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Costs of quality assurance in the German medical market

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I dedicate this dissertation to my son, Shayan, who is the sunshine of my heart. I hope this work will be an inspiration for his career in the future.

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ABSTRACT

The central subject of this dissertation, combined with a methodological study, is the economic analysis of Quality Assurance in the German health care system.

With the help of the study an estimate of the total costs in the German health care market shall be given. The focus of the analysis is on Companies, Political Bodies, Liberal Professions and Public Corporations which are part of the health care system including Certification Bodies, which lead to costs from using Quality Assurance and interacting with the health care system.

First, a systematic literature search was conducted to determine the costs.

It was found that there are no articles or publications that address the topic of total cost of quality assurance. A continuation/update of existing studies was therefore not possible.

To be able to estimate the total costs of Quality Assurance in the German health care market, the Quality Assurance costs were surveyed using a bottom-up analysis.

After identifying organizations and collecting relevant data, the total costs of quality assurance in the German healthcare market were estimated using a mathematical calculation.

In general, ensuring quality is an original part of the actions of all professional groups and institutions working in the health care system. Due to this importance, it is remarkable that an economic analysis of the total costs has never taken place before. One reason for this may be the "complexity of the German health care system". Furthermore, the costs of quality assurance are not listed separately, but as part of general administrative expenses. Controlling and transparent presentation of the costs is therefore not possible.

The cost estimation and the database created for this study about the parties involved in quality assurance in the German health care market can be a useful support for further studies in this field of research.

Keywords: Quality Assurance, Costs of Quality Assurance, German Medical Market, Health Care, Quality Management, Administrative Costs

RESUMEN

El objetivo principal de esta investigación es el análisis económico de la Garantía de Calidad en el sistema sanitario alemán y, en concreto, de los costes asociados al mismo.

Este estudio pretende ofrecer una estimación de los costes totales asociados a la garantía de calidad en el mercado sanitario alemán. El análisis se centra en las empresas, los organismos políticos, las profesiones liberales y las corporaciones públicas que forman parte del sistema sanitario, incluidos los organismos de certificación, que generan costes derivados del uso de la Garantía de Calidad y de la interacción con el sistema sanitario.

En primer lugar, se realizó una búsqueda bibliográfica sistemática para determinar los costes. De esta manera, se constató la falta de artículos y publicaciones que aborden el tema del coste total de la garantía de calidad y la necesidad de crear algún método que realice dicha estimación.

Para poder estimar los costes totales de la garantía de calidad en el mercado sanitario alemán, se estudiaron los costes de la garantía de calidad mediante un análisis ascendente. Tras identificar las organizaciones y recopilar los datos pertinentes, se estimaron los costes totales de la garantía de calidad en el mercado sanitario alemán mediante un modelo matemático.

En general, garantizar la calidad forma parte original de las actuaciones de todos los grupos profesionales e instituciones que trabajan en el sistema sanitario. Debido a esta importancia, llama la atención que nunca antes se haya realizado un análisis económico de sus costes totales. Una de las razones puede ser la "complejidad del sistema sanitario alemán". Además, los costes de la garantía de calidad no figuran por separado, sino como parte de los gastos administrativos generales. Por lo tanto, no es posible un control y una presentación precisa de los mismos.

La estimación de costes y la base de datos creada para este estudio, sobre las partes implicadas en la garantía de calidad en el mercado sanitario alemán, pueden ser un apoyo útil para futuros estudios en este campo de investigación.

Palabras clave: Garantía de calidad, costes de la garantía de calidad, mercado médico alemán, asistencia sanitaria, gestión de la calidad, costes administrativos

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LIST OF ABBREVIATIONS

AOK	Allgemeine Ortskrankenkasse (German) = General Local Health Insurance
APS	Aktionsbündnis Patientensicherheit (German) = Patient Safety Action Alliance
AQUA-Institute	Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen (German) = The Institute for Applied Quality Promotion and Research in Health Care
AWMF	Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (German) = Association of the Scientific Medical Societies
BÄK	Bundesärztekammer (German) = German Medical Association
BDA	Berufsverband Deutscher Anästhesisten (German) = Professional Association of German Anesthesiologists
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (German) = Federal Institute for Drugs and Medical Devices
BGB	Das Bürgerliche Gesetzbuch (German) = The German Civil Code
BGH	Bundesgerichtshof (German) = Federal Supreme Court
bifg	BARMER Institut für Gesundheitssystemforschung
bPS	benignen Prostatasyndroms (German) = Benign Prostate Syndrome
BQS	Institut für Qualität & Patientensicherheit (German) = Institute for Quality & Patient Safety
CEN	European Committee for Standardisation
cf.	Confer (Latin) = to compare or bring together
CIR	Critical Incident Reporting
CIRS	Critical Incident Reporting System
COPD	Chronic Obstructive Pulmonary Disease
DÄT	Deutscher Ärztetag

DCV	Deutscher Caritasverband (German) = German Caritas Association
DEKV	Deutscher Evangelischer Krankenhausverband (German) = German Protestant Hospital Association
DGAI	Deutsche Gesellschaft für Anästhesiologie und Intensivmedizin (German) = German Society for Anaesthesiology and Intensive Care Medicine
DIN	Deutsches Institut für Normung (German) = German Institute for Standardization
DKG	Die Deutsche Krankenhausgesellschaft (German) = German Hospital Federation
DMP	Disease Management Program
DNQP	Das Deutsche Netzwerks für Qualitätsentwicklung in der Pflege (German) = The German Network for Quality Development in Care
DPR	Deutscher Pflegerat (German) = German Nursing Council
DRG	Diagnosis Related Groups
DWdEKD	Diakonisches Werk der EKD -Evangelischer Krankenhausverband- (German) = Protestant Hospital Association
EBM	Evidence-Based Medicine
EFQM	European Foundation for Quality Management
e.g.	Exempli gratia (Latin) = for example
EKK	Ersatzkassen (German) = Substitute health insurance funds
EMP	Employees
EN	European Norm
e.V.	Eingetragener Verein (German) = Registered Association
et al.	Et alii (Latin) = and others
et seq.	et sequens (Latin) = and the following
Etc.	Et cetera (Latin) = and so forth
f.	Folio (Latin) = following
G-BA	Gemeinsamer Bundesausschuss (German) = Federal Joint Committee

GENESIS	Gemeinsames Neues Statistisches Informations-System (German) = Joint New Statistical Information System
gGmbH	Gemeinnützige Gesellschaft mit beschränkter Haftung (German) = Non-profit limited Liability Company
GKV	Gesetzliche Krankenversicherung (German) = Statutory Health Insurance
GmbH	Gesellschaft mit beschränkter Haftung (German) = Limited Liability Company
GMG	GKV-Modernisierungsgesetz (German) = Modernization Act
GP	General Practitioner
GRG	Gesundheitsreformgesetz (German) = Health Care Reform Act
Hrsg.	Herausgeber (German) = Publisher
i.e.	Id est (Latin) = that is
IQTIG	Institut für Qualitätssicherung und Transparenz im Gesundheitswesen (German) = Institute for Quality Assurance and Transparency in Health Care
ISO	International Standards Organization
IVM	Intravitreale Medikamenteneingabe (German) = Intravitreal drug administration
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
KBV	Kassenärztliche Bundesvereinigung (German) = Associations of Statutory Health Insurance Physicians
KHEntG	Krankenhausentgeltgesetz (German) = Hospital Remuneration Act
KHG	Krankenhausfinanzierungsgesetz (German) = Hospital Financing Act
KHSG	Krankenhaus Struktur Gesetz (German) = Hospital Structure Act
KKVD	Katholischer Krankenhausverband (German) = Catholic Hospital Association

KTQ	Kooperation für Transparenz und Qualität im Gesundheitswesen (German) = Cooperation for Transparency and Quality in Health Care
KV	Kassenärztliche Vereinigungen (German) = Associations of Statutory Health Insurance Physicians
KZBV	Kassenzahnärztliche Bundesvereinigung (German) = Associations of Statutory Health Insurance Dentists
Lat.	Latin
LEP	Leistungserfassung in der Pflege
loc. cit.	Loco citato (Latin) = in the place cited
LP	Lipoprotein
MDK	Der Medizinische Dienst der Krankenversicherung (German) = Medical Services of the Health Insurance Companies
MRSA	Methicillin-Resistant Staphylococcus
MVZ	Medizinisches Versorgungszentrum
NQSZ	Der DIN-Normenausschuss Qualitätsmanagement, Statistik und Zertifizierungsgrundlagen (German) = The DIN Standards Committee Quality Management, Statistics and Certification Principles
NVL	Nationale Versorgungsleitlinie (German) = National Health Care Guideline
Para.	Paragraph
pCC	proCum Cert
PET	Positronen-Emissions-Tomographie (German) = Positron Emission Tomography
PKK	Primärkassen (German) = Primary Health Insurance Funds
PKV	Verband Privater Krankenversicherer (German) = Association of Private Health Insurers
PRO	Patient Reported Outcome
QA	Quality Assurance
QALYs	Quality Adjusted Life Years

QISA	Qualitätsindikatorensystem für die ambulante Versorgung (German) = Quality Indicator System for Outpatient Care
QMH	Qualitätsmanagementhandbuch
QSKH-RL	Die Richtlinie über Maßnahmen der Qualitätssicherung in Krankenhäusern (German) = The Guideline on Quality Assurance Measures in Hospitals
QSR	Qualitätssicherung mit Routinedaten (German) = Quality Assurance with Routine Data
RUMBA	Relevant, Understandable, Measurable, Behaviorable, Achievable
SGB	Sozialgesetzbuch (German) = German Social Code
SHI	Statutory Health Insurance
SQG	Sektorenübergreifende Qualitätssicherungsverfahren (German) = Intersectoral Quality Assurance Procedures
SVR	Sachverständigenrat (German) = German Council of Economic Experts
UNSCC	United Nations Standards Coordinating Committee
vs.	Versus
WHO	World Health Organization
WIdO	Wissenschaftliches Institut der AOK (German) = Scientific Institute of AOK
ZEFQ	Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen (German) = Journal for Evidence, Continuing Education and Quality in Health Care
Zi	Zentralinstitut für die Kassenärztliche Versorgung (German) = Central Institute for Statutory Health Insurance Physicians
ZQP	Zentrum für Qualität in der Pflege (German) = Centre for Quality in Care

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1 INTRODUCTION

In the German Statutory Health Insurance System (Gesetzliche Krankenversicherung – GKV), there is not only an efficiency requirement, but also a quality requirement: the quality and effectiveness of services must correspond to the generally recognized state of medical knowledge and take medical progress into account (§ 2 (1) sentence 3 SGB V). To ensure this, hospitals, contracted physicians and medical care centers are obliged to participate in measures for inter-institutional quality assurance (QA) and to introduce and further develop quality management (QM) within the institution. In a narrower sense, these measures for QA across facilities and for QM within facilities represent the measures for quality development of patient care in the GKV system that have been subsumed under the umbrella term "quality assurance" to date.

In the meantime and against the backdrop of this quality requirement, an increasingly complex set of regulations for mandatory QA has emerged. As an interim result, however, it must be stated that mandatory QA is increasingly failing to fulfill its original purpose of promoting quality. This is due, on the one hand, to a backlog in system maintenance and continuous further development of QA procedures, and, on the other hand, to an increasing neglect of QM within facilities (Klakow-Franck 2020). If, for example, against the backdrop of the Corona pandemic, the QA procedure "community-acquired pneumonia" is perceived only as a burden and not as useful, both for the patients concerned and for the hospitals, this must be seen as a serious alarm signal for the internal state of the facility-internal quality culture in German hospitals.

Even the newer goals of QA - cross-sectoral QA and quality-oriented care management – have not yet been achieved. However, the reasons for this delay in a quality push in the healthcare system cannot be found in QA alone, but also in the framework conditions of the healthcare system (Klakow-Franck 2020).

Although scientific research has been late in addressing the topic of QA, the number of publications has grown rapidly (e.g. the bibliographies in Mörsch 2005; Poll 2008; Hensen 2019; Große 2021).

In fact, in recent years there have been many proposals to ensure and manage the quality of treatment in medical institutions more rigorously. It is often argued that QA and QM have been introduced late in the health care sector compared to industry (Haeske-Seeberg 2001: 35; Schupeta & Hildebrandt 1999: 19).

Other authors (Jaster 1997: 97) point out that QA is of course not new in medicine, but takes another approach and has other indications to comparable projects in other industries. This includes, for example, the extremely long training of providers, the manifold medical certificates or the posthumous diagnosis confirmation by pathological examination (Obst 2005: 12).

Quality promotion as the purpose of classical QA

The legally binding QA according to SGB V, as we know it today, has its technical and methodological origins in the 1960s. In this context, the Munich Perinatal Study[1] is referred to as the "mother" of all cross-institutional QA procedures. The basis for this was the identity of the independent medical profession, which understood the quality controlling of its actions to be the very essence of the medical profession. As such, QA was and still is enshrined in medical physicians' law and in the laws of the healing professions and federal states.

Thus, quality of patient care has been one of the most frequently used buzzwords in health policy and health services research for years. This is justified, among other things, by the increasingly complex care processes, the economization

[1] The Munich Perinatal Study (1975 to 1977) and the resulting Perinatal Survey are generally regarded as the starting point of today's statutory QA in the field of perinatal medicine. Obstetrics was the first specialty in Germany to start addressing the issue of QA and thus quality development of its own treatment.

of the health care system and the justified desire of the public for transparency in the service sectors (Ollenschläger 1999: 418 et seq.; Riskin 2009: 237 et seq.).

QA is one of the inherent duties of every physician and arises from the professional code of conduct. Accordingly, the individual physician is obligated to practice his profession conscientiously according to the precepts of medical ethics and, in particular, according to the rules of medicine (Ollenschläger & Thomeczek 1996: 360 et seq.).

The conscientious practice of the profession requires the necessary professional qualifications and compliance with the recognized state of medical knowledge (cf. § 2 Musterberufsordnung Ärzte – Physicians' Professional Code). The professional regulations serve, among other things, to ensure the quality of medical and dental practice in the interest of the health of the population. The civil law treatment contract between the physician and the patient also imposes an obligation on the physician to provide treatment in accordance with the generally recognized professional standard which exists at the time of treatment, in accordance with § 630a (2) BGB, i.e. lege artis[2] treatment.

[2] There are specialist fields and professions that are subject to strong change. These include, in particular, medicine, technology, and construction law or practice. Anyone who wishes to contract their services can legally expect the service provider to deliver a quality that is free of legal and material defects and, moreover, complies with the current rules in the relevant field. While material and legal deficiencies are comparatively easy to detect, the incorrect application of the current rules in a particular field is more difficult to prove. Medical science and medical practice attempt to demonstrate whether and, to what extent, medical action can be subjected to certain rules, the non-observance of which can trigger liability from a medical point of view as a violation of generally accepted rules and therefore legally as a violation of the duty of care (Baumbusch, Schindler, Schultheis, Vahlensieck 1965: 366).

This did not suffice for the legislator for the provision of care to the statutory insured. QA in medicine in Germany is now primarily determined by Volume 5 of SGB and the transference of the form of these legal requirements to the Joint Federal Committee (Gemeinsamer Bundesausschuss – G-BA). With the Act on the Modernization of Statutory Health Insurance (GKV- Modernisierungsgesetz, GMG) on January 1, 2004, the new G-BA was formed as a cross-sectoral institution of joint self-government. Since then, the G-BA has been entrusted with the task of defining the QA requirements for GKV-accredited physicians and dentists as well as inpatients. This is primarily intended to streamline and standardize decision-making processes for QA in the different sectors (inpatient, outpatient, dental) (cf. legislative justification for the GMG, § 137 Paragraph 1 SGB V). This intention of the legislator was further developed in the subsequent health care reforms. The aim is to keep QA as uniform and rigorous as possible in the care sectors. Suitable measures are to be developed to ensure the quality of medical services and make them more transparent. QA in medicine represents different approaches and measures to ensure defined quality requirements. It is not an instrument for increasing quality. At best, this results from an increase in quality requirements (Thomeczek et al. 2003: 585 ff.).

Against this background, a wealth of methods, measures and organizations have been established in Germany with the aim of maintaining or improving the quality of medical care and patient safety. In view of the effort and costs involved, there have been repeated calls for established QA or QM programs to be reviewed for their practicality, effectiveness and cost appropriateness (Helou, Schwartz, Ollenschläger 2002: 205 et seq.).

The central subject of this dissertation, combined with a methodological study, is the economic analysis of QA in the German health care system.

With the help of the study an estimate of the total costs in the German health care market shall be given. The focus of the analysis is on companies, organizations, associations and institutions which are part of the health care system including certification bodies, which lead to costs from using QA and interacting with the health care system.

1.1 PROBLEM DEFINITION

The quality of QA has become a central guiding principle in healthcare. As a result, there are currently hardly any healthcare organizations that have not already been confronted with a QA procedure or program. The legislator has also reacted to the increased importance of the topic of quality in health care with corresponding laws and legal standards. For the first time, QA was uniformly regulated nationwide in the Health Care Reform Act (Gesundheitsreformgesetz – GRG) of 1989 and Health Care Structure Reform Act of 2004. Ensuring and improving the quality of health care has become the most important philosophy in the health care system for all participants in the system: care providers, funding agencies, politicians, and patients, in addition to the principle of economic efficiency (Geraedts 2020). Although the terms QA and QM are sometimes given different meanings by the legislature and the self-government, there is no clear demarcation in terms of content. Accordingly, the German Sachverständigenrat (SVR)[3] also states that there are no indications of a contradiction between these concepts or procedures. The SVR describes these concepts as secondary

[3] The German Council of Experts (Sachverständigenrat) for the assessment of developments in the health care system has the task of preparing expert reports every two years and within this framework:

- To analyse the development of health care with its medical and economic effects
- To develop priorities for the reduction of deficits in health care provision and existing overprovision, taking into account the financial framework conditions and existing efficiency reserves
- To present proposals for medical and economic orientation data, as well as to point out possibilities and ways for the further development of the health care system.

technologies that are used to improve care processes, for example in the area of therapy or diagnostics (SVR 2002, 121).

The consolidation, modification and improvement of the quality of inpatient and outpatient care has, as already mentioned, become the most important guiding principle in the health care system for all those involved in it, alongside the principle of economic efficiency. However, the complexity of the health care system and the resulting increase in the lack of transparency of service provision has meant that information on quality, costs and benefits can hardly be interpreted clearly and conclusively (Helou, Schwartz, Ollenschläger 2002: 205 et seq.).

Better information about quality is an urgent desire, not only for the patient. As Porter & Teisberg (2007: 1103) show, universal QA in the health care system could lead to a paradigm shift from an economic perspective: "Today's preoccupation with cost shifting and cost reduction undermines physicians and patients. Instead, health care reform must focus on improving health and health value for patients." It seems plausible if, according to the authors, quality-based competition based on total transparency about patients' needs and the available treatment options and their costs will lead to dramatically improved treatment outcomes among providers, but also increase physician satisfaction.

External influences on QA

For some years now, an increased influence of non-medical experts on the health care system and especially its organizations has been observed. On the one hand, this is evident under the term Evidence Based Medicine (EBM), which pushes health teaching too strongly in the direction of science with a plethora of regulations, guidelines, directives and standards. On the other hand, under various concepts such as QA, quality promotion, QM, quality control, total quality management, benchmarking, balanced score card, accreditation, certification, process management, etc., a sector, managed by experts, has become institutionalized (Nothacker, Muche-Borowski & Kopp 2014: 550 ff.).

The self-proclaimed goal is to improve care performance and provide necessary management processes. While the Model of Business Excellence of the European Foundation for Quality Management (EFQM) is usually oriented to the management concept as well as the German Institute for Standardization (DIN ISO

9000 ff.), which develops content and formal standards for the evaluation of organizations, certification procedures of various accreditation institutions, such as KTQ, check whether a quality management system with different requirements is implemented or not (Klemperer, Dierks 2011). Furthermore, it is worth mentioning that an interdisciplinary research and development sector with the goal of QA has developed to take into account international innovations and concepts in this field. Nevertheless, despite extensive achievements in the field of quality research and development, some factors still appear unaddressed (Nothacker, Kreienberg, Kopp 2017: 3 ff.).

In the meantime, well-founded doubts are also growing in the German-language literature as to whether the hopes for improved quality of care associated with the legal obligation to provide QA are actually being fulfilled (Bertelsmann Stiftung 2005; Geraedts 2007, Hildebrand 2005; König & Geraedts 2006; Schrappe 2005; Simoes et al. 2004). From the perspective of the organizations that are supposed to deliver the quality, the utility, value and purpose of procedures is less and less apparent, given the spectrum of quality assurance procedures (Bandemer 2005). Concepts and procedures of QA, which mainly measure quality objectively and whose results should be used to improve processes and services, have themselves now reached an enormous complexity that they contribute to uncertainty and lack of transparency in the system.

Given the scarcity of resources in the health care system and the rapid increase in the number of organizations offering QA, as well as an increasing influence of non-medical experts on the health care system, the question of an economic analysis of the system must be given more attention than ever. Especially since there is no corresponding cost analysis of the entire German health care system in the field of QA in the relevant literature to date.

The importance and evolution of the topic with regard to QA in health care have provided the impetus for the following questions:

1. Which organizations exist in the German health care market that deal with the topic of quality assurance?

2. What are the costs incurred for quality assurance in these organizations?

Against this background, the aim of this dissertation is, in its first step, to identify organizations, political bodies, corporations, institutions and companies that operate measurements, perform certifications and establish quality assurance systems in the context of QA. Subsequently, an estimate of the total costs of QA for the German health care market will be given based on the collected data.

Furthermore, selected tools and concepts of QA that are applied in the context of medical care are examined in more detail.

1.2 STRUCTURE OF THE DISSERTATION

This thesis is divided into *eleven* chapters. The *second* chapter, which follows the introduction, aims to clarify the concept of quality in the context of medical care. There is noteworthy disagreement in the literature about what quality really is, how to measure it, and how best to use the measurements. By means of some examples from the relevant literature, this disagreement is shown. Therefore, this chapter provides a critical review of previous research on the concept of quality and then develops a unified model.

Chapter *three* deals with the knowledge base of quality assurance approaches in the fields of evaluation and organization or management. According to the logic of quality assurance approaches, formulated on the basis of the scientific ideal of knowledge, guidelines, lists of best performers, certificates or management programs appear as tools that can be reshaped at will and adapted to the recognized valid standards of knowledge. However, the origin of the standards and criteria on the basis of which quality is to be assessed and promoted is rarely questioned.

As shown in the previous chapters, quality is by no means subject to unchanging, rigid specifications and laws. In order to maintain a level of quality under changing conditions and to improve quality in the event of general deficiencies, a suitable set of instruments is required. This includes regular checks and audits. There is therefore a corresponding need for regulation on the part of the state to ensure that quality is maintained and improved in the health care system. Chapter *four* thus first discusses the concept of QA in the context of

healthcare and describes the role of the state in regulating QA as well as the historical origins of QA in Germany.

Chapters *five* and *six* deal with selected concepts and instruments as well as QA procedures in the field of health care. The decision of medicine and healthcare to underpin their goals and development with a structured quality program, based on their status quo, presupposes an understanding of quality as a comprehensive concept of thought that not only occupies a medical-technological component, but is determined by a fundamental and comprehensive mindset on the concept of quality (Schreiner-Hecheltjen 2015). In principle, various concepts are available to medicine and healthcare for implementing a QA profile. Each of the QA concepts is characterized by specific requirements, has particular benefits and opportunities, but also harbors difficulties or even risks. These must be precisely weighed and examined for the success strategy of the relevant medical facility and its development. QM and QA require different quality techniques and quality tools, each targeted and known (Kamiske 2009; Theden & Colsman 2002).

In chapter *seven*, the methodology of the study is presented and justified. The aim of the study was to provide an estimate of the total costs of quality assurance in the German healthcare market. First, an attempt was made to answer this question within the framework of systematic research. During this analysis, it had to be determined that there are no corresponding publications dealing with the total costs of QA. In order to be able to estimate these total costs for the first time, it was necessary to identify corresponding organizations in the field of QA as a first step in order to be able to subsequently analyze their cost structure. In the course of this chapter, the identification and survey of the relevant costs will be presented. Chapter *eight* then presents the mathematical calculation used to estimate the total costs of QA in the German health care market.

In chapter *nine*, the political bodies and public corporations are examined and described in more detail due to their importance for the German health care system. The selection of these actors is based on table 17 from the methodology chapter.

In chapter *ten* and *eleven*, the thesis is concluded by summary/discussion and outlook on the possible further research of the topic.

2 DEFINITIONS AND THEORETICAL BASICS

2.1 THE TERM OF QUALITY IN THE CONTEXT OF MEDICAL CARE

The following explanations and definitions are based on the research and investigation results of Christian Thielscher, who derived a precise definition of the term quality in medicine.

There is remarkable disagreement in literature about what quality really is, how to measure it and how best to use the measurements. Some examples may illustrate this:

- Some authors use a quality concept that primarily refers to the terms structural, process, outcome quality (e.g. Siebers 2005, but also very many other authors in the bibliography), others also use different definitional elements (e.g. Schubert et al. 2007) and still others focus on characteristics of quality indicators (e.g. Zorn & Ollenschläger 1999).
- Some authors believe that a set of such quality indicators is the best way to measure quality, others use much more comprehensive approaches (cf. e.g. Mainz 2003 and Arah et al. 2006).
- Some of the results are markedly contradictory. Some authors believe, for example, that data generated in hospitals can be used for external quality communication, others simply reject this (see, for example, Heller et al. 2003 vs. Hochreutener 2004).

Therefore, this chapter provides a critical review of previous research on the concept of quality and then develops a unified model.

2.2 DEFINITION OF QUALITY

As mentioned above and will become clearer in the following, there is no uniform understanding of quality in literature. Here, a number of definitions are first presented and then tested on concrete examples. The definitions are:

a) Mainly general definitions of the term "quality" (mainly definitions that cover "quality" as a whole):
   - national and international standards that define "quality"
   - the quality concept of Garvin
   - the SERVQUAL-Concept[4].

b) Mainly medical definitions:
   - Lohr's concept of quality and related definitions
   - Donabedian's definition of medical quality and his understanding of structure, process and outcome
   - the implicit quality definition of a performance measurement system for OECD health systems.

c) Guidelines

d) Others

This chapter does not deal with individual (survey) methods, indicators, data sets, QALYs, etc. that are used to measure quality in medicine.

2.2.1 Mainly General Definitions

a) National and international standards

EN ISO 9000:2005 defines quality as "the degree to which a set of inherent characteristics meets requirements". Similarly, the DIN 8402 it replaced read:

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[4] SERVQUAL (made up of service and quality) is a standardized procedure for measuring the quality of services and the resulting customer satisfaction. The method was developed in the 1980s by Parasuraman, Valarie Zeithaml and Berry (PZB model). The approach is one of the most cited and in practice most used procedures for measuring service quality.

Further explanation in next chapter.

"Quality is the totality of characteristics of an entity with respect to its ability to meet specified and anticipated requirements."[5]

Schubert et al. (2007) explain: *"In concrete terms, this means that for each 'unit' - whether it is a screw, a travel booking, a laboratory value, a sonography finding, a fracture treatment or a diabetes therapy - it must first be agreed which measurable characteristics are in any way suitable, and to what extent, to fulfil the specified requirements (= defined quality). There is no such thing as 'good' or 'bad' quality - either the product or service meets the requirements or it does not. The specification is almost always made by the customer. In the industrial sector, customers and suppliers agree on compliance (= conformity) with individual specifications or national / international standards. In the service sector, customer requirements are often determined through surveys. Not only in the health sector, are certain quality requirements with varying degrees of bindingness also defined by parliament (law), corporate bodies (guidelines, further training regulations) or expert committees (guidelines or recommendations of professional societies), but the definition of quality also makes it clear that 'good quality' can be completely different from the customer's and expert's point of view. While a medical expert might, for example, recommend an aggressive therapy with considerable side effects, with a view to the statistical chance of tumour remission, the patient as a client may focus their remaining lifetime being pain-free and thus arrive at different criteria for the assessment of treatment quality."*

[5] The definitions of quality reveal a semantic difficulty of the concept of quality. Originally, "quality" meant (any) property; in the meantime, only a desirable property. Today, quality is "good". There is no opposite; the opposite of quality is usually described as "bad quality". "Quality" can therefore mean either "good quality" or "good and bad quality" as a generic term.

From this it becomes clear:

1. The standard does not define content quality in terms of requirements for hospital services - especially medical -. This must be done by other studies.
2. Quality is on the one hand a property of the product or its creation, and on the other hand what the customer, an expert etc. perceives.
3. Since in the medical field it is not always easy to see what characteristics a product should have (think of material products such as endoprostheses: should they contain cement or not - as well as services, e.g. an operation: what comprises a "good" operation and what is a "good" result). This results in a considerable information problem for the patient.

b) Garvin's definition of quality

A similar but not identical result is provided by Garvin's definition of quality (Garvin 1994). Garvin distinguishes between five different perspectives:

1. In the product-related view, quality is a (technical or measurable) property of a product or service.
2. The manufacturing-oriented approach refers to the manufacturing process of a product, e.g. compliance with technical specifications.
3. In the customer-oriented view, it is about the customer's opinion regarding performance. Quality is therefore the extent to which the customer's needs are satisfied with this product or service.
4. The cost-benefit view refers not only to the suitability of the product but also to its costs.
5. Finally, in the transcendental understanding of quality, quality is a purely subjective, non-measurable experience of a person regarding the characteristics of a product, for example a service.

The model is discussed in connection with the other models (see below).

c) The SERVQUAL-Concept

SERVQUAL is a concept developed specifically for measuring the quality of services (Parasurman et al. 1988). It assumes that consumers have an expectation of "quality" and measure the perceived characteristics of a service against it.

The actual assessment is made based on 5 dimensions:

- Reliability: the accurate and reliable performance of the service.
- Assurance: politeness, appearance etc. in order to convey trust.
- Tangibles: external appearance of persons and facilities, etc. in the provision of the service or good.
- Empathy: sensitivity.
- Responsiveness: willingness to respond to the customer's wishes and provide the service.

These dimensions are assessed with around 40 questions, each relating to the customer's expectation and experience.

Grönroos (2005) points out that one can distinguish technical and functional quality as well as the image of a service in customer perception. For further studies cf. the literature review in Dietrich (2005).

Other general definitions will not be discussed here. Although the presentation is not exhaustive in this respect, even this brief overview shows that there is no uniform view of service quality so far: already these few definitions overlap, but also differ considerably from each other. Undoubtedly, they are useful for detecting components of service quality or customer satisfaction, but they do not provide a clear procedure for measuring this in the special case of medical treatment. It is therefore examined below to what extent more specific, here: medical quality definitions lead further.

2.2.2 Medically Defined Definitions

1. Lohr's concept of quality and related definitions

Gruhl, Klemperer (2008) refer to the definition by Lohr, Schroeder (1990) as leading the way: "*Quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."*

Faber (2002: 70) defines: "*A high quality of patient services exists when hospital treatment, taking into account the patient's disposition, constitution, biography and compliance as well as the state of medical knowledge and technology, offers the best possible guarantee of achieving a preferred treatment outcome and corresponds to the wishes and expectations of patients as well as the value system in society*." The author then attempts to integrate elements of service theory (see below).

Similarly, Viethen (1995: 13) defines: *"Quality of medical care is the totality of characteristics of a process or an object with regard to its suitability to fulfil given requirements in the sense of the patient and taking into account the current state of knowledge in medicine."*

The legal definition in § 70 SGB V is also related in terms of content:

"Quality, humanity and economic efficiency

1. *The health insurance funds and service providers must ensure that the insured people receive care that is needs-based, uniform and in accordance with the generally recognised state of medical knowledge. The care provided to insured people must be needs-based and appropriate, must not exceed what is necessary and must be of the required quality and provided economically.*
2. *The health insurance funds and the service providers have to work towards humane health treatment for their insured persons by taking appropriate measures."*

A brochure of the Federal Ministry of Health (Bundesministerium 2006) defines:

"What is quality and what does it mean for patients?

1.1 The focus is on patients

Medical services must be geared to the needs of patients. Patients should be in the centre of the health care system. They must be able to rely on the fact that the services are sufficient, appropriate and in line with their needs, correspond to the generally recognized state of medical and nursing knowledge and do not exceed what is necessary. The services must not only be provided economically, but above all in the professionally required quality.

1.2 Checklists provide orientation/guidance"

All definitions require two components: the treatment must meet medical standards and produce a desired outcome for the patient. The main difference between the definitions is that Lohr and Faber target not only individual patients but also entire populations.

With this kind of definition, however, it remains open whether quality basically requires both components or not. For example, if a patient is cured by a procedure that does not (yet) reflect the current state of science, is it then a qualitatively "good" service? Or vice versa: if physicians find a procedure correct, but the specific patient does not?

They are also close to a tautology. Lohr's definition could be shortened to: *"Good quality is what is good for the patient and professionally done", or even shorter: "good is what is good and well done."*

2. The Donabedian Model

When Donabedian is quoted in connection with quality, it is usually only with reference to his definition of structure, process and result (e.g. Mörsch 2005). However, Donabedian's theoretical approach is much broader.

