care reforms over the last decade have also tried to solve these structural problems although the main focus has been on cost containment. The relevant changes regarding the sectorization will be discussed in Sect. 1.3.

1.2 Cancer Genomics Changes Medical Practice

Cancer is a medical field on the verge of a paradigm shift towards personalized medicine and customization of health care (Goldstein et al. 2012). These changes also have an impact on how hospitals and office-based oncologists cooperate. Especially targeted therapies are currently revolutionizing cancer treatment. These drugs interfere with specific molecules involved in cancer cell growth and survival. Traditional chemotherapy drugs, by contrast, act against all actively dividing cells (National Cancer Institute 2015). The targeted therapy approach is based on the molecular understanding of the cancerous cell. Because cancer progression is facilitated by activation of oncogenes (tumor promoting proteins) and inactivation of tumor suppressors, the tumor can be eradicated by reversing these alterations. The key technology needed to identify the genetic alterations is DNA sequencing and genotyping. This technology is costly and currently

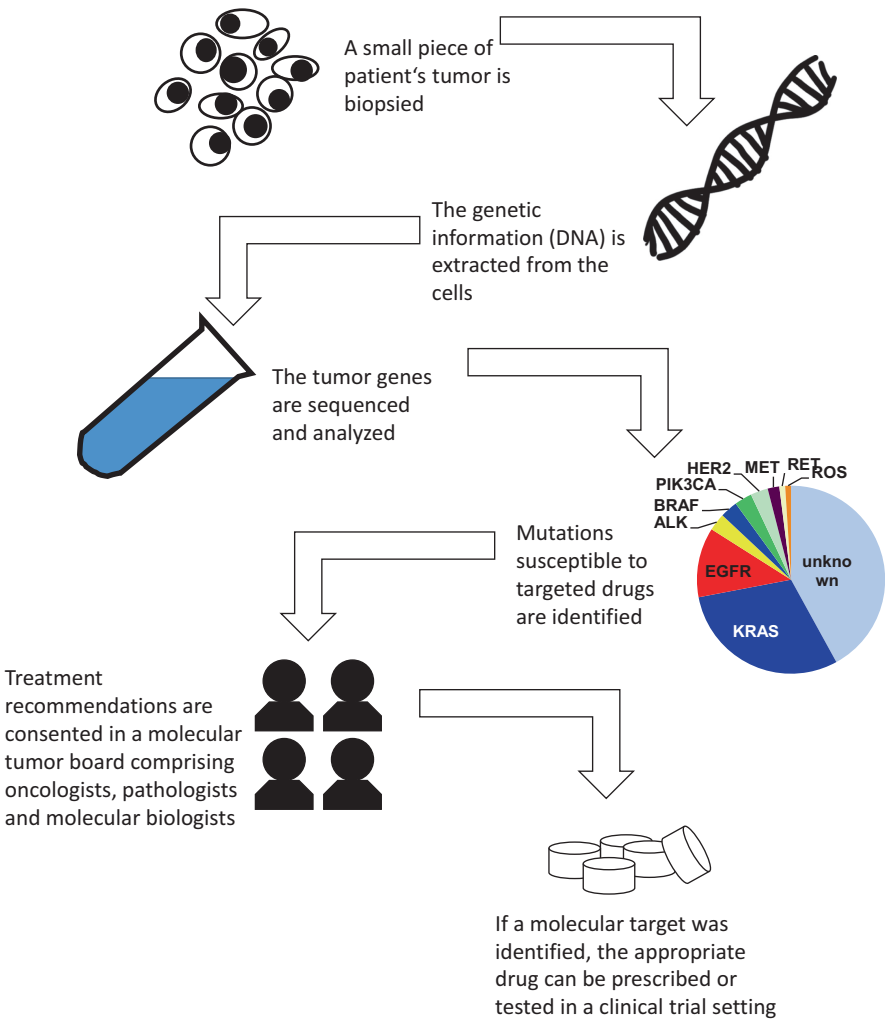


Fig. 1 Basic steps from biopsy to targeted therapy

improving at a fast pace. For example, at the CIO Köln Bonn the methods and machinery have been updated almost on a yearly basis between 2012 and 2015. The more advanced the technique, the less tumor material is needed for an increasing number of genetic alterations to be identified. Furthermore, expert knowledge of molecular biologists, pathologists and oncologists is required to interpret the vast data and to conclude treatment options for the patients. Fortunately, the patient does not have to travel to the next CCC to get the results since only a sample consisting of a few cells is needed (Fig. 1).

1.3 Economic Trends in Ambulatory Oncology

The advances in oncology reinforce the trend towards outpatient treatment ('ambulantization'). Less side effects and a patient-friendly administration of drugs (oral instead of intravenous application) are two major factors contributing to this trend. In recent years the German health policy sought to adapt to the medical trends and to overcome the strict separation of ambulatory and inpatient care (Jahn et al. 2012). In this context the question arises how economic issues can follow the medical progress.

The outpatient reimbursement system in Germany is heterogeneous. Numerous reforms over the last years led to a growing diversification of the outpatient sector. Basically there are two separate systems:

- (a) the outpatient system for office based physicians and
- (b) the outpatient system in hospitals.

For hospitals there is no consistent form of reimbursement of outpatient treatment. In fact there are more than a dozen different reimbursement systems. Based on the Social Security Code V (SGB V) and also in the context of research-related treatment at university hospitals the major options are (Lüngen 2007):

- Appropriations, § 95 SGB V
- Disease management program, § 137 SGB V
- Integrated care, § 140 SGB V
- University outpatient system, § 117 SGB V
- Outpatient surgery in hospital, § 115 SGB V
- Outpatient treatment in hospital, § 116 SGB V

Especially this fractured legal framework makes it difficult to overview and control different reimbursement systems in the outpatient hospital sector (Lüngen and Rath 2010).

Since a few years the economic impact of the outpatient units in hospitals has continuously been increasing. The following figure of § 116b registrations and related health fund costs illustrates the development. From 2007 to 2011 there was a steep increase in registrations and costs in this specific ambulatory reimbursement system (Fig. 2).

With two major health care reforms in 2007 and 2012 ("Gesetzliche Krankenversicherung Wettbewerbsstärkungsgesetz GKV-WSG" and "Versorgungsstrukturgesetz GKV-VStG") the options of outpatient reimbursement in hospitals were extended. One of the main goals was to improve intersectoral cooperation between the traditional outpatient sector and the hospital. The § 116b SGB V comprises the diagnostics and treatment of complex diseases including cancer and also requires special qualifications of personnel, interdisciplinarity and special medical equipment.