First, Donabedian defines the content of quality (Donabedian 2003: 5). Quality arises from the application of "science and technology of health care" in practice:

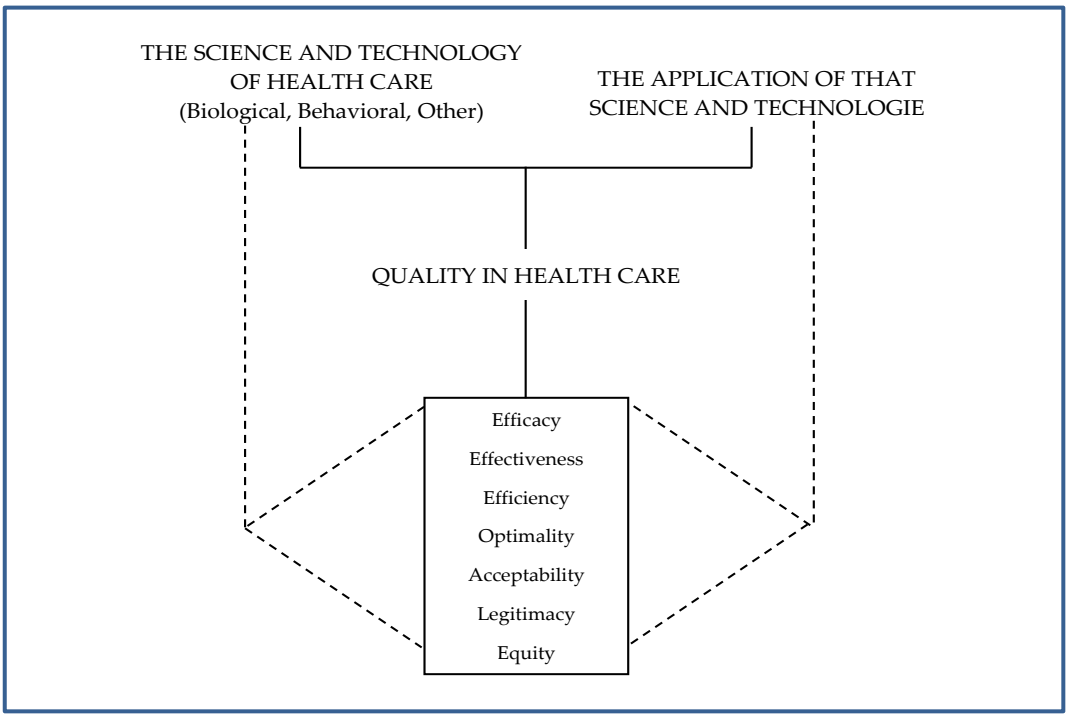

Figure 1: Quality Components According to Donabedian

He further defines these "components" of quality as follows:

1. *"EFFICACY*
   The ability of the science and technology of health care to bring about improvements in health when used under the most favorable circumstances.
2. *EFFECTIVENESS*
   The degree to which attainable improvements in health are, in fact, attained.
3. *EFFICIENCY*
   The ability to lower the cost of care without diminishing attainable improvements in health.
4. *OPTIMALITY*
   The balancing of improvements in health against the costs of such improvements.

5. *ACCEPTABILITY*
   Conformity to the wishes, desires, and expectations of patients and their families.
6. *LEGITIMACY*
   Conformity to social preferences as expressed in ethical principles, values, norms, mores, laws, and regulations.
7. *EQUITY*
   Conformity to a principle that determines what is just and fair in the distribution of health care and its benefits among members of the population."

This representation is an extension of an earlier classification by Donabedian, in which he distinguishes "technical quality", "inter-personal quality" and "amenities" (Donabedian 1988).

Only when measuring quality does the famous structure-process-outcome model come into play (loc. cit., p. 46 et seq.):

*"**Structure***

This is meant to designate the conditions under which care is provided. These include:

1. *Material resources, such as facilities and equipment*
2. *Human resources, such as the number, variety, and qualifications of professional and support personnel*
3. *Organizational characteristics, such as the organization of the medical and nursing staff, the presence of teaching and research functions, kinds of supervision and performance reviews, methods of paying for care, and so on.*

Process

This is taken to mean the activities that constitute health care – including diagnosis, treatment, rehabilitation, prevention, and patient education – usually carried out by professional personnel, but also including other contributions to care, particularly by patients and their families.

Outcome

These are taken to mean changes (desirable or undesirable) in individuals and populations that can be attributed to health care.

Outcomes include:

1. *Changes in health status*
2. *Changes in knowledge acquired by patients and family members that may influence future care*
3. *Changes in the behaviour of patients or family members that may influence future health*
4. *Satisfaction of patients and their family members with the care received and its outcomes."*

Donabedian details the representation of outcomes as follows:

Classification of Outcomes

A. CLINICAL

1. Reported symptoms that have clinical significance
2. Diagnostic categorization as an indication of morbidity
3. Disease staging relevant to functional encroachment and prognosis
4. Diagnostic performance - the frequency of false positives and false negatives as indicators of diagnostic or case finding performance

B. PHYSIOLOGICAL-BIOCHEMICAL

1. Abnormalities
2. Functions
   a. Loss of function
   b. Functional reserve - includes performance in test situations under various degrees of stress

C. PHYSICAL

1. Loss or impairment of structural form or integrity - includes abnormalities, defects, and disfigurement
2. Functional performance of physical activities and tasks
   a. Under the circumstances of daily living
   b. Under test conditions that involve various degrees of stress

D. PSYCHOLOGICAL, MENTAL

1. Feelings - includes discomfort, pain, fear, anxiety (or their opposites, including satisfaction)
3. Beliefs that are relevant to health and health care
4. Knowledge that is relevant to healthful living, health care, and coping with illness
5. Impairments of discrete psychological or mental functions
   a. Under the circumstances of daily living
   b. Under test conditions that involve various degrees of stress

E. SOCIAL AND PSYCHOLOGICAL

1. Behaviors relevant to coping with current illness or affecting future health, including adherence to health-care regimens, and changes in health-related habits
2. Role performance
   a. Marital
   b. Familial
   c. Occupational
   d. Other interpersonal
3. Performance under test conditions involving varying degrees of stress

F. INTEGRATIVE OUTCOMES

1. Mortality
2. Longevity

3. Longevity, with adjustments made to take account of impairments of physical, psychological or psychosocial function: "full-function equivalents"
4. Monetary value of the above

G. EVALUATIVE OUTCOMES

Client opinions about, and satisfaction with, various aspects of care, including accessibility, continuity, thoroughness, humaneness, informativeness, effectiveness, and cost" (loc. cit., p. 48).

Donabedian himself emphasizes the separation between definition and measurement of quality:

"Structure, process and outcome are not attributes of quality. They are only kinds of information one can obtain, based on which one can infer whether quality is good or not." (loc. cit., p. 47).

3. Quality as a basis for performance measurement of different OECD health systems

As part of a comparison of the performance of different OECD health systems, a framework was developed that provides an implicit definition of quality in health care (Arah et al. 2006). It emphasizes the distinction between quality of care on the one hand and quality of population health on the other:

"Performance of what - and to what ends?

In trying to measure performance, policymakers and researchers need to form a clearer image of what it is they want to measure and the key goals of health policy. Here, we make a distinction between conceptual frameworks for health care system performance (or health care performance) and those for health system performance (or health performance).
…

Health care performance refers to the maintenance of an efficient and equitable system of health care without emphasizing an assessment of the non-health care determinants. That is, in an assessment of health care performance, the direct functioning of the delivery system of health care is evaluated vis-à-vis its established public goals for the level and distribution

of the benefits and costs of personal and public health care. A health care performance evaluation is, therefore, concerned with linkages between health care and health… However, in many health care systems, clinical preventive services are used to influence clinically relevant lifestyles, for example smoking cessation as part of cardiac care.

Health performance is a much broader conceptual approach to measuring performance by explicitly using non-health care determinants, health care, and contextual information to give a clearer picture of population health. Again, the main policy goals may be efficiency and equity, but a much wider view of the determinants of health and their costs must be adopted. The equitable distribution of health status itself is an important concern, and responsiveness to consumers is augmented by the concern to influence lifestyles.

Given that a health performance framework is largely concerned with all the interrelations among health, health care, and non-health care factors, health performance subsumes health care performance."

In the following, the non-medical determinants of outcomes (e.g. the gene pool of the population) are taken as given and are not the subject of consideration. In the terminology according to Arah et al. (2006), we are talking here about *"health care performance", not "health performance."*

2.2.3 Guidelines, Regulations etc.

Guidelines differ from the definitions given so far in that they provide a definition of good quality in terms of content.

Guidelines are "*tools for medical and nursing decisions in everyday situations". Since 1990, "they have become an essential part of European health care systems. They are spreading like an epidemic; the expectations of them are enormous and range from a rapid improvement in health care to the realization of potentially great savings*" (Selbmann 1998: 199 et seq.).

The purpose of guidelines is to find the right therapy: Which diagnostic and therapeutic procedures are necessary with the individual patient? Which procedures are unnecessary or even obsolete? Which therapy can be performed in polyclinics and which therapy must be performed in hospitals? (Reinauer 1998: 91 et seq.)

Guidelines are not new. As early as 1997, 170 guidelines were available on the Internet, and another 460 were in development. The society that publishes the guidelines, the AWMF (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V.), has existed for about 40 years (Reinauer loc. cit.). According to the AWMF website, around 180 scientific societies are currently affiliated.

The AWMF (AWMF 2009) writes about guidelines:

"Guidelines" of the Scientific Medical Societies are systematically developed aids for physicians to make decisions in specific situations. They are based on current scientific findings and procedures which have been proven in practice and ensure more safety in medicine, but are also intended to take economic aspects into account. The "guidelines" are not legally binding for physicians and therefore have neither a liability-creating nor liability-exempting effect."

In contrast to medical textbooks, guidelines only deal with individual diseases or symptom complexes. On the other hand, they (usually) represent the opinion of a professional society (e.g. for surgery), thus a large number of physicians. Accordingly, the coordination effort is considerable.

Unfortunately, guidelines are not suitable for every situation. In particular, they are not applicable in especially difficult and / or complex situations where they are needed most urgently: Especially for that one percent of the population that needs about 30% of the health care budget because of its comorbidity and other obstacles, there are and will be hardly any evidence-based guidelines in the future (Selbmann loc. cit.).

A recent study confirms this: the aforementioned work by Boyd et al. (2005) shows that in such a patient, the simple addition of the relevant individual guidelines can lead to adverse effects.

Also in 2009, guidelines are still far from being accepted by all physicians (Schubert et al. 2009); in particular, how realistic they are is doubted.

If one refers to quality in terms of treatment procedures, then implementation regulations (X-ray ordinances, ultrasound agreement, etc.) also define content-related quality standards, in particular for the structural component of quality. The X-ray Ordinance regulates, for example, who may operate X-ray facilities, what standards they must meet, etc.

This also includes checklists, such as those recently recommended by the German Society for Surgery for the performance of operations (DPA 2009).

2.2.4 Further Definitions

Eichhorn (1994: 167) refers to the extent of the deviation between a desired result and the actual result as quality: *"In the field of medical care, the concept of quality is primarily defined under pragmatic aspects. According to this, quality considerations include statements about the difference between what can and should be achieved in patient treatment (requirements specification for the quality-determined characteristics) and what has actually been provided (actual expression of the bundle of the quality of characteristics).*"

Similarly, Seelos (1997): "Quality of medical care, pragmatically defined, refers to the difference between what can be achieved in patient care and what has actually been achieved."

Müller-Osten (1980) refers to the demands for good quality on the attending physician: *"Qualified medical action consists in a summation of mental, ethical, manual and instrumental efforts, which are based on knowledge and ability that includes experience, intuition, empathy, human dedication, a sense of duty and a sense of responsibility. This*

qualified medical action depends on certain manual skills as well as adequate spatial and technical equipment."

Faber (2002: 71) makes an attempt to enrich the quality of medical services with elements of service theory:

<table>
<tr><th colspan="3">1. Technical Quality</th><th colspan="3">2. Functional Quality</th></tr>
<tr><th>Selection of Suitable Services</th><th>Provision of the Services to the Required Extent</th><th>Correct Performance of the Services</th><th>Performance Environment</th><th>Hospital-Staff-Patient Relationship</th><th>Method of Service Provision</th></tr>
<tr><td>Correct interpretation of symptoms and diagnostic results</td><td>Completeness and accuracy of the diagnosis - provision of all necessary measures for this purpose</td><td>Craftsmanship and skill</td><td rowspan="3">General:
Convenience, comfort
Tranquillity
Preservation of privacy
Specifically, e.g:
Cleanliness
Low number of beds in the room
Sufficient sanitary facilities
Balanced diet</td><td>Social: self-determination, dignity
Rejection of coercion
Acceptance without prejudice
Equal treatment of all patients</td><td>Avoidance of long waiting times.
Consideration of needs when planning services.</td></tr>
<tr><td>Use of scientifically proven methods</td><td>Provision of the necessary services in therapy and care</td><td>Care</td><td rowspan="2">Individual:
Sympathy, concern, human attention, politeness
Comprehensive information
Reassurance, support
Respect for intimacy and privacy, confidentiality.
Consideration of individual wishes.
Availability of sufficient time on the part of the staff.
Avoiding rushing and pushing the patient.</td></tr>
<tr><td>Selection of the method with the largest positive difference between opportunities and risks</td><td>Avoidance of unnecessary services in diagnostics, therapy and care</td><td>Use of appropriate in-kind services</td></tr>
<tr><td colspan="3">Adherence to the basic standards and critical consideration of the current state of the dynamic standards against the background of own practical experience.
If care exceeds own capabilities and equipment - call in experts or refer to other hospital.
Provision of capacities in accordance with the guarantee contract (quality of the provision services).</td></tr>
<tr><td colspan="6"></td></tr>
<tr><td colspan="6">Alternative treatment locations, treatment procedures and treating persons
Duty of the attending physician to inform
Patient consent requirement</td></tr>
</table>

Table 1: Medical Quality and Service Theory

2.3 PRACTICAL TESTS

Below, the quality definitions already mentioned are first discussed using a real example case of a gastroscopy. Subsequently, the significant results are summarized.

1. None of the quality definitions mentioned (without guidelines) allows one to distinguish "good" from "poor" quality from within the definition. In the example of gastroscopy, one first has to know that a "teething ring with cuff", "four sprays", etc. are parts of a well-performed treatment.
   Thus, if one wants to separate good quality from bad quality, what is "good" must be defined in terms of medical content, illness for illness, i.e. how the treatment is to be carried out (and who is to carry it out, e.g. a physician vs. a nurse).

2. On the other hand, the detailed definitions (e.g. Garvin, Donabedian) are useful in retrospect to identify quality aspects that are fulfilled or violated.
   Donabedian clearly distinguishes between medical activity - only this he describes under the keyword "quality" - and the result of this activity, which he calls "outcome".
   For Donabedian, the result of the gastroscopy is an "outcome" - not: quality. Points 2 and 3 of his outcome definition apply here:

   "Outcomes include:
   1. Changes in health status
   2. Changes in knowledge acquired by patients and family members that may influence future care
   3. Changes in the behaviour of patients or family members that may influence future health
   4. Satisfaction of patients and their family members with the care received and its outcomes."

   Besides the outcome, structure and process are also measurably better in the successful gastroscopy case in contrast to the other: the practice equipment (structure), the four sprays instead of one, two assistants instead of one (process), etc.

Quality, on the other hand, according to Donabedian, refers in the example case to the term “efficacy”, “effectiveness”, etc. To be precise, the unsuccessful gastroscopy is a problem of “efficiency”: “The degree to which attainable improvements in health are, in fact, attained”. (In this case, health improvement refers to the patient's diagnosis and clarity about their complaints).

Furthermore, one can see that this was a problem of the application of technology and not of “science and technology” (the gastroscopy as such worked in the second case).

Interestingly, in terms of acceptability as a component of quality, the patient might prefer the unsuccessful gastroscopy (one instead of four unpleasant sprays) - but only if they do not understand why these four sprays are necessary.

3. You can recognise further aspects if you modify the case.

Variant 1: assume that the gastroscopy would have been successful in the first case as well (as should indeed happen in most cases if the patient does not struggle too much). In this case, the benefit of separating quality and outcome becomes clear.

Because (according to Donabedian) the result would have been “good” but the “quality” still poor.

As will be seen below, many quality measurement methods attempt to derive the quality of providers from past outcomes, and from this in turn the likelihood of desired outcomes in the future (admittedly, this relationship is not always accurately represented).

Variant 2: the patient is dissatisfied with the diagnosis.

It would be easy to imagine that the patient is dissatisfied with the diagnosis as in case 2, for example according the principle: my pain is not imaginary but real, so there must be a recognisable disease.

Garvin would conclude in this case that quality in the transcendental view is poor even in the successful gastroscopy. In the product-based view, it is not entirely clear who has the power of definition: the patient is dissatisfied with the product diagnosis; most other observers would find that the service was correctly performed and therefore OK; still others will argue that the explanation of the findings was inadequate for the specific patient.

With Donabedian, nothing changes in terms of "quality". The outcome, on the other hand, is indeed not optimal from the patient's point of view ("Satisfaction of patients and their family members with the care received and its outcomes"). This implies that (i) the patient's satisfaction is part of the outcome and (ii) in general (especially within the limits of financial possibilities) it is the patient who decides what treatment is appropriate (and not the physician, the health insurance company, society, or others).

Variant 3: the drunkard.

In this case, the patient is NOT organically healthy, but has varices in the oesophagus due to liver damage caused by excessive alcohol consumption. We only consider the case of successful gastroscopy, but further assume that the per capita alcohol consumption in the country under consideration is above average compared to other countries.

In this case, the ISO definition and Garvin deliver the result that the quality is "good". In Donabedian's model, several quality dimensions are violated (efficacy, efficiency etc.), but only if one assumes that preventive measures are part of the quality of medical care.

It is very clear in the definition of Arah et al. (2006) that prevention is "still" a component of the health care system; he mentions that among other things: "in many health care systems, clinical preventive services are used to influence clinically relevant lifestyles, for example smoking cessation as part of cardiac care".

By also looking at the health system, he would also examine in this case whether there are reasons for the high alcohol consumption (e.g. social tensions etc.).

2.4 EXTENSIONS OF THE QUALITY CONCEPT

It is important to define what you are looking at quality from, e.g.

- The quality of treatment of an individual case, or
- The satisfaction of a group of patients with the overall treatment process or a specific treatment procedure, or
- The expected probability that a treatment to be carried out in the future will be of good quality and / or provide good results.

Depending on the case, very different procedures for measuring quality can be usefully employed - from pathological examinations to patient surveys and auditing.

The quality of medical treatments has an extremely dynamic component. All medical research is successfully aimed at constantly introducing new therapeutic procedures into practice and thereby making others obsolete.

As a result, a treatment that provided "good quality" yesterday (e.g. open gall bladder removal) may already be outdated today (e.g. after the introduction of endoscopic surgical procedures). Quality considerations are therefore not only disease-specific, but also time-specific.

"Patient satisfaction" can itself be an outcome (in the sense: the patient's satisfaction is the actual goal of treatment), but also a measure of the process quality of a hospital (poor patient satisfaction scores indicate problems in treatment).

Last but not least, if one wants to identify differences in quality, one would have to have an idea of how pronounced the differences are and what they are based on. In the case of the quality of service provision by physicians, these could

be: the knowledge of the physician (e.g. in selecting the right intervention), his or her technical skill, the application of new treatment procedures that have just been developed, economic (mis)incentives, etc.. Depending on the quality problem one suggests, one must use appropriate measurement procedures. Without knowing the reason for quality differences, worthless data may be produced: if one does not know what one actually wants to measure, the measurement procedure used may be suboptimal.

1. Quality can refer to the actual treatment of an individual patient (the one specific treatment is correctly selected and delivered), but also to treatment procedures for groups of patients (treatment procedure X is better than procedure Y) as well as the quality of practitioners (physician X operates better than physician Y).

   This means that there is one quality per treatment situation (that of the patient) as well as one quality per disease and patient group (for example: qualitatively correct performance of a gastroscopy in otherwise healthy people) as well as quality as a characteristic of the practitioner (more precisely: a higher probability that a qualitatively good treatment will be carried out in the future). (Unterrieder 2004: 33 argues similarly, but then gets caught up in the complexity of the concept of quality).

   Guidelines only enable a quasi-automatic estimation of quality. In their case, it is relatively easy to compare the actual course of a treatment with the optimal procedure. However, this only applies to the technical side of quality; the specific subjective view of the individual patient is not taken into account in guidelines.
2. As far as quality is taken into consideration for a patient, its assessment is based on the needs of that patient. Since the patient's needs are disease-specific, this also applies to quality and its measurement. This also concerns groups of patients with the same disease.
   Since the needs also depend on the personality of the patient(s), a component that is patient-specific and subjective flows into the quality assessment.

3. While the patient knows his or her needs, they do not always know the advantages and disadvantages of all possible treatment options. In such cases, the physician and patient must work together to select the right treatment.
4. Hospital treatment includes medical, but also nursing and other services (hotel quality etc.). Depending on which part of the treatment or whether the entire service complex is to be assessed, different measurement methods are also appropriate.
5. Insofar as it is a matter of measuring technical-medical quality (both in individual cases and as a characteristic of a physician, etc.), one must know which deviations are to be measured in the first place. To do this, one must know which treatment would be optimal in the particular situation or which characteristics the optimal physician should have ("gold standard") and to what extent reality deviates from this.

   This means that when assessing quality, one really needs to know before measuring where quality differences can come from (manual dexterity, knowledge level, equipment availability, personal commitment, personal preferences, organizational issues, etc.) and how widespread they are. In order to ascertain this, one basically has to observe and compare disease-specific treatment procedures (as was done with the gastroscopy).

   The procedure is obviously enormously time-consuming, but indispensable - it goes far beyond the development of guidelines, because this only defines the gold standard, but not the treatments actually carried out and the reasons for their deviation from the guidelines -. Even if differences in results are measured by chance without this preliminary work, it is not clear whether they are meaningful and what they mean.

   However, if quality is not measured directly, but indirectly via a survey (e.g. of physicians), one must at least know what to ask for - this also assumes that one knows the gold standard and deviations.

This consideration also shows the connection between guidelines and the quality dimensions found in the present work: Guidelines are a possible gold standard; in order to measure quality, one must also know what deviations exist, what significance they have and how they are measured.

6. The assessment of "quality" can vary in complexity. In some procedures it is evident (prescription of glasses), in others it is not (surgery on a difficult tumour). It follows that, depending on the disease, the requirements for assessing quality can be different. For simple procedures, questioning the patient is sufficient; for difficult ones, the assessor must have considerable background knowledge.

   Looking at the above examples, it is striking that it is often quite easy to judge the "quality" if you have the relevant knowledge.
   In other studies, it may also be sufficient to measure indicators (e.g. mortality rates with or without morbidity correction, see below).
7. Furthermore, medicine evolves, i.e. the quality of treatment procedures can quickly become obsolete.

Overall, it makes no sense to talk about the quality of hospital services (as is unfortunately often done), because this term is far too imprecise for a purposeful discussion.

Instead, it is necessary in each case to define which section of the following quality dimensions one chooses and, if necessary, wants to examine:

1. Diseases under consideration
   Disease / diseases or combinations thereof under consideration.
2. Type and number of treatments considered
   Preventive vs. curative treatment; single case vs. several / many cases.
3. Number and organization of practitioners considered
   Individual physician vs. department vs. hospital etc.
4. Purpose of the observation / research question
   Retrospective assessment of a treatment vs. prognosis about the quality of future treatments; if future treatment quality is to be predicted: should this refer to the average of all diseases, to specific (severe) diseases, etc.?

5. Type and scope of the operation under consideration
   Individual OP vs. medical and hotel services; scope and elements of the bundle of goods considered.
6. Aspect of the operation considered
   Structure, process, result; quality.
7. Definition of the result
   Patient satisfaction vs. medical-technical outcome – assumes definition of gold standard.
8. Viewer's perspective
   Patient vs. physician vs. quality assurance provider; personal attitudes of the patient etc.
9. Suspected causes for quality differences.
10. Measurement method.
11. Time of the investigation.

It would be useful for quality studies to identify in advance what exactly they are examining along these dimensions.

Since the above-mentioned quality dimensions also determine how quality measurement is to be carried out, they can also be referred to as the "determinants" of quality measurement.

2.5 DIMENSIONS OF QUALITY

One-sided orientation leads to a limited view. An attempt should therefore be made to take into account all points of view as far as possible (Garvin 1984: 25 et seq.). The different views also show that quality can be interpreted very differently and that the development of the concept of quality is still in flux (Eichhorn 1997: 18). Over time, the product-oriented view has changed to a more process-oriented view (Zapp & Dorenkamp 2002: 42 et seq.).

Since quality in service enterprises in the health care sector is more difficult to capture than in industry, further criteria are needed. For clarification, using the example of in-patient care for the elderly, the three classical quality dimensions of Donabedian structure, process and result are presented below. This has already

been done in chapter 2.2.2 – although it is done here in somewhat more detail. The interaction dimensions and the social dimension are also presented, whereby customer orientation is taken into account in the quality dimension (Eichhorn 1997: 18).

2.5.1 Potential (Quality)

The term structural quality coined by Donabedian is determined by the relatively permanent characteristics of the service providers (Donabedian 1982: 4 et seq.). In addition, within the framework of potential quality, the resources used and thus the existing commitment are also considered. Furthermore, the performance capability, i.e. the possibility to provide services, is also taken into account. This consideration of performance is more succinctly represented in the term potential quality than in the term structure quality from Donabedian. Exemplary elements for an inpatient facility are the use of staff (ratio of qualified staff), the consumption of material resources, the structural design, financial characteristics and the provision of services (Bettig 2007: 64). It is assumed that a good nursing result is achieved when qualified staff and good technical equipment are used (Eichhorn 1987: 40). The potential quality results from the comparison of an actual and a target requirement of the potentials, whereby it is questionable how the potential quality characteristics are to be measured individually. In an inpatient facility, an objective description of the potential characteristics exists if structural standards are met and the required quota of skilled workers is met or even exceeded. However, it cannot be concluded from this that good potential quality results in good outcome quality. It is only possible to make a statement about what quality can be achieved with the given structural potential. Information on potential quality can be found in the Common Principles and Standards for Quality and QA according to § 80 SGB XI in Fully Inpatient Care Facilities. According to this, a full inpatient care facility is a permanent grouping of persons and material resources that must be able to guarantee holistic care and provision for the residents (Common Principles and Standards for Quality and QA 1996 - Gemeinsame Grundsätze und Maßstäbe zur Qualität und Qualitätssicherung 1996). In this context, the care services offered are to be provided under the ongoing

responsibility of a registered nurse. The registered nurse is therefore responsible for the application of the quality standards in the care sector, the professional planning of the care processes, the professional execution of the care documentation, the duty roster of the nursing staff oriented to the patients care needs and the execution of staff meetings (Wolke 2000: 80).

2.5.2 Process (Quality)

Donabedian defines process quality as normative behaviour determined by the state of medical research and societal values and norms (Donabedian 1980: 80).

The process concept can be defined as follows: "A process is the structured sequence of tasks. These tasks are related to each other in a goal and purpose-oriented manner and are only designed for the fulfilment of tasks with defined input and output variables and monetary added value, taking into account temporal conditions" (Zapp & Dorenkamp 2002: 26). The quality of a process is determined by the parameters of time, quality and costs. Therefore, the quality indicators are to be selected in such a way that, in addition to the lead time, measured values regarding the output quality are also determined (Scholz & Vrohlings 1994: 74).

In the inpatient facilities, the Common principles and standards for quality and QA, in accordance with § 80 SGB XI in fully inpatient care facilities are based on the quality characteristics for the process quality. In this context, based on performance specifications and information on the range of services and the prices to be paid, the care concept, the spatial equipment and personnel, counselling services, as well as participation in QA measures, are to be recorded. The care concept shall be oriented towards up-to-date care knowledge. Furthermore, care plans must be drawn up for each resident, taking into account the information provided by the resident, relatives or others involved in the care. It must be possible to derive the performance and the care process on the basis of appropriate and continuous care documentation. When organizing the duty roster, continuity of care for the resident must be ensured, for example, by forming care teams. Furthermore, regular staff meetings must be held. The residents should be integrated into the local community as much as possible.

2.5.3 Outcome (Quality)

The quality of results includes the treatment outcome with regard to the residents' state of care. The physical, psychological and social well-being of the residents as well as the achievement of the set care goals are to be presented. In the Common principles and standards for quality and QA according to § 80 SGB XI in full inpatient care facilities, it is required to regularly review the results of care and provision (Wolke 2000: 232). This is done on the basis of the following characteristics (from the common principles and standards for quality and QA according to § 80 SGB XI in full inpatient care facilities):

- Maintaining existing self-sufficiency skills and reactivating those that have been lost,
- Maintaining and improving communication skills,
- Support of general orientation,
- Coping with crisis situations,
- Enabling participation in the social activities and the right to make choices and have a say in decisions

as well as

- The level of satisfaction of the resident.

Donabedian assumes a direct link between process quality and result quality[6]. If it is to be determined which factors influence a certain result and which possibilities of guidance and control exist, the specifications of result standards and the control of whether these are adhered to are not sufficient. In addition to the pure result or the output of the services rendered, the analysis of the structure as the starting point of performance and the process as a controllable combination of production factors are also fundamental (Scholz & Vrohlings 1994: 91 et seq.).

[6] Finis Siegler points out that the Donabedian model assumes causality between the quality dimensions that cannot be empirically proven (Finis Siegler 1997: 133).

Quality is therefore to be regarded as a multi-dimensional concept, for the measurement of which it is necessary to develop different measurement or evaluation procedures for each individual quality dimension (Finis Siegler 1997: 132 et seq.).

Quality in the sense of process management is understood as the deviation from defined output standards. A defect always expresses the unfulfilled expectation of the customer. Consequently, quality can also be described as a process parameter that measures the degree of conformity of the output to defined specifications of external and internal customers. In measuring quality, the focus is on reducing error correction costs, eliminating process-related weaknesses and increasing customer satisfaction (Zapp & Dorenkamp 2002: 133). A measurement of the output quality is therefore significant, if the customer notices an error that is due to a lack of quality, this not only has a negative effect on satisfaction, but also on the image of the entire health facility. The effect of the output is called the outcome.

2.5.4 Interaction (Quality)

The fact that the customer is directly involved in the service process places the interaction between the service provider and the customer at the centre of the service event. In contrast to an industrial enterprise, where the production process can be controlled by the system characteristics of the productive factors, in a service enterprise unpredictable influences are possible during the interaction due to the participation of the human being (Eichhorn 1997: 23). From this, quality of interaction can be defined as the perceived quality on the part of the customer, patient or resident and their relatives. The definition of quality is given individual, resident-oriented aspects by considering this dimension.

The following criteria can be named, for example, for inpatient care for the elderly with regard to the quality of interaction:

- Respecting the values and needs of the residents,
- Harmonisation of times, e.g. meal times and visiting times,
- Inclusion of family members and friends,

- Information and communication between residents and the facility,
- Communication by the facility with other stakeholders,
- Comfort and support in the case of pain and grief

With regard to the measurement of this quality dimension, it is obvious that it is hardly possible to use objective and absolute standards, but that the health care facility must work here with subjective, relative quality variables and derive indications from the recurring, stable and thus measurable behavioural structures of the residents and their relatives, which represent the interaction quality level (Eichhorn 1997: 23).

2.5.5 Quality of the Social Dimension

Inpatient care institutions for the elderly must increasingly take into account the requirements of society and the public. For this reason, the social dimension of quality must also be considered, which especially takes into account aspects of health and safety, environmental protection and protection of property and the conservation of resources (Eichhorn 1997: 26). The following examples can be cited in relation to inpatient care for the elderly:

- Possibility of using and making use of the services,
- Adequacy of care,
- Consumer-friendliness of the services (Straub 1997: 351).

In summary, the basis for the elaboration is a quality concept that describes the suitability of the corporate entity to fulfil defined requirements, taking into account the potential, process, result, interaction and social dimensions (Zapp 2008: 17).

2.6 MEASURE QUALITY

As already explained in previous chapters, the concept of quality is defined in a very abstract manner, but on the other hand, there is no single quality measure that describes the quality of a care unit or a service provider in its entirety.

The figure below shows the context in which the safeguarding and improvement of the quality of care is located: Starting from optimal quality of care that is achievable according to the current state of knowledge through the available resources, systematic observation and evaluation are used to examine whether this quality is actually achieved (Bettig 2007). Once it has been achieved, safeguarding measures to maintain this quality afterwards are to be created if necessary (QA). If it is not achieved, appropriate quality improvement measures must follow to remedy the deficits: Quality improvement. QM cannot shift the optimal quality towards the maximum quality. This is the task of medical research and health policy.

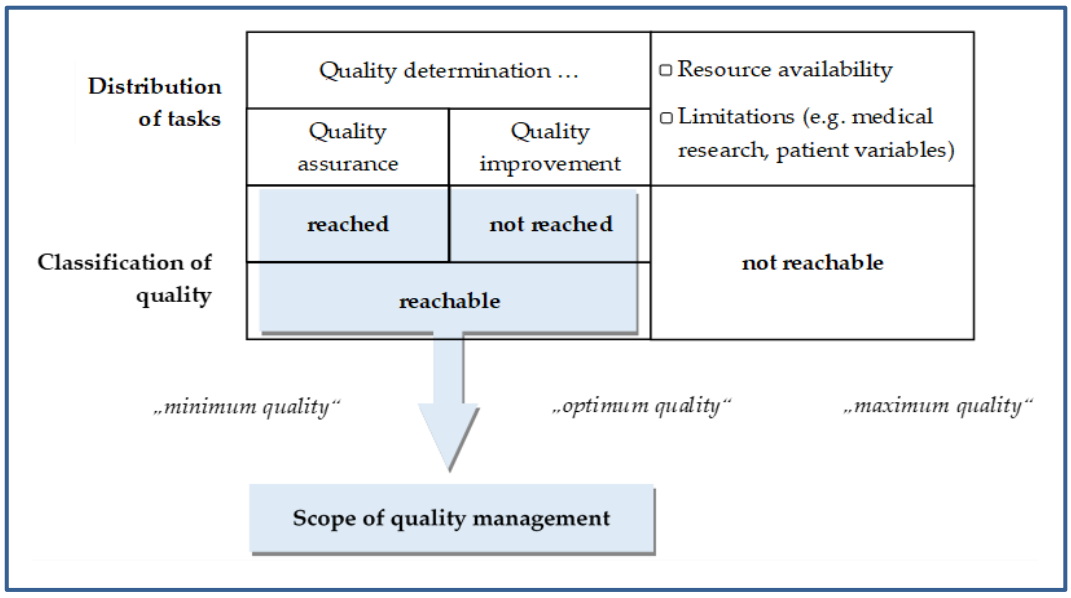

Figure 2: Quality of Medical Care – The Modified ABNA Principle (Achievable Benefit Not Achieved)

2.6.1 Quality Indicators and Reference Ranges

The three essential starting points for the quality assessment of medical care are:

- The technical execution
- The physician-patient relationship and
- The scope of service.

Technical execution involves the application of medical knowledge, taking into account the technical possibilities. Satisfactory technical execution leads to an increase in "health gain", it interacts with resource use and risk assessment (Cuny & Vokmar 2015).

The interpersonal relationship between physician and patient, for example, takes into account the conformity of treatment and care with ethical or social conventions and is essentially determined by the needs of the patient.

In this list of quality-determining criteria, patient satisfaction with the success of treatment, for example, is not taken into account.

Donabedian describes in his trilogy "Explorations in Quality Assessment and Monitoring" the essential methodological aspects of quality measurement and assurance:

- Structural quality is the description of the framework conditions that are given for medical care in individual cases.
- It includes the relatively stable characteristics of the human and material resources used, e.g. the level of training of the attending physicians, their equipment as well as the organizational and financial conditions under which the medical care process takes place.
- Process quality describes the characteristics of all medical, i.e. medical, nursing and administrative activities that take place within and between the providers and consumers of health services.
- Outcome quality is the description of the changes in the health status of patients or population groups that can be attributed to medical, i.e. medical, nursing and administrative actions, including the effects of these changes.

The advantage of this subdivision of quality characteristics is, among other things, that they are each associated with different responsibilities for quality:

- Among others, the hospital owners and administrations are responsible for structural quality, but also the self-governments, which with the professional regulations, the further training regulations, the quality agreements, etc. are responsible for the quality of the health care system. They create the conditions for achieving a high level of structural quality.
- All those who contribute directly or indirectly to the direct care process are responsible for process quality: the medical, nursing and administrative staff.
- Responsibility for the quality of outcomes is undisputedly attributed primarily to the patients themselves.

Patient satisfaction and their quality of life are increasingly important quality aspects today, in addition to "medical" results.

Structural, process and outcome quality either concern all services or only some tracer situations in the hospital. The term "tracer situation" comes from D. M. Kessner, and these are characterised by the following properties, among others: they should

- be representative of larger service areas
- originate from areas in which valid standards (in the sense of guidelines for optimal care) exist and
- be selected in such a way that the measurement of outcome quality is possible.

To measure quality, quality indicators are needed which, with the help of reference ranges, distinguishing between good and poor quality. Indicators for process quality are usually derived from directives or guidelines, for the development of which consensus conferences, Delphi methods and nominal group processes are available.

A quality indicator is defined as a measure that can be used to distinguish between good and poor quality. The reference range is the set of values of an indicator that can be associated with good quality. However, the reference range should not be confused with the norm as the average or most frequent expression of an indicator (Zapp & Dorenkamp 2002). As a rule, good or poor quality cannot be inferred from the norm of an indicator.

When defining quality indicators in terms of content and form, the following characteristics must be taken into account:

- They should measure quality in the three dimensions of structural, process and outcome quality
- They should follow the so-called RUMBA rule (A more in-depth analysis is provided in chapter 5.2.4):
  - **R**: (Relevant) important for a selected problem area
  - **U**: (Understandable) comprehensible for service providers and patients
  - **M**: (Measurable) measurable with high reliability and validity
  - **B**: (Behaviourable) possessing the ability to indicate changes in behaviour
  - **A**: (Achievable) be attainable and reasonably applicable

- They should be highly sensitive and specific, i.e. they should rarely trigger false alarms in situations that are not problematic, but problematic situations should seldom be missed.

Quality indicators can be divided into percentage indicators, which describe the occurrence of certain characteristics of the quality indicator as relative frequencies and can be compared with target values (e.g. for the process surgical frequency, for the outcome, complications), and into red flag indicators, for which each occurrence of an event marked in this way indicates a problematic situation (e.g. unexpected deaths in hospital or suicides in a psychiatric ward). When a red flag indicator occurs, individual case analyses and studies on avoidability are usually indicated, whereas in the case of a percentage indicator, further statistical

analyses are possible, and necessary, in order to have greater certainty about the existence of a quality deficiency on the one hand and to identify possible causes on the other (e.g. Debatin et al. 2010).

2.6.2 General Indicators and Tracer Situations

Quality indicators can relate to the entire range of services of a care facility or only to selected situations such as specific diagnoses or invasive procedures. The following table provides a selection of general process indicators for inpatient care, as used e.g. in a hospital quality report:

Process Quality	Quality of Outcomes
• Waiting times e.g. at admission / emergency admission • Frequency of consumption of antibiotics, psychotropic drugs, blood products etc. per time and ward • Completeness and retrievability of medical records • Use of services (e.g. CT, X-ray, laboratory, operation) • Number of autopsies	• Patient experience • Employee satisfaction • Complications (e.g. fever, pulmonary cardiovascular complications, decubiti) • Nosocomial infections • Iatrogenic complications (e.g. unintentional organ injuries during surgery) • Unplanned invasive measures • Unplanned readmission within 30 days of discharge

Table 2: A Selection of General Process Indicators for Inpatient Care (own Representation)

Since quality can often not be measured with these general indicators in such a way that artefacts can be excluded and causes of quality deficiencies can be identified, the selection of individual care areas in which quality and its possible influencing variables are observed and measured in more detail (tracer situations) is a good idea.

The Joint Commission on Accreditation of Healthcare Organizations[7] (JCAHO) recommends selecting such tracer situations:

- Which occur frequently (high volume)
- Involve a high risk for patients (high risk)
- And/or are problem prone.

An essential prerequisite for the determination of a suitable tracer in this context is the selection of criteria. The relevant requirements for a tracer are:

- Tracers should exert functional influences
- Tracers must be easy to diagnose and well-defined
- Tracers should be sufficiently well known to allow retrospective statistical work on distribution in the population
- Tracers should be definable from a qualitative point of view
- The tracer problem should occur with sufficient frequency
- Medical treatment should be in accordance with standard practices and methods
- Treatment methods should be defined for at least one of the following: screening, diagnosis, treatment, rehabilitation
- Non-medical factors must be taken into account in terms of independence of service provision and tracer stability.

If suitable tracer conditions can be identified according to the above criteria, a catalogue of criteria based on the "lowest common denominator" (= "minimal data set") must be drawn up. These criteria must include the essential elements of the disease history, diagnosis and therapy. Applicable disease histories are to be

[7] JCAHO, 1991, Primer on indicator development and application Joint Commission on Accreditation of Healthcare Organizations. One Renaissance Blvd, Oakbrouk, Terrace, ILL.

evaluated on the basis of the catalogue in order to determine the quality of diagnosis and therapy (Zapp 2008).

Since the mid-1970s, the tracer method has also been tested several times in Germany.

Here the following proved to be true

- Diagnostics
- Surgical procedure
- OP findings
- Intra-op findings
- risk factors
- complications

as focal points that were readily accessible to the tracer method. A number of disease patterns or problem management situations in care and nursing can be mentioned as further areas of application of the method:

- Myocardial infarction
- Pneumonias
- Prostate cancer
- Intensive care
- Relevance of the surgery indication
- Antibiotic therapy
- Autohemotherapy and donated blood administration
- Pre and postoperative anesthesiological care
- Decubitus prophylaxis.

One advantage of the method is undoubtedly that it can be well integrated into the relevant existing documentation system. In many cases, tracers can also be implemented step-by-step to the existing basic documentation (Zapp 2008). In this case, a few items are added in the preliminary phase, which usually provides information about feasibility and the expected degree of goal achievement.

The additional documentation of quality problems through observation of service provision is gradually being added, whereby results from patient and staff surveys can also be included in the questionnaire structure, e.g. patient satisfaction.

2.6.3 Importance and Techniques for Developing Guidelines

The existence of consensual guidelines for service provision ("clinical practice guidelines") is of central importance for QM. Depending on the evidence and the binding force given to them, terms such as directives (must), guidelines (should) or recommendations (can) should be used (Preiß & Timmer 2007).

From a QA perspective, guidelines, formerly called standards, have two functions:

1. As a guide to the delivery of services (process or outcome quality).
2. As a benchmark for measuring quality by considering them as target quality against which actual quality is compared.

In the care sector, there are also sometimes very detailed ideas about guidelines. Areas for the development of guidelines are, for example:

- Standards for the size of nursing units, for the qualification of night carers, for the furnishing of patients' rooms, for daily routines on the ward (structural quality).
- Standards for individual nursing services (including decubitus, pneumonia, thrombosis and constipation prophylaxis, including their process design and the necessary nursing aids, behaviour towards special patient groups, e.g. children, the elderly) (process quality).
- Standards on care outcomes, e.g. patient well-being and satisfaction to avoid infectious or non-infectious hospitalism (outcome quality).

There are three principles to be followed when using guidelines:

- Guidelines can be developed outside a hospital or practice; however, externally produced guidelines usually require internal adaptation.
- Guidelines have an indication, the correctness of which must be checked in each individual case. As a rule, there are individual cases for which the

correct indication is not or no longer given. However, the reasons for not following the guideline must then be documented.

- Guidelines must be reviewed for their validity at intervals and updated if necessary. This means that guidelines must be adapted to the changing state of current knowledge.

Of the methods for developing directives and guidelines, consensus conferences are the most popular. Their advantage over the other methods is that a broad consensus can be sought in direct dispute with a relatively large group of participants without having to suppress other opinions. Consensus conferences usually take place in nine steps - spread over a period of 12 months - and represent a mixture between an in-depth inventory of knowledge ("science base") and the gathering of expert/user experiences ("experience base"):

1. Formation of a preparation group.
2. Selection of topics and breakdown of the question into sub-topics that do not overlap. If possible, this is done by the preparation group.
3. Formation of a panel (in total 9 to 15 experts, users and lay people) and distribution of the sub-topics to panel members by the preparation group.
4. Compilation of the state of knowledge and experience by panel members.
5. Invitation to the consensus conference with detailed documentation on the state of knowledge and experience widely distributed by the preparation group.
6. Presentation of the statements to the plenary by the panel members.
7. Open discussion, possibly in working groups.
8. Attempt to reach consensus in plenary.
9. Official announcement in one focused message.

If no consensus emerges in step 8 (note: the joint statement that no consensus is possible because medical knowledge is not yet sufficient is also a consensus), the contentious points are to be discussed again in step 7.

2.6.4 Methods of Quality Control and QA

The problem-oriented quality improvement process comprises five steps, of which the first two correspond to quality control. Traditional second opinion systems allow both control and immediate assurance of quality.

The majority of existing QA measures address quality monitoring ("benchmarking") with the help of clinic profiles, from which the clinics can see their position in comparison with other clinics. Such statistical comparisons are methodologically not entirely unproblematic (Bührlen-Armstrong 1997).

Information systems in medicine can support data collection and quality monitoring as well as ensure the current quality of care through reminder and advisory functions. However, the evaluation of QA measures, for which a number of methods exist from biometrics, is often neglected (Hart 2001).

According to the paradigm of the problem-oriented quality improvement process, the basic principle of "observe, evaluate, improve" is translated into a systematic approach with the following steps:

1. Observation and measurement of care in a selected area with the help of quality indicators. Spontaneous reports of problems can also be included in the problem-solving process.
2. Comparison of the characteristics of the quality indicators either with reference areas, with their own earlier results or results of others with the aim of identifying deviations of the actually provided quality of care from that which is optimally achievable. If a deviation or weakness is identified, steps 3 to 5 follow.
3. From problem analysis to suggestions for a possible solution to the problem.
4. Checking whether the implementation of a selected solution has led to the desired effect, namely the elimination of the identified problem. If this is not the case, another solution must be found.

5. Once an effective solution to the problem has been found, care must be taken to ensure that the quality achieved is also maintained through appropriate safeguards.

The first two steps can be understood as quality control, steps three and four fall under quality improvement activities and step five would be QA in the narrower sense.

2.6.5 Traditional Second Opinion Systems

Irrespective of the problem-oriented approach of the quality improvement process, there are traditional QA measures in hospitals which - even if their process is not very transparent and systematic - have a controlling and corrective as well as a prophylactic effect (Rosenbrock 2004: 71-80). These include in particular:

- decisions made at different levels of the hierarchy
- consultant or senior physician rounds
- consultation
- clinical supervision
- Chart review and
- Conferences, e.g. X-ray and mortality conference.

Second opinion systems of this kind are usually not based on explicit guidelines, but on implicit, often subjective control and correction procedures, which also only work as long as the expression of one's own opinion is also encouraged by the relevant bodies.

In Germany, Section 137 of the German Social Code, Book V (SGB V) has made it a legal requirement to obtain a second opinion before major surgical interventions since 1989. However, as of 1995 this provision had not yet been implemented in any federal state.

2.6.6 Quality Monitoring and Comparative Statistics

The terms “quality monitoring, benchmarking, comparative statistics” are closely associated with a certain form of QA activities based on the model of perinatal surveys or QA in surgery. The basis of these measures is the merger of specialised departments or hospitals in order to obtain an overview of the quality of their own services, by anonymously comparing their own results with those of others (Hensen 2019).

These measures usually take place in the following steps:

- Systematic and standardised collection of quality-relevant information by means of documentation sheets or computers.
- Collecting the data carriers, first in the department or hospital and then in the organizational headquarters.
- Final data check; the first data check already takes place in the department or hospital carrying out the documentation.
- Calculate the statistical indicators for process and outcome quality at the organizational headquarters.
- Presentation of comparisons between the departments or hospitals; possibly an external audit at the organizational headquarters. Feedback of the quality indicators and the comparative results (self-audit) to the departments or hospitals.

The aim is to give the departments involved the opportunity to detect weaknesses and to be aware of the existence of “top departments”.

Typically, the following information pyramid is provided:

- Clinic-specific statistics:
  All quality-relevant information and quality indicators per clinic can be found here. By comparing with previous results, it may be possible to identify patterns or trends in one's own quality of care.

- Overall statistics:
  The exact same quality-relevant information and quality indicators as above are shown together in these statistics based on data from all hospitals. The comparison of the hospital's own results with those of all other hospitals gives an initial orientation.
- Profile:
  The profiles provide participants at a glance with a graphical and/or numerical comparison of their own position to that of all other participants' results.

These benchmark or comparison techniques contain a number of methodological problems:

1. Due to the graphical representations, the number of quality indicators is limited, so that only the absolutely essential quality indicators can be presented.
2. The way in which the hospital's own values, the distribution of the values of all hospitals and the reference ranges are presented can provide different impulses for quality improvement.
3. The choice of reference ranges must be made in such a way that not too many false alarms are triggered or justified alarms are omitted. The number of cases plays a role in the choice of the length of the reference ranges, so that confidence intervals of relative frequencies are also used to form reference ranges.
4. Comparability of the patient clientele of the hospitals must be given. This comparability can be achieved either by selecting comparable hospitals by selecting homogeneous patient groups in hospitals or by case-mix adjustment using indirect standardisation or logistic regression.

Because of these methodological difficulties, the comparison techniques should not be used by the uninformed to make a final decision about good or bad quality.

2.6.7 Statistical Quality Control

Statistical quality control (other names: Statistical Process Control SPR, Statistical Process Control SPC) is an instrument based on mathematical-statistical principles. The instrument is used to maintain an already optimized process in this optimized state through continuous observation and, if necessary, minor corrections (Pimentel & Barrueto 2015).

The most important method for monitoring a process is the use of quality control charts, which was developed by W. A. Shewhart in the early 1930s. Quality control charts are based on the knowledge that every process has inherent variations, even if the process itself does not change. Quality control charts help to determine whether a process is characterized by random influences (scatter) and therefore to be considered stable and predictable, or whether it is characterized by systematic influences considered unstable and therefore out of control.

The measured values of the process (individual values or aggregated values) are entered into a form on which the arithmetic mean, already determined from previous values, and the tolerance limits, calculated from one to three times the standard deviation, are plotted (Gupta & Kaplan 2017).

The decision as to whether a process is out of control is made on the basis of certain rules, in which the trend of successive measured values, in particular, plays a decisive role. Based on the results of the quality control chart, it is not possible to intervene directly in the observed process.

Rather, it is only after the analysis of the data approach that intervention and thus possibilities for improvement, can be identified. In medicine, the method of statistical process control is mainly used in medical laboratories for continuous monitoring of analyses.

2.6.8 Use of Information Systems in QA

The following methods of information processing, ordered from the most basic to the highest technical complexity, are suitable for supporting QM:

- Tally sheets for recording individual quality indicators
- Data collection forms for recording all quality-relevant data
- Data collection programs on PCs with interfaces for further processing of the data
- Isolated documentation and evaluation systems for quality control
- Integrated departmental information systems that simultaneously support QM and the processing of patient care within a department
- Hospital information systems that collect and process all the information that accumulates in a hospital and is necessary for QM and make the benefits available to users in an appropriate manner.

Particularly for the last two stages, there is often still a shortage of requirement definition by clinicians and nurses who are experienced in QM. This cannot be done by medical informatics alone (Mateus 2015).

The following functions necessary for QM can also be supported with the help of suitable hospital information systems (Lux & Raphael 2010):

- Communication between inpatient and outpatient care. Only rarely do important late outcomes such as wound infections occurring after hospital discharge, or re-interventions performed in another hospital, made known to the primary treating hospital. Systematic communication with the physicians providing follow-up care or surveys of patients supported by the DP system on their experiences and the later outcomes they experienced could remedy the situation.
- Routine monitoring of quality indicators, e.g. monitoring of quality with general and inter-hospital indicators. The data of § 301 SGB V to be transmitted by the hospitals to the health insurance funds in a timely and machine-readable manner - diagnoses (on admission, transfer,

discharge), procedures used, transfers and reasons for transfers, lengths of stay, etc. - contain quality indicators that the hospitals can use for QM.
- Support of current care through simultaneous interventions, for example when guidelines are deviated from.
- Access to international literature and case databases and communication with experts electronically.

2.6.9 Evaluation of QA Measures

Quality indicators for QA measures include the following components:

- Structural quality
- Statements on the organizational structure of the QA measure (responsibility hierarchy, QA commission, suggestion scheme etc.)
- Quantification of the infrastructure available for the QA measure (personnel, DP, accompanying measures, etc.)
- Existence of facilities supporting quality activities such as well-functioning medical record archives, computerised hospital information systems, semi-automated quality monitors, etc.
- Process quality
- Number of QA activities carried out, e.g. number of
  - QA meetings
  - measures to find problems
  - problems actually identified
  - process analyses, quality studies and problem analyses
  - solutions to problems put into practice
  - training and motivational activities.
- Resource consumption
- Quality of results
- Awareness of QA programs among staff and patients,
- Quality awareness among service providers at all hierarchical levels,
- Improvement and stability of the treatment process,
- Improvement and stability of treatment outcomes,
- Economic benefit.

An assessment of effectiveness and efficiency can, if necessary, also be done implicitly, i.e. without explicitly-formulated quality indicators, nevertheless a checklist is also quite useful in this case (Kolip 2019).

2.7 SUMMARY

It is important to define what aspect you are looking at quality from, e.g.

- the quality of treatment of a single case, or
- the satisfaction of a group of patients with the overall treatment process or a particular treatment procedure, or
- the expected probability that a treatment to be performed in the future will be of good quality and / or provide good results.

Depending on the situation, very different procedures for QA and quality measurement can be usefully employed - from pathological examination to patient surveys and auditing.

The quality of medical treatments has an extremely dynamic component. After all, medical research as a whole is successfully aimed at constantly bringing new therapeutic procedures into practice and thereby making others obsolete.

As a result, a treatment that was "good quality" yesterday (e.g., open biliary resection) may already be obsolete today (e.g., after the introduction of endoscopic surgical procedures). Quality considerations are therefore not only disease-specific, but also time-specific.

"Patient satisfaction" can itself be an outcome (in the sense that patient satisfaction is the actual goal of treatment), but it can also be a measure of a hospital's process quality (poor patient satisfaction scores indicate problems in treatment).

Last, but not least if it is desired to identify differences in quality, an idea of how pronounced the differences are and what they are based on would be needed. In the case of the quality of services provided by physicians, these could be, for example: the knowledge of the physician, e.g., in selecting the right intervention,

his or her practical skills, the application of new treatment procedures that have been recently developed, economic (mis)incentives and so on. Depending on the quality problem examined, appropriate QA and quality measurements must be used. Without knowing the reason for quality differences, worthless data may be produced: if it is not known what is actually trying to be assessed, the procedure used may be suboptimal.

The idea of deriving quality differences from data that are available anyway is tempting at first glance.

Unfortunately, a detailed analysis shows that only few data are publicly available. In particular, data according to §301 SGB V and §21 KHEntgG are only available to certain recipients, mainly health insurers. These are mainly data on admissions, transfers, coded diseases and treatments, and DRG data. The informative value of the data is limited due to imprecise coding.

It is currently unclear whether and which of these data are published by the health insurance funds.

In this respect, only the data in the quality reports remain as a publicly available data source. Their section on structural, process and outcome quality is currently not sufficiently informative due to weak standardization.

With regard to the frequency of illness and treatment according to the quality report, the literature disagrees on which illnesses have a correlation between frequency and outcome. If there is a correlation, it is not clear exactly how it works. For example, it could be that the quality does not increase proportionally with the quantity, but that the quality increases up to a certain threshold value, but above which there is no longer any correlation or the quality even decreases again.

3 CONCEPTUAL APPROACHES TO QUALITY DEVELOPMENT

3.1 RELEVANT CONNECTIONS

The work of the American Donabedian in the 1950s and 1960s was one of the earliest attempts to analyze the fundamental interrelationships of modern medical care from an epistemological point of view and to systematize them.

In a first analysis, the author localized as the three essential starting points for the quality assessment of medical care

- The technical design
- The physician-patient relationship and
- The scope of service.

Technical execution involves the application of medical knowledge, taking into account the technical possibilities. Satisfactory technical execution leads to an increase in "health gain" It interacts with resource use and risk assessment.

The interpersonal physician-patient relationship, for example, takes into account the conformity of treatment and care with ethical or social conventions, and is essentially determined by the needs of the patient.

Criticism of this early system is certainly justified, as Donabedian only provides an incomplete enumeration of quality-determining criteria on a horizontal level and does not take into account, for example, patient satisfaction with the success of treatment.

In a further approach, the same author therefore attempts to systematize quality in a second dimension. His concept of differentiating between structural, process and outcome quality (chapter 2.2.2), which was adopted as the basis for QA in the medical profession at the 96th German Medical Congress in May 1993, is internationally recognized.

Since changes in patients' health status have rarely been subject to operational definitions, quality assessments based on treatment outcomes are difficult to

manage. Effective QA programs require clear treatment objectives and precise targets for each treatment case, so that the degree of achievement of objectives and the quality of care can be evaluated. A major focus of future developments will therefore have to be the definition of meaningful reference points in the form of quality indicators and quality criteria.

The difficulties of assessing quality on the basis of treatment outcomes are precisely the hurdle that healthcare providers currently have to overcome, as changes in the patient's state of health have not yet been precisely and operationally defined, and thus cannot be measured.

This is mainly due to the fact that often no treatment goal is specified for the individual case, against which the degree of goal achievement and the quality of care could be measured. It should also be critically noted that the tacit assumption of a positive correlation between service provision and medical care is not subject to scientific, mechanistic laws and may therefore only be used for quality assessment under differentiated consideration.

3.2 PROFESSIONAL APPROACHES

The original knowledge goal in the context of profession-related research on outcome quality is to test the effectiveness of medical interventions (Wennberg & Gittelsohn 1973; Cochrane 1972). In the context of clinical research, the effects of individual agents or interventions are inferred from a medical science perspective. An approach to measuring and assessing quality of care that is significant for health services quality research originated with Archibald Cochrane (1972). Cochrane established “the thesis of overuse” in response to the inflationary expansion of medical services provided by the National Health Service in Great Britain. He distinguishes health care interventions according to whether or not they are demonstrably effective (in the statistical sense) or whether a particular intervention achieves a measurable increase in health compared to a non-intervention (Badura 1999: 23). Accordingly, any intervention that is likely to change the natural course of a disease for the better is effective (Cochrane 1972: 2). Cochrane derives the definition and the standards for testing effectiveness from the medical knowledge of the primarily scientific-physiological view of patients. Cochrane's historical

contribution to quality research in health care can be seen in the fact that he focused on systematically examining the effects of therapeutic, diagnostic and preventive medical services of the professional field of medicine with the help of randomized control trials, and subsequently thus significantly increased the influence of science as a regulator of the medical profession (Vogd 2002).

In contrast, research into process quality in health care aimed to describe structures and processes of care and, at the same time, to evaluate them in terms of expected effects. The rationale for this research approach, i.e., the first systematic examination of the topic of process quality in the professional field of action of medicine, was presented by the physician Avedis Donabedian (1980; 1982). Donabedian places the evaluation of a process at the centre of his definition of quality, i.e., the degree of correspondence between previously formulated criteria and the service actually provided. Donabedian developed a conceptually alternative basis for quality research compared to Cochrane by noting that quality in the field of professional services would be so complex that at least three dimensions of quality would need to be considered: structural, process, and outcome quality. He pointed out that the interaction process between practitioner and patient should be the main object of quality observation (Donabedian 1980: 79). Consequently, high-quality processes can be observed when they are at a high level of compliance with the rules of the professional system, the medical profession. In this respect, Donabedian's understanding of quality can be understood as a model of professional self-direction, in which the development and definition of process standards are undertaken by the medical profession itself, which is also the primary addressee of these standards.

3.3 EVALUATION

The origins of health-related evaluation research can be seen in the pioneering scientific work of Roethlisberger and Dickson (1934) and Mayo (1945). In the so-called “Hawthorne studies”, Roethlisberger and Dickson (1934) examined the consequences of psychological and social stress in the workplace. The real heyday of evaluation research was at the beginning of the 1960s in the USA and at the beginning of the 1970s in Europe with the introduction of extensive reform

measures by the state in the social, education and health care sectors (e.g. Suchmann 1967). From the beginning, state reform programs in the education, health and social sectors were linked with the requirement to review the effects of various program measures. In this context, evaluation research was to become simultaneously observer, legitimator and activator for corresponding policy fields (Hellstern & Wollmann 1984: 27). In the wake of the first approaches, the focus of evaluation research shifted mainly to the relationship between costs and benefits of corresponding programs. Efficiency aspects increasingly moved into the field of interest (Rossi et al. 1988).

In the following, two central approaches of evaluation research are presented: the so-called control paradigm, which focuses on results-oriented proof of effectiveness, and the development paradigm. Here the goal is to stimulate a development or learning process (Kromrey 2000a; 2000b).

Both approaches represent ideal types. Michael Quinn Patton presents more than 50 different types of evaluation designs in his standard work "Utilization-Focused Evaluation" (1997). Accordingly, the diversity is not described here, but only the advantages and disadvantages of the two basic approaches and the possibilities and limitations for evaluating health services.

3.3.1 Control Paradigm

With the onset of the upswing in health, education and social policy measures in the early 1970s, the positivist paradigm initially dominated within evaluation research. According to this position, the evaluator, such as Cochrane, assumes that he or she is confronted with an objective social reality with its own laws and that he or she examines the mechanisms of action underlying this reality on the basis of hypotheses. Following this position, preference was given to experimental research designs to elucidate the true relationships between causal forces (Cook & Matt 1990: 20), so that decisions about reform measures are based on objective statements about the real performance of corresponding programs. Donald Campbell, who described the world as a "laboratory for social experiments" (Campbell 1969: 409 ff.), attaches the greatest importance to internal validity in the context of evaluation. This means that there should be a clear, causal relationship

between two variables (Cook & Campbell 1979; Scriven 1967). Analogous to the guiding idea of the positivist-scientific ideal of knowledge, it looks at the effects of measures with the help of a precisely quantifiable number of target variables and their characteristics in order to prove the effect of a program or an intervention (Badura & Strodtholz 2003).

Cochrane was concerned with testing the effectiveness of interventions under ideal conditions (efficacy) and not under everyday conditions (efficiency). Consequently, the generalizability of corresponding results (external validity) can be doubted, as the complex context in the provision of health-related services is not included analytically from this perspective. Furthermore, in the conduct of empirical studies, it is often not possible to choose a randomized experimental design due to ethical implications (Badura & Strodtholz 2003).

The epidemiological model has been increasingly criticized by parts of evaluation research for the fact that not only the quality of hypothesis-supported causal evidence of individual impact mechanisms must be in the foreground, but that criteria of usefulness with regard to the optimization of reform measures must be regarded as an essential quality feature for evaluation research (Cronbach 1981; 1982; Lange 1983; Patton 1987). In the further development of quantitative approaches, multidimensional ones aim to examine effectiveness under real conditions and to complement the structures and processes relevant for service delivery (Badura, Grande, Janssen & Schott 1995; Campbell & Stanley 1966, Phillips, Palfrey & Thomas 1994). According to Rossi et al. (1988), results of a well-conducted quasi-experimental study can claim greater validity than those of a lacking experiment.

The effects of quantitative evaluation research, which in the broadest sense is committed to the epistemological position of logical positivism, can currently be observed under the keywords “evidence-based medicine” (EBM), guidelines, peer review procedures, certification or “best practice ranking” in the health care system. The aim of these approaches is to define procedures and standards as binding orientation for the actors working in practice on the basis of quantitatively collected parameters. Such conceptions of evaluation research are ultimately based on the fundamental assumption of the possibility of an objective description of the state of social reality with the option of using a set of methodological instruments to record cumulative knowledge that can be used beneficially in practice.

3.3.2 Development Paradigm

Process-oriented evaluation research (referred to here as the development paradigm) denies the existence of a single true objective or value judgement-free reality. Instead, it assumes that reality is constructed from different perspectives, which may well be in contradiction and conflict with each other (Guba & Lincoln 1989). Representatives of this approach use more qualitatively oriented research methods in order, for example, to be able to interpret the results in their social contexts (Hellstern & Wollmann 1984). The main object of the analyses are interpreted social realities, subjective interpretations of meaning and modes of perception of the subjects acting in the field of study (Badura & Strodtholz 2003: 723). According to Bortz (1984: 15 f.), for example, this explicitly does not include studies or questions that ask about the causal significance of statistically isolated characteristics that, unlike in reality, are only effective in combination with other clearly defined influencing variables.

From a process- or development-oriented evaluation perspective, it seems important not to make the care process quantifiable and thus transparent within the framework of proofs of effectiveness under ideal conditions or in a quasi-experimental design under conditions close to everyday life, but to present the interrelationships that are considered relevant in everyday action in an explorative way and to interpret them, taking into account the complexity of the individual case. The methodological characteristic of interpretative approaches in evaluation research is the inductive procedure with the purpose of reproducing reality as naturalistically as possible (Guba & Lincoln 1989; Chen 1990).

In the further development of the development-oriented evaluation approach, these approaches within evaluation research aim to accompany interventions or programs during their implementation phase. In doing so, information about the program and the course of the intervention should be collected and evaluated with the intention that knowledge and decision-making aids for steering the programs can be generated from it on an ongoing basis (Rossi et al. 1988).

Following Scriven (1967), such approaches are referred to as formative evaluation or accompanying research (Rossi et al. 1988), and their epistemological function is directed more towards the applicability of programs and measures,

rather than being expected to provide a conclusive assessment of the effects of one program or another. It should be critically noted in this context that the evaluator, who is himself involved in the process of program implementation, tends to find what he is looking for and does not start from a more skeptical basic attitude regarding the impact of an intervention or a program. A critical starting hypothesis, but one rarely pursued by such evaluation projects, would have to assume that no effects whatsoever emanate from the program or reform measure under study (Øvretveit 2002: 28). In empirical reality, the opposite approach is usually contested (Øvretveit & Gustafson 2003).

3.3.3 Summary

The evaluation of health-related services can make a significant contribution to the further development of quality in the health care system. Both approaches of impact analysis (control paradigm) and the procedures that can be assigned to the paradigm of development-oriented evaluation have their own strengths in making statements about effects of interventions in the health system. The advantage within the control paradigm is the valid proof of whether an intervention has an effect or not. The disadvantage lies in the consideration of the complexity of the individual case, which is a typical feature of the health care system. As long as the object of study can be narrowed down in terms of the variables to be taken into account, quantitative effectiveness studies seem appropriate for evaluating individual measures. If, on the other hand, the number of variables to be taken into account increases, e.g. by person-related, social and context-related influences such as the organization of service provision, the possibility of unambiguous interpretation of corresponding findings becomes more difficult or, statistically speaking: the reliability of such statements is doubted (Øvretveit & Gustafson 2003; Kromrey 2000a; Kromrey 2000b; Pollit 2000). Overall, it can be said that an evaluation of QA measures from the point of view of effectiveness within the control paradigm is difficult (Marshall et al. 2000; Campbell et al. 2000; Siegrist 1999).

Regardless of the methodological difficulties in tracing the quality or the effects of services in the health system and especially the effects of measures related

to the improvement of service provision by means of evaluation, outcome-oriented approaches to evaluation or quality research dominate in the health system.

Based on the epistemological position of logical positivism, the control paradigm claims to quantitatively measure the effects of individual services and to causally attribute their influence to a number of specific variables, or to predict which quality can be expected with a certain predictive probability (Badura 1999: 35).

3.4 ORGANIZATIONAL APPROACHES

The concept of health promotion focuses on shaping the social preconditions for health. These preconditions are to a large extent created in and through organizations, which are an essential part of the social and physical environment of people in the modern age. Alongside societies, functional systems, social movements, interaction systems and groups, organizations are understood as being a special type of social system that shapes life in modern times from birth to death to such an extent that sociologists have diagnosed a "society of organizations" (cf. Perrow 1991) for modern times.

Organizations, from kindergartens to old people's homes, influence people's patterns of thinking and behaviour just as much as they determine the quality of accessible natural, technical and social resources. Decisions that seek to influence the shaping of human living conditions are themselves embedded in complex organizational structures and processes. Essential conditions for the health of the population in the modern age are therefore difficult to improve without an understanding and knowledge of the internal developmental dynamics of organizations and their relationship to their environment. An important health promotion strategy is therefore targeted interventions in organizations. However, since health promotion as a relatively new social task can only be delegated to specialised health promotion organizations to a limited extent, this basically concerns all established organizations. Here, health promotion faces the challenge of integrating health as a goal and criterion into the decisions and programs of a wide variety of types of organizations and anchoring it there.

3.4.1 Organizational Development in the Setting Approach

This approach to the development of health promotion is already laid out in the Ottawa Charter on Health Promotion of the WHO (1986) with the introduction of the setting approach[8] (setting approach/living environment approach). In the WHO Health Promotion Glossary (1998), organizational development is described as a central method of setting development. This is because an organization is usually assigned to a setting and has agency with regard to the setting and the ability to act as an actor also vis-à-vis the environment of the setting. Since health promotion must be understood as a communication strategy, the setting itself can only be addressed by health promotion via the organization assigned to the setting and its members (Pelikan 2011: 63-72). Therefore, the health-promoting development of settings always also has organizational development at its core.

But what can be understood by this in detail? Organizational development means the planned and methodically controlled change of organizations such as businesses and companies, schools, hospitals, universities, prisons, offices and administrations. Therefore, organizational development is also applicable to an entire community, city or region as a geographical administrative unit (Bär-Sieber

[8] A setting is a social context in which people spend time in their everyday lives and which has an influence on their health.

This social context is relatively permanent and its members are also subjectively aware of it. It is expressed through formal organization (e.g. company, school, day care centre), regional situation (e.g. municipality, district, neighbourhood), same living situation (e.g. pensioners), common values or preferences (e.g. religion, sexual orientation) or a combination of these characteristics.