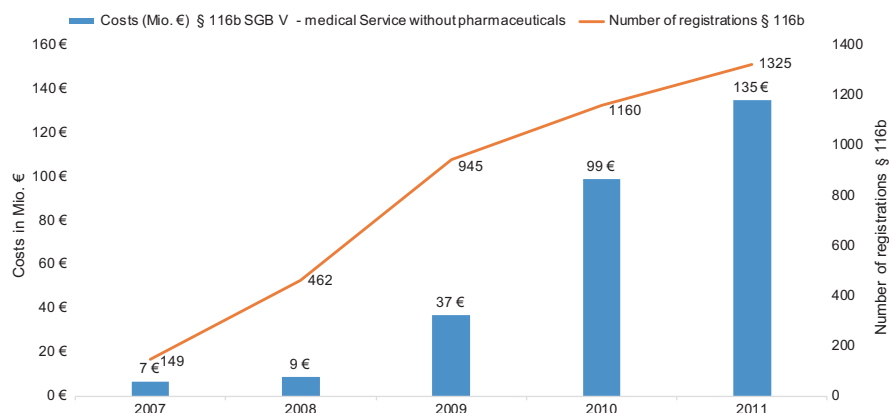


Fig. 2 Development of ambulatory care in hospitals § 116b SGB V (based on Schmedders 2012)

Inclusion criteria for § 116b are:

- diseases with severe course of disease
- rare (orphan) diseases with a small number of cases and
- diseases which require highly specialized diagnostic and therapeutic measures.

The participation in the reimbursement according to § 116b depends on many preconditions which have to be fulfilled by the health care providers. The directive of the Federal Joint Committee contains specific requirements for the process and structural quality e.g. requirements concerning organization, documentation, minimum quantities of cases, quality assurance and collaboration with office-based physicians. One of the biggest future challenges will be to fulfill personnel requirements such as providing a leading team, a core team and a supporting team from the two different sectors (Jahn et al. 2012). There has been a slow development of the § 116b SGB V: The requirements of the first oncological disease—gastrointestinal tumors—were defined as late as 2014.

Outpatient units in university hospitals are essential for medical research, teaching and the training of the students and young doctors. Based on § 117 SGB V university hospitals are allowed to do clinical research in an outpatient setting (Wissenschaftsrat 2010). In practice, these units are fully integrated in the whole ambulatory and teaching process at universities. Therefore, these outpatient departments are also involved in patient treatment beyond clinical research. A study on outpatient units at university hospitals from 2003 revealed that these units also play an important role in the regular outpatient care (Lauterbach et al. 2012). A lump sum is reimbursed and there is no cost-based re-financing (Lüngen 2007). In 2010, the German Council of Science and Humanities recommended to reform the standard fee system to a more differentiated and performance-based remuneration (Wissenschaftsrat 2010).

2 Potential Solutions

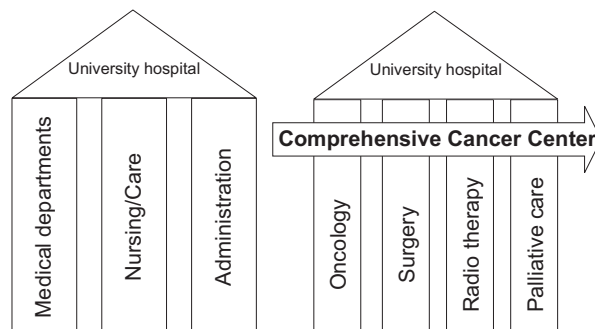
2.1 Cross-Sectional Organization Design in Oncology

Traditional hospital structures follow a functional organization approach and are characterized by departments in which each unit follows a profession (see Fig. 3). This top-down hierarchy classification requires a high degree of standardization and formalization but the complexity in dynamic health care markets limits this type of organization. As a development from the function-orientation the divisional form includes the concept of clinical governance that tries to integrate quality improvement, patient-orientation and financial transparency. Highly specialized and autonomous departments generate an isolated perspective that emphasizes the lack of interdisciplinarity. To avoid the conflict of integration and specialization cross-sectional structures can be implemented. Especially in cancer treatment the combination of divisional and matrix modules allows an integrative cancer center structure that is essential for multidisciplinary treatment (Lauterbach et al. 2010).

In Germany, several types of cancer centers have been established at federal level by the Federal Government (National Cancer Plan 2012), the German Cancer Aid (Deutsche Krebshilfe, DKH) and the German Cancer Society (Deutsche Krebsgesellschaft, DKG). These centers are typically located at hospitals—in this setting many specialized medical and supportive departments work together at central space. Three types of cancer centers can be distinguished: *organ centers* (C), *oncology centers* (CC) and *comprehensive cancer centers* (CCC) (Fig. 4).

Organ centers are specialized in organ-related treatment of one cancer entity (e.g. intestinal cancer or lung cancer). Hospitals with three or more organ centers can consolidate those in an *oncology center*. These two types of cancer centers are evaluated and certified by the DKG by certain quality requirements (Krebsgesellschaft). Comprehensive cancer centers are located at university hospitals. In addition, they perform basic and *translational research* (Pfaff et al. 2011). A selected group of these academic centers are funded as *Oncology Centers of Excellence* by the DKH. As of spring 2015, there are 13 *Oncology Centers of Excellence* in Germany (Fig. 5).