Settings are interesting from a health point of view if they provide important impulses for or influence the perception of health, health burdens and/or health resources as well as all forms of coping with health risks (balance between burdens and resources).

2015: 107-167). Through organizational development, the structures and culture of an organization, as well as the communication and cooperation behaviour of its members, are to be examined and changed internally and externally in a comprehensive and longer-term process. The aim of organizational development, in cooperation with the members of an organization, is to make the working and production conditions of this organization more humane and to increase its flexibility and performance in a dynamic environment. In this context, increasing performance not only means increasing productivity, but also involves organizational learning, problem-solving abilities and thus the organization's ability to survive. Organizational development is not only based on business management principles, but also on social science principles.

Of the different approaches to changing organizations (e.g. change management, business reengineering, learning organization, intelligent organization, smart organization), organizational development, with its accumulated knowledge of theory, methodology and practice about the conditions, possibilities and difficulties of targeted change in organizations, is particularly well suited for the implementation of health promotion in the setting approach. Moreover, in contrast to change management, organizational development is based on a development concept that takes into account the people involved and affected and their well-being and tries to make them motivated owners of a sustainable development process (Bauer et al. 2014). This concept therefore also corresponds to the principles of participation (participation: co-decision-making by citizens), empowerment (aptitude) as well as equality and sustainability of health promotion and is also connectable to their comprehensive concept of health. Organizational development should also be applied within specific health promotion institutions and organizations with the aim of increasing their effectiveness, efficiency and internal health promotability. Helper syndrome is also a risk for health promoters and not beneficial for them and the cause.

3.4.2 Taylor's Organizational Approach and the further Development of the Approach

The first statistical methods for organizational analysis originated in the American material goods production sector. The foundation of quantitative approaches to quality control goes back to Frederick W. Taylor, who developed the approach of "scientific management" at the beginning of the 20th century (Taylor 1913). His aim was to use experiments to uncover rationalisation potential in the organization of work, e.g. to optimise physical work performance or to increase the performance of workers through incentive and reward systems. Taylor's experimental trials served more to solve practical problems than to test scientific hypotheses. For this reason, these results were often doubted with the argument that such experiments, which reduce people and organizational events to a number of variables that are comparatively easy to measure compared to reality, could hardly claim to be generalised, since the multitude of possible influencing variables in the context of organizations would not be taken into account (Kieser & Walgenbach 2003: 32 ff.; Kieser 1999: 92 f.).

The human relations movement emerged from the criticism of Taylorism. While Taylor saw possibilities for increasing the productivity of organizations in the dissection of work processes and in the development of different remuneration systems, Roethlisberger & Dickson (1927) and Mayo (1945) recognized the importance of social processes for general job satisfaction and productivity. In the further development of "scientific management", the researchers Roethlisberger & Dickson (1927), as founders of the human relations movement, came to the conclusion that a large part of work performance in organizations could be explained by interpersonal factors. The researchers' hypothesis was that workplace illuminance would have an impact on the performance of female workers in the "Hawthorne Works". However, the results turn out to be extremely contradictory. In essence, the aim was to prove the correlation between illuminance and labour productivity experimentally. In the continuation of these experiments, the research group around Elton Mayo found out that the productivity of workers, as still assumed by Taylor, was not only causally based in the physical working conditions, but depended significantly on group psychological processes. Good interpersonal relations were seen as an essential factor for improving morale, performance and a sense of responsibility (Kieser & Walgenbach 2003: 38).

Organizational performance and thus also the quality of products were henceforth also associated with psychological and social processes in companies.

Both Taylorism and the human relations movement have pursued the goal of increasing organizational performance using statistical research methods based on quantifiable characteristics such as productivity and job satisfaction. Both approaches limited the question to the analysis of individual organizations. Due to the close connection to business administration, the focus was on the applicability of the results for individual companies (Kühl, Strodtholz & Taffertshofer 2005: 15). Although Taylorism is currently labelled as being outdated, Taylor's central principles can be found in the organization-related approaches to assessing and promoting quality, such as in the series of standards of DIN ISO 9000 ff. (Walgenbach 2000) or in benchmarking (Walgenbach & Hegele 2001). According to Taylor, quality in mass industrial production was determined by calculated error rates in product manufacture. Quality is thus defined in "measurement-control loops" on the basis of statistically calculated defect or success rates (Seghezzi 1994). QM based on standardized company ratios is thus seen as a "child and companion of scientific management" (Wächter 2004: 1221).

The approaches shown in figure 3, outline different stages in the development of quality-improving management models. Assuming an increase in performance in the course of the further development of corresponding procedures, three basic forms of quality-enhancing approaches are distinguished in the current literature:

Based on statistical methods of troubleshooting, quality control approaches attempted to quantify the deviations of a given product from a desired target state (Shewhart 1931). In the further development of the classical approach, quality monitoring or QA procedures became part of work organization. Within the framework of quality control loops, a standard was defined at various stages of the production process, which, when adhered to, was intended to ensure a certain level of quality.

Work process improvements were thus adapted to control or feedback loops with the aim of minimising error rates in the production process and increasing the quality of the products. In its third stage of development, QM is currently

understood as a comprehensive management tool that should permeate an organization in its entirety and, above all, involve all organizational members. In addition, the needs of customers are defined as the absolute benchmark for quality (Garvin 1988) and the guiding maxim is issued that QM requires a permanent process of change (cf. figure 3).

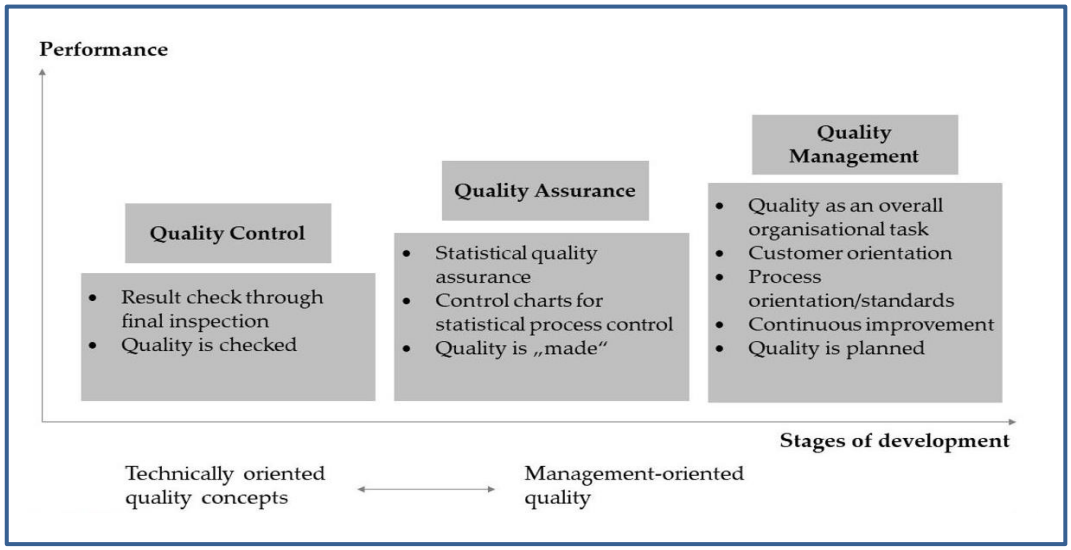

Figure 3: Development Stages of QM (Source: Pietsch-Breitfeld 1999, 14)

The methodological instruments of quality control and QA understood in this way in the more engineering-scientific variant are mainly of a technical and statistical nature (e.g. Rinne & Mittag 1995; Pfeifer 2001) and use simple methods of representation of descriptive statistics. Such conceptions of quality development, transferred to quality development in health care, are ultimately based, just like the approaches of clinical or quantitative evaluation research (e.g. Cochrane 1972; Campbell 1969), on the assumption of the possibility of an objective description of the state of social reality. With the claim to accumulate knowledge stocks with the help of a methodical-quantitative set of instruments, which are to be used beneficially in practice. Following Campbell's (1969) approach of experimental evaluation or clinical research based on Cochrane (1972), an appropriate quantification of the products is assumed, as in the field of industrial material goods production. In quality control and QA approaches, the product quality

represents the dependent variable to which the work processes are then to be aligned or standardized.

In summary, it can be stated at this point that the concepts for quality development that have arisen from the field of industrial material goods production (which can be assigned to the model of quality control and QA) can only be transferred to the field of health care with restrictions. On the one hand, this is because the quality of products in health care cannot be measured in a comparable way as is the case in the production of material products. Excluding the influence of possibly confounding variables is a highly- demanding methodological task. It may be doubted whether this condition can be fulfilled in the regular review of care in the form of quality control or QA. On the other hand, it can be assumed that the type of professional service organization in the health care system can differ from other organizations. The processes in everyday care compared to manufacturing processes in the secondary sector may not be standardised by management.

Another variant of quality development, more management-oriented than the quantitative and engineering view of quality improvement, was developed by authors such as Edwards Deming (1986), Kaoru Ishikawa (1985), Masaaki Imai (1994) and Philip Crosby (1979). As a reaction of the American automotive industry to the emergence of the Japanese economy, Japanese management strategies and tools such as the quality philosophy “Gemba-Kaizen” -conclusions to success in competition- (Imai 1994), the cause-effect diagram of the chemist Ishikawa (1985) or the often cited “Plan-Do-Check-Act cycle”, which goes back to Deming and was expanded by Ishikawa, gained the greatest popularity in American and European management. Deming's (1986) publication entitled “Out of the Crisis” argued that American industry would only be able to defend itself against the Japanese economy if there was a complete reorientation of companies in terms of the products they produced. Investment in quality was seen as equally important to competitiveness as a pure orientation towards productivity.

Deming (1986: 23 ff.) conceived a 14-point program for improving quality and productivity with the formulation of basic principles of organizational transformation. In contradiction to the demand for quantification of organizational processes and results described in quality control and QA approaches, he explicitly emphasises that control cycles for checking quality run counter to the goal of

increasing the overall quality of a company (Deming 1986: 28 ff.). In addition, he states that performance targets in the form of numerical quotas (standards) at the level of the work process and also at the level of management in the form of quantifiable targets stand, in principle, in the way of the goal of an organizational transformation to a quality organization (Deming 1986: 70 ff.). All in all, Deming's quality-promoting principles can be interpreted as value patterns that aim at stronger personal responsibility for the employees, the clear responsibility of management for quality improvement as well as the orientation towards customer needs.

Joseph M. Juran (1973) and Ishikawa (1985) see important starting points for quality development in the establishment of a quality-oriented corporate philosophy, above all in the control of the process. In essence, process control in this context means the systematic approach in the context of the Plan-Do-Check-Act cycle. Above all, Ishikawa's concept emphasises the participation of employees at all levels and during all phases of the improvement process. This is especially in the form of group-oriented cooperation in quality circles.

Philip Crosby became famous with the statement “Quality is free”. His approach to quality improvement is characterised by the so-called “zero defect approach”. He pointed out that non-compliance with process requirements leads to high consequential costs (quality error costs). Accordingly, the goal of the approach he pursues is to preventatively identify potential factors of faulty processes and to thus avoid errors.

Masaaki Imai sees his approach of “Gemba-Kaizen” as a new paradigm within management sciences (Imai 1988, 1994). His basic understanding of quality is based on the term “gemba”, which means “place of action”, and on the term “kaizen”, which in Japan means “continuous improvement involving everyone” (Imai 1988: 13). From this he concludes that management must focus its attention more than before on the actual place of action, on the area where operational business takes place. Furthermore, he emphasises learning or continuous improvement. The kaizen philosophy assumes that all levels of life, whether working life or social life can constantly be improved (Imai 1988: 13). Imai explicitly states that “Western management” generally refers more to the control of work and must therefore be increasingly replaced by the Japanese understanding of support management (Imai 1988; 1994).

Cultural factors play a central role in explaining the success of Japanese companies. Virtues such as punctuality, diligence, discipline or mutual consideration as well as the tradition of a cultural community are regarded as essential success factors of Japanese management (Kühl 2002a: 115).

In contrast to quantitative approaches to quality control and QA, which propagate an increase in quality through the measurement of various indicators, the Japanese QM movement is of the opinion that the efficiency of organizations and thus the quality of outcomes can be achieved through the introduction of cultural values. If applied research can be assumed in the context of these approaches, the analyses mostly refer to the presentation of successfully presented individual projects with rather anecdotal evidence (Bigelow & Arndt 1995).

3.4.3 Summary of Presented Approaches

The aim of the approach mentioned in the last section was to present the perspectives, the methodological as well as methodological and analytical conceptions of the disciplines significantly involved in quality development in health care. The differences in the approaches to measuring, evaluating and promoting quality in the health care system go back to the different specific theoretical traditions. Thus, it is obvious that medical approaches to quality assessment are mainly limited to the professional working context of physicians. Medical interventions, diagnostics, drug-based or technology-supported therapy, are thus assessed according to whether or not they contribute to the recovery process of patients. In evaluation approaches, the criterion of the effectiveness of a program is traditionally in the foreground, whereas in business management conceptions, evaluation is based on criteria of efficiency. Another ideal-typical difference is the extent to which the various approaches aim to enable the system's stakeholders to deliver improved quality. In the currently existing QM programs, the attempt is mostly made to combine different elements of quality assessment and development (e.g. EFQM model as well as DIN EN ISO 9000 ff.).

The common features of quality-improving procedures from the field of medicine, evaluation research and business management concepts are that they are still in the early stages of researching the quality of health-related services. What

all approaches have in common is their explicit orientation towards the patient or, in business management models, towards the customer. Another common feature is that the direct transfer of quality assessment concepts to the field of health-related services is made difficult because the concept of quality cannot always be clearly defined (see chapter 2.2). Depending on which concrete reference problem is chosen, different characteristics arise with regard to what is to be measured, evaluated and promoted as quality. The evaluation of a medical intervention, a treatment procedure or a certain organizational form in health care can, under certain circumstances, turn out very differently from the perspective of medicine. Strictly speaking, purely medical criteria of treatment success can contradict an economic assessment with regard to cost-benefit relations, or the interests and criteria of hospital staff in quality can contradict the expectations of funders. Moreover, it cannot be assumed that the wishes of patients with regard to quality correspond in principle to those of the medical experts or the funders. In this respect, it is a highly challenging, if not impossible, goal to develop a total quality model that is able to integrate all quality dimensions.

The most important commonality is that all approaches to quality development strive to present seemingly rational criteria, principles or standards for evaluation, measurement and promotion as binding for the practice of care. From the fields of the medical profession, evaluation research or business management, it is basically assumed that quality can be objectified. Quality thus acquires the character of an objectifiable measure. Approaches to quality promotion based on this state of knowledge are characterised by the assumption that the promotion of quality can be designed according to rational principles and standards, such as the causal assumption formulated by Donabedian (1980; 1982) that high structural quality results in high process quality and this in turn results in high outcome quality. The resulting procedural logic of quality development, which is not explicitly formulated but is intrinsic in the approaches, basically follows the pattern that procedures for rational problem solving, which have to be carried out again and again, must follow the following pattern:

Define standards in order to later record and measure deviations. Subsequently, deviations are to be explained and avoided (Furusten 2000: 75 ff; Hackmann & Wagemann 1995).

The emergence of the standards and criteria by which quality is to be assessed and promoted is rarely questioned. The deductive science perspective is based on the assumption that relationships are interrelated in an orderly manner and proceed according to certain regularities. In the sense of the principle of causality, there must be a specific cause for every event. The task of science is to discover these regularities and the more knowledge there is about the structures and regularities, the more the observed events become explainable and future events predictable (Kromrey 1991). The majority of conceptual approaches from medicine, evaluation research and business management to the development of standards in health care principally follow the position with the aim of increasing the effectiveness and efficiency of care on the basis of objective knowledge about regularities and structures of the system (Badura & Feuerstein 1994).

4 DEFINITION AND RELEVANT CONTEXTS OF QA IN HEALTH CARE

4.1 DEFINITIONS OF TERMS OF QA

As already shown, quality is by no means subject to unchangeable, rigid specifications and laws. In order to maintain a level of quality under changing conditions and to improve quality in the case of general deficiencies, a suitable set of instruments is required.

This includes regular checks and inspections, such as those that have been part of manufacturing processes in industry for four decades and have recently become increasingly common in the service sector.

Quality controls and quality reviews are used to monitor the quality of mass-produced goods and mass-produced services using statistical methods. Quality control is used to determine the extent to which any deviations in the quality of goods or services from the norm that may have been noticed have arisen by chance or can be attributed to a (systematic) error. In the case of the latter behaviour, the causes of the misconduct must be investigated and, in a further step, error elimination must take place (Homburg 2015).

The official understanding of the term "quality assurance" is used below to describe all instruments in the manufacturing or service process that are suitable for stabilizing or improving the quality of goods and services in order to fulfil the functional expectations placed on them. The DIN-ISO series of standards 9000ff. expands this definition to the effect that all QA activities must be subject to a planned, systematic approach.

Quality controls, quality monitoring and quality inspection, together with quality planning and quality control, are therefore to be understood as methods of an overriding QA system within the framework of QM (Reisinger et al. 2013).

The frequently encountered view that QA is a synonym for in-depth documentation is therefore erroneous. Rather, documentation is a prerequisite for QA, and the same applies to the statistical methods applied to the results. But even

data collection and evaluation alone still do not constitute a QA program. Decisive elements of actual QA, beyond the two points already mentioned, are goal setting, analysis, inference and solution implementation; QA thus implies assessment and intervention.

Starting with an initial idea, followed by a written concept and ending with institutionalization, the development of a QA program goes through three essential stages according to Selbmann:

- Model phase (scientific study)
- Study phase (broad-based study)
- Program phase (routine)

The foundation of the model phase is the idea of an 'innovator', where QA is needed as well as how it could be measured. Then adequate tools and methods have to be developed or gathered. This includes, for example, standards and norms.

In the study phase, besides the innovator, so-called early adopters participate in the first implementations in practice. The feasibility and consensus of the program are tested, and the first indications of effectiveness are to be expected.

This phase is typically the domain of professional societies, professional associations and smaller working groups, not least in the university sector.

Upon entering the program phase - or phase of institutionalization - the program must prove to be practicable for the so-called late adopters and prove itself in routine use. Questions of permanent funding and proof of effectiveness will be finally clarified at this point.

4.2 STATE CONTROL OF QA

Whereas, until a few years ago there was still widespread trust in the medical profession to ensure the continuity and improvement of quality, this function of the profession has increasingly been called into question as a result of the scientification of medicine and changes in the political framework conditions. The changes in the health policy framework and with it the increased complexity of care

are generally regarded as societal motives for dealing with the issue of quality. Therefore, there is a need for corresponding regulation on the part of the state, which ensures the safeguarding and improvement of quality in the health care system. The legislator has reacted to these requirements with a series of regulations and thus created the basis for QA and QM, as well as creating guidelines and evidence-based medicine for the outpatient and inpatient sector. Chapter 4.5 describes the relevant laws in more detail.

From the perspective of the state, these standards are primarily intended to prevent undesirable developments in the quality of service providers (Schrappe 2001: 421). Without going into the content of individual regulations at this point, the question arises as to which underlying control system, in which form, and with which means, quality in the health care system should be ensured and promoted in the future. According to Robra et al. (2003), the residual state function must essentially concentrate on monitoring proper contractual activity and establishing the transparency of health care services. In other words: regulation through information (Robra et al. 2003: 51).

In political terms, this form of deregulatory or corporatist control of quality is to be understood in such a way that the role of the state is limited to controlling only the institutions of self-regulation. As a result, it has less of a mandate to determine the content and services itself, but is increasingly tasked with evaluating the quality of the services provided in the health system on the basis of various characteristics (Kaufmann 2002: 188 f.). In the context of ensuring and promoting the quality of services provided in the health care system, this form of state control means, in concrete terms, that the state limits itself to asking the self-administration (health insurance funds, service providers) to define requirements for quality and at the same time assigns it the task of checking the extent to which their compliance is met in the system (Robra 2005: 4 f.). For their part, the self-governing partners obligate institutionally independent organizations, associations or foundations, e.g. accredited by the German Accreditation Council (DAR: Deutscher Akkreditierungsrat) and the Trägergemeinschaft für Akkreditierung (TGA GmbH), to ensure and improve care according to certain quality standards. These organizations, associations or foundations take over the review of quality as well as the provision of methods for the promotion of quality in the health care system,

with procedures that are, in part, very differently weighted in terms of content. This form of QA and promotion is currently mainly linked to whether or not various procedures such as quality reporting, certification, etc. are introduced, but not to content-related criteria set by the legislator for regulation.

Following the analyses of Michael Power (1997a) of the "Audit Society" in connection with the review, measurement and promotion of quality in the field of health care, it can be assumed that these forms of review and promotion of quality, which are connected with quality-improving procedures, focus on key figures of the QM system rather than on the actual or substantial operation of organizations and the actors acting in them. Power draws attention to this connection using the example of Total Quality Management (TQM):

"TQM is less a set of secrete operational practices and more a programmatic umbrella for a number of different changes, not least as a stimulus to self-auditing (Munro & Hatherly 1993). The appeal of TQM and notions of quality lies in their ambiguity, their diverse and fluid meanings (Wilkinson & Wilmot 1995) which do not necessarily corresponded to common sense: quality is not about high standards but those which are uniform, predictable, and verifiable. Quality assurance, as an element of TQM, has more to do with a certain style of management process" (Power 1997a: 58 f.).

This view is intended to draw attention to the fact that forms of review and promotion of quality rely only on the control of control (Power 1997a: 82 ff.).

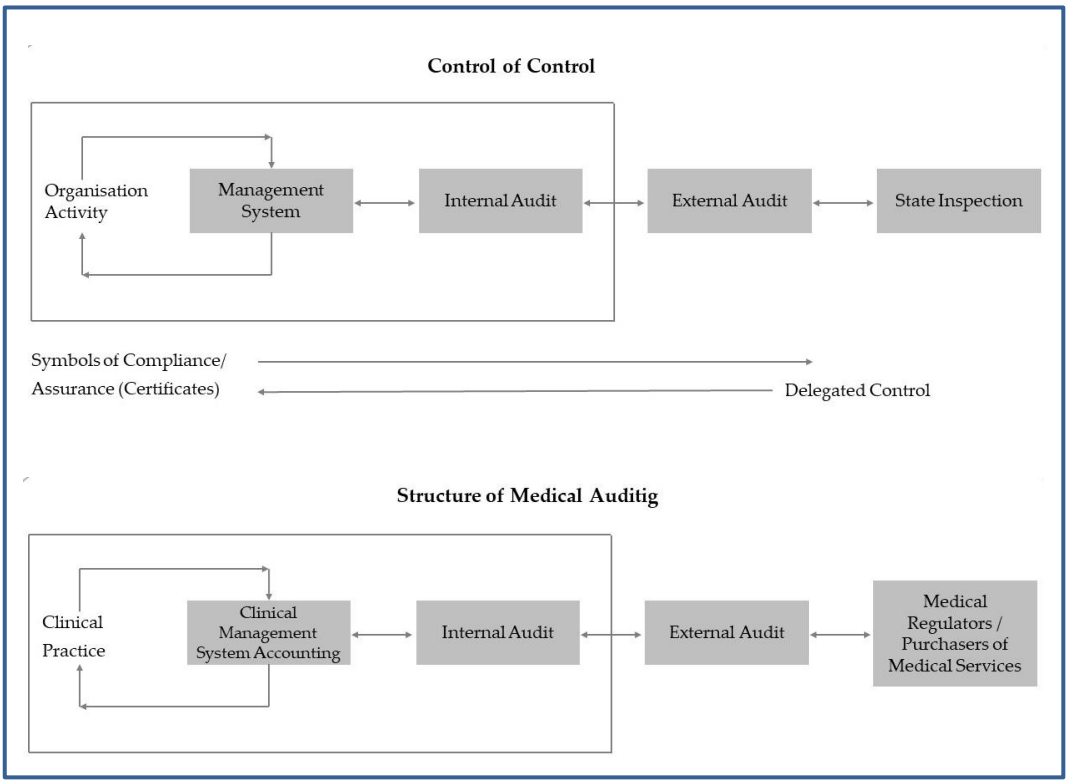

Figure 4: Forms of Control in the Context of Self-Regulatory Procedures (Power 1997b, 10 and 12)

This means that in the context of the formulation of quality standards, only the symbols of compliance with consensually agreed standards of management or so-called peers presented by the management system (of a hospital, a practice, etc.) or by clinical practitioners are controlled in the context of medical audits. The basic idea and hope of this form of control and deregulatory promotion of quality, according to Power (1997b), is thus more linked to commitments or symbols than to real action. And the consequences of this form of regulation are ambiguous:

"*The basic idea and hope is that auditee, subject to the gaze of the regulatory body, is stimulated to engage in further processes of self-audit through which practices and procedures are constantly improved relative to benchmark standards of performance (…) audit has become an important symbol of acceptability, indicative of ideals of transparency, accountability and managerial willingness to learn (…) all the ideological momentum that auditing has acquired, it remains an ambivalent practice and it is unclear what it produce*" (Power 1997b: 9 f.).

In principle, different tensions arise from this form of regulation of organizations in the health care system. On the one hand, between organizational action, meaning here the real treatment process, and the management system or leadership. On the other hand, they arise between the symbols represented by the organization and external controlling instances. Both for the medical profession and for the organization as a whole, this form of control of control leads to possibilities of decoupling in order to evade administrative, management-related or state control attempts.

Already in this short overview it has become clear that the consequences that can be triggered with the promotion of quality in the health care system are possibly far more diverse than generally assumed. It can be stated that with the introduction of regulations and procedures for quality assurance and QM, the complexity related to the question of possibilities for quality improvement has increased considerably. At the same time, it can be observed that in the course of this development it is not always clear who is actually responsible for quality.

4.3 PARADIGM OF QA

The merits of the Hungarian Ignaz Semmelweis in uncovering the causes of childbed fever with the consequent establishment of medical hygiene are generally acknowledged. However, the fact that Semmelweis' activities are also - and most notably - worthy of special appreciation from the point of view of QA is to be shown in the following in a brief outline:

A strict, keen logic, coupled with extraordinary tenacity, characterized Semmelweis' approach when he, the assistant physician in the obstetrics department of the General Hospital in Vienna, noticed the high mortality rate of women in labour in his department in the 1940s [1].

Semmelweis then studied the statistics of mainly Austrian and English hospitals of the past centuries to see the suspected, unusually high mortality rate fully confirmed [2].

In a deductive approach according to Skoda's exclusion method - modus tollendo ponens - he finally isolated germs as the cause of mortality [3] and - as

carriers of the 'pestilent substances' - the contaminated hands of physicians and students [4].

As a means of cleansing, Semmelweis enforced washing with chlorinated lime before every examination; he brought this demand across to students and physicians by imposing appropriate sanctions [5].

Continuous observation of the statistics proved the effectiveness of the hygiene measures: After the introduction of the washing, there was a clear decrease in maternal mortality [6].

A multiple flare-up of mortality could in any case be linked to hygiene rules that were knowingly or unknowingly not observed [7].

The essential steps in the Semmelweis discovery can be systematized as follows:

1. Idea, problem
2. Correctness check
3. Observation: finding the cause
4. Working hypothesis: problem mechanism
5. Conclusions and consequences: Create solution approach
6. Verifying effectiveness
7. Continuous observation

Exactly this procedure practiced by Semmelweis is nowadays regarded as the basis for the organizational process of a QA program, known as the “paradigm of quality assurance”.

A flowchart of this control loop, which has to be run continuously, is shown in figure 5.

Based on these basic principles, more complex forms of procedural QA can be designed for the medical care sector.

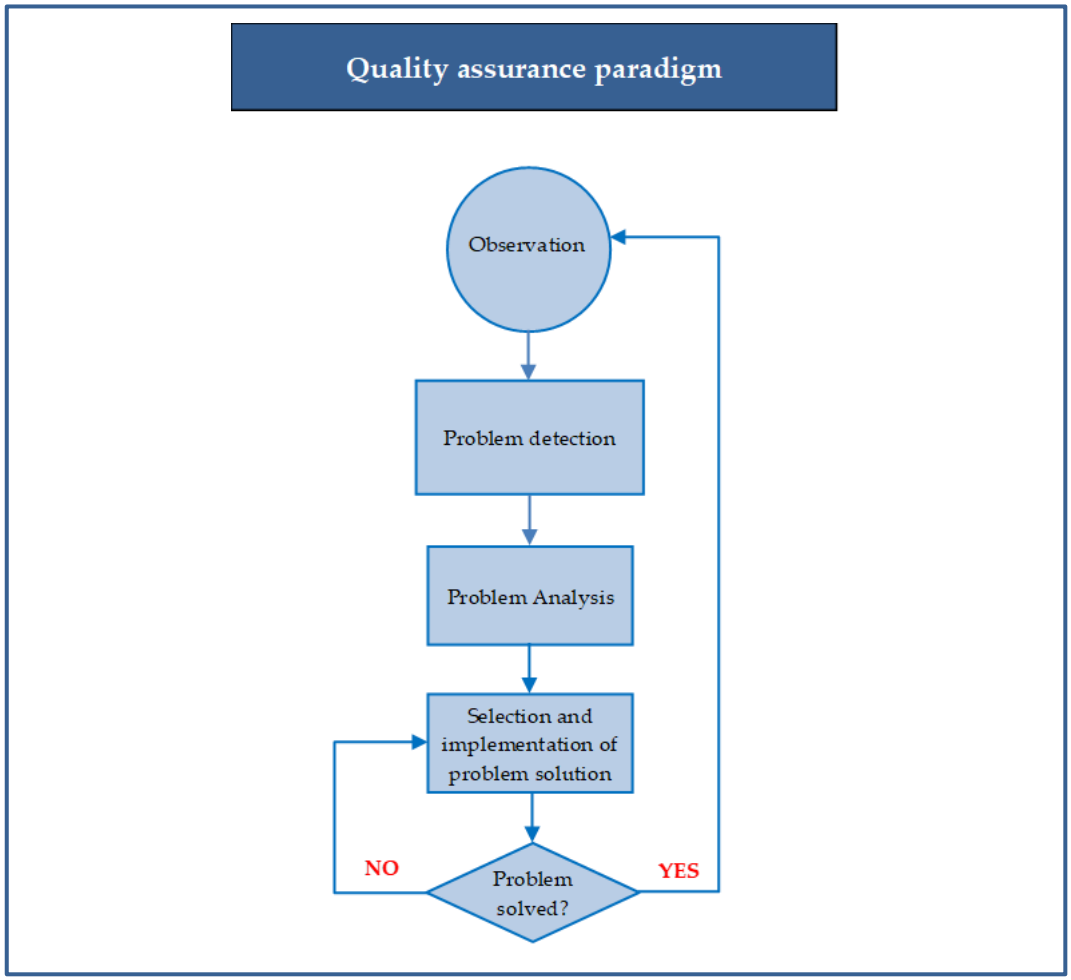

Figure 5: Paradigm of QA

This can be explained in more detail using the diagram in figure 6:

The QA process naturally begins with problem identification, i.e. with the recognition of specific problems in medical care, for example on the basis of personal experiences, discussions with colleagues or concrete examinations. This problem identification is followed by the setting of priorities in order to narrow the target lens.

In the next phase, the operational definition of the quality criteria is carried out by a body designated for this purpose, e.g. a technical committee or an expert conference.

If no explicit comparative criteria in the form of international or national standards or norms can be used, the panel must agree on the formulation of implicit quality criteria by consensus decision. The quality criteria are systematically structured into a catalogue of requirements.

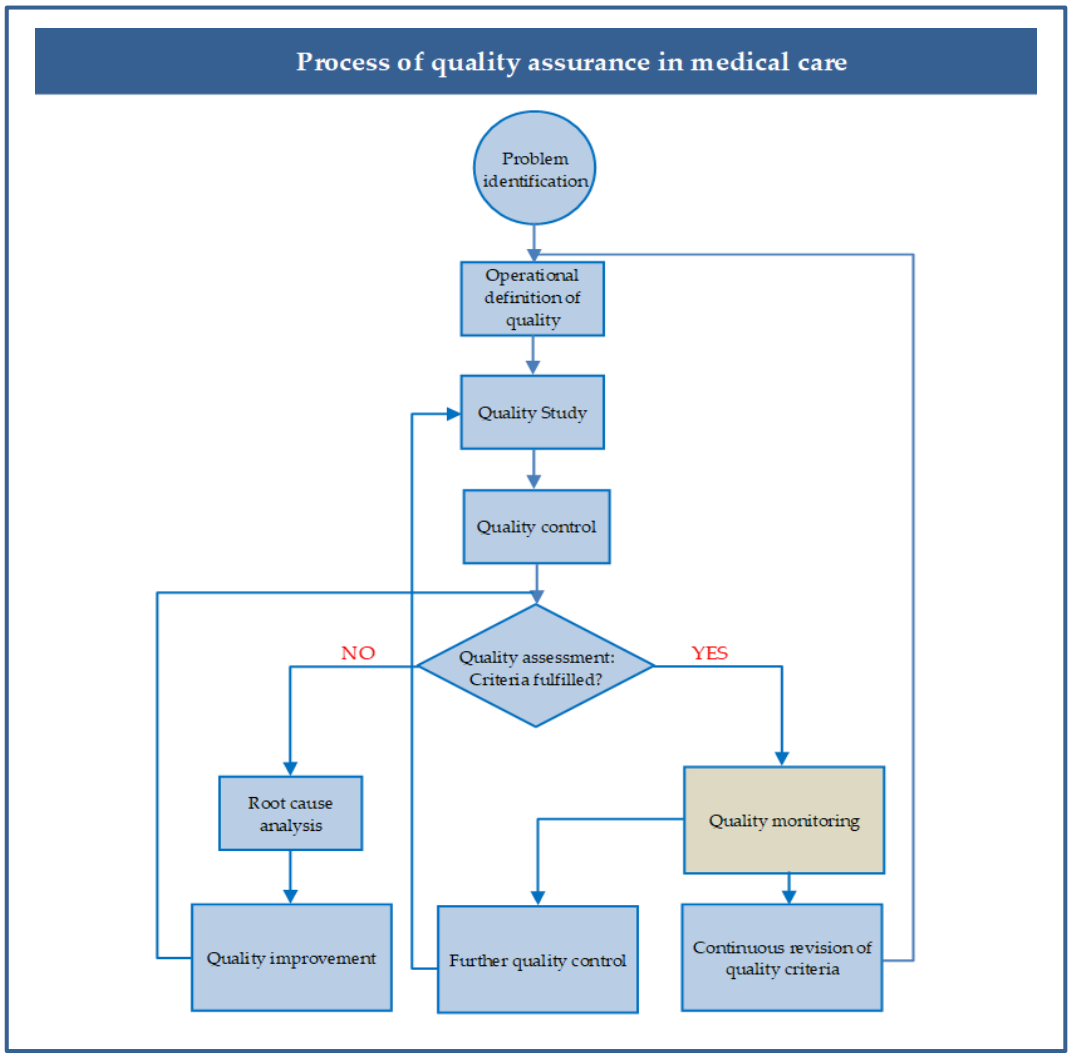

Figure 6: Process of QA in Medical Care

In the following step, which is called quality study, detailed observations are made on the selected problem area. This includes, for example, the retrospective study of medical records on the formulated problem or also a prospective approach in the case of changed therapy. The aim of the quality study is primarily the acquisition of meaningful data material.

The quality study is followed by the so-called "quality control". At this point, a target-performance comparison is made between the catalogue of requirements and current practice on the basis of the data material reviewed, which leads to a final quality assessment.

If the criteria of the catalogue of requirements are deemed to be fulfilled, quality monitoring follows to further observe the previously identified problem area. If, on the other hand, the quality assessment has revealed an intolerable discrepancy between the catalogue of requirements and current practice, the quality control is followed by a root cause analysis. Proposals for improving quality must be worked out and, after realization, must again be submitted to a quality study phase. The alternative developed must therefore undergo the control cycle described above until the quality assessment ultimately produces a positive result (Payne et al. 2013).

In addition, the aforementioned quality monitoring functions as a continuous "background" structure. On the one hand, this serves to dynamically adapt the catalogue of requirements to new or changed quality criteria, on the other hand, it represents the basis for further, problem-oriented quality studies.

In a concluding consideration of the QA mechanisms discussed, the following guiding ideas can be formulated:

- Quality and QA are independent of consensus and there are neither uniform procedures nor uniform standards.
- QA grows out of targeted, critical self-observation.
- QA serves to solve problems and it must not degenerate into an end in itself.
- Basic and progress documentation are not QA per se; like the statistical procedures, they merely form the basis for it.

- Essential prerequisites for QA programs are problem identification and target definition.
- Characteristic features of a QA program are not only the result but also the conclusions and consequences derived from it.
- QA programs require constant, critical monitoring.

4.4 HISTORICAL ORIGIN OF EXTERNAL QUALITY COMPARISONS IN GERMANY

The Munich Perinatal Study (1975 to 1977) was the first step from health services research to systematic external QA under the later direction of Prof. H. K. Selbmann (Conrad 1977). The reason for this was a neonatal mortality rate in the Munich area in the years 1970 to 1972 that was perceived to be too high. Through uniform documentation of the participating hospitals and the hospital-related, comparative evaluation of the study, the aim was to:

- Provide a picture of the quality of neonatal care in the Munich region
- "First steps are taken in the direction of independent self-monitoring of the participating clinics" and
- "Statistical records are provided to answer common perinatological questions" (Conrad et al. 1977).

This is considered to be the birth of external QA in Germany, which was soon followed by other projects, e.g. in surgery, neonatology, anesthesiology and many more.

4.4.1 Principle of External Comparisons

The principle of external comparisons was already based in these first procedures on the definition of relevant quality characteristics (e.g. neonatal mortality), the implementation of uniform documentation, the statistical evaluation of the data and their professional assessment with regard to quality of care. This already forms the basic structure of quality indicators, namely the

definition of the quality objective, the quality measurement as well as the quality assessment.

Comparative measurement of quality of care can be used to determine whether a service provider achieves attainable quality (see figure 7). Achievable quality is empirically derived from the best results of such a quality comparison or from corresponding studies. In addition, certain quality requirements can be set on the basis of social norms. The achieved quality of a facility is usually determined as a statistical result of case documentation and the examination of conspicuous results in professional dialogue. The task of QA and internal QM is to minimize the gap between achieved and actually achievable quality of care. Medical progress and further development of care in all its aspects ensure that the limit of achievable quality is continuously evolving, e.g. through new procedures, medicines, forms of care, etc. Furthermore, professional standards define the minimum standard of care quality that must not be fallen short of. This already briefly outlines the basic structures of external quality comparisons and external QA.

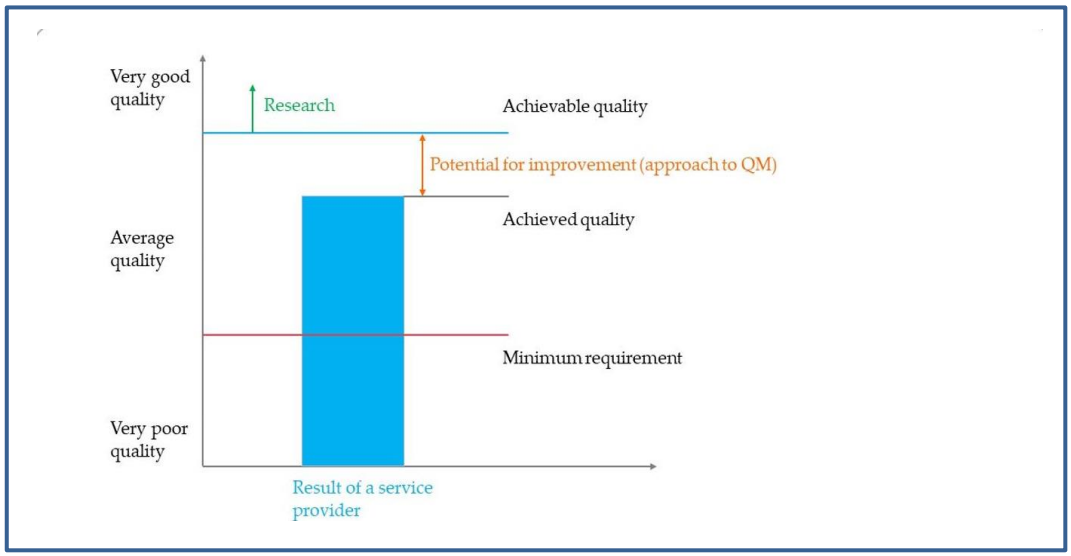

Figure 7: Difference between Achievable and Achieved Quality at a Service Provider as a Starting Point for Internal QM

External comparisons were used early on for medical QA, as they make it possible to formulate quality standards on the basis of empirical data and to identify potential for improvement (achievable not yet achieved) at individual facilities. In this context, quality requirements are already legitimized by the fact that some facilities have already achieved a corresponding quality of care. Only what is feasible is demanded. The internal QM of the facilities then tries to minimize the shortfall of the achieved quality behind the achievable quality (see figure 7).

4.4.2 Extension of the Term QA

The orientation towards the detection of deficits on the basis of statistical quality comparisons explains the early coining of the term "quality assurance", which is intended to ensure a required level of quality. Fittingly, the current standard definition of QA formulates that it is directed towards generating confidence [...] that quality requirements will be met (DIN EN ISO 9000:2005, quoted from Sens et al. 2007).

The understanding of QA in the health care system has grown historically. Of course, the establishment of QA measures in the health care system on a legal basis also has the goal of creating confidence among the population in the quality of health care through instruments of measurement, control, dialogue, continuous improvement and, above all, transparency. QA is composed of the most diverse activities of the stakeholders in the health care system.

In the practice of external QA in the German health care system, the understanding of the procedures has broadened to include that the goal is not only to measure quality and eliminate quality deficits, but also to promote the further development of care quality. The Hospital Structure Act, for example, provides not only for deductions for insufficient quality, but also for surcharges for extraordinarily good quality, and the quality contracts according to § 110a SGB V are intended to promote an above-average level of quality in certain service areas through selective contracts. In this way, the QA concept of external QA differs from that of DIN EN ISO 9000.

This leads to the (apparent) dilemma that two meanings are found for the same word "quality assurance", namely that of the standard and that which corresponds to the growing understanding of external QA in the health care system. In relation to the health care system, the definition of the norm is the correct one. At the same time, however, at the level of the concrete projects according to §§ 136 ff. SGB V, the trust aspect recedes into the background, as it would interfere with the mandate to critically examine and report, if the creation of trust were the primary goal.

4.4.3 Process Purposes of QA

QA procedures can have different purposes, which result from the respective mandates by the G-BA:

- Quality promotion (e.g. traditional procedures of external inpatient QA)
- Information (e.g. patient information on quality of care of individual service providers)
- Regulation through planning of care structures (quality indicators relevant to planning)
- Regulation through selective contracts with incentives (quality contracts according to § 110a SGB V)
- Regulation through collective agreement quality surcharges and discounts

According to the different purposes, the measurement and evaluation instruments have to meet very different requirements. This has an impact on the development and design of the procedures.

4.4.3.1 Quality Improvement

Quality promotion, as practiced in the QA procedures of external inpatient QA by the regional headquarters (and in future - also across sectors - by the regional working groups) in cooperation with the facilities, serves to provide

targeted feedback on quality results and to support the internal QM of the individual facilities. These measures correspond conceptually to the targeted promotion of quality development among the service providers with corresponding opportunities for collegial dialogue, exchange of experience, learning from the best, but also for agreeing on goals.

Quality promotion is always the purpose of a procedure, especially for case-related indicators that deal with process and outcome quality. All quality indicators are suitable for quality promotion; this procedural purpose does not have to be commissioned separately (Opp 2014).

4.4.3.2 Information

Transparency is a fundamental requirement of QA procedures and not a special purpose of the procedure. It stands for the transparent availability of quality results within the framework of the legal regulations. However, it has been shown that the abundance of these individual results is so great that it can hardly be used by the public. Unmanageability leads to a certain lack of transparency due to the amount of information. Targeted information in the sense of "public reporting" is therefore distinguished from transparency. Information is derived from existing data in such a way that its contents provide helpful answers in certain information and decision-making situations and a manageable basis for decisions. For this purpose, it must be defined which information people need in typical information and decision-making situations and in which form it can best be used. Examples include the establishment of a website that can be understood by laypeople, which patients can use to compare the quality of care provided by different facilities in order to find the most suitable one for treatment, or the use of quality seals and certificates to inform patients about particularly qualified care facilities (Reisinger et al. 2013).

Transparency and information offerings should always be available at the same time. Information is a suitable summary of a wealth of transparent individual data, which thus becomes manageable. On the other hand, the information offered

is legitimized by the fact that its derivation from available individual data can be transparently verified.

The creation of information draws on existing individual data and examines it for usability, if necessary through appropriate transformation, aggregation and explanation. It may well be that information offered also uses data that is not available as quality results, but can nevertheless be useful, for example, for patients when selecting health care facilities for their treatment. This includes, for instance, information on the range of care or the accessibility of a facility. In principle, all quality indicators can be used for targeted information. However, it must be examined as to whether the questions and results of the indicators can provide to a sufficient extent, answers to the patients' concerns (Reisinger et al. 2013).

4.4.3.3 Regulation by Planning of Supply Structures

According to Section 6 (1) of the Hospital Financing Act (KHG: Krankenhausfinanzierungsgesetz), the regional governments draw up hospital plans in order to ensure, according to Section 1 of the Hospital Financing Act (KHG), "high-quality, patient and demand-oriented care of the population with efficient, high-quality and independently operating hospitals." In order to be able to take the quality of care of the facilities into account in hospital planning, IQTIG develops corresponding quality indicators as well as benchmarks and evaluation criteria for the quality results on behalf of the G-BA in accordance with §136c Para. 2 Sentence 1 SGB V. Facilities that "exhibit a significant degree of inadequate quality, and this not just temporarily, may not be included in the hospital plan, either in whole or in part" (Section 8 (1a) KHG). Planned hospitals that exhibit a significant degree of inadequate quality (not only temporarily) in accordance with the requirements specified in Paragraph 1a, Sentence 1 [...] are to be removed from the hospital plan, either in whole or in part, by revoking the assessment notice" (Section 8 (1a) KHG).

The quality indicators to be identified or newly developed for this procedural purpose must relate to aspects of care that are relevant to planning and must be able to demonstrate "insufficient quality to a significant degree". In this context,

both the planning relevance and the criteria for the quality level specified by law must be defined. For this purpose, the G-BA has commissioned a comprehensive concept from IQTIG, the completion of which is planned for the end of April 2018. Since 1 January 2017, however, a first pilot project of the quality indicators relevant to planning in the service areas of gynecology, obstetrics and breast surgery has been in routine operation. This falls back on quality indicators that are already used within the framework of the QSKH-RL[9]. In the first concept for the procedural purpose of hospital planning (IQTIG 2016), criteria for the selection of service areas, for the definition of planning relevance, for the identification of insufficient quality and for the selection of suitable quality indicators were defined for the first time.

Since the quality indicators of this first concept only refer to those of the QSKH-RL, it is the case-related quality indicators that say something about care practice. For hospital planning, however, structure-related quality aspects are also important and these will be taken into account in the further development of the planning-relevant quality indicators.

4.4.3.4 Regulation by Selective Contracts with Incentives

The quality contracts according to § 110a SGB V are selective contracts that can be agreed by health insurance companies with selected hospitals in four selected areas of care. "The aim of the quality contracts is to test the extent to which a further improvement in the provision of inpatient treatment services can be achieved, in particular by agreeing on incentives as well as higher quality requirements." (§ 110a SGB V). The choice and measurement of incentives is the responsibility of the contracting health insurance companies and hospitals. The G-

[9] QSKH-RL: Guideline pursuant to § 136 Para. 1 SGB V in conjunction with § 135a SGB V on QA measures for hospitals authorised pursuant to § 108 SGB V (Richtlinie über Maßnahmen der Qualitätssicherung in Krankenhäusern: QSKH-RL).

BA selected the following four health care areas for the testing of quality contracts by plenary resolution on 18 May 2017:

- Endoprosthetic joint care
- Prevention of postoperative delirium in the care of elderly patients
- Respiratory weaning of patients who have been ventilated long-term
- Hospital care for people with intellectual disabilities or severe multiple disabilities in hospital

4.4.3.5 Regulation by Quality Surcharges and Deductions

§ 136b SGB V stipulates that *"the G-BA [...] shall regulate a procedure" that "enables the health insurance companies and hospitals to agree [...] quality surcharges for extraordinarily good service and quality deductions for inadequate service.*

For this purpose, it shall, in particular, publish assessment criteria for exceptionally good and inadequate quality on an annual basis". By resolution of the G-BA of 20 October 2016, *"the underlying concept [...] shall also enable an evaluation across indicators"*. Furthermore, §5 para. 3a Hospital Remuneration Act (KHEntG) regulates:

Quality increases or reductions shall be applied to the services or service areas concerned for admissions from the first day of the following month of the agreement. They shall be applied to admissions until the last day of the month in which the contracting parties determine in accordance with sentence 1 that the prerequisites for the further levying of quality surcharges or discounts no longer exist. If the contracting parties determine insufficient quality in accordance with sentence 1, the agreement shall also include that the quality deficiencies are to be remedied within one year from the date of the agreement; no quality reductions are to be levied during this period. If the quality deficiencies are not remedied within one year, the agreed quality discount shall be levied if the contracting parties determine that the prerequisites for the levy continue to exist; in this case, the quality discount shall be levied at double the amount for a period of twelve calendar months (Mateus 2015). The time limit for the levying of quality discounts according to § 8 paragraph 4 sentence 2 number 2 to a maximum of three years shall be observed.

According to § 8 Para. 1b KHG

Planned hospitals which, in accordance with the requirements set out in paragraph 1a, sentence 1, exhibit a significant degree of inadequate quality, not only temporarily, or for which quality deductions pursuant to Section 5, paragraph 3a of the Hospital Remuneration Act have been levied for a maximum of three consecutive years, [...] shall be removed from the hospital plan, in whole or in part, by revoking the assessment notice.

4.5 LEGAL FOUNDATIONS OF QA

Competence and organization

QA in outpatient care is characterized by a multitude of different responsibilities and stakeholders. Among the stakeholders, a distinction must be made between:

- The legislator and other state standard-setters (for example, in the case of the Verification Ordinance and the X-Ray Ordinance)
- The joint self-government of physicians, health insurance companies and the G-BA,
- The medical self-governance (medical associations and associations of panel physicians).

The GKV-accredited physicians must observe the guidelines and requirements of all three stakeholders in their work. Conversely, this means that the associations of GKV-accredited physicians do not prescribe all quality standards affecting the GKV-accredited physician or monitor compliance with them, but only the specific contractual standards that the joint self-government or the self-governance of physicians prescribe. Three legal sources are decisive for this:

- The law on panel physicians (SGB V as well as derived standards, for example directives of the G-BA)
- State standards (e.g. X-ray Regulations, Medical Devices Operator Regulations, Infection Prevention Act)

- Occupational law (e.g. professional regulations, further training regulations).

Standards of QA

The legal basis for QA in the statutory health insurance system is SGB V. In addition, the GKV-accredited physician has to observe other laws or regulations that regulate structural quality issues in particular. The basic paragraphs of the SGB V include:

§ 70

This paragraph is considered a general clause for GKV-accredited medical care. In addition to financial efficiency and humanity, it also requires an obligation to provide qualitatively assured care.

§ 75

The assurance and promotion of the quality of medical activity is one of the most important prerequisites for patient and demand-oriented payable care, carried out by specialists to a high standard. QA of medical services aims at maintaining and, if necessary, increasing the quality of the work process and the work results. This can only be realized if problems are identified in time, sufficiently analyzed and feasible proposals for improvement are developed quickly and successfully applied. An essential task of QA is still to create and maintain the structural conditions for high quality medical practice in education and training. In addition to this, however, there is also a need for dynamic procedures based on personal responsibility and self-motivation to evaluate, secure and improve the quality of processes and results in the sense of a self-learning system. This is intended to improve cooperation in the work of GKV-accredited physicians, promote professional competition and guarantee the quality of care, especially from the patient's point of view. With this objective in mind, the KBV issues guidelines for QA procedures in GKV-accredited medical care pursuant to Section 75 (7) SGB V.

§ 91

The G-BA is a body of joint self-administration and is formed by the KBV, the KZBV, the German Hospital Federation and the GKV-Spitzenverband[10]. The decision-making body of the G-BA consists of an impartial chairperson, two further impartial members, one nominated by the National Association of Statutory Health Insurance Dentists, two each nominated by the KBV and the German Hospital Federation and five nominated by the GKV Umbrella Organization. For decisions that do not affect all service sectors, from 1 February 2012 all five votes of the service provider side will be transferred proportionately to those members who have been nominated by the service provider organization concerned.

In addition, the legislator has created special regulations for the participation of patients. § Section 140f (2) of the German Social Code, Book V (SGB V) stipulates that the patients' interest groups and the organizations advising them in the G-BA, are granted a right of involvement in decision-making.

Since 1 September 2012 at the latest, the expected administration costs resulting from the decisions of the G-BA, in line with Section 2 (2) of the Act on the Establishment of a National Regulatory Council, must be presented in a comprehensible manner justifying the decision. To determine the administration costs, the methodology pursuant to § 2 Para. 3 of the Act on the Establishment of a National Regulatory Council shall be applied.

§ 92

The G-BA shall adopt the guidelines on the provision of adequate, appropriate and economic care for insured persons that are necessary to ensure the

[10] The GKV-Spitzenverband is the central representative body of the statutory health and long-term care insurance funds in Germany. It shapes the framework conditions for intensive competition for quality and efficiency in health care and nursing care.

provision of medical care. According to § 92 Para. 1 Sentence 2 No. 13, this also includes the guidelines on QA. These guidelines adopted by the G-BA have the character of sub-legislative standards.

§ 135

According to § 135 Para. 1 SGB V, new methods of examination and treatment in GKV-accredited medical care may only be invoiced if the G-BA has issued guidelines for this purpose. These guidelines must contain recommendations:

- To recognise the diagnostic and therapeutic benefits of the new method
- The necessary qualifications of the physicians
- The equipment requirements
- The required records of medical treatment.

If the review of the above criteria shows that they are not met, the examination and treatment methods can no longer be billed as GKV-accredited services at the expense of the health insurance company.

Pursuant to § 135 Para. 2 SGB V, the contracting parties to the Federal Minding Agreement may, for medical examination and treatment methods which by their nature require,

- Special knowledge and experience of the physician
- Special equipment in the practice or
- Other requirements needed for the quality of care

agree uniformly on corresponding requirements within the framework of QA agreements for the performance and billing of these services for GKV-accredited physicians.

The organizations recognized under the statutory order pursuant to Section 140g shall be included in the consultations of the contracting parties prior to the conclusion of agreements. In order to increase transparency, the reasons relevant to the decision must also in future be published in the German Medical Gazette or on the Internet.

§ 135a

The service providers are obliged to ensure and further develop the quality of the services they provide. The services must correspond to the up-to-date state of scientific knowledge and be provided in the professionally required quality. GKV-accredited physicians, medical care centers, accredited hospitals as well as providers of preventive services or rehabilitation measures and facilities with which a care contract exists, in accordance with Section 111a, are obliged, in accordance with Sections 137 and 137d, to participate in inter-facility QA measures. These particularly to improve the quality of outcomes and to introduce and further develop QM within a facility.

§ 135b

The associations of GKV-accredited physicians must implement measures to promote quality in GKV-accredited medical care. The organizations must document their goals and results and publish them annually. Quality reports on QA activities are standard in all GKV-accredited physicians' associations. Likewise, the associations of GKV-accredited physicians must check the quality of the services provided in GKV-accredited medical care, including the services provided by attending physicians, on a case-by-case basis by means of random sampling; in exceptional cases, full surveys are also permissible.

To this end, the G-BA shall develop uniform criteria for quality assessment in GKV-accredited medical care in guidelines pursuant to Section 92 of the German Social Code, Book V, as well as guidelines on the selection, scope and procedure of quality audits in accordance with Section 299 (1) and (2). In this context, the results according to § 137a par. 3 nos. 1 and 2 shall be taken into account.

In order to promote the quality of GKV-accredited medical care, the associations of GKV-accredited physicians may conclude joint contractual agreements with individual GKV funds or with the regional associations of GKV funds responsible for their district or with the associations of substitute GKV funds, in which special service, structural or quality features are defined for certain services in a uniformly structured and electronically documented manner.

§ 136

The G-BA shall determine for GKV-accredited medical care and for accredited hospitals fundamentally uniformly for all patients, by means of guidelines pursuant to Section 92 (1) sentence 2 no. 13, in particular

- The obligatory QA measures pursuant to § 135a, paragraph 2, § 115b, paragraph 1, sentence 3 and § 116b, paragraph 3, sentence 3, taking into account the results pursuant to § 137a, paragraph 3, nos. 1 and 2, as well as the basic requirements for an institution's internal QM system.
- Criteria for the indication-related necessity and quality of the diagnostic and therapeutic services performed, in particular costly medical-technical services; in this context, minimum requirements for the quality of structures, processes and results shall also be defined.

The guidelines are to be issued across sectors, unless the quality of service provision can only be adequately ensured by sector-specific regulations. Directive mandates on selected areas are presented in § 136a.

§ 136d

The G-BA has

- To determine the status of QA in the health care system
- Identify the need for further development
- Evaluate the effectiveness of QA measures that have been introduced
- To develop recommendations for QA based on uniform principles, including their implementation
- To prepare regular reports on the status of QA.

§ 137

The G-BA must define a system of consequences for non-compliance with quality requirements, for example, according to Section 136, in escalation levels. Measures may include: reductions in remuneration, loss of entitlement to remuneration for defined services, informing third parties of violations, publication of information on non-compliance with quality requirements.

§ 137a

The G-BA pursuant to Section 91 shall establish a professionally independent, scientific Institute for QA and Transparency in Health Care.

For this purpose, it shall establish a foundation under private law, which shall be the sponsor of the Institute. The Institute works on behalf of the G-BA on measures to ensure QA and the presentation of care quality in the health care system. In particular, it is to be commissioned

- To develop risk-adjusted indicators and instruments, including modules for supplementary patient surveys, for the measurement and presentation of care quality, if possible across all sectors
- To develop the necessary documentation for inter-institutional QA, taking into account the requirement of data economy
- To participate in the implementation of inter-institutional QA and, if necessary, to include the other facilities pursuant to Section 137a (3) sentence 3
- To publish the results of the QA measures in an appropriate manner and in a form that can be understood by the general public,
- To additionally present the quality of outpatient and inpatient care on the basis of suitable social data for the further development of QA for selected services,
- To develop criteria for evaluating certificates and quality seals that are widely used in outpatient and inpatient care.

§ 137b

The Institute pursuant to Section 137a shall be commissioned by the G-BA for the purpose of developing and implementing QA. Personal data for the purpose of QA may be used in consideration of § 299.

The results of the commissions' work are sent as recommendations to the G-BA, which must take them into account within the scope of its standard-setting competence.

§ 137f

The G-BA recommends to the Federal Ministry of Health suitable chronic diseases for which structured treatment programs (disease management programs) are to be developed to improve the course of treatment and the quality of medical care.

The following criteria are to be considered in the selection:

- Number of insured persons affected by the disease
- Opportunities to improve the quality of care
- Availability of evidence-based guidelines
- Cross-sectoral need for treatment
- The course of the disease can be influenced by the insured person's own initiative
- High financial costs of the treatment.

§ 139a

On 1 April 2004, the G-BA founded a legally independent scientific Institute for Quality and Efficiency in Health Care (IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen). It is active on issues of fundamental importance for the quality and efficiency of the services provided within the framework of the statutory health insurance, in particular in the following areas:

- Research, presentation and evaluation of the current state of medical knowledge on diagnostic and therapeutic procedures for selected diseases
- Preparation of scientific papers, expert opinions and statements on questions of quality and efficiency of the services provided within the framework of statutory health insurance, taking into account age, gender and life situation-specific characteristics
- Evaluation of evidence-based guidelines for the epidemiologically most important diseases
- Making recommendations on disease management programs
- Assessing the benefits and costs of medicines

- Provision of general information, comprehensible to all citizens on the quality and efficiency of health care, as well as on the diagnosis and therapy of diseases with significant epidemiological importance.

4.6 QUALITY-ASSURED SERVICES IN OUTPATIENT CARE

Around two thirds of all diagnostic and therapeutic services in GKV-accredited medical care are now subject to special QA measures. The aim of quality assurance is to provide patient care that corresponds to up-to-date scientific knowledge. Therefore, the tasks of QA are constantly adapted to new medical findings and the increasingly complex work processes that are in practice.

The self-generated charts in annex 1 show the development from 1990-2016.

Every year, further services are added for which special QA requirements are defined and agreed by the G-BA or the partners of the Federal Minding Agreements. In addition, new examination and treatment methods are constantly being added to the catalogue of statutory health insurance by the G-BA in accordance with medical progress. While at the beginning of the 1990s only seven areas of GKV-accredited medical care were subject to QA, today there are already more than 60 service areas.

In numerous medical fields, from AIDS to cytology, there are specific requirements that a panel physician must fulfil in order to receive authorization from the KV to work in this field. These licenses are also subject to conditions for their revalidation. For example, the Association of Statutory Health Insurance Physicians determines the current quality standard in detail through spot checks or proof of regular documentation.

4.7 CROSS-SECTORAL QA

In many cases, the same medical services are provided in both the outpatient and inpatient sectors. Patients are often cared for in both sectors in the course of treatment. The legislator has therefore obliged the G-BA to develop procedures for cross-sectoral QA, in addition to the already existing sector-specific QA procedures (Broge 2018).

For the development and implementation of QA measures and for the presentation of the quality of care, the G-BA established a professionally independent, scientific institute in accordance with § 137a SGB V, which acts on its behalf. On 1 January 2016, the Institute for Quality and Transparency in Health Care took over the tasks of the institution according to § 137a SGB V, which until the end of 2015 were still entrusted to the Göttingen AQUA-Institute (description in chapter 6.1). The trustee of the Institute for Quality and Transparency in Health Care is the foundation of the same name governed by private law, whose establishment was decided by the G-BA on 21 August 2014.

The framework guideline of the G-BA on inter-institutional and inter-sectoral QA measures already came into force in 2010. This created the prerequisites for recording and evaluating treatment results of outpatient and inpatient care across sectors. The guideline determines the structures for implementing cross-sectoral QA, which are required in particular at the State level, and specifies the tasks of the organizations involved (Broge 2018).

In February 2015, the first specific procedure for cross-sectoral QA was adopted by the G-BA in a guideline: Percutaneous coronary intervention and coronary angiography is the first examination and treatment method in which contract physicians and hospital physicians are assessed according to the same QA specifications. The procedure is based on two data sources: Documentation by the physician and social data available from the health insurance companies.

The regular operation and thus the obligatory data collection for the participating physicians (invasive cardiologists) began on 1 January 2016. Nationwide, about 660 physicians in about 370 practices perform about 90,000 cardiac catheter examinations and, where necessary, percutaneous coronary interventions. The documentation is done electronically. GKV-accredited physicians transmit the encrypted data to the data collection point of the respective

Association of Statutory Health Insurance Physicians on a quarterly basis. The Association of Statutory Health Insurance Physicians pseudonymizes the information of the practice and the operating facility number, and forwards the data with the relevant practice pseudonym to a trust center. This in turn pseudonymizes the patient-identifying data (Broge 2018).

The data from both data sources - those of the physicians and those of the health insurance funds - are combined and evaluated. Based on this evaluation, the practices and hospitals participating in the procedure receive an annual feedback report.

The QA procedure is to be supplemented by the patient perspective in the future. Therefore, the Institute for Quality and Transparency in Health Care was commissioned to develop a patient survey on 21 April 2016.

In order to evaluate the results and initiate QA measures, the associations of GKV-accredited physicians, associations of GKV-accredited dentists, regional hospital associations and the associations of health insurance companies including substitute funds, establish so-called regional working groups. While the associations of GKV-accredited physicians have already started their work in their function as data collection agencies, the founding of the State working groups is still pending.

In December 2016, the second intersectoral QA procedure was adopted by the G-BA. The QA procedure "Prevention of nosocomial infections: postoperative wound infections" is largely based on social data and case-related documentation in hospitals. The only documentation obligation in the GKV-accredited medical sector consists of a facility-related documentation on hygiene and infection management once a year (Broge 2018). Due to the complex merging of inpatient and outpatient data with social data at different points in time, there will initially be a so-called trial guideline, which is to come into force on 1 January 2017 and will be valid for five years. The QA procedure will affect about 8,000 contract physicians who perform surgery, such as surgeons, orthopedists, gynecologists and urologists in about 5,500 facilities.

4.8 SUMMARY

QA includes regular checks and inspections, statistical methods and a planned, systematic approach. The development of a QA program goes through three essential stages: model phase, study phase and program phase. The program must prove to be practicable for all users and demonstrate its effectiveness. Documentation and statistical methods are prerequisites for QA, but goal setting, analysis, inference and solution implementation are essential elements of an actual QA program.

This chapter has discussed the need for regulation of the health care system to ensure and promote quality resulting from changes in the health policy framework and the increasing complexity of care. The state has responded with a series of regulations and guidelines aimed primarily at preventing aberrations among health care providers. It also examines the tension between organizational action and management systems and the potential consequences of promoting quality in healthcare. It is noted that responsibility for quality is not always clear-cut.

Furthermore, the development of the understanding of quality assurance (QA) in the healthcare system was discussed, which has grown historically and includes instruments of measurement, control, dialog, continuous improvement and transparency. While the standard definition of QA aims to create confidence that quality requirements are being met, external QA in the German health care system has broadened its goal to include promoting the advancement of quality of care. This has led to the same term being used for two different meanings, which can lead to confusion. It can be stated that while the definition of the standard for the healthcare system is correct, at the level of concrete projects, the trust aspect of QA takes a back seat to the mission of critical review and reporting.

5 CONCEPTS AND TOOLS OF QA IN SCOPE OF HEALTH CARE

5.1 PARAMETERS OF QA

Risk, crisis and emergency situations demand and lead to the highest level of competence in management. The degree of quality in management and the strength of its QA can be measured and verified by its process concepts for risk constellations and for crisis and emergency events. Risks, crises and emergencies involve the highest challenges for QM, especially in medicine (Malik 2005).

Risk profiles, crisis constellations and emergency events in a company, a practice, a clinic often mean acutely threatening situations for all those involved - first and foremost for the patient - often existential situations of different platforms, closely connected via functional interfaces in terms of responsibility and management. Risk and resulting crisis constellations precede the event "emergency" in many cases when retrospectively analyzing using causal connections. Responsibility and tasks for the required QM are cross-interface and equally interface-connecting with graduated action planning and defined intervention limits as well as instructions for action (Schreiner-Hecheltjen 2015: 115).

Flowcharts for the individual process flows are helpful and target-oriented. High management quality, according to national and international evaluation standards, is demonstrated in the handling of risk, crisis and emergency situations, especially in medicine (Campbell 2003). The core objectives of management for risk, crisis and emergency situations is the prevention of the causal and the subsequent events with the prerequisite of a concrete and differentiated examination of the general and in each case potential specific possibilities of risk, crisis and emergency events for a company. This is an essential requirement for all constellations in medicine, for all areas of medical activity and a fundamental requirement of patient safety (Perlitz 2010). Harm avoidance, harm prevention, at least the highest possible harm reduction have been basic ethical precepts for physicians since Hippocrates (Müller 2006: 13-25; Obermeier 1990: 306-349).

Risk, crisis and emergency management are the main tasks of corporate responsibility (Brühwiler 2011; Gleißner 2005).

The responsibility of every medical activity includes, with medical knowledge and with QM knowledge, a concrete examination of the phenomena of risk, crisis and emergency events of its specific medical activity. A fundamental approach to this task is the goal - especially with the increasingly shortening half-life of medical knowledge - to always be up-to-date and online in the knowledge of one's own medical qualification. Risk, crisis and emergency management are the core contents and uncompromising tasks and demands in terms of prevention and QM in every medical enterprise (Pippig 2005).

In the following, general QM considerations on risk, crisis and emergency events in the context of medical activity are to be pointed out. The core objective is prevention in its original meaning.

5.1.1 Risk – A Management Responsibility

The term risk is defined differently in the various scientific disciplines. Common to all disciplines is the definition of risk as the description of a situation with the possibility of leading to negative consequences and less often as the description of the existence of a risk with the consideration of positive consequences in the sense of creative opportunities in risky actions (Finke 2003; Wiedensohler 2003: 514-515).