Fig. 3 Functional-orientation in hospitals and process-based cancer organization



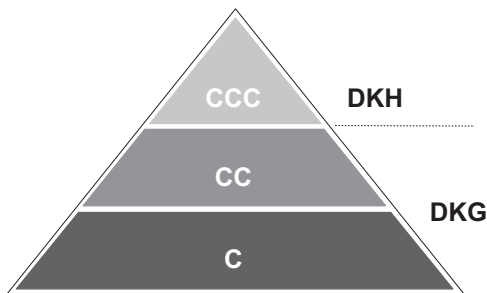


Fig. 4 Three stage model of oncology care in Germany

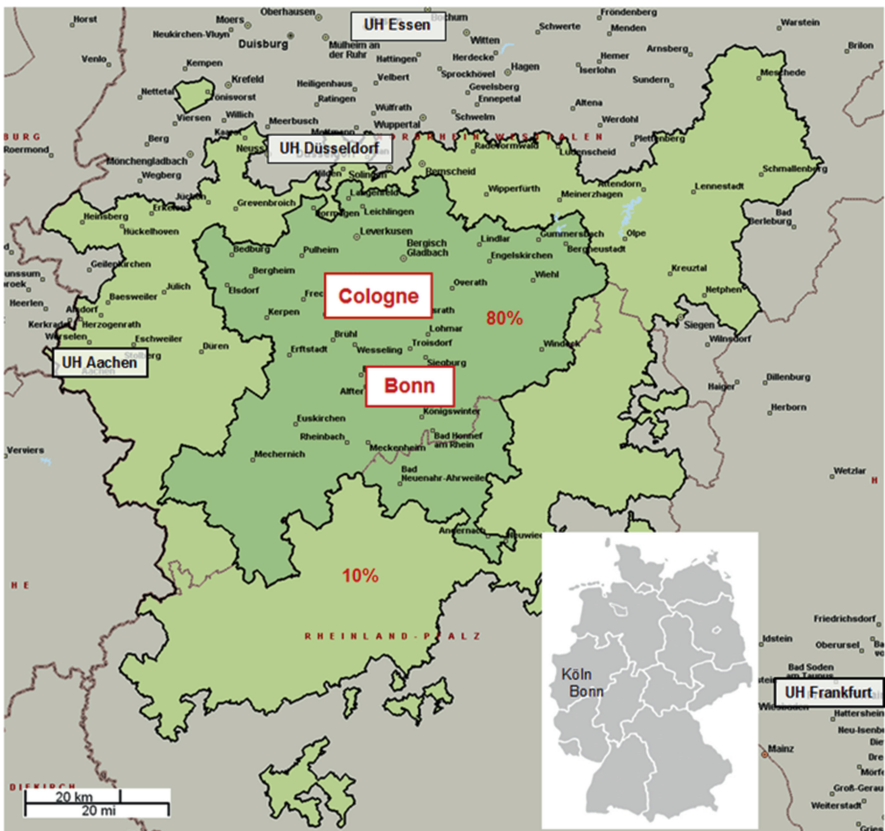


Fig. 5 Catchment area of the CIO Köln Bonn (own illustration, based on standard administrative data of the university hospitals Köln and Bonn)

The CIO Köln Bonn serves a catchment area of 4.5 million inhabitants, and it is one of the largest CCCs in Germany. It integrates the university hospitals in Köln and Bonn. All clinical units involved with the therapy and care of cancer patients work together to systematically and consistently improve all medical and allied health services provided for cancer patients.

2.2 The Future Lies in Networking

Within networks including office-based oncologists and regional hospitals patients can be treated close to their home. Molecular diagnostics should be limited to research-driven comprehensive cancer centers whereas patient treatment can be provided in local practices and hospitals. For example, the Network Genomic Medicine (NGM) Lung Cancer was founded in March 2010 by the Lung Cancer Group Cologne and the Department of Pathology at the Cologne University Hospital. Initially limited to North Rhine-Westphalia (NRW) but currently represented by over 200 nationwide interdisciplinary network partners (clinical oncologists, molecular pathologists, surgeons etc.), NGM provides comprehensive and centralized high-quality Next Generation Sequencing (NGS)-based multiplex genotyping for all inoperable lung cancer patients and stands for the implementation of personalized medicine into the routine cancer care in Germany. The lung panel covers DNA mutations and structural aberrations with a broad spectrum of proto-oncogenes and tumor suppressor genes including all predictive biomarkers for established targeted therapeutics, for drugs undergoing clinical trials and for the rapidly emerging cancer immunotherapeutics. The obtained information is stored in a central database established by NGM Lung Cancer. NGM focuses its work on advanced lung cancer as the most frequent cause of cancer death in Europe and is paradigmatic for the achievements of personalized cancer therapy (Buettner et al. 2013; Levy et al. 2012). In particular, lung cancer treatment is not only a medical challenge. The lack of curative treatment options and high prices of new drugs raise new questions on health economics (Glossmann et al. 2010). The gained mutational and immunologic profiles contain epidemiologic information which is of importance for the evaluation of the cost efficacy of personalized lung cancer care. Using the example of lung cancer as a prototype, the transfer of intersectoral networking to other solid cancer entities (e.g. melanoma, colorectal cancer, upper gastro-intestinal cancer and breast cancer) is possible. The algorithm of lung cancer biomarker diagnostics may be transferable to the treatment of other solid tumors. Personalized cancer therapy is based on the concept of oncogene addiction and uses the vulnerability of molecularly defined tumor subgroups to specific inhibitors. The evidence of significant improvement in overall survival by treatment with personalized medicine compared to standard chemotherapy in lung cancer patients who have previously been successfully genotyped (*EGFR*-mutant or *ALK*-rearranged) is given (A genomics-based classification of human lung tumors 2013). A broad implementation of personalized medicine in Germany has to accomplish comprehensive access of patients to molecular diagnostics and drugs,

Founded in 2010, supported by the Ministry of Innovation, Science and Research NRW

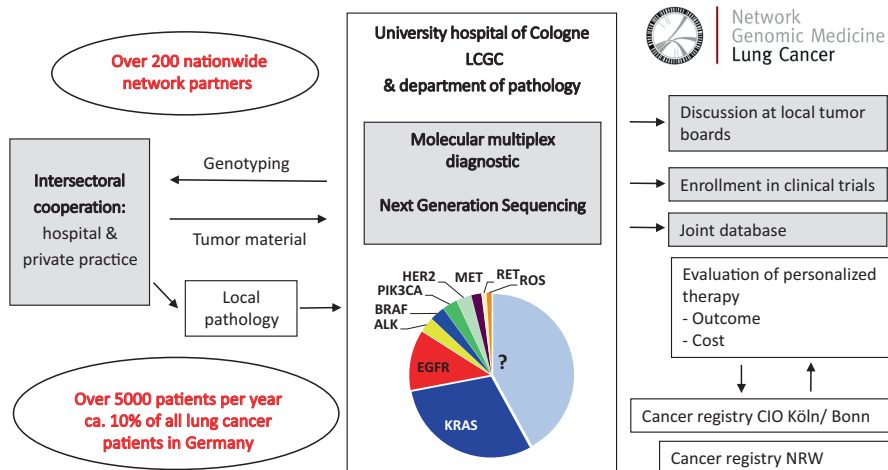


Fig. 6 Network Genomic Medicine

education of physicians and patients, evaluation of personalized treatment and cost-reimbursement strategies. The AOK Rheinland/Hamburg, one of the largest public health insurances in Germany, has contracted with NGM for full reimbursement of molecular multiplex testing and initiation of a joint evaluation program in April 2014. In 2015, further nationwide public and private health insurances followed this example and joined the integrated care contract. NGM reinforces networking by focusing on centralized molecular diagnostic of tumor material and by giving feedback to constituent partners to promote decentralized patient treatment and improve know-how transfer. The establishment of further regional diagnostic centers is planned to reinforce patients access to personalized treatment approaches that are already in clinical evaluation. Apart from the participation in clinical trials, the intersectoral networking enables data collection and evaluation and improves non-commercial research within new therapeutic areas e.g. off-label use. These data can be used by federal authorities as e.g. the Joint Federal Committee (G-BA), for decision making related to the approval of new drugs, approval enhancements etc. (Fig. 6).