Risk in health care includes all avoidable adverse events with different consequences in connection with a patient treatment, from an error analysis to the development of an error culture (Möllemann et al. 2005: 377-384; Rall et al. 2002: 1033-1042). The author Dechner, J. speaks of risk management in hospitals as a general topic of responsibility. In health care, following the law of Heinrich, the general definition of a risk by Gausmann, P. on the probability of occurrence of damage is the practical base from which to work (Gausmann 2005: 307-310; Gausmann 2007: 1-4).

The law of Heinrich (Heinrich 1941) states that catastrophic events, crisis and emergency situations, are not foreseeable and do not arise by chance and fate, but

are preceded by a number of work errors, carelessness and deficient work processes declared as being insignificant.

These facts can be clearly visualized. In the baseline study population of 3,846 patients, 300 (< 10%) were victims of minor negligence. In 29 patients (< 1%), harm was just averted; in one of 3,846 patients (0.38%), serious harm occurred. The consequence of Heinrich's law is the demand for increased error detection, error prevention and error correction already at the blunt end of the risk mountain to avoid the accidents at the pointy end of the iceberg (von Eiff 2003: 478-481; Lina 2000).

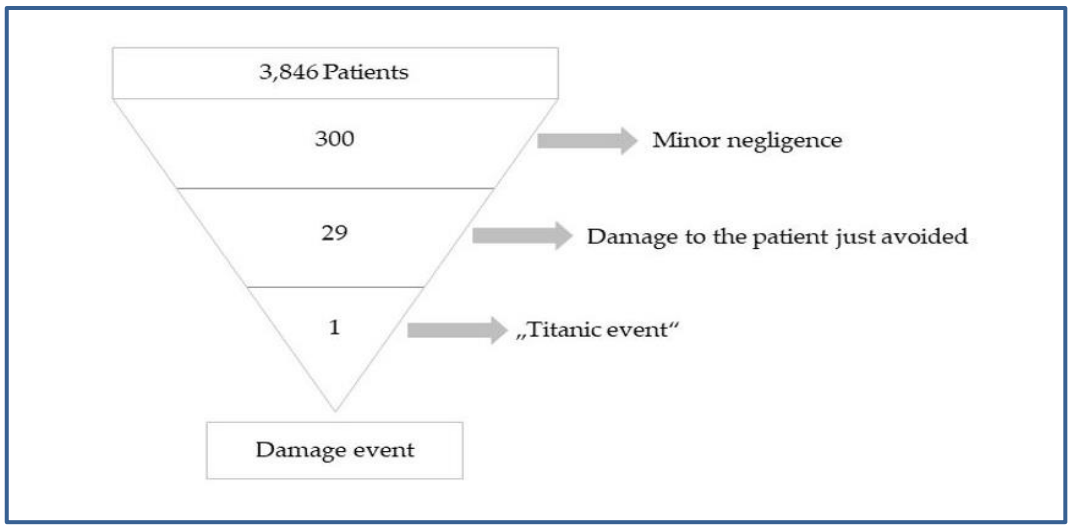

Figure 8: Heinrich's Law as interpreted by von Eiff, CKM, 2003

The risk iceberg clearly shows the importance and significance of the phenomenon of risk in medicine. The imperatives are risk prevention and risk management.

Risk management is one of the core features of successful QM, a core feature of QA, a core feature of patient safety (Schreiner-Hecheltjen 2015: 121).

Risk management is the first management task and the first management responsibility (Brühwiler 2007). Risk management must be integrated as a functional pillar of QA in the daily routine practice of every medical company with a master plan drawn up by the management and a selected team of experts. It

should contain guiding principles and clear guidelines for all measures of action, with basic, compulsory and regular training for all potentially relevant people (Brühwiler 2011). Risk management is a rating basis for a company (Keitsch 2007; Wiedemann 2006). Risk management is a sure success factor (Romeike 2009; Wolke 2007). Risk management is a transparent corridor approach topic for all areas of a company, including all operational vertical and all strategic horizontal levels (Brühwiler 2001; Erben & Romeike 2008; Fiege 2006). Basic quality requirements for the process of risk management itself are knowledge-based strength of action, documentation precision, secure information channels and communication competence (Obermeier 1999; Pateisky 2004: 73-77).

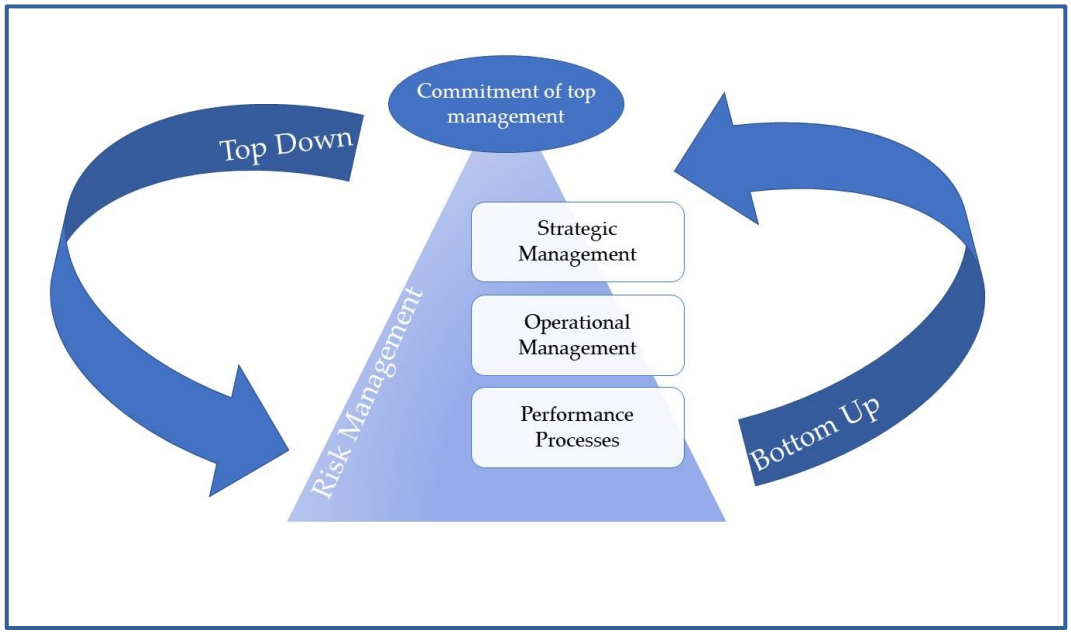

Figure 9: Top-Down Approach of ISO 31000 and ONR 49000 According to Brühweiler, B., 2011

The importance of risk management has been defined since November 2008 in the international standard ISO 31000 "Risk-Management-Principles and Guidelines" with three specific features (Krause & Borens 2009; Ollenschläger 2001: 1404-1410):

1. Risk management has a comprehensive top-down approach
2. Risk management is a management task with a corridor through all corporate levels
3. Risk management is a general and universal basic standard:
   The standard chapters of ISO 9001 apply:
   - Management responsibility
   - Management of resources
   - Risk management process
   - System monitoring

At the beginning of 2012, with emphasis on the importance of risk management in health care, the German version of the standard DIN EN 15224 was published on the basis of DIN EN ISO 9001:2008 with the aim of a European standard for all services in health care.[11]

5.1.1.1 Risk Measures

In evidence-based medicine, for both curative and preventive disciplines, certain measures of success and risk have been established based on the comparison of an intervention/treatment (RI) with a control group (RK)[12]. Success and risk assessments are particularly important for off-label use (see chapter 5.2.2) prescriptions (Lehmacher 2004: 523-532; Fletcher 2007).

[11] Health care services - QM systems requirements EN ISO 9001:2008 EN 15224:2012.

[12] RI= Risiko-Intervention (risk intervention), RK= Risikokontrollgruppe (risk controll group).

1. The *absolute* risk difference *RD = RK - RI* describes the absolute gain of the success shares of the treatment compared to the control.
2. NNT "Number Needed to Treat" results from the inverse of the risk difference as *NNT = 1 / RD*. It can be interpreted as the number of people treated for an additional success.
3. RRR Relative Risk Reduction is defined as *RRR = RD / RK*. It can be interpreted as the proportion of controls that would benefit from treatment.
4. NNH "Number Needed to Harm" is defined as the inverse of an increase in risk if more side effects occur in treatment than in the control group.

These measures of success and risk make sense for certain questions. Relative risks are mainly used in epidemiology for small risks. Odds ratios are used as an approximation to relative risks, since they can be calculated for both prospective and retrospective studies. In evidence-based medicine and health economics, absolute risk differences RD and "Numbers Needed to Treat" NNT are more important than relative risk measures, since absolute differences measure the patient-related magnitude and not only the proportion of events that can be reduced by an intervention.

5.1.1.2 Electronic Medicines Management as a Risk Management Concept

Medication and drug safety have increasingly become issues in medicine, with a growing platform for successes and equally for potential errors (Anderson et al. 2002: 479-490; Mekhjian et al. 2002: 529-539). Indications and contraindications[13] from EBM results and empirical research, compatibilities in a

[13] Contraindications indicate the circumstances under which a medicinal product must not be used. Typical examples of contraindications are: Hypersensitivity (allergy to the medicine, the group of medicines or related

patient's individual medication pattern and side effect spectra are supporting pillars of the "medication safety" checklist (Santell et al. 2003: 760-770; Hirschberg 2010). In addition to the purely medical safety aspects, there are interprofessional and organizational, as well as economic tasks and responsibilities in the clinical-inpatient area and at the interfaces between hospitals, physicians' practices and outpatient departments. The functionality of the numerous interfaces in a medication process harbours diverse and serious sources of error, as von Eiff, W. has clearly shown for the traditional medication process (von Eiff 2007, 2008: 20-25). Clear, transparent, plausible and verifiable documentation is uncompromisingly necessary in reaching this target.

The requirements for optimal, and in every respect efficient, drug therapy are high and, from a QM point of view, need concepts and pathways to be carefully and constantly checked with the cornerstones of the QM cycle: plan-do-check-act.

From a QM perspective, one way to meet the requirements of modern pharmacological therapy with increasing drug safety is the electronic management of drug therapy with models of electronic drug cabinets. Increasingly, electronic medication management is also being worked on and tested in Germany, as in other European countries (Rose et al. 2009: 1890-1893; Pfeiffer & Auer 2009: 324-329), as an essential QM process of safety and economic efficiency within the framework of the entire medication logistics including all opportunities and all conditions for clinical routine (Bates et al. 1999: 313-321; von Eiff 2008: 9, von Eiff 2009).

Compared to the traditional prescription and dispensing of medicines, the individual steps and phases of individual medication from prescription to the correct intake by the patient, with their various interfaces, have only become transparent, controllable and analysable in the development of electronic medication cabinets (Mekhjian et al. 2002: 529-539; Messerli 2010; Meyer 2008).

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substances), diseases and organ disorders such as liver and kidney insufficiency, combination with certain medicines that can cause drug interactions.

QM aspects for electronically managed drug therapy are, according to Schreiner-Hecheltjen:

1. As a medication management system, electronic medication cabinets electronically support all central components of the medication process: prescription, control, safety, storage, withdrawal, service recording.
2. Conventional drug cabinets have reached their limits due to the increase in drug assortments and their interactions.
3. Electronic medication regulation enables electronic linkage to all other procedures and services.
4. Guidelines and processes of medication therapy: prescription, control of the administration and information about the patient are documented.
5. With regard to medication errors, the basis for an error culture is in place. Every necessary prescription is checked and documented.
6. For medication management, cost savings result from optimisation of product ranges and storage quantities as well as the reduction of expired products.
7. Electronic medication management connects vertical and horizontal levels of the entire process organization in patient treatment.
8. The interfaces of medication management internally: medical field, nursing, pharmacy, as well as externally: other institutions and general practitioners, are integrated, checked and adapted.

Electronic medicine cabinets, as an optimal and optimizing QM tool regarding all aspects of modern drug therapy, are a proven way to increase patient safety with documented implementation of the principles and tenets of drug therapy, which are:

1. Correct medicine
2. Correct patient
3. Correct dosage: prescription, calculation, device setting
4. Correct timing
5. Correct administration: location, access, quality
6. Correct combination: interactions

Electronic medication management represents an efficient preventive contribution to medicine on the topic of patient safety with higher efficiency, lower error rates, more exact control and the support of goal-oriented interprofessionality. Electronic medication management is a supporting pillar in the development of e-health[14].

5.1.1.3 Surgical Safety Checklist of the WHO as a Risk Management

The 19-point surgical checklist presented by the WHO[15] in June 2008 as part of a global initiative "Safe Surgery Saves Lives" for safe surgery deserves targeted and special attention in the risk management profile of surgical medicine (WHO 2009). The topic of patient safety as an essential quality feature was precisely formulated in the USA in 2000 by the Committee on Quality of Health Care Institute of Medicine in Washington DC. In a report "To Error Is Human: Building a Safer Health System" it was precisely formulated (Kohn et al. 2000). In Germany, the concept of the WHO Checklist for the Operating Room was evaluated very positively by both the German Society for Surgery, supported by the German Society for Anesthesiology and Intensive Care Medicine (Bauer 2009: 26-28; Fudickar et al. 2012) and the Action Alliance for Patient Safety APS[16] (APS 2010).

The introduction of a surgical checklist according to the WHO model means a change in the safety culture in interdisciplinary and interprofessional clinical

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[14] e-health (electronic health) is a collective term for the use of digital technologies in the health sector. It refers to all tools and services that use information and communication technologies for prevention, diagnosis, treatment, monitoring and management in health care.

[15] WHO: World Health Organization (https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery).

[16] APS: Aktionsbündnis Patientensicherheit e.V. (Action Alliance Patient Safety).

process management. Checklists are a proven control instrument in aviation to increase safety by avoiding undesirable and, in particular, preventable events. Medicine can learn from aviation (Sax & Browne 2009: 1133-1137). The occurrence of adverse events becomes more likely the more people interact, even at a high level of safety and in very specialized professions, and the risk of error increases the more steps are required on the patient (Flin et al. 2002: 68-78). The ever-increasing specialization in medicine requires an increasing division of labour in patient care.

Management is challenged to improve the quality of the interface and communication problems. Work processes must increasingly be coordinated on an interdisciplinary and interprofessional basis. Work compression due to economically induced time pressure is the reality of clinical routine. Under these conditions, error-producing conditions must be recognized and eliminated as far as possible. Usually, multifactorial system failures can be analyzed, such as workload, communication deficits, supervision problems, insufficient resources, inadequate environment and special patient characteristics (Schilling 2010: 224; Marery et al. 2006: 746-752; Haynes 2009: 491-499; Krizek 2000: 1359-1366).

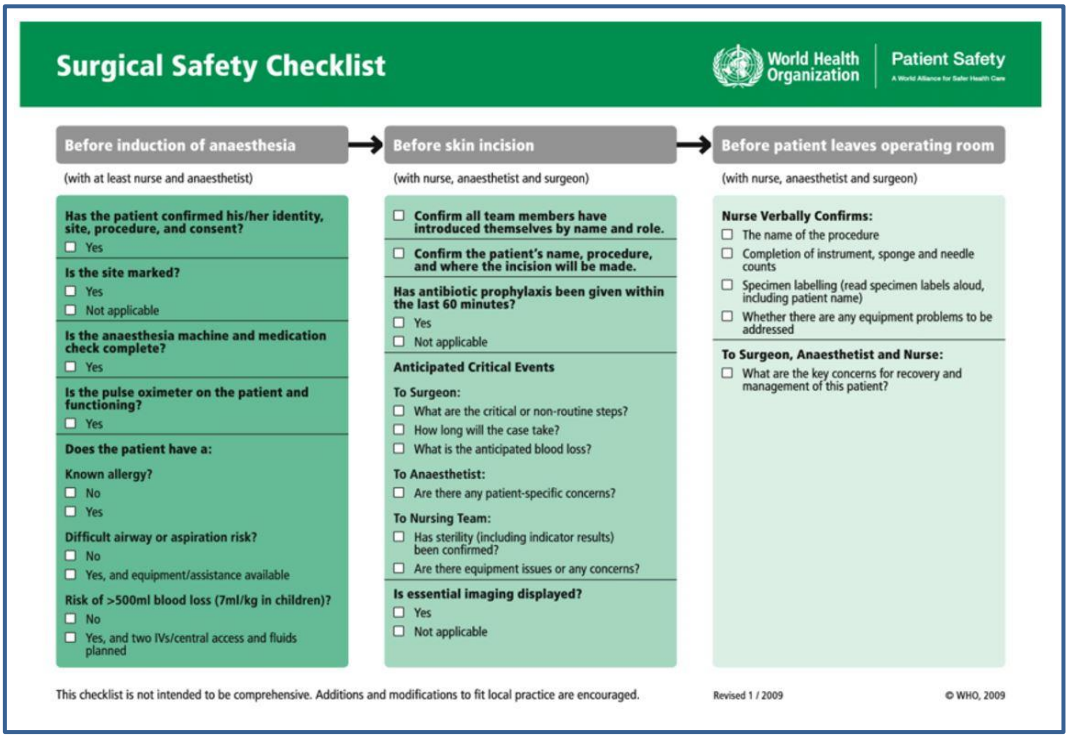

Figure 10: Surgical Safety Checklist - Original List

The WHO checklist was designed to check compliance with specified and formulated safety standards, to control the availability of required resources and to regulate the distribution of tasks and responsibilities. Reproducible and uniformly documented process sequences, agreed upon by the team, contribute to patient safety in the operating theatre and to personal safety in air traffic. Checklists are working tools that serve as reminders to ensure that processes that have been clearly established and defined are objectively reproducible and always run in the same way and documented in a comprehensible manner.

5.1.2 Crisis – A Management Responsibility

A crisis is defined as an unintentional and unplanned process event of limited duration, limited influenceability and with ambivalent starting possibilities. Causal or accompanying phenomena are instability and disturbances in process flows and conflicts, as A. J. Garth and Merten formulate.

The cause, extent and significance of a crisis situation can be very different, such as change crises, control crises, result-induced crises, survival crises, structural and strategic crisis situations with very different dimensions. Strategies for crisis avoidance, for mitigating the consequences of crises, are determined by the availability of decision-critical information, the ability to manage negative events promptly and objective as well as targeted communication to objectify the potential cause-effect chain of the situation that has occurred (Gallandi 2008). Successfully dealing with a crisis situation requires all the necessary expertise and knowledge and high-level communication skills (Schulz 2005; Nolting & Tießen 2008).

With his traffic light model of 4 crisis levels, A. J. Garthhas very clearly shown a navigation path for crisis communication, as well as for initiating all the necessary information, interventions and positioning of behavioural measures in each case.

Level green - Observation monitor phase

- Situation uncritical
- Time for prevention measures

Level yellow – Set time for first interventions

- Situation critical
- First phenomena
- First signs

Level red – Acute action phase

- Situation very critical
- All measures required

Level blue – Outcome analysis for the development of sustainable prevention

- Recovery phase
- Time for evaluation and consequences

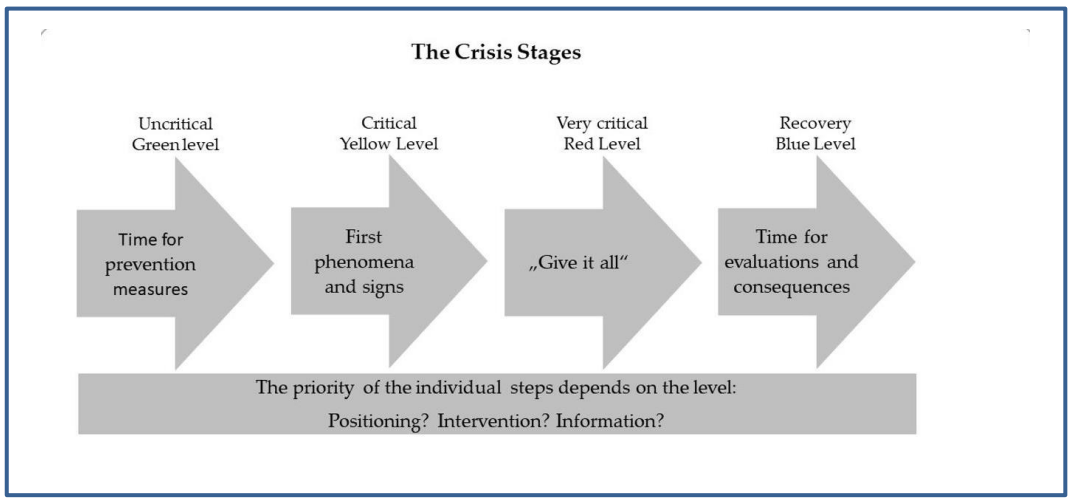

Figure 11: The 4 Crisis Stages, A. J. Garth, 2008

Crisis management that works in an emergency means developing crisis management concepts in advance and integrating them into a normal ongoing routine (Roselieb & Dreher 2008).

Successful crisis management, like risk management, needs a master plan (Schreiner-Hecheltjen 2015: 146).

Crisis management begins with the exact analysis of the particular crisis situation. Precise documentation of the crisis event by a designated minute-taker who records the entire chronology of the crisis process, e based on a checklist. This is the working template for the subsequent comprehensive analysis of the crisis event. From the crisis analysis, categories of measures can be developed for a step-by-step plan of the action required in each case.

Crisis management concepts should also be anchored in a special section of the QMH[17] in the training and further education program of all personnel professionals in a company. All relevant people must be regularly trained in the management of potential crisis situations and must always be up-to-date. Crisis safety is strengthened by setting up a crisis team in the company (Gahlen & Kanaster 2007).

Crises, like mistakes, mean opportunities for learning and milestones for continuous improvement in management towards a crisis and mistake handling culture in management and proof of its quality. Crises are often the escalation of insidious problems or unidentified risks. Problem and risk analysis are the task and content of a phase before the crisis, the prevention phase. Successful crisis management is built on the concepts of preventing a crisis, implementing early warning and monitoring systems for specific events and analyzing crisis potentials (Deming 1982).

[17] QMH: Qualitätsmanagementhandbuch (Quality Management Manual).

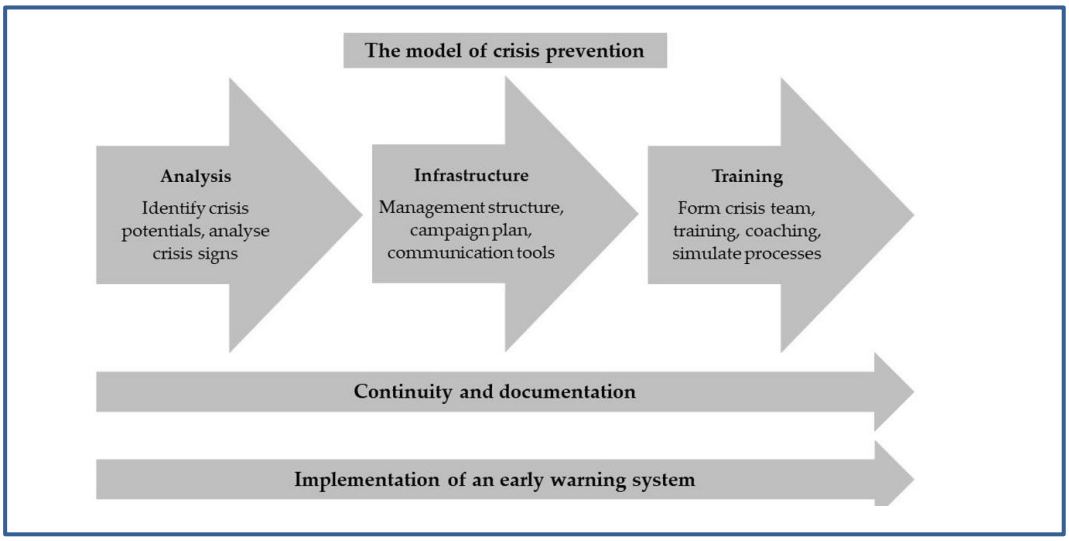

Figure 12: The Model of Crisis Prevention According to A. J. Garth, 2008

The decisive factor is the immediate recognition of the situation, the immediate application of the necessary measures and the subsequent analysis of results and measures taken.

In principle, the cause and course of a crisis hold the opportunity for positive innovative decisions or negative catastrophic consequences for the future (Roselieb & Dreher 2008).

5.1.3 Emergency – A Management Challenge

The emergency situation means either a predicted escalation of a risk or crisis constellation or an acute unforeseen and unforeseeable emergency event. In medicine, emergency always means a major threat.

The main potential emergencies in medicine are cardiovascular arrest, stroke, acute airway obstruction, major blood and volume loss and shock.

A medical acute emergency is an emergency that no longer allows any time delay until emergency measures are initiated. Time delay in the use of the emergency program means further harm to the patient. For example, for each minute of resuscitation, the chances of success decrease by 10% for each minute of cardiac arrest (Thöns et al. 2007). Emergency means the immediate and direct use

of targeted emergency measures, the use of a preventive emergency program that is permanently at the ready. In any situation, emergency means loss of safety, acute threat with the consequential damage.

Emergency management is always the top prevention task. Emergency management means:

- Unconditional targeted prevention thinking, in preparation for a quick and targeted response in an emergency
- Planned and organized approach in an emergency
- Rapid, targeted response to damaging events

so that the emergency does not become a major disaster (Thöns et al. 2007).

According to the BSI[18] standard, emergency management in hospitals, as in any medical company, means managing security in the sense of operational continuity management (BSI 2008).

[18] BSI: Bundesamt für Sicherheit in der Informationstechnik (German Federal Office for Information Security).

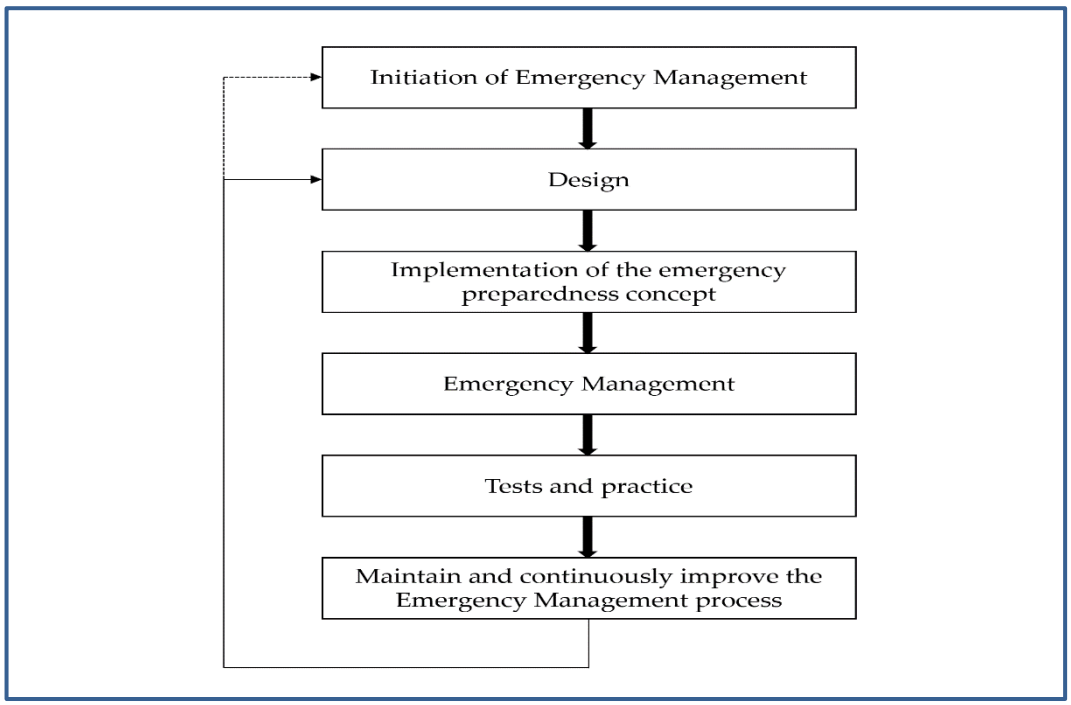

Figure 13: Emergency Management Procedure. BSI Emergency Management: Standard 100-4, Version 1.0

5.1.4 Critical Incident Reporting System (CIRS)

All QM models developed for and applied in the health sector have two cardinal features in common as benchmarks of high quality. Clearly formulated at the beginning of 2012 in the new and first European standard 15224:

- Patient safety
- Risk management

An effective management measure to establish, achieve, maintain and continuously develop these two quality objectives without compromise in all areas of health care is the management of a CIRS.

The historical development of Critical Incident Reporting CIR began in 1818 in the USA after the explosive explosion of the manufacturer Du Pont on 19 March 1818 with the development of the accident pyramid from Du Pont for conceptual

work safety. The concept of the Du Pont accident pyramid expresses a significant correlation between the number of unsafe acts and the number of minor and severe accidents (Roughton 2008; Käfer 2010; Preuße 2010). The reduction of unsafe acts leads to a reduction in the frequency and severity of resulting accidents.

I his research work, Heinrich worked out regularity in the numerical relationship between accidents and near-accidents, between mistakes and near-misses. The so-called Heinrich's Law (Heinrich's Triangle 300-20-1) states that it is not the major errors that lead to disaster, but the minor errors that precede a disaster (Heinrich 1941). In 1954, CIR was used for the first time in the American Air Force. In 1996 Staender and Scheidegger introduced the first CIR in medicine in Basel (Scheidegger & Sauter et al. 1996; Staender 2000: 65-82). In 2006, Rall (Rall et al. 2006: 20-24) published the characteristics of effective incident reporting systems to increase patient safety in anesthesia and intensive care. These two medical disciplines are characterized by a high degree of complexity in all diagnostic and therapeutic processes of modern surgical medicine (Scheppokat 2004: 998-999; Hansis 2005: 179-183; Scheidegger 2005: 169-174). According to Rall et al. the tenth most frequent cause of death in Germany is due to errors in medicine. According to their own information, the Medical Services of the Health Insurance Companies (MDK: Der Medizinische Dienst der Krankenversicherung) issued a total of 5,094 specialist medical reports on suspected treatment errors in 2016. In the same period, the number of expert opinions carried out by the MDK after a suspected treatment error rose from 14,828 to 15,094.

5.1.4.1 Concept of Error Culture

The establishment and management of a CIRS has 4 objectives (Schreiner-Hecheltjen 2015: 165):

1. Preventing errors from taking effect
2. Having a good risk culture
3. Having a good error culture
4. Having a good safety culture

A functioning and effective CIRS presupposes an error culture in the sense of an error culture B between all those involved. While the type A error culture describes a philosophy of blame and sanction, the type B error culture includes a state in which errors are accepted, in which transparency prevails, and in which errors are particularly regarded from the point of view of how a repetition of the error can be avoided and what is to be learned from it. The error thus has the function of a teaching base. Prevention, in the sense of avoiding a repetition of a mistake, is only possible in line with a cultural change in dealing with mistakes. In this context, the path of personal condemnation after type A error processing should be abandoned and replaced by the path of an open safety culture with type B error processing (Köberling 2005: 1042-1044; Köberling 2007: 936-938; Hager-van der Laan 2010: 260-262). According to the concept of a safety culture, errors and incidents are problems of the overall system and no longer of the individual. With these considerations, the term error culture was questioned and it was suggested to replace it with the term safety culture (Schrappe 2007: 516-521; von Eiff, Middendorf 2007).

The APS suggests 7 phases for the successful introduction of a CIRS in a hospital and in practices or an MVZ[19] (Artes & Hart 2006; Schrappe et al. 2007; Schwanekamp 2008):

1. Decision phase
2. Planning phase
3. Introduction of CIRS
4. Implementation of evaluation and assessment
5. Organization of improvement measures in risk management
6. Dealing with feedback
7. Evaluation of initial experiences in CIRS

The explanation of the individual phases is not the subject of this work.

[19] MVZ: Medizinisches Versorgungszentrum (Medical Care Centre).

5.1.4.2 Benefit Opportunities and Perspectives

A CIRS is a QM program for the detection, processing and prevention of critical events and near misses. The CIRS concept is particularly suitable for detecting critical events in typical routine treatments and long-established standards. Medicine could learn from space and aviation that continuous registration and the prompt processing of near misses that results, has a greater learning potential than the usual complication conferences. CIRS helps to prevent the transition from error to harm. Maintaining a CIRS is an effective internal communication element of the institution. CIRS is an effective element in risk management to increase patient safety, as strongly insisted upon by EU standard 15224 of 2012. CIRS is an effective CIP[20] in the overall QM based on the ISO standards of a clinic. The first concepts for setting up CIRS in a network between various hospitals and hospital groups are underway both nationally and internationally. The "CIRS Working Group" of the APS is considering the draft of a CORE data set CIRS (Schwanekamp 2008; Hart & Cartes Febrero 2007). Following the Swiss model of CIRNET, a web-based communication platform on which all hospitals practicing CIRS exchange information, the CIRS working group and the APS are also planning to develop a CIRNET concept in Germany. Comparable disciplinary concepts are being tested and developed in the DGAI and the BDA in cooperation with ZEFQ. Today, CIRS is an established assessment standard for quality in medicine, firmly anchored in the national, Germany-wide interdisciplinary and interdisciplinary network for CIRS as reporting and learning systems for critical events CIRSmedical[21], which was awarded the Medicine

[20] CIP: Continuous Improvement Process is a way of thinking that aims to strengthen the competitiveness of companies with constant improvements in small steps. CIP relates to product, process and service quality.

[21] CIRSmedical is anonymous and enables mutual learning from safety-relevant events such as near misses, critical incidents, errors and risks in health care. For this purpose, it can be used by all healthcare workers as well as patients.

Management Prize by the ÄZQ[22] in 2012 (Thomeczek 2012). The Patients' Rights Act, registered in the BGB[23] in February 2013, has added another positive accent to the safety culture of medicine. According to a survey by the European Commission in 2012, Germany is among the top nine nations that deal with the topic of patient safety in a particularly goal-oriented manner (Jonitz 2014).

However, even with a well-run CIRS, a residual risk cannot be ruled out. Strictly adhering to anonymity, which is sometimes discussed in different ways for good reasons, still poses certain problems from a medical-legal point of view. In terms of personnel policy, a CIRS must not be abused. The financing of CIRS with all necessary resources must be specifically approved by the management in awareness of its overall value for the entire institution. The quality of CIRS does not depend on the numerical number of reports, but on their processing and the development of resulting improvement measures. Limits and problems in the successful development and management of a CIRS in health care are determined by the conviction and commitment of each individual contributor.

5.2 SELECTED QA TOOLS

5.2.1 Evidence-Based-Medicine

The term evidence-based medicine is derived from the term “evidence” and describes a method of scientific knowledge that has defined criteria for the

[22] ÄZQ: Ärztliches Zentrum für Qualität in der Medizin – The Medical Centre for Quality in Medicine is a scientific institute jointly sponsored by the German Medical Association and the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung).