2.3 Clinical Trial Management: The Backbone of Innovation

Conducting clinical trials is one of the main challenges for CCCs. Clinical trials are time-consuming and expensive, but in oncology with focus on the evidence-based medicine the process of conducting clinical research is indispensable being the backbone of treatment progress and bringing benefits to patients through research activity. In addition to evidence, in the long-term clinical research has a general

impact on the conduct of care of those individuals who failed to join clinical trials. Thus, clinical trials enable treatment opportunities besides the standards, complement daily practice and improve clinical care (Selby 2011). High-quality clinical trials in oncology require dedicated interdisciplinary experts and well-defined organizational structures (Herrmann and Sehner 2011). Clinical trials are time-consuming and cost-intensive due to strict protocol-related regulations and continuous monitoring, with staff being the main cost factor (Emanuel et al. 2003). Clinical sites are supposed to establish standardized operating procedures (SOPs) that have to be maintained and refreshed continually, and provide regular staff training in accordance with the applicable law, all of which require additional resources (Fink and Wicke 2010). There are only a few official guidelines for cost calculation related to specific research procedures, e.g. assessment of adverse events. Common German reimbursement systems for inpatient and outpatient treatment (e.g. Diagnosis-related Group System, DRG) do not take into account the particular tasks of study coordinators, different hourly-based rates considering the level of experience of various study team members and high-level personnel or institutional overheads. Hence, trial-related staff costs, e.g. set-up cost, recruitment cost and study management effort beyond the patient treatment need to be calculated severally. Structural links and organizational interrelationships among participating departments, hospital administration, external study groups, authorities, clinical sponsors and clinical/ contract research organisations (CRO) etc. make the trial-related intra- and inter-institutional coordination and study management a big time-consuming and cost-intensive challenge. The CIO Köln Bonn comprises world leading study groups (e.g. German CLL Study Group, German Hodgkin Study Group and Lung Cancer Group Cologne) and several decentralized clinical trial units subordinated to various internal departments. Developing and maintaining an appropriately trained study team is essential to the success of the quality of clinical trials (Baer et al. 2011). Not only medical staff (physicians and study nurses) but also project/data managers, controllers and study coordinators are involved to conduct clinical trials, especially on purpose of investigator initiated trials (IIT). To improve transparency of the research site costs the Clinical Trials Center Cologne (CTCC) offers various services to decentralized clinical trial units (CTU) at the Cologne University Hospital. It has developed the STudy site bUDGETing Tool (STUDGET). The STUDGET fee schedule can be used for further budget and contract negotiation, the site personnel can expeditiously compare the proposed budget with the STUDGET fees. In addition, STUDGET can be used by investigators to calculate case payments including institutional overheads for participating sites during the planning of mono- or multicentre IITs (Arenz et al. 2014). Having a good handle of site costs is essential to foster a transparent relationship between CTU and trial sponsor. Both commercial and non-commercial sponsors prefer working with CTUs with a clear overview of their research site costs being able to conduct the budget negotiation in a professional and timely manner (Baer et al. 2010). Further challenges for investigators and interdisciplinary study team members result from an increasing complexity of regulations, the time and financial constraints and growing business

aspects, e.g. the complexity of contracts and CRO pressures (English et al. 2010). Therefore, adequate reimbursement is essential to establish and to manage successful CTUs and study groups with broad opportunities and workforce excellence, which in turn affects data quality, patient outcome, the overall duration of trials and then again keeps the overall cost at a low level (Arenz et al. 2014).

2.4 Standardized Care and Interdisciplinarity

The kaizen quote by Taiichi Ohno¹ *‘Without standards there can be no improvement.’* applies especially to cancer care. Doctors and nurses should have access to up-to-date standards to be able to treat patients with the best available care. Online standard operating procedures (SOPs) are therefore a key tool. These electronic documents are based on current national guidelines and are blended with center-specific information. The specific information includes detailed descriptions on the active clinical trials (e.g. of Cologne University Hospital) with in- and exclusion criteria, hints on when to involve early intervention palliative care depending on tumor entity and stage, an algorithm for psycho-oncological support and directions on when to present the patient at a tumor board. SOPs are written by interdisciplinary oncological project groups (IOP). The IOP coordinators are responsible for keeping the SOPs updated and in consensus with all the group members from various medical specialties. Comprehensive interdisciplinary cancer care embraces an individualized, face-to-face medicine as well as the best available treatment based on translational research and supplemented by supportive care.

The core structure is the interdisciplinary tumor ambulance. The key person is the patient navigator. These navigators are trusted persons for the patients and their families and they also organize all necessary steps of care including scheduling interdisciplinary consultation hours, initiating molecular diagnostics and contacting the study physicians for recruitment of patients into clinical trials. Furthermore, they arrange early palliative care consultations, psycho-oncological support and contact to self-help groups. Whenever avoidable, patients should not be sent from one specialist to the next but rather the specialist to the patient. The interdisciplinary tumor ambulance concentrates all these activities on one spot. For instance, in the ambulance, early phase clinical trial teams take care of patients participating in clinical trials. Also, the patient is not sent to the palliative care facilities but (members of) interprofessional early palliative care teams meet with the patient in the ambulance. These organizational structures are supported by services like patient pathways, interdisciplinary tumor boards and special consultation hours for first contact and second opinion for all cancer entities.

¹ The Japanese business man Taiichi Ohno is considered the father of the Toyota Production System, which became/the precursor of lean manufacturing in the United States.

3 Practical Experience

3.1 Comprehensive Cancer Centers as Hubs of Regional Care Networks

From an organizational perspective the structures in a CCC should all be in line with the purpose to provide the best available care for the cancer patient (Fig. 7). There are four modules to be managed: Medicine and Care, Education and Science, Hospital Management and CCC Organization.

These modules are embedded in a framework of quality standards and economic limits and influenced by defined processes and regulatory limits of in- and outpatient care (*sectorization*). Beyond these internal aspects, a CCC is part of a local health network.

In cancer networks regional cooperation with external health care providers is essential. These networks include office-based physicians as oncologists and pathologists, specialized hospitals and CCCs. Based on the three step model of oncology centers in Germany CCCs are university hospitals dedicated to do research on more effective approaches to prevention, diagnostics and treatment of cancer.

Within the network the CCCs function as hubs to bring innovation to the patients including molecular diagnostics, high-resolution functional molecular imaging and new drugs within clinical trials as well as new concepts of early integration of palliative care or integrating physical exercise during cancer treatment (Beckmann et al. 2007).

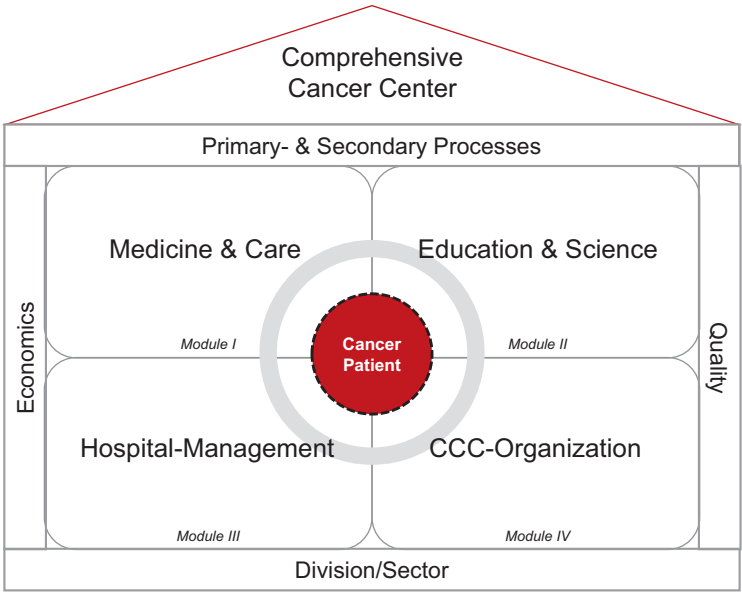


Fig. 7 Functionality of comprehensive cancer centers

3.2 Palliative Medicine and Psychosocial Care

Palliative medicine is mainly concerned with medical and nursing care of seriously ill and dying people and it aims to reduce suffering from a disease. For a long time, palliative medicine has been integrated only at a late stage of illness. Nevertheless, current evidence of clinical trials shows that an early involvement of palliative health care professionals significantly influences the course of disease. Effects are e.g. improvement of the patients’ quality of life, prolonged survival or a reduction of number of hospital stays (Pott and Domagk 2013).

In the field of oncology a unique concept has emerged in recent years: From the time of diagnosis of incurable cancer the treating physicians involve the palliative care team to ensure a broad oncologic care. Based on the patients’ symptoms and needs these teams develop an appropriate supportive treatment together with the patient. This approach of ‘early palliative care’ or ‘early integration’ is recommended e.g. by the American Society of Clinical Oncology (ASCO) (Gaertner et al. 2013). Figure 8 illustrates the intensity of palliative cancer care needed over the course of disease (Gaertner et al. 2011).

Palliative medicine has become tremendously important and, like psycho-oncology (see below), an integral part of the treatment and care of cancer patients [Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (AWMF) 2014].

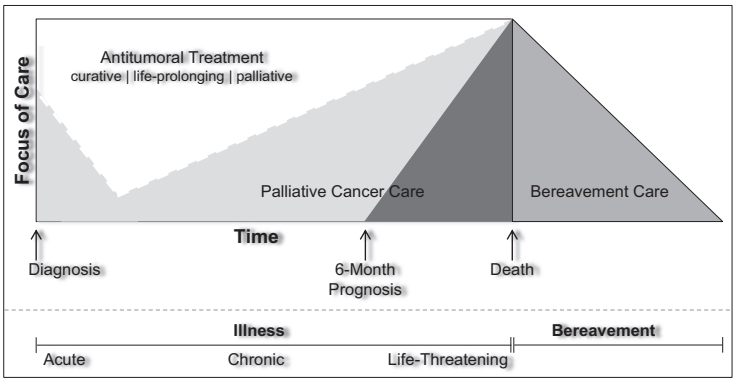


Fig. 8 ASCO approach of integration of specialized palliative care with permission

3.3 Psycho-Oncology

Psycho-oncology is a young discipline (Herschbach and Mandel 2011) which aims to implement scientifically approved psychosocial aspects into the treatment and care of patients (Holland et al. 2010). Psycho-oncology encompasses a wide range of tasks aimed at supporting cancer patients and their families in dealing with the disease and treatment effects, reduce mental stress and maintain a high level of independence and thus quality of life. It is essential to recognize a psychosocial burden at an early stage. The key element is the consequent use of diagnostic screening tools for psychological distress and psychosocial needs (e.g. the Hospital Anxiety and Depression Scale (HADS) (Herschbach and Weis 2010). Based on the screening result a demand-oriented care approach of psycho-oncological interventions can be offered at any time (psychosocial support in the diagnosis, treatment, rehabilitation, aftercare and palliative care) (Mehnert 2014). Today psycho-oncological care is part of oncological guidelines and a criterion for certification as a cancer center by DKG and DKH. In addition, its importance is reflected in the National Cancer Plan (Herschbach and Mandel 2011).

3.4 Oncological Training Therapy

Studies have shown a positive influence of sport therapeutic interventions on cancer (Schmitz et al. 2010). Numerous side effects, such as fatigue, nausea, vomiting, lymphedema, incontinence, atrophy etc. can be minimized by sports therapy. There is evidence that especially in breast cancer, prostate cancer and hematological diseases exercise programs can positively influence physical fitness, muscular strength, the psyche and the quality of life (Hayes et al. 2009). The oncological training therapy at the CIO Köln Bonn transfers recent scientific findings into practical sports therapy.

3.5 Cancer Registries

Cancer registries store information about all cancer patients. There are two different forms of cancer registries: population-based registries and clinical registries. The second form discerns state-related as well as institution-related cancer registries. The population-based registries only collect basic data such as name, date of birth, sex, address, tumor type and stage. This data is used primarily to gather information about the regional and national development of the cancer burden. These data sets are also collected by the country-related cancer registries. In addition, they record the diagnostic procedures as well as histological, molecular, treatment-related and follow-up data.