[23] BGB: Das Bürgerliche Gesetzbuch, The German Civil Code is the central codification of German general private law.

evaluation of scientific studies and their synthesis (Kunz & Ollenschläger et al. 2014: 15 et seq.). Evidence-based medicine ("empirical evidence-based medicine") is a more recent developmental direction in medicine with the explicit requirement that patient-oriented decisions in medical treatment should be made, if possible, on the basis of empirically proven effectiveness. The term was coined in the early 1990s by Guyatt Gordon and Sackett David at McMaster University in Canada (Sacket & Rosenberg 1996: 71-72). The concept was first published in German-speaking countries in 1995 (Deutsches Netzwerk EbM[24]). While evidence in the English language has the meaning "proof, evidence, indication", depending on the context, the meaning in the German language is "obviousness", which does not require proof. The English translation for this would be "obviousness". A proposed designation "evidence-based medicine" has not been able to gain acceptance in Germany. In 2000, "evidence-based guidelines" were introduced into the German Social Code SGB V with §§ 137e, 137f, 137g, 266 and structured treatment programs for chronic diseases (Becker & Kingreen 2014: SGB V).

The application of evidence-based medicine in Europe has not led to directives, i.e. binding regulations, but to guidelines that define corridors and allow justified deviations (Ollenschläger & Bucher 2004).

Rosenbrock postulates evidence-based medicine as well as QA in health-related primary prevention (Rosenbrock 2004a: 71-80). In both curative and preventive medicine, therapeutic decisions are derived from three sources:

1. Processed study results: external evidence
2. Clinical experience: internal evidence
3. Patients' wishes and preferences

[24] Deutsches Netzwerk EbM, Chronik der EbM: http://www.ebm-netzwerk.de.

According to Schreiner-Hecheltjen three definitional elements are important in today's understanding of the definition of evidence-based medicine:

1. **Explicit presentation of the basis for decision-making**
   Evidence Based Medicine is a method of recognisably disclosing the basis of medical decisions so that they can be used and communicated with regard to individual patient care, education, institutional decision-making situations, implementation by cost bearers and health policy decisions.
2. **Combination of internal and external information**
   Analogous to the approach of Sackett, D.L. (Woolf & Grol 1999: 527-530), the existing internal information, clinical experience, is combined with the best available external knowledge (studies, meta-analyses). The external information can be both individual studies and syntheses of studies.
3. **Assessment of validity (rating) and weighted recommendations (Grading)**
   The external information is not only identified, but also assessed according to scientifically developed criteria with regard to its internal and external validity: Rating process - and weighted with regard to recommendations for the concrete clinical or other decision-making situation: Grading.

5.2.2 Off-Label-Use

"Off-Label-Use" is understood to mean the use of a medicinal product outside the areas of application (indications, patient groups) approved by the national or European regulatory authorities. In principle, physicians are allowed to use medicinal products beyond the scope of the marketing authorization. However, such off-label use is only covered by health insurance in exceptional cases.

This is because, in principle, a drug can only be prescribed in Germany at the expense of the statutory health insurance if it is used for the treatment of diseases for which a pharmaceutical company has obtained marketing authorization from

the competent authority (Federal Institute for Drugs and Medical Devices – BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte), the Paul Ehrlich Institute (PEI) or the European Medicines Agency (EMA). This results in requirements for the relationship between physician and client/patient and for setting the course for conflict-free drug therapy from the funding agencies and the courts. Both require a detailed, precisely documented explanation of the specific indication of the medicinal product, including all potential side effects, in the absence of an alternative.

5.2.3 Norms and Standards

The national and international standards form the authoritative background for QA (Stratmann 2000; Gaebig 2002; Rothery 1994).

A standard is a document drawn up, and agreed upon by the parties involved, by a national, European or international circle of experts and by a recognized institution concerning a process or a service. The document of a standard contains technical characteristics and/or other concrete criteria to be applied uniformly in the form of rules, guidelines or definitions. The application of a standard guarantees all parties involved a clear reference in the area of technical characteristics, quality, feasibility and safety. Products and services bearing the seal of a standard should be used in a targeted manner and can be both comparable and compatible. A standard is a summary of best practice on a defined subject. The creation of a standard is the result of joint work by research institutes, manufacturers and users under the charge of a national standards organization.

Norms, like standards, have no direct legal force, but can serve as recommended legally- binding references in the indirect relationship of third parties.

In the standardization project, up to date technology and science, economic efficiency and international harmonization are strictly taken into account.

The German Institute for Standardization DIN e.V. with its headquarters in Berlin is, according to the agreement with the Federal Republic of Germany of 5 June 1975, the institution responsible for standardization work in Germany and represents German interests in the worldwide and European standardization

organizations. DIN as DIN EN ISO ensures German participation in international standardization. As already mentioned, standards do not have the legal force in themselves. In its ruling of 14 May 1998 - VII ZR 184/97, the Federal Court of Justice (BGH) stated that DIN standards are not legal standards, but recognized regulations with the character of recommendations[25] [26](Schreiner-Hecheltjen 2015: 66).

Their application is voluntary. Only through the legal acts of third parties can standards acquire binding force when they are referred to in private contracts or in laws and regulations. By applying them, legal disputes can be avoided because they contain unambiguous specifications. Standards are not intended to provide technical solutions, but rather to formulate requirements that allow for different solutions. They promote innovation, technology and knowledge transfer as well as market maturity.

Standardization activities relieve the state of rule-making and at the same time ensure that the current state of science and technology is reflected in the standard. The state has a particular interest in standardization when it comes to maintaining public order, e.g. in occupational health and safety.

The state provides DIN with project-related funds for these areas. Following Schreiner-Hecheltjen, standards can have the following meaning:

- **Economic**
  - as an indicator of innovative technological performance
  - as a vehicle for technology transfer
  - with a positive effect on competitiveness

[25] DIN e.V., 1998, QM, (Statistik, Umweltmanagement, Normensammlung) statistics, environmental management, collection of standards. DIN EN ISO 8402.

[26] DIN e.V., 2000, QM, (Statistik, Umweltmanagement, Normensammlung) statistics, environmental management, collection of standards. DIN EN ISO 9000:2000.

- through the opening of new markets

- **For a company or organization**
  - as an internal contribution to the company's success
  - as knowledge and time advantages
  - to improve colleague - customer contacts
  - to reduce transaction costs
  - to reduce adaptation costs
  - to reduce liability risks
  - to improve its image

- **For the client or consumer**
  - to increase security
  - to improve trust
  - to raise quality
  - as a simple operation

The European Committee for Standardization: Comité Européen de Normalization - CEN - based in Brussels with 30 national members of the EU member countries in the standardization organization - is responsible for the European Standards - EN.

At European level, standards are an expression of self-government. Mandates for concrete standardization projects are awarded by the European Commission within the framework of its directive.

The different abbreviations from the number of the standard mean:

DIN: DIN standard with exclusive or predominantly national significance
DIN EN: German version of a European standard
DIN ISO: Unchanged national adoption of an ISO standard
DIN EN ISO: Standards under the auspices of CEN and ISO

The International Organization for Standardization ISO (gr: isos = “equal”) - based in Geneva - with representatives from 150 countries - also from the former UNSCC - United Nations Standards Coordinating Committee - was conceived as

an international association of standardization organizations of international standards. The German Institute for Standardization e.V. (DIN) has been a member of ISO for the Federal Republic of Germany since 1951.

In medicine, three standards have become established for practice from the plethora of ISO standards:

- ISO 9000: (Qualitätsmanagement-Systeme: Grundlagen und Begriffe) Quality Management Systems: Fundamentals and Concepts[27] (Glaap 1993)
- ISO 9001: (Qualitätsmanagement-Systeme: Anforderungen) Quality management systems: Requirements[28] (Campbell & Scheibler 2003; Cassel 2007)
- ISO 9004: (Qualitätsmanagement-Systeme: Leitfaden Leistungsverbesserung) Quality Management Systems: Performance Improvement Guide[29] [30] (Brauer 2002)

These numbers "9000 ff" are followed by the last year of editing and updating. ISO standards are usually reviewed every four years.

The currently valid DIN EN ISO standard is 9001:2015 after the last revision in 2015.

At the beginning of 2013, the first publication of the German version of DIN EN 15224 based on the concept of DIN EN ISO 9001 with supplementary aspects of patient safety and patient risk took place as the basis for a European standard for all services in the health care sector.

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[27] DIN e.V. 2000, DIN EN ISO 9000:2000.

[28] DIN e.V. 2000, Normen DIN EN ISO 9000:2000.

[29] DIN e.V. 2000, Normen DIN EN ISO 9000:2000.

[30] NQSZ im DIN 2000, DIN EN ISO 9000:2000.

Norms are often referred to as standards in practice, although the terms are not homogeneous according to their exact development definitions. A standard has sound directional guidance. A standard is a guiding idea.

A standard is a publicly available document developed with the participation and consensus of all parties involved. A standard is based on results from science and technology with the aim of promoting the common good. Structural, process and outcome quality can be formulated and reviewed with the help of standards and criteria. Standards are an ideal way to continuously improve quality, because they show actual-target-standard-values through regular measurements as a basis for measures of desired improvements in success. Baartmans, P.C., and Geng, V., define quality by measure in health care with the introduction of quality standards (Baartmans & Geng 2006). In medicine, the standard procedure for a specific problem is defined as a guideline (Bollschweiler 2004: 493-500).

According to the definition of Field M., the essential content of standard procedures written in guidelines is to provide systematically developed information and instructions from the members of a specialty for diagnostic and therapeutic procedures, for specific clinical pictures and about the scientifically generally recognized and justified methods of treatment (Field & Lohr 1990). The relevant specific performance and quality standard is formulated (Field & Lohr 1992; Möller & Seghezzi 2001).

5.2.4 Indicators

An indicator (lat. Indicare = to indicate) is a tool that indicates certain information that is generally not directly measurable.

The following definitions are intended to make the term "indicator" more tangible according to Schrappe (Schrappe 2004b: 408-419; Schrappe 2004c: 420-425):

- an indicator is a measurable fact that is meaningful with regard to a selected phenomenon (indicandum).
- an indicator is a variable whose value is typical for a state, a phenomenon, and with which the degree of achievement of a goal can be measured.

- an indicator is a tool that makes it possible for tracking to become transparent processes by indicating the attainment of or departure from certain states and subsequently enables information about a certain fact or phenomenon.
- an indicator is an operator that generates an indication.
- an indicator is a parameter that can be measured well and that validly predicts defined events and processes.

At the heart of the definition of an indicator is prediction. The indicator itself does not itself always indicate quality, but refers to the fact that the probability increases or remains constant that certain events are imminent.

Indicators are classified according to their conditions of use.

The following classification is formulated for the application of indicators in health care:

- Epidemiological classification
- Classification according to quality aspects
- Content classification - hospital level
- Content classification - health care system

Following the classic definition from the JCAHO, a quality indicator is a quantitative measure that can be used to monitor and assess the quality of important process, performance, management and support functions that affect an outcome, service and production process.

An indicator is not a direct measure of quality. It is more of a tool that can be used to assess performance and draw attention to potential problem areas that need intensive review within an organization.

Incorrectly, the term quality indicator is often used not in the sense formulated by T. Sheldon, but with the term key figure (Kazandijan, Wood & Lawthers 1995: 39-46).

Indicators are not to be seen solely as key figures, but working with indicators implies a method of cognition and management at the programmatic and normative level, which gives great importance to traceability and continuous improvement as a supporting idea and central concept (Sheldon 1998: 45-50).

A quality indicator is, in agreement with the definition of quality indicators (Schrappe 2004c: 420-425), in health care in consensus papers of ÄZQ, AWMF and ZEFQ (ÄZQ, AWMF, ZEFQ 2002: 4 et seq.). An indicator for quality is to be understood in a first approximation as a construct which, against the background of the complexity of medical service provision, enables an explicit representation of the quality of care with a justifiable effort of measurement (ÄZQ 2009: 12 et seq.). The assessment of the measurement effort and the type of quality aspects to be represented, differ depending on the use of the indicator; indicators that describe the quality of care from the perspective of the health care system differ from indicators from the perspective of payers or institutions.

The Medical Centre for Quality in Medicine (ÄZQ) published a position paper of the expert group on quality indicators (Geraedts & Jäckel et al. 2005: 329-331).

For the term indicator, the following general principles are defined by AHRQ - Agency for Health Care Research of Quality (Davies & Geppert 2001: chapter 2 et seq.):

1. **Selection:** Indicators must be selected from a large number of potentially quality-relevant parameters. The effort for indicator measurement has to be in reasonable proportion to the expected benefit. One of the most common misunderstandings is that parameters of all kinds are immediately referred to as indicators, although such measured values only describe a small aspect of a process, but do not capture the totality of the process.
2. **Abstraction:** Indicators may or may not be directly relevant to quality and typically are not.
3. **Targeting**: Indicators describe quality, but are dependent on the respective perspective and understanding of quality.
4. **Feasibility:** according to Kazandijan (Kazandijan 1995: 25-27), "Indicators do not measure quality, people do!". This statement refers to the fact that the measurement of the indicator is the task of motivated and correctly performing staff. There must be no organizational or other obstacles to measurement.

5. **Validation:** Indicators need to be checked by means of a precise methodology whether they measure what they are supposed to measure and whether they do so with sufficient accuracy.

The characteristics defined and required for an indicator:

- Validity
- Reliability
- Objectivity
- Practicability

Which mean:

Validity. A measurement procedure is valid to the extent that it captures what it is supposed to measure (Rost 1996: 34). One criterion for validity is the selection of the individual questions or general items from which the measurement procedure is formed. In practice, two forms are significant: congruent and discriminant validity.

Congruent validity exists when the measurement procedure provides essentially the same results as other measurement procedures that are intended to capture the same thing.

Discriminant validity exists when the measurement procedure reveals differences where they must exist according to the definition of the construct. Discriminant validity is also referred to as sensitivity.

Reliability means dependability. A measurement procedure is reliable to the extent that it delivers the same results under the same conditions.

Objectivity of a measurement procedure is the extent to which it produces the same results regardless of who is using it. Three types of objectivity can be distinguished: execution objectivity, evaluation objectivity and interpretation objectivity.

A procedure is *execution-objective*,

if the persons using the procedure cannot influence the results.

Example: written survey with guaranteed anonymity.

A procedure is *evaluation-objective*,

if different people arrive at the same results when coding the data.

Example: Questionnaires with predefined answer categories.

A procedure is *interpretation-objective*,

if different people come to the same further interpretations in view of the consistent results.

Practicability of a measurement method is given to the extent that it can be used under the given conditions.

Other AHRO criteria for an indicator are:

- **Ocular variability**
  Clinical applicability and relevance
- **Precision**
  Independence from random or systematic differences in patient collectives
- **Comorbidity adjustment**
  Availability of a correction if differences exist
- **Construct variability**
  Corresponding results by other indicators
- **Practical applicability**
  Combinability with other indicators, ability to actually improve quality

The AHRO formulated the RUMBA rules, the criteria that make it possible to subsequently check results (Kazandijan 1995: 25-27; Ishikawa 1982: 29 et seq.).

Each individual criterion should meet five requirements.

As already mentioned in chapter 2.6.1, the RUMBA rule is composed of the first letters of the following terms:

- Relevant: Criterion relevant, directly related to the topic
- Understandable: Clear formulation of the criterion understandable for all without room for interpretation
- Measurable: Clear measurability of the criterion

- Behaviourable: Defining the criterion for unambiguous observability with clearly defined responsibility
- Attainable: Criterion for the attainability of the described target

The RUMBA rule summarizes as properties for concrete indicators:

- Indicators should be relevant to the underlying problem
- Indicators must be understandable for staff and stakeholders
- Indicators must be measurable with high reliability and validity
- Indicators must be capable of being influenced by measures
- Achievable goals must be definable through indicators

To develop indicators, the following four steps should be distinguished:

1. Identification of the problem that gives rise to the use of measurement methods
2. Formulation of the requirements for the measuring instruments
3. Analysis of the problem with selection of possible measurement instruments
4. Validation of the instruments with definition of the indicator

5.2.5 Key Figures

Key figures are an important measurement tool in QM. In recent years, the trend towards being number-oriented has increased.

Medical companies must increasingly see themselves as business enterprises for health because of their health policy responsibility. Shareholder and stakeholder value concepts have found their way into medicine, as has earned value analysis (EAV) with the basic test values: planned expenditure, actual expenditure, service rendered, estimated residual and estimated total expenditure, schedule variance (Anbari 2003: 12-23; Schmidt & Junker 2003: 4-5). Cost variance must increasingly be part of the economic evaluation of medical services.

Economic management of medical services requires the precise quantification of facts instead of prose reports. Clear, quantified facts are required. Numerical quantification in a business process needs key figures.

Indicators are measured values for the meaningful and meaningful condensation and comparison of existing information (Groll 2003: 55-57).

Definition and function of key figures are:

- Values that are measurable
- Values that are measured
- Values that condense information
- Values that set a relationship to each other
- Values that are to be compared with each other
- Values that are compared with a reference value

A key figure is a measurement figure which serves to quantify and which is based on a provision for the quantitative reproducing measurement of a quantity, state or process. Indicators are used to make processes measurable and thus capable of improvement. In this function, they are also explicitly required and mandatory by standards (Ossola-Haring 2006: 113 et seq.).

The following definitions and explanations are adapted from Schreiner-Hecheltjen

Key figures are divided into:

- **Absolute key figures**
  Examples: Process time, number of employees, project costs
- **Relative key figures** = ratio key figures
  - Dimensional relative ratios
    Example: Costs per customer/patient
  - Dimensionless relative key figures
    Example: percentage of a process, return on sales

A key figure value is the value of the key figure at a certain point in time. For example, the number of employees on 31.12.2019.

Indicators therefore need comparative values or a context in order to be meaningful. The importance of indicators lies in the possibility of precisely setting and agreeing on goals and agreements, precisely describing and assessing states or changes in state:

- compared to time
- compared to empirical values
- compared to guideline values (specifications).

Key figures can be used within a project in:

- Initialisation
- Agreement on objectives
- Description of activities
- Planning
- Effort estimation
- Steering, controlling and progress management
- Performance measurement

Key figures must be developed professionally.

With professionally used key figures:

- Project goals, work packages and agreements can be formulated precisely and monitored more easily
- Agreements are fixed more precisely for the contracting parties and effort estimation and implementation are facilitated
- Progress can be communicated and continuous development made transparent
- Strengths are emphasised through transparency, confidence and motivation among project and company members
- Uniform interpretations of data and results are ensured for all company members through transparency
- Transparency avoids misunderstandings

In order to be able to work successfully with indicators, minimum requirements are necessary from all those involved. Everyone must be prepared to engage in precision. Transparency in the project/company must be achievable. A project plan must be completely up-to-date and feasible.

In principle, different key figures are to be defined according to differentiated scales:

1. **Cardinal scale**
   Objective scale of values with a fixed zero point

Example: costs, time consumption

2. **Ordinal scale**
   Subjectively defined scale that expresses a marginal order.
   Example: School grades for customer satisfaction
3. **Relative values**
   Values that describe a quantity in relation to another quantity, often as a percentage or factor.
   Example: Proportion of budget used, proportion of activities completed.
4. **Absolute values**
   Values that describe a quantity without reference to another quantity with ordinal or cardinal scaling.
   Example: budget consumed in euros, number of completed activities
5. **Reference to the past**
   Values measured or planned in the past
   Example: Costs of the last project month
6. **Reference to the present**
   Values measured or planned in the present
   Example: accrued costs at current project status
7. **Future reference**
   Values assumed or specified for the future
   Example: predefined total budget for a project
8. **Original values**
   Measured values that have not been aggregated, calculated or estimated.
   Example: Number of completed activities
9. **Derived values**
   Values derived by calculation, aggregation trend analysis or estimation.
   Example: Rate of completed activities

The key figure control of a process proceeds with the following seven phases, in which the key figures can make clear statements:

1. **Orientation**
   - Check feasibility
   - Establish comparability

2. **Initialisation**
   - Concretise objectives
   - Prioritise sub-goals
3. **Goal definition**
   - Operationalise objectives
   - Settle conflicts of objectives
4. **Planning**
   - Map out the operational path
   - Determine performance structure
5. **Effort estimation**
   - Evaluate activities
   - Establish plausibility and comparison
6. **Control**
   - Check target/actual values
   - Record need for action
7. **Measuring success**
   - Determine extent
   - Communicate successes

5.2.6 Peer Review

Peer reviews are a special form of audit in the medical field, characterized by the fact that they are carried out by professionally and hierarchically equal persons (Grol 1994: 147-152). A peer review is conducted by two to three professional colleagues. In the preparatory phase, the department to be visited, e.g. a laboratory, a ward or a practice, fills out a standardized questionnaire. The questionnaire contains information on the respective specialist department, its performance development, QA procedures and the admission, diagnostics, treatment, care, transfer, discharge as well as the completion of treatment of the patients. The visitation itself usually lasts one day, during which information is collected through assessment protocols.

In addition, documents are evaluated, medical care processes observed and targeted interviews conducted. At the end of the peer review, expert feedback is given with suggestions for improvements. Finally, the visitors

prepare an audit report for the department visited. The contents of the audit report are treated confidentially. Only the department visited decides whether and with whom the results are discussed. The conducting of peer reviews is considered a valuable proof of quality in the context of certifications.

5.3 INTERNATIONAL QUALITY INDICATOR PROJECT (IQIP)

The QIP Quality Indicator Project began in 1985 in the USA, developed at Maryland Hospital with the aim of identifying ways to improve care and safety for patients (Hilgenfeld 2009). The project quickly gained a lot of interest worldwide. Since 1991, health organizations outside the USA have participated in the project. In 1997, the nomenclature was changed to IQIP to reflect the needs and regulations of non-US participants in the project, and today more than 500 health organizations participate worldwide. IQIP is also available in Germany with increasing numbers of participants (Möller 2001).

The IQIP program is a system for evaluating medical care services in hospitals and other health care facilities. It is based on the measurement of scientifically sound and internationally applicable performance indicators. The IQIP program allows the assessment of performance and quality development both within a health care organization and in comparison with other participating facilities. The comparison facilities can be selected according to predefined classifications and criteria. The anonymity of the participating institutions and data protection are preserved. Examples of important topics of the IQIP program are acquired infections and medication errors.

Internationally, the IQIP program has proven itself for almost 20 years as the basis for certifications and accreditations according to all common procedures. It creates essential prerequisites for fulfilling the increasingly strict legal obligations for QA and supports the transparency of performance and

quality that goes hand in hand with DRGs[31] and LEPs[32]. In connection with the specific QA procedures, the IQIP program enables an interdisciplinary outcome assessment for the first time. The IQIP program represents a sophisticated and goal-oriented QM tool for external QA (Schreiner-Hecheltjen 2015: 114).

5.4 CERTIFICATION

Certification of conformity is defined by EN 45012 as an action by an impartial third party to demonstrate that there is reasonable confidence that a properly designated product, process or service is in conformity with a particular standard or other normative document (Anonymous 2001, DGQ 2003: 26 et seq.).

Certification is a process of verifying the orientation of a standard and its compliance. Products, training courses, courses, proof of training standards, qualification and competence of staff, process and entire systems are certified. Certification is applied for at an accredited institution. The procedure is carried out by an impartial institution or person and, if the result is positive, demonstrates the ability to provide a defined service, compliance with existing standards, agreements and the company's own specifications. Certification means a declaration of confidence regarding the quality of a product, a service and that the system is oriented towards the standards of a QM system in all its activities (Kahla-Witzsch 2002). Confirmation is given of processes that

[31] Since 2004, hospitals no longer charge according to daily rates, but on the basis of diagnosis-related lump sums (DRG = Diagnosis Related Groups).

[32] The scientifically based method "Performance recording in nursing" (LEP: Leistungserfassung in der Pflege) consists of standardized recording and statistical evaluation procedures for health care and nursing services in the inpatient and outpatient sector.

conform to standards, the existence of a QM system, customer orientation and responsibility towards the public.

Certificates represent a leap of faith in quality capability (Selbmann 2007: 3-4). An essential prerequisite for a certificate is the demonstrable handling of visible quality deficiencies with verifiable improvement measures as defined in QM. In the case of products, quality deficits can be measured against the objects. For services, comparison with other services, conformity with recognized standards and customer satisfaction are decisive. An organization has specific, individual, internal and external customers.

In the certification process, a distinction is made between the following audits (Gietl & Lobinger 2003/2004; Klakow-Franck 2005: A-1486):

- Internal audit
- Pre-audit
- Certification audit
- Surveillance audit

Audit

Audit refers to the test procedure by which the certification capability is determined. The documents appertaining to the QM system are examined and hearings are held in selected areas and performance levels. In an audit, the current state is analyzed and after certification has been achieved within the framework of certification control, as well as whether the defined quality objectives and the required processes have continued to be met or if further development has taken place.

Investigations are conducted by internal or external independent experts (Oberender & Hacker et al. 2002: 356-358):

- To what extent requirements and guidelines are fulfilled
- If a system meets the standards or self-imposed goals
- Processes and products are quality capable
- People are adequately trained and undergo further training.

The procedure serves to:

- Determine the performance of a system
- Inform the management about the implementation of the agreements
- Determine the prerequisites for a quality award.

The audit procedure also serves to monitor further development or renewal of the quality certificate.

In the internal audit, an institution systematically audits itself according to the specifications of the chosen standard system for certification. The internal audit is an institution's most important QM tool and navigator. The internal audits are carried out by trained staff from the institution itself. The various processes are examined and the changes necessary for the desired certification are suggested along with a prepared action plan. According to the degree of quality deficits identified, the action plan is programmed and processed.

Internal audits are a basic component of the ongoing QM of an institution in order to achieve the quality level required for certification or to maintain it for re-certification. Internal audits should take place on an annual basis in all areas of an institution. The internal auditors should not have any responsibility in the area to be audited. They audit the areas for their compliance with the defined quality requirements and draw up recommendations for improvement and further development. Internal audits are useful independently of certification, since the institution not only checks standard-compliant and internal performance, the pursuit of objectives according to the quality agreements, but also useful information is gained for the company about its change needs.

The QM of a company essentially includes the training and further education of the staff in special fields and quality science. This also includes the training of a sufficient number of auditors who can carry out the independent internal audits required by the standard.

The pre-audit includes, according to a list of questions from the certification body, the verification of the compliance of the entire QM system with the standards and the self-imposed quality characteristics. The pre-audit can be carried out by the selected certification body or another suitable QM consultancy. In the pre-audit, the deficits and inconsistencies measured against a defined QM parameter list are

identified and recommendations are made for revision with a view to planned certification. The duration of the pre-audit is one to two days, but the correction of the deficiencies often takes months. An audit report is drawn up by the certification body that includes conformities to the standard or deviations and measures to remedy them. After a phase of adjusting the deficits in the standard, the certification audit takes place.

According to Schreiner-Hecheltjen the following audit perspectives can be distinguished:

- Compliance Audit: Compliance with a set of rules
- System Audit: Audit of the management system
- Process Audit: Audit of individual processes
- Product Audit: Testing of products with regard to customer expectations
- Project Audit: Determination of the progress of projects
- Document Audit: Audit of documentation care and document control

The preliminary work of the institution to be certified contains the following requirements:

- Quality mission statement
- QM System
- Internal audits
- Annual management review
- Quality Manual QMH
- Selection of a certification body
- Pre-audit (chosen certification body, other approved QM consultancy)
- For the certification audit. verbal information, allowing observation opportunities and spot checks, clarifying discussions, processing the documents of the certification body (e.g. questionnaire).

During certification, two external auditors from QM and an appropriate specialist discipline, in the health care system of an appropriate medical specialty,

randomly examine defined processes of the institution to see to what extent the standard requirements, in the case of certification, e.g. according to DIN EN ISO, the requirements formulated in the five QM processes of the QM cycle, in the version of the catalogue of criteria of DIN EN ISO standards published by the NQSZ in 2008 (annex 3) , are implemented in clinical practice. Minor deficits allow certification with formulated indications; more serious deficits must be addressed as a deviation from the required quality level before certificate recognition.

The certification audit subjects the entire system, the entire institution in the QM process to a final audit after weak points from the pre-audit have been eliminated. If the requirements formulated in standards and self-agreements are met, the certificate is issued.

A certificate is limited in time with a validity of three years and annual monitoring until re-certification. Quality development is usually monitored annually by the certification company until re-certification (Liebelt & Schrappe 2004: 468-482).

Surveillance audits, which are carried out once a year to inspect the further development of the QM system, can also be organized as internal audits.

QM systems in medicine and, in particular, QA programs require the systematic assessment of structural, process and outcome quality according to defined rules.

QM and QA must also be assessed in terms of cost-effectiveness (Daigh 1991: 42-52). For their assessment, costs, benefits and their relationships have to be evaluated. Integrated quality tools such as guidelines, standards, patient pathways and telemedicine form the basis for systematic and effective QM. The costs of QM are quality costs (Fleming & Koppelmann 2004: 15-17). According to Daigh quality costs can be divided into error prevention, testing and error costs.

As a rule, the largest part of the quality costs in the hospital are the error costs with 75% of the total revenue, audit costs make up 20% and error prevention costs 5% of the total costs. The investment costs of QM, i.e. error prevention and inspection costs, are compared with the savings from a reduction in error costs and the clinical benefits. With increasing quality, the error costs decrease, while the error prevention and testing costs increase. It makes economic sense to minimize the aggregated costs, the total costs (Schmidt 1996: 224-227).

The result of studies on cost-effectiveness in a QM system predominantly confirms an increase in efficiency, a strengthening of strategic success factors such as an increase in patient and staff satisfaction, a higher level of training in referring physicians, an increasing quality of treatment and a competitive advantage (Zink & Voß 1997). Although comprehensive cost-effectiveness analyses are still lacking due to different target parameters, a QM system (QMS) is generally classified as cost-effective.

According to the requirements of the ISO standard the certification of an institution means:

- Voluntary decision for high quality
- Award for quality according to international standards
- Award for quality at a high level
- Increase in confidence of customers/clients/patients
- Strengthening the economic factor of the company
- Stabilisation and further development of quality in the company
- High personal commitment
- Creative path to performance enhancement
- Creative path to occupational and personal professionalism
- Individual personal decision of each employee in the institution on quality
- Differentiated approach to risk
- Creative way to minimise risk
- Differentiated positive handling of mistakes
- Differentiated development of error impact analyses: Development of an error culture
- High costs: material and ideological

The precise processing of all requirements from the five QM processes of the QM cycle according to Deming consistently lead to risk reduction and performance improvement for all management, core and support processes in an institution.

Certification has no legal basis. Certification means the individual, voluntary, personal decision of a company or organization for a transparent and verifiable quality, aligned to specific standards.

A certificate for an institution is a rating of quality, which has been voluntarily applied for and acquired from a certification company on its own initiative.

The successfully completed certification means continuation of the quality work to, not only maintain the level of quality achieved, but to increase it with the aim of re-certification.

The work concepts carried out for certification can be supplemented by the QM measure concepts in a quality-targeting manner:

1. The conduct of peer review
2. Participation in the IQIP (see chapter 5.3)

Certification of a medical enterprise strengthens the physicians working there in their current as well as future dual roles in the context of modern health policy (physicians, medical practitioners and health managers) to be for their patients. Comparable aspects also apply to the tasks of nursing and practice staff (Schreiner-Hecheltjen 2008).

Individual and group practices, hospitals as a whole and, depending on the QM system selected, individual departments, centres and areas as well as medical - also interdisciplinary - networks are certified, and preventive medicine concepts are currently being discussed and prepared. Candidates for certification that are essential for a hospital are the surgical departments and the intensive care units (Schreiner-Hecheltjen 2009).

Certification makes physicians ambassadors for high quality in medicine and permanently equips them for current and future changes in health policy framework conditions in their primary medical mission. Certification enables physicians to follow new paths with responsibility and expertise for their patients.

5.4.1 KTQ

In four years of development work, experts from hospital practice under the leadership of representatives of the umbrella organizations of the health insurance companies, the German Medical Association, the German Hospital Federation and

the German Nursing Council have developed a procedure that has been used since 2002 to evaluate QM in hospitals. The aim of KTQ certification[33] is always to improve and optimize processes and results within patient care.

The central result of the development work is the so-called KTQ catalogue. In this KTQ catalogue, categories were compiled from questions asked within the framework of the certification of acute hospitals, in order to be able to make statements about the quality of the process flows in medical care. The current 70 criteria are divided into the following categories:

- Patient orientation
- Staff orientation
- Hospital safety
- The information system
- Hospital governance and
- QM

The KTQ assessment procedure itself is divided into several steps. First, a self-assessment of the facility takes place. Here, the above-mentioned criteria are recorded using the KTQ catalogue. The self-assessment is carried out using the PDCA cycle[34]. The aim of the self-assessment is for the facility to identify its own strengths and weaknesses. Furthermore, the self-assessment shows the chances of obtaining the KTQ certificate.

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[33] KTQ: Kooperation für Transparenz und Qualität im Krankenhaus (Cooperation for Transparency and Quality in Hospitals).

[34] The Plan-Do-Check-Act method, abbreviated PDCA method or PDCA cycle, is a classic method of quality development. The PDCA cycle describes the perpetual cycle of planning, acting, controlling and reacting in order to achieve an ever higher level of quality in terms of efficiency as well as customer and employee satisfaction.

In a further step, an external assessment is carried out by experts, the KTQ assessors. They also carry out the assessment using the questionnaire. Points are awarded per criterion in the individual phases of the PDCA cycle. To receive the certificate, 55% of the total number of points must be achieved. Furthermore, the quality report of the respective facility must be available on the internet for the duration of the certificate's validity (3 years). The quality report essentially contains a presentation of the performance and internal QM of the respective facilities. Patients and staff can thus obtain important information about the facility.

In the course of a KTQ visitation, the facts presented in the self-assessment report are scrutinized by visitors. The following weaknesses can be identified:

- The limitation of the procedure to the area of acute care
- The insufficient consideration of clinical outcome quality (medical and nursing)
- The risk that this procedure can be defined as a subsystem of existing Joint Commission procedures (JCAHAO).

Furthermore, experts criticize that although the KTQ assessment system is often described as a neutral body, this is only true to a limited extent, in that the shareholders of KTQ are the self-governing partners.