Typically, each federal state in Germany runs a population-based cancer registry and a state-based registry. They receive information of cancer cases from the whole state by physicians, medical practices and hospitals (here, the institution-related

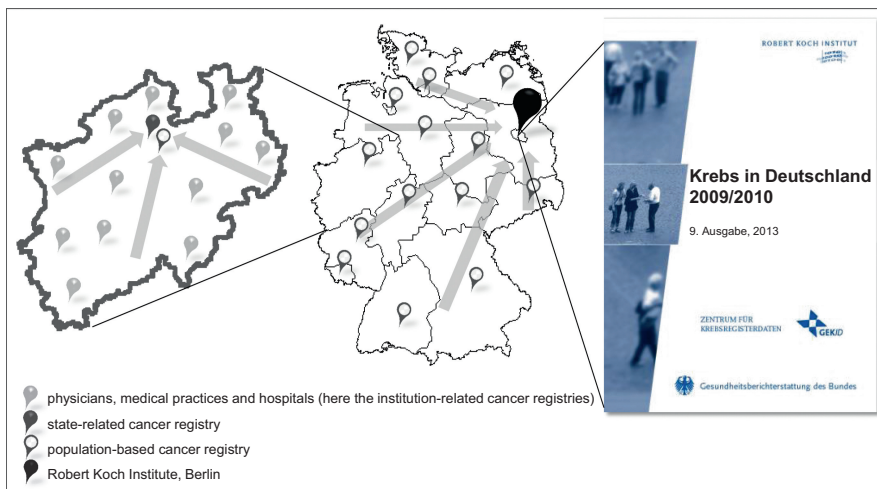


Fig. 9 Flow of registry data in Germany

cancer registries) (Robert Koch Institute). In most countries with cancer registries data is forwarded to a central country registry (in Germany the Center for Cancer Registry Data (ZfKD) at the Robert Koch Institute in Berlin. All the collected data enables public health professionals to better understand and address the cancer burden. Registry data is essential for programs which are focused on risk-related behaviors (e.g. tobacco use and exposure to the sun) or on environmental risk factors (e.g. radiation and chemical exposures). Such information is also essential for detecting when and where cancer screening efforts should be enhanced and for monitoring the treatment provided to cancer patients. In addition, solid registry data are crucial to a variety of research efforts, including those aimed at evaluating the effectiveness of cancer prevention, control or treatment programs. Figure 9 illustrates the flow of registry data in Germany.

In general, the quality of any registry database clearly depends on a careful process that defines any element of the database to be collected. In Germany, this task is assumed by the *Working Group of German Tumor Centers* (ADT) and the *Association of Population-based Cancer Registries in Germany* (GEKID) (Bundesministerium für Gesundheit 2012). These groups published a joint working paper that includes all items necessary (standard oncologic basic data set) (Bundesministerium für Gesundheit 2014). It is the theoretical background for any cancer documentation.

However, the quantity and the level of diversification of medical and biological information of patients with cancer has grown notably in the last years due to new diagnostic and treatment options. All these data sets are saved in many different and independent IT systems (e.g. clinical information system, pathology's or radiology's database). Only by merging the data sets of all patients it is possible

to create a big database that can deliver the necessary output for sound scientific evaluation. Physicians, medical practices and hospitals deliver their single data to the mentioned cancer registries. The aim is to gather a complete summary of patient history, diagnosis, treatment and survival status for each oncologic patient.

The institution-related cancer registries are playing a crucial role. Usually, these registries are implemented at hospitals with a focus on treatment of patients with oncologic diseases. They collect on a smaller scale (in comparison to the country-related registries) any oncological information of usually their own patients in one database. In addition to the tasks discussed above, the captured data is utilized for e.g. certifications and—at institutions like comprehensive cancer centers—for research and evaluation of their own developments and patients' treatment.

Merging the datasets poses one of the major challenges in the process but is crucial. Only then cross-linking of data becomes possible which provides the basis for medical and health-economic research.

The progress and the expansion of the structures of all cancer registries are facilitated by national law. In Germany, several laws have been established in the last two decades on national and federal state level. The first task was to define the population-based data set. The latest laws aimed to foster the development of the clinical cancer registries. With the Cancer Detection and Register Law the cornerstone for the recording of clinical cancer information on the national level was laid (Bundesministerium für Gesundheit, 2013). Tumor documentation requires a lot of personnel resources which are currently not regularly financed. Nevertheless, a lot of institutions run their own institution-related cancer registries.

4 Summary and Outlook

Cancer care is complex and challenges a comprehensive cancer center in a number of ways. From an organizational perspective the structures need to be in line with the purpose to provide the best available care. These structures include standardized care and interdisciplinarity, clinical trials, DNA sequencing and genotyping capacities and clinical cancer registries. Furthermore, the center needs to actively participate in regional health care provider networks.

From a medical point of view there is a clear trend towards personalized medicine. Beyond new diagnostics and treatment there are additional patient needs that must be met including palliative and psycho-oncological support as well as physical exercise.

From a political and financial perspective there is sectorization and a trend towards ambulantization. Refunding for ambulatory care in hospitals remains complex and inadequate.

From our perspective, cancer patients will survive longer with a good quality of life thus leading to cancer as a chronic disease rather than a fast killer. The gain comes with a downside: the financial burden for society will also increase and needs to be faced.

References

- A genomics-based classification of human lung tumors (2013) *Sci Transl Med* 5(209):209ra153. doi:10.1126/scitranslmed.3006802
- Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (AWMF) (2014) d. K. e. V. D. u. D. K. e. V. D. S3-Leitlinie, Palliativmedizin für Patienten mit einer nicht heilbaren Krebserkrankung. Retrieved 19 Dec 2014, from http://leitlinienprogramm-onkologie.de/uploads/tx_sbdownloader/1.Palliativmedizin_Langfassung_Konsultation.pdf
- Arenz D, Hero B, Eichhorst BF, Langer M, Pester L, von Tresckow J, Vehreschild JJ, Vehreschild MJGT, Cornely OA (2014) Estimating site costs prior to conducting clinical trials. *Clin Invest* 4(3):227–234. doi:10.4155/cli.14.3
- Baer AR, Hohneker JA, Stewart TL, Verschraegen CF (2010) Negotiating for success: navigating the contracting process for an exemplary research program. *J Oncol Pract* 6(2):107–110. doi:10.1200/jop.091082
- Baer AR, Zon R, Devine S, Lyss AP (2011) The clinical research team. *J Oncol Pract* 7(3):188–192. doi:10.1200/jop.2011.000276
- Beckmann MW, Adler G, Albers P, Bruns J, Ehninger G, Hauschild A, Neuhaus P, Schmiegel W, Schmitz S, Schmoll H-J, Weller M, Wiegel T, Bamberg M (2007) Onkologie Dreistufenmodell optimiert Behandlung unter Kostendeckung Wie die künftigen Strukturen der onkologischen Versorgung in Deutschland aussehen sollten. *Dtsch Arztebl International* 104(44):3004
- Buettner R, Wolf J, Thomas RK (2013) Lessons learned from lung cancer genomics: the emerging concept of individualized diagnostics and treatment. *J Clin Oncol* 31(15):1858–1865. doi:10.1200/jco.2012.45.9867
- Bundesministerium für Gesundheit (2012). Retrieved 19 Dec 2014, from https://www.bundesgesundheitsministerium.de/fileadmin/dateien/Publikationen/Praevention/Broschueren/Broschuere_Nationaler_Krebsplan_-_Handlungsfelder_Ziele_und_Umsetzungsempfehlungen.pdf
- Bundesministerium für Gesundheit (2013) Gesetz zur Weiterentwicklung der Krebsfrüherkennung und zur Qualitätssicherung durch klinische Krebsregister (Krebsfrüherkennungs- und -Registergesetz—KFRG). Retrieved 19 Dec 2014, from [http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBI&jumpTo=bgbl113s0617.pdf#_bgbl_%2F%2F*\[%40attr_id%3D%27bgbl113s0617.pdf%27\]_1437126274677](http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBI&jumpTo=bgbl113s0617.pdf#_bgbl_%2F%2F*[%40attr_id%3D%27bgbl113s0617.pdf%27]_1437126274677)
- Bundesministerium für Gesundheit (2014) Bekanntmachung. Aktualisierter einheitlicher onkologischer Basisdatensatz der Arbeitsgemeinschaft Deutscher Tumorzentren e.V. (ADT) und der Gesellschaft der epidemiologischen Krebsregister in Deutschland e.V. (GEKID). Retrieved 17 Jul 2015, from http://www.tumorzentren.de/tl_files/dokumente/Module%20zum%20Basisdatensatz/Bundesanzeiger_BDS_28.04.14.pdf
- Deutsche Krebsgesellschaft. Retrieved 19 Dec 2014, from <http://www.krebsgesellschaft.de/deutsche-krebsgesellschaft/zertifizierung.html>
- Emanuel EJ, Schnipper LE, Kamin DY, Levinson J, Lichter AS (2003) The costs of conducting clinical research. *J Clin Oncol* 21(22):4145–4150. doi:10.1200/jco.2003.08.156
- English RA, Lebovitz Y, Giffin RB (2010) Transforming clinical research in the United States: challenges and opportunities workshop summary. Institute of Medicine, Washington, DC
- Fink T, Wicke D (2010) Klinische Studie—Herausforderung mit signifikanter Auswirkung. *Biotechnologie 10'11'Kapital, Markt, Wirtschaft*. Retrieved 20 Feb 2015, from http://www.portusco.com/images/Klinische_Studie_mit_siknifikanter_Auswirkung.pdf
- Gaertner J, Weingartner V, Wolf J, Voltz R (2013) Early palliative care for patients with advanced cancer: how to make it work? *Curr Opin Oncol* 25(4):342–352. doi:10.1097/CCO.0b013e3283622c5e
- Gaertner J, Wolf J, Hallek M, Glossmann JP, Voltz R (2011) Standardizing integration of palliative care into comprehensive cancer therapy—a disease specific approach. *Support Care Cancer* 19(7):1037–1043. doi:10.1007/s00520-011-1131-y

- Glossmann JP, Walshe R, Bernschein A, Wolf J (2010) Ökonomische Aspekte des Bronchialkarzinoms. *Der Onkologe* 16(10):1003–1008. doi:10.1007/s00761-010-1907-6
- Goldstein I, Madar S, Rotter V (2012) Cancer research, a field on the verge of a paradigm shift? *Trends Mol Med* 18(6):299–303. doi:10.1016/j.molmed.2012.04.002
- Hayes SC, Spence RR, Galvão DA, Newton RU (2009) Australian Association for Exercise and Sport Science position stand: optimising cancer outcomes through exercise. *J Sci Med Sport* 12(4):428–434
- Herrmann U, Sehner N (2011) Klinische Auftragsforschung—Ein Geschäftsfeld im Krankenhaus. *DZFK* 5(6):77–82
- Herschbach P, Mandel T (2011) Psychoonkologische Versorgung im Nationalen Krebsplan. *Der Onkologe* 17(12):1107–1114
- Herschbach P, Weis J (2010) Screeningverfahren in der Psychoonkologie. Testinstrumente zur Identifikation betreuungsbedürftiger Krebspatienten. Eine Empfehlung der PSO für die psychoonkologische Behandlungspraxis, 2nd edn. Retrieved 21 Dec 2014, from http://www.dapo-ev.de/fileadmin/templates/pdf/psa_broschuere2.pdf
- Holland JC, Breitbart WS, Jacobsen PB, Lederberg MS, Loscalzo MJ, Mccorkle RS (2010) *Psycho-oncology*, 2nd edn. Oxford University Press, New York
- Jahn R, Farrenkopf N, Wasem J, Walendzik A (2012) Neuordnung der ambulanten Onkologie: Gutachten im Auftrag des Berufsverbandes der niedergelassenen Hämatologen und Onkologen eV, der Deutschen Gesellschaft für Hämatologie und Onkologie eV und der Deutschen Krebsgesellschaft eV. Retrieved 15 Dec 2014, from https://www.wiwi.uni-due.de/fileadmin/fileupload/WIWI/pdf/IBES_Gutachten_Neuordnung_der_ambulanten_Onkologie-1_final_3_3.pdf
- Lauterbach K, Lünen M, Schrappe M (2010) *Gesundheitsökonomie, management und evidence-based medicine*, 3rd edn. Schattauer, Stuttgart
- Lauterbach S, Potthoff S, Lünen K, Klostermann G, Stock S, Müller B (2012) Bestandsaufnahme der Rolle von Ambulanzen der Hochschulkliniken in Forschung, Lehre und Versorgung an ausgewählten Standorten (Hochschulambulanzenstudie). Retrieved 15 Dec 2014, from http://www.gesundheitsforschung-bmbf.de/_media/Gutachten_Ambulanzen_26.pdf
- Levy MA, Lovly CM, Pao W (2012) Translating genomic information into clinical medicine: lung cancer as a paradigm. *Genome Res* 22(11):2101–2108. doi:10.1101/gr.131128.111
- Lünen M (2007) Ambulante Behandlung im Krankenhaus Zugang, Finanzierung, Umsetzung Gesundheitsökonomie: Politik und Management. LIT, Berlin (Bd. 3)
- Lünen M, Rath T (2010) Ambulante Öffnung der Krankenhäuser—Welchen Anteil können Krankenhäuser in der onkologischen Versorgung abdecken? In: Klauber JG, Geraedts M, Friedrich J (eds) *Krankenhaus-report 2010*. Schattauer, Stuttgart
- Mehnert A (2014) *Psychoonkologie*. *Gynäkologe* 47(6):427–434. doi:10.1007/s00129-014-3388-y
- National Cancer Institute (2015) Targeted cancer therapies. Retrieved 20 Feb 2015, from <http://www.cancer.gov/cancertopics/factsheet/Therapy/targeted>
- Nationaler Krebsplan (2012) Handlungsfelder, Ziele und Umsetzungsempfehlungen. Retrieved 15 Dec 2014, from http://www.bmg.bund.de/fileadmin/dateien/Publikationen/Praevention/Broschueren/Broschuere_Nationaler_Krebsplan_-_Handlungsfelder_Ziele_und_Umsetzungsempfehlungen.pdf
- Nichols M, Townsend N, Scarborough P, Rayner M (2014) Cardiovascular disease in Europe 2014: epidemiological update. *Eur Heart J* 35:2950–2959. doi:10.1093/eurheartj/ehu299
- Pfaff H, Neugebauer E, Glaeske G, Schrappe M (2011) *Lehrbuch Versorgungsforschung: Systematik—Methodik—Anwendung*, vol 1, 1st edn. Schattauer, Stuttgart
- Pott G, Domagk D (2013) *Integrierte Palliativmedizin: Leidensminderung-Patientenverfügungen-Sterbebegleitung-intuitive Ethik*. Schattauer, Stuttgart
- Robert Koch Institut. Zentrum für Krebsregisterdaten. Retrieved 21 Dec 2014, from http://www.rki.de/Krebs/DE/Content/ZfKD/Aktuelles/unterschiede_epi_klin_reg.html
- Schmitz KH, Courneya KS, Matthews C, Demark-Wahnefried W, Galvao DA, Pinto BM, Irwin ML, Wolin KY, Segal RJ, Lucia A, Schneider CM, von Gruenigen VE, Schwartz AL, American College of Sports Medicine (2010) American College of Sports Medicine roundtable

- on exercise guidelines for cancer survivors. *Med Sci Sports Exerc* 42(7):1409–1426. doi:10.1249/MSS.0b013e3181e0c112
- Schmedders M (2012) Einfluss der ambulanten spezialfachärztlichen Versorgung auf die Gesundheitskosten. Retrieved 15 Dec 2014, from http://www.dgim.de:82/portals/pdf/korporative_MG/20121024_Schmedders_Herbstsymposium.pdf
- Schwartz FW, Wille E, Fischer C, Kuhlmei A, Lauterbach K, Rosenbrock W, Scriba P (2000) Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen. Bedarfsgerechtigkeit und Wirtschaftlichkeit. Gutachten, 2001
- Selby P (2011) The impact of the process of clinical research on health service outcomes. *Ann Oncol* 22(Suppl 7):vii2–vii4. doi:10.1093/annonc/mdr418
- Wissenschaftsrat (2010) Empfehlungen zur Weiterentwicklung der ambulanten Universitätsmedizin in Deutschland. <http://www.wissenschaftsrat.de/download/archiv/10052-10.pdf>. Accessed 15 Dec 2014

Florian Kron gained his first practical experiences in health care management at the AMEOS Group based in Zurich in the department Mergers and Acquisitions. He obtained a diploma in health economics at the University of Cologne in 2012. At present he is the head of the economic division at the First Department of Internal Medicine at the University Hospital in Cologne. As member of the management team in the Center for Integrated Oncology (CIO) Köln Bonn he is focusing on economic issues in hematology and oncology. Florian Kron is writing his dissertation in economics of cancer treatment.

Andreas Bernschein has studied health economics at the University of Cologne with a focus on business policy, evidence-based medicine and health technology assessment. After graduating he has focused on health economic evaluation, business processes and quality management at the Center for Integrated Oncology (CIO) Köln Bonn. He is Head of the Clinical Cancer Registry and manages health economic issues. He is doing his doctorate on application of data of clinical cancer registries.

Anna Kostenko obtained a Diploma in Health Economics at the University of Cologne in 2012. Since April 2012 she is the Head Economist of the clinical trial unit at the First Department of Internal Medicine at the University Hospital Cologne and is focusing on financial aspects and personnel management in clinical trials (phase I–IV). In June 2014 she became scientific coordinator of the Network Genomic Medicine (NGM). She is currently writing her dissertation in the field of economics of clinical trials.

Jürgen Wolf is currently Medical Director of the Center for Integrated Oncology (CIO) at the University Hospital Cologne. He holds a professorship for Interdisciplinary Translational Oncology at the University of Cologne and is speaker of the CIO lung cancer program.

Prof. Wolf received his MD degree from the University of Freiburg. From 1986 to 1990 he spent his postdoctoral fellowship at the German Cancer Research Center Heidelberg in the tumor virology group of Prof. H. zur Hausen. In 1990 he started his clinical training in the Department of Internal Medicine, Cologne University Hospital. He is board-certified in internal medicine and haematology/medical oncology. From 1990 to 2003 he headed the Laboratory for Research on Hodgkin's Lymphoma in Cologne. From 2000 to 2004 he was co-chairman of the German Hodgkin's Lymphoma Study Group. Since 2004 he has been coordinating the establishment of the CIO at the Cologne University Hospital. In 2005 he initiated the lung cancer program at the CIO and founded the Lung Cancer Group Cologne (www.lungcancergroup.de) focusing on personalized early proof of concept trials. In 2010 he co-founded the Network Genomic Medicine (NGM) aiming at implementing lung cancer genotyping and allocation of patients to personalized treatment in routine clinical care (www.ngm.de).

Michael Hallek received his MD degree from the University of Munich, Germany, in 1985. He trained in pharmacology and internal medicine from 1985 to 1990 at the University and Technical University of Munich. From 1990 to 1992, he spent 2 years as a research associate at the Dana Farber Cancer Institute at Harvard Medical School, Boston, USA, before returning to the University of Munich, where he continued his training in internal medicine and in hematology and oncology. From 1994 to 2005, he was head of the Gene Therapy Program at the Gene Center of the University of Munich and at the National Centre for Research on Environment and Health (GSF), Munich. In 1994, he founded the German CLL Study Group and is its chairman until today. Since 2003, Dr. Hallek is Professor of Medicine, Director and Chair of the Department of Internal Medicine I at the University of Cologne. Since 2007, he is also the chairman of the Center for Integrated Oncology (CIO), the joint comprehensive cancer center of the Universities of Cologne and Bonn. Since 2011, he is a Member of the National Academy of Sciences (Leopoldina). He received numerous awards such as the Paul Martini Prize in 2012 and the Binet-Rai Medal in 2013.

Jan-Peter Glossmann was trained in medicine in Germany (Köln), Austria (Innsbruck) and Canada (Montreal). Additionally, he obtained a Master of Public Health in Boston at the Harvard School of Public Health with a focus on health care management followed by a fellowship in administrative management at Harvard Health Services. Back in Cologne he continued to focus on financial aspects and quality management in cancer care. He is a trained hematologist-oncologist and Chief Financial Officer of the Center for Integrated Oncology (CIO) Köln Bonn.

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