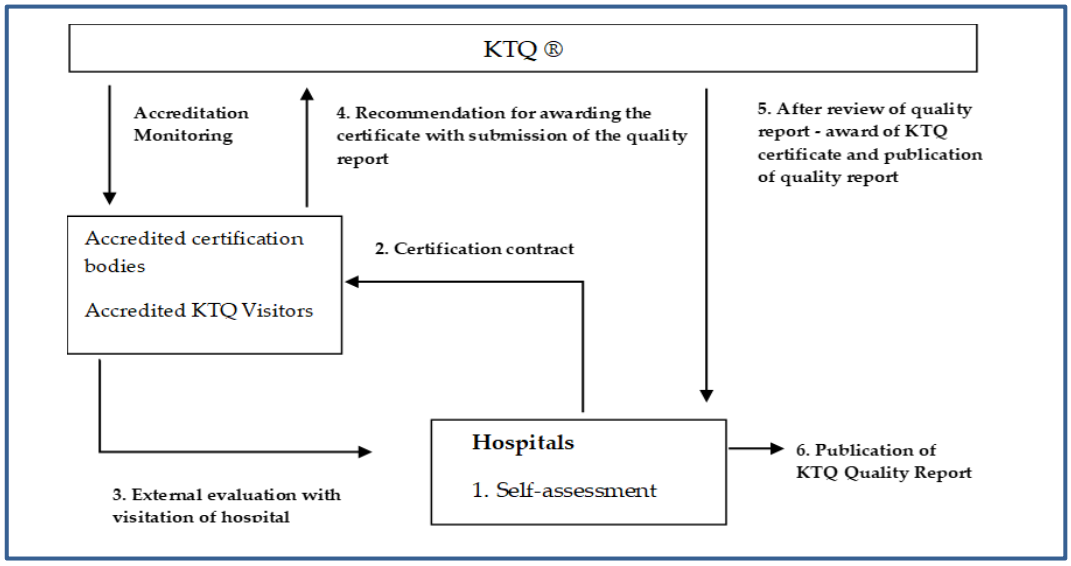

Figure 14: The Stages of the Certification Process at KTQ

KTQ is an important provider of QM documentation systems for facilities throughout the health care system in Germany. The abbreviation KTQ is used both for KTQ-GmbH itself and for the KTQ procedure it represents. The shareholders of KTQ-GmbH (owners) are parties involved in self-administration in the health care system: the German Medical Association, the central associations of the statutory health insurance, the German Hospital Association, the German Nursing Council and the Hartmannbund (figure 15). KTQ is a registered trademark.

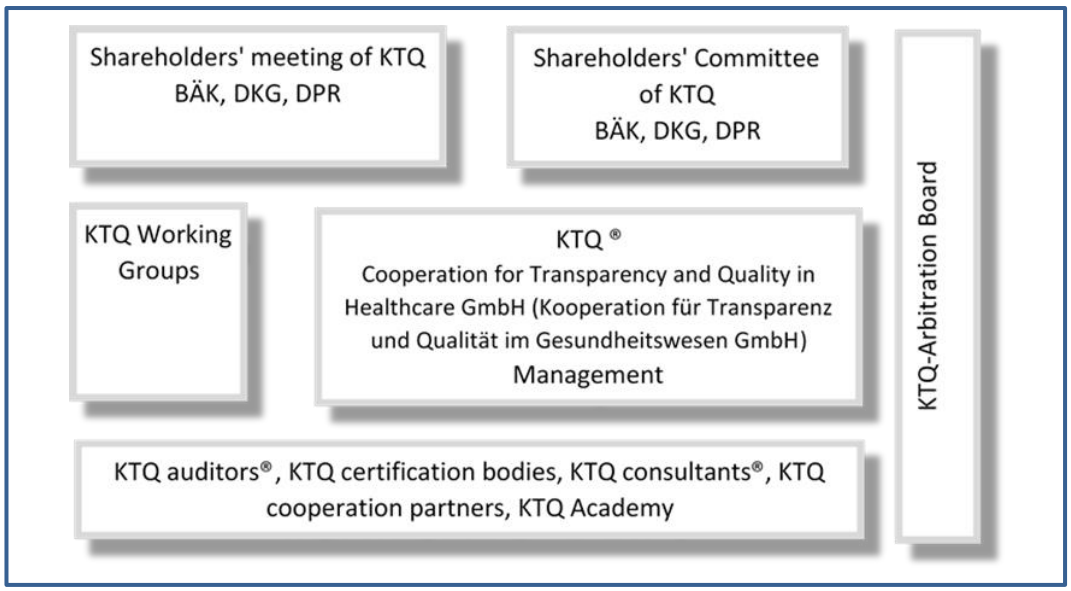

Figure 15: Parties Involved in the KTQ Process

5.4.2 pCC

proCum Cert GmbH (pCC-Certification) is a religious certification company founded in spring 1998 at the initiative of the Catholic Hospital Association (KKVD) together with the German Protestant Hospital Association (DEKV) and their welfare associations Caritas (DCV) and Diakonie (DWdEKD), as well as their insurance service Ecclesia.

The medical and nursing quality criteria were specified at federal level together with KTQ, the association of the DKG, the German Medical Association

(BÄK) as well as the German Nursing Council (DPR) and all umbrella organizations of the cost bearers.

proCum Cert has also developed quality criteria on topics that particularly characterize church hospitals and strengthen their profile. These include responsibility as a provider, social competence in dealing with patients and employees, spirituality and responsibility towards society. The core activity of proCum Cert is the assessment of companies and institutions in the health, social and educational sectors whose objectives are value-based, non-profit or church-based.

proCum Cert sees itself as a know-how multiplier and service provider for clients to improve care and support services towards clients, patients and residents and other customers.

The certification process is divided into different steps:

- Self-assessment (analogue proCum Cert quality manual)
- External assessment and visitation (inspection and review of the facility based on the self-assessment by interdisciplinary pCC team of assessors)
- Issue of the certificate (for three years)
- Publication of the quality report (on the internet)

The pCC certificate is acquired incl. the KTQ certificate. For this purpose, the pCC, the KTQ, the BÄK and the umbrella organizations of the cost bearers have formulated medical and nursing quality criteria at the federal level.

proCum Cert carries out various certification procedures and assessments according to established sets of rules. Cooperations with special certifiers enable synergy effects and cost advantages in the combination of sets of rules, which proCum Cert uses in the customer's interest. A complete list can be found in the annex 2.

One of the strengths of the procedure is that it is also an innovation from the German health system, based on KTQ, which was developed specifically for health institutions and in consultation with the above-mentioned partners. This is also a peer review process, as the facts presented in the self-assessment report are scrutinized during a visitation.

Similar to KTQ, the weaknesses described are that it only applies to the hospital sector, that clinical outcome quality is not in the foreground, that there is a lack of independence due to the proximity to the provider and that it contains criteria that are methodologically difficult to measure, such as spirituality.

5.4.3 QEP

QEP (Qualität und Entwicklung in Praxen – Quality and development in practices) is a QM system of the Associations of Statutory Health Insurance Physicians, which has been used since 2004 and with which certification has been possible since 2006.

The system has a modular structure and is aimed at physicians and psychotherapists in private practice, regardless of the specialty and size of the practice. It is an instrument with which QM can be introduced in practices and optimized step by step. QEP is indicator-based and focuses on patient care in the practice.

The establishment and further development of QM in practice according to QEP is voluntary and subject to a fee. The quality objective catalogue is the central instrument of QEP. The catalogue does not have a normative character, but is a tool for identifying and implementing the requirements and challenges of QM in a structured way. It represents a summary of all goals that broadly represent the various aspects and contents of the work in medical practices. The majority of these goals are based on existing legal obligations and other normative requirements. In the catalogue, the quality objectives are divided into five categories and thus outline a large part of the generally valid requirement profiles for a practice that are important for quality. Both the structure of the catalogue as a whole and the division of the individual categories according to the process of patient care are process-oriented. Against the background of the system's objectives, patient care is the central category. The other parts deal with patients' rights and patient care, staff and continuing education, practice management and practice organization as well as the tasks of quality development. Goals that are particularly decisive for the quality of patient care are highlighted as so-called core goals. Another QEP instrument is the manual, which contains instructions for establishing the QM

system in the form of implementation proposals, self-assessment forms and sample documents (Broge 2018). The practices can adapt the sample documents to their individual needs and circumstances and use them to build up a QM practice manual. With the help of the QEP manual, the practice should also develop its own catalogue of quality goals, which describes the specific core goals to be strived for.

The starting point for every certification is the structured self-assessment of the practice. This can be done using the self-assessment forms of the manual or with the help of the quality goals of the catalogue, in which the goals of the QEP catalogue are questioned in relation to one's own practice and thus self-assessment takes place. The self-assessment forms the basis for the external assessment. In an on-site inspection of the practice, external QEP inspectors decide whether all evidence of the QEP core objectives have been successfully implemented. If this is the case, the QEP certificate is awarded. It is valid for three years.

5.4.4 EFQM

EFQM (European Foundation for Quality Management) is a non-profit organization founded in 1988 in the Netherlands by 14 European companies with the support of the European Commission. EFQM is committed to the dissemination and application of QM systems based on the EFQM Model. The EFQM Model for Business Excellence was introduced in 1991 as a framework guideline for the self-assessment of organizations and as the basis for an award program (Zink 2004).

It consists of three levels of recognition:

Level 1: Recognition of commitment to excellence, i.e. the institution is at the beginning of its efforts and continuous quality improvements. The focus is on the self-assessment process to identify and understand the current level of performance. Areas for improvement are to be defined and improvement actions initiated for at least three areas

Level 2: Recognition for achieving excellence requires a structured approach to identifying strengths and areas for improvement. The goal of the EFQM assessment is to achieve at least 400 points

Level 3: Finalist (European Quality Award), i.e. the focus is on organizations whose quality level has reached international top quality and which consequently belong to the potential candidates for the Quality Award.

The model can be used by all organizations in both the public and private sectors. Unlike QEP and KTQ, it has not been developed specifically for the health sector. The EFQM QM system is an example of total QM. It is a corporate model that is intended to provide a holistic view of the respective organization. For this reason, the EFQM approach distinguishes nine criteria, which are broken down into further sub-criteria. They are subdivided into the five enabler or prerequisite criteria: Leadership, Policy & Strategy, People, Partnerships & Resources and Processes, and the four Outcome Criteria, which include employee- and customer-related outcomes, as well as society-related and key results. These criteria are of varying degrees of importance within the EFQM process - customer-related outcomes alone account for 20 per cent. This illustrates the model's strong focus on aligning the organization with the customer relationship (Lang 2013).

As such, EFQM can also be seen as an instrument that provides guidance for the establishment and continuous development of a company's management system. Strong customer orientation is one of the eight basic principles on which EFQM builds its QM system. The other seven are:

- development of partnerships (with suppliers),
- social responsibility,
- results orientation,
- employee development and employee participation,
- management by processes and facts,
- leadership and goal consistency, and continuous learning,
- improvement and innovation.

Similar to QEP and KTQ, EFQM certification is also fee-based and voluntary. The performance improvement strategy recommended by EFQM is to implement a self-assessment process. Self-assessment is a comprehensive, systematic and regular review of activities and results in the organization. For this purpose, a company answers questions summarized in a catalogue on the nine criteria of the

EFQM model (figure 16). A total of 500 points must be achieved in each of the enabling or prerequisite criteria and the result criteria. With a successful self-assessment, an organization can participate in the three-level award program ("Levels of Excellence"). In addition, the prerequisite for an award or a certificate is the external assessment by EFQM validators, the prioritization and implementation of improvement projects and/or the achievement of a minimum score in the assessment. The three-stage procedure includes the two certificates "Committed to Excellence" and "Recognized for Excellence", each valid for two years, as well as the EFQM prize "European Excellence Award" (until 2005: "European Quality Award"). This has been announced annually since 1992 and is awarded to the best companies in the categories large companies, organizational units, public sector and small and medium-sized enterprises (< 250 employees).

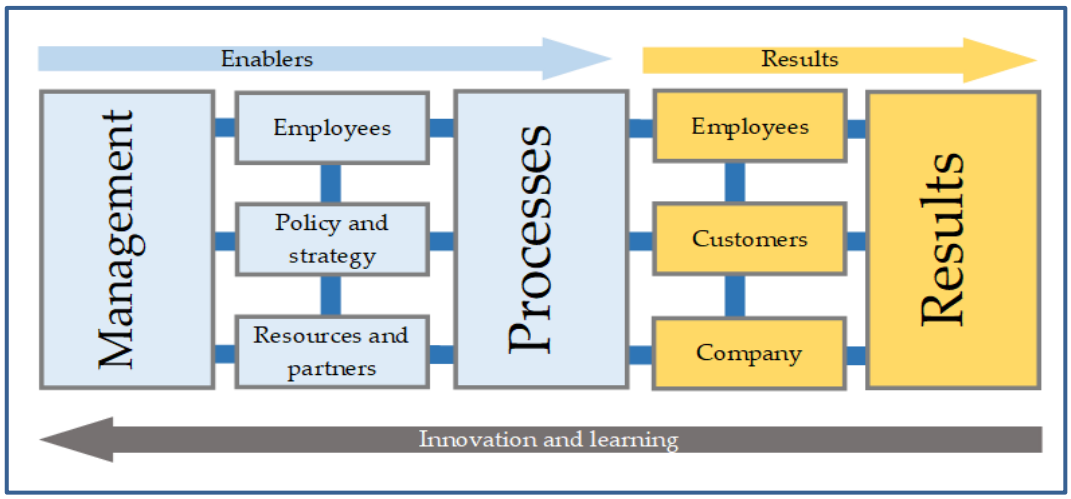

Figure 16: EFQM-Model

5.4.5 EPA – Seal of Practice

The European Practice Assessment (EPA) is a quality management system that supports a continuous quality process in medical practices. It is designed to take into account the specific working methods of physicians in private practice and to understand the practice as a "learning system".

EPA is a process-oriented QM system specifically for physicians in private practice and, unlike other systems, is not based on a QM manual but on indicators. These indicators are measurable variables that allow to characterize an actual state and to formulate a desired goal.

The core of the EPA is a collection of indicators and instruments, which are supposed to describe essential quality-relevant characteristics of a medical practice. These have been created in a multi-year (2000-2005) development and validation process in collaboration with various medical faculties and practitioners.

Methods and instruments are written and oral surveys of patients, employees and general physicians and development of a practice profile. Further methods are: Surveys via visitation of the practice and development of the practice's point of view by comparison with other similar practices.

The EPA Visitor is a consultant and presents the practice's performance in comparison with others during an on-site visit. He discusses and agrees on improvements in organization and infrastructure. Following the visit, the improvements can be implemented by using the benchmarking database or optional participation in meetings, quality circles or workshops. In the final step, the implemented measures are evaluated after six months at the latest.

5.4.5.1 Indicator-Based Systematics

The development of the indicators of EPA was carried out according to scientifically sound methods (e.g. Delphi Rating) in a multi-stage process.

The first results were discussed at an international workshop in spring 2004. The results of an international comparative study were presented to the general public in Berlin in January 2005. Parallel to these international activities, the development of CEPOL in Germany was advanced by the AQUA-Institute to such an extent that broad implementation could begin in summer 2004.

The indicators and items of the EPA basic model were examined for their applicability in the paediatric, specialist and psychotherapeutic fields and augmented by further instruments in order to do justice to the different fields of specialisation. For example, in paediatric and adolescent medical practices, a special patient survey is conducted for children and adolescents or accompanying

persons. In psychotherapeutic and specialist practices, for which interdisciplinary communication is of outstanding importance, a survey of referring colleagues is conducted. The feasibility and relevance of the models were confirmed in two pilot studies.

EPA uses more than 200 quality-relevant aspects - the quality indicators - to map the extent to which certain requirements for an ideal medical practice are met. This comprehensive analysis of the current strengths and weaknesses of each participating practice forms the basis on which the practice can develop further according to its own individual ideas.

The quality indicators are grouped thematically into 34 dimensions and 5 overarching thematic areas, so-called domains. The domains cover all essential areas of practice management:

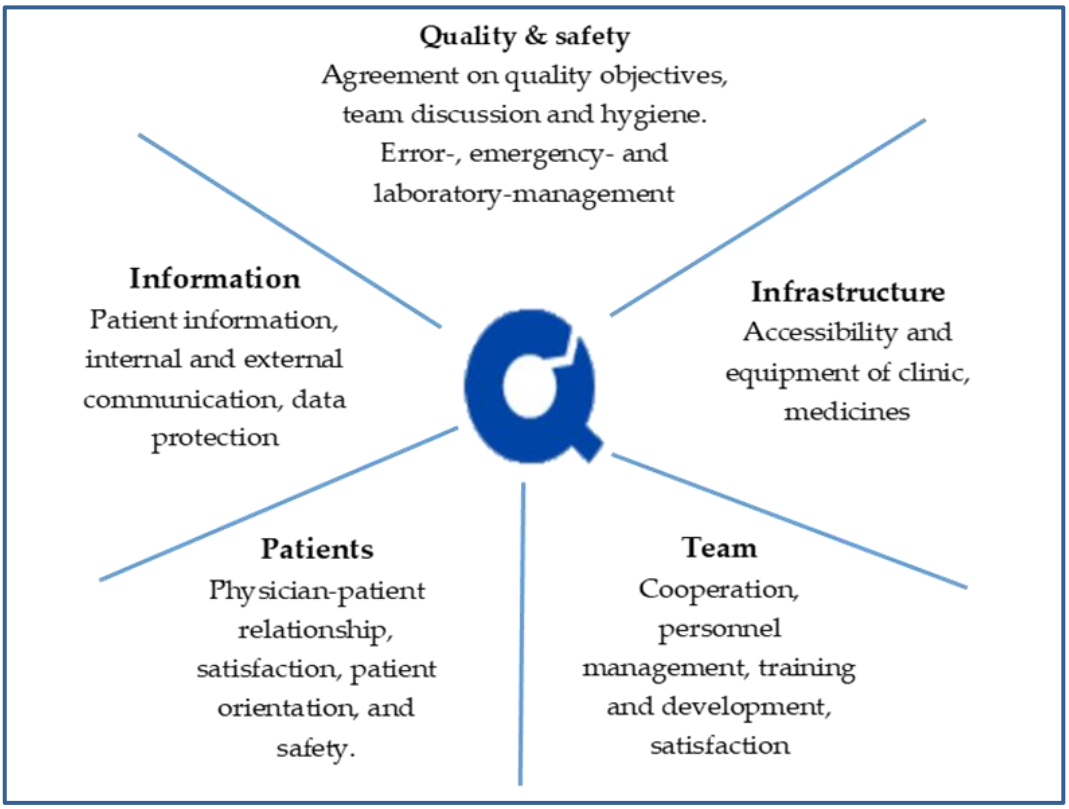

Figure 17: Domains of Quality Indicators EPA

5.4.5.2 Cycle of Quality Development

The European Practice Assessment is based on the quality cycle, also known as the quality spiral, QM cycle, PDCA cycle or DEMING wheel. It is the basic model for understanding QM. It describes a systematic and continuous cycle of further development.

The status of the practice organization is determined on the basis of an as-is analysis. Areas with potential for improvement are identified. In this way, adequate measures can be planned and implemented in a targeted manner. The QM cycle closes with an internal evaluation of the implemented measures and then starts anew. In this way, a permanent process of further development is established.

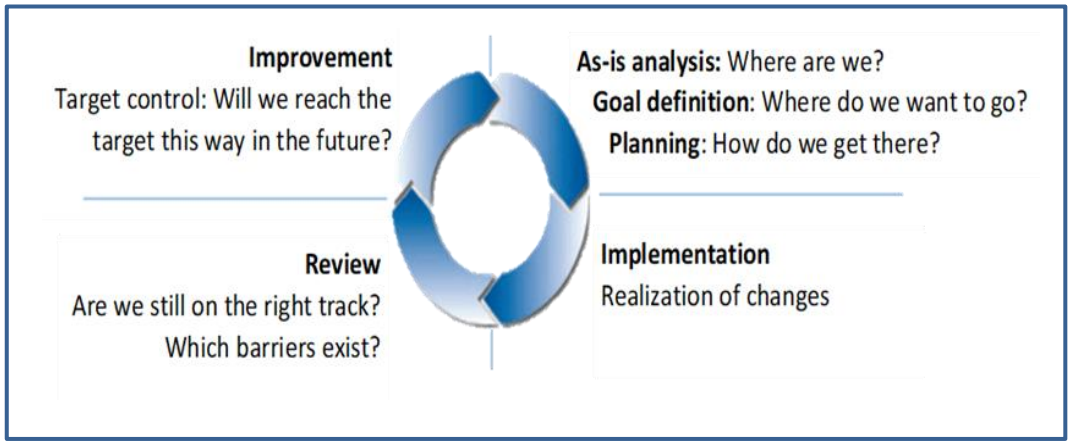

Figure 18: Quality Cycle EPA

5.5 ACCREDITATION

Accreditation (accredere = to believe) is, like evaluation and certification, a basic term in QM. Common to all three terms is the performance of an evaluation (Selbmann 2003: 35-40). The terms are different in terms of their assessment content and objectives. Accreditation refers to the determination and certification that an inspection body fulfils the requirements for carrying out certifications of QM procedures, conformity assessments. Another definition of accreditation is the

formal recognition of competence EN 45001. The term accreditation refers to the approval procedure that testing and certification bodies must go through if they wish to obtain authorization to carry out quality assessments according to DIN EN ISO 9000 et seq. or similar. The requirements for testing and accreditation bodies, as well as for certification bodies, are regulated in the DIN EN 45000 et seq. series of standards and relate to the assessment and recognition of testing competence. Accreditation means the formal recognition of testing competence, the competence to test the testers. Accreditation in general refers to the process, the result of a formal review, in the course of which the extent of compliance with defined requirements is assessed. Depending on the degree of conformity between predefined requirements and actual conditions, different accreditation ratings can be pronounced (Schubert & Ebner 2004: 462-468).

The most well-known healthcare organization in North America that has developed different accreditation programs is the JCAHO.

At European level, the EA[35] is authoritative.

In Germany, the TGA[36] is a leading accreditation centre, especially for the health sector.

5.6 SUMMARY

QA in healthcare encompasses a variety of concepts and tools aimed at improving and ensuring the quality of care.

In this chapter, the most important concepts and tools used and applied in the German healthcare system were presented.

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[35] EA: European Co-Operation for Accreditation.

[36] TGA: Trägergemeinschaft für Akkreditierung (German Association for Accreditation GmbH).

One example of the application of QA concepts and tools in the health care system is the introduction of clinical guidelines for the treatment of diabetes. The guidelines specify which diagnostic tests should be performed, which medications should be prescribed, and which behaviors should be recommended. Using the guidelines ensures that all patients receive the same high-quality care, regardless of where they are treated. Peer reviews can help ensure that guidelines are implemented correctly, and patient surveys can help provide feedback and continuously improve the quality of care.

QA concepts and tools are of great importance to the health care system for several reasons:

- Improving patient safety: by implementing quality standards and procedures, errors in diagnosis, treatment and care can be avoided, leading to improved patient safety.
- Increasing efficiency: by implementing QA measures, inefficient processes can be identified and improved, resulting in reduced costs and resources.
- Increase patient satisfaction: quality standards and procedures help improve patient satisfaction by ensuring that patients receive the best possible care and treatment.
- Public confidence: The public's confidence in the healthcare system is enhanced when they can be assured that certain quality standards are being met and that their healthcare needs are being taken seriously.

6 SELECTED QA PROCEDURES

6.1 QUALITÄTSSICHERUNG MIT ROUTINEDATEN (QSR) – QA WITH ROUTINE DATA

QSR is a procedure to make the quality of care in hospitals measurable without creating more documentation work for physicians and nursing staff.

QSR uses administrative and billing data from hospitals and the AOK, which have to be collected anyway. The central advantage of QSR compared to traditional QA procedures is that illness events after a hospital stay are also included in the measurement. Treatment results can be better assessed overall through long-term observation (Klein 2013).

The QSR quality indicators are determined and published for selected services. Valid quality information is important for patients and physicians when selecting hospitals and for hospitals in their internal QM. Health insurance funds use this information to be able to take quality aspects into account in contractual regulations.

The GKV routine data comprise a large number of insured person-related benefit data:

- Billing data from all care sectors
- Coded diagnoses and service numbers
- Billing data for medicines, remedies and aids
- Data on statutory long-term care insurance

The AOK alone has routine data on 24 million insured persons nationwide with more than six million hospital cases and around 350 million outpatient

practice contacts annually[37] [38]. Such data, collected for administrative purposes, also form a valuable basis for descriptive and analytical studies on various issues. Routine data are considered established in quality measurement (Swart & Heller 2007: 93-112).

QSR is therefore a low-effort quality procedure with anonymized routine data. The hospitals are evaluated on the basis of quality indicators that take into account the complications that occurred during the course of treatment. Since treatment results also depend considerably on patient-related factors such as age and concomitant diseases, great importance must be attached to effective risk adjustment in order to be able to compare results. In addition to the QSR indicators, indicators based on routine data are, for example, German Inpatient Quality Indicators (G-IQI)[39] and Austrian Inpatient Quality Indicators (A-IQI). When evaluating routine data, already developed quality indicators can also be applied for health services research (Jeschke & Günster 2015).

One example is QISA, the "Quality Indicator System for Outpatient Care", which was developed by the AQUA-Institute on behalf of the AOK Federal Association. QISA is designed as a manual with a flexible and expandable stock of individual volumes sorted by care areas and common diseases. Using clearly

[37] <http://www.ekmed.de/routinedaten/download/symposium_2012/guenster.pdf.

[38] Currently, there are 25.5 million insured persons. The number of hospital cases and outpatient practice contacts has remained almost the same.

[39] The system of Inpatient Quality Indicators (IQI) serves to measure the quality of care of inpatients in all hospitals in a uniform manner. The measurement is carried out by means of quality indicators that are compiled on the basis of routine data of the hospitals. The aim is to identify anomalies and possible weaknesses in treatment processes in hospitals in order to derive quality-improving measures accordingly. The system was introduced in the USA in the 1990s. In Europe, it is used in Germany, Austria and Switzerland.

defined indicators, physicians' practices, physicians' networks and other care models can measure, evaluate and improve the quality of their medical work.

AQUA-Institute:

The Institute for Applied Quality Promotion and Research in Health Care GmbH (AQUA-Institute)[40] is a service company located in the scientific environment that specializes in quality promotion projects in the health care sector.

Among other things, the AQUA-Institute deals with the analysis of data from the health care system, the development of quality indicators, the conceptualization of quality-promoting measures and health reporting. Another focus is on the development of software products for the health care system.

In the years 2009 to the end of 2015, the Institute was commissioned with the tasks as an institution according to § 137a SGB V (old version) and supported the G-BA in the implementation of external statutory QA. One of the essential tasks was to continue the QA that had been focused on the hospital sector until then and to develop new cross-sectoral QA procedures (SQG: Sektorenübergreifende Qualitätssicherungsverfahren). The procedures developed and agreed with the G-BA applied nationwide. The health policy goal was and still is to coordinate the quality requirements for both sectors in a meaningful way in order to achieve better and more efficient quality of care in the interest of patients and service providers. The AQUA-Institute was commissioned in particular with this:

- to develop indicators and instruments for the measurement and presentation of the quality of care that are coordinated as far as possible across sectors,

[40] AQUA-Institute: Das Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen.

- to develop the necessary documentation for inter-institutional QA, taking into account the requirement of data economy,
- participate in the implementation of inter-institutional QA and, if necessary, involve other institutions, and
- publish the results of the QA measures by the institution in an appropriate manner and in a form understandable to the general public.

On 31 December 2015, the contract between the AQUA-Institute and the G-BA ended. As of 1 January 2016, responsibility for these QA tasks was transferred to the Institute for Quality Assurance and Transparency in Health Care (IQTiG). The reason for this was an amendment to § 137a SGB V with the objective of avoiding recurring tenders and the associated frictional losses when changing institutions, and instead to establish a permanent institution.

6.1.1 Methodological Basics of the QSR Procedure

The basis of QM in the QSR procedure is anonymized routine data (mainly billing data) from the AOK. This includes data on:

- Diseases and interventions
- Lie times
- Transfers
- Billed hospital charges for inpatient treatments

Diseases are coded for billing purposes in Germany using ICD-10 (International Classification of Diseases, 10th revision) and all procedures are coded using OPS (Operation and Procedure Code).

The data is analyzed in conjunction with further administrative insured person data of the health insurance fund, such as age, gender of the patients and insured person status (member, insured person, pensioner). In the process, all data are anonymized in such a way that different treatment episodes (i.e. care in different hospitals, with different physicians and therapists) can be assigned to one

patient without the identity of the patient being known or being able to be determined.

By looking at the individual course of treatment, it is possible to exclude certain patients from the analyses who had already undergone a similar intervention in the previous year and therefore do not have fairly comparable initial conditions. By analyzing follow-up periods, a consideration of quality indicators beyond the hospital stay is given. Patients who were not members of the AOK during the entire follow-up period are excluded from the analyses.

Thus, longitudinal analyses are carried out in the QSR procedure. In addition to indicators relating to the initial hospital stay, indicators were also developed that are necessary for evaluations in the follow-up[41]. This creates a much more meaningful picture.

Hospital mortality, for example, is not a uniform measure, but depends on the length of stay. For hospitals, the observation period ends with the transfer of a patient. Complications or deaths beyond the hospital doors can therefore not be recorded in hospital reports. Particularly against the background of decreasing length of stay in hospitals, however, it is essential to look at events beyond the initial hospital stay. The QSR procedure makes consistent use of this possibility to measure the quality of outcomes. Within the framework of the QSR, not only hospital mortality but also mortality within 30 days, 90 days and one year after hospital admission is reported. In addition to mortality, other events are considered

[41] Follow-up refers to the subsequent verification of the effectiveness and sustainability of theses, clinical studies or scientific investigations. With follow-up, it is analyzed at a certain time interval whether the previous statements or theses have been confirmed and whether they are still valid. In clinical research, follow-up is used to verify the lasting effectiveness of new procedures and the long-term effect on test persons. The special challenge here is to maintain long-term contact with the test persons and to take into account other positive as well as negative external influences in the overall relationship of the studies.

and analyzed, e.g. new hospital admissions due to specific complications in defined follow-up periods (QSR-Klinikbericht 2015).

The revision rate, i.e. the frequency of necessary re-operations, is a frequently chosen indicator of the quality of outcome after implantation of a total knee joint endoprosthesis. However, a hospital only has knowledge of a revision surgery in those cases where patients undergo another operation in the same clinic (in-house). The routine data of the health insurance funds, on the other hand, are independent of the location of the revision surgery. In the analysis of revision rates, the focus in Germany was primarily on in-house events. An evaluation of hospital-related in-house and one-year revision rates using the example of the implantation of a total hip joint endoprosthesis within the framework of the QSR procedure showed how necessary a more comprehensive follow-up is for meaningful quality measurement. It came to the conclusion that the hospital-related in-house and one-year revision rates after the initial hospital stay are hardly related. Thus, there were quite a few hospitals that had an in-house revision rate of zero, but at the same time a relevant revision rate within one year. In other clinics, the situation was exactly the opposite. As a result, almost one third of all complications only occur in the follow-up period.

In the QSR procedure, SMR values (a standardized mortality or morbidity ratio) are calculated as the ratio of observed events to expected events as a measure of the quality indicator:

$$\text{SMR} = \frac{\text{observed events}}{\text{expected events}}$$

The expected events are calculated using logistic regression models. In order to ensure a fair comparison of hospitals, a risk adjustment is carried out according to patient characteristics. The risk adjustment is carried out according to the gender and age of the patients as well as according to relevant concomitant diseases, partly also according to the diagnostic and therapeutic procedures applied. Only those concomitant diseases are used for risk adjustment for which it can be assumed that they already existed at the time of admission. The Elixhauser score used to record comorbidity takes into account a total of 30 concomitant diseases or disease groups

and has so far been used in particular in the area of routine data (Elixhauser et al. 1998: 8-27).

An SMR of 1 is equivalent to the statement that the risk-adjusted mortality or morbidity of the hospital under consideration is average. An SMR of 1.5, on the other hand, indicates an increase in risk-adjusted mortality or morbidity by 50% (below-average hospitals), an SMR of 0.5 a reduction to half the average value (above-average hospitals).

6.1.2 Measurement of the Procedure

The results of the QSR procedure are compiled for hospitals for internal QM in the form of a hospital report. In addition, clinic-related quality results for endoprosthetic operations have been published for patients and interested parties since 2010. The results of the hospitals can be accessed in the AOK Hospital Navigator[42] , in cooperation with the White List of the Bertelsmann Foundation. The QSR procedure does not claim to assess the quality of the entire range of services provided by hospitals. Rather, selected service areas are defined and analyzed in detail.

In October 2017, the hospital results from the QSR procedure were updated in the AOK Hospital Navigator. The AOK hospital search portal offers QSR results on treatment quality in eight service areas[43]:

1. Hip endoprosthetics
2. Knee joint endoprosthetics
3. Hip fracture
4. Gall bladder removals

[42] https://weisse-liste.krankenhaus.aok.de/.

[43] http://www.qualitaetssicherung-mit-routinedaten.de/.

5. Appendectomies
6. Therapeutic cardiac catheterisation in patients without myocardial infarction
7. Interventions for benign prostate syndrome
8. Prostate carcinoma.

The QSR indicators take into account treatment courses of up to one year on the basis of routine data and refer to the reporting period 2013 to 2015 with follow-up including 2016. A total of around 783,000 interventions in AOK-insured patients were evaluated (annex 4).

The QSR Clinic Report was developed to support the clinic's internal QM. It offers a large number of key figures per service area and enables benchmarking of one's own hospital with the national average with regard to the indicators presented. The detailed report contains key figures prepared on an annual basis, such as:

- Indicators for selected performance areas
- Service case numbers
- Patient structure characteristics such as age and comorbidity
- Length of stay
- Transfers

In addition, mortality and general and specific readmissions with respect to the same disease and other principal diagnoses are reported (Heller 2008: 1173-1182).

With the clinic report, it is possible to compare the quality of results of the respective clinic in terms of the individual indicators with the AOK national average. For example, mortality within 30 days for heart attacks can be presented as the standardized mortality ratio (SMR) of a clinic. By comparing mortality rates during a hospital stay with mortality rates after 30 days, 90 days and one year, it is also possible to differentiate, at least by way of orientation, between problems within the hospital and any problems in post-inpatient care. For example, it is possible to show the mortality after myocardial infarction at different times of death for a hospital in direct comparison with the national average. In such a

presentation, it becomes clear at a glance whether, after appropriate risk adjustment, the mortality of heart attack patients in this hospital is on the national average or is particularly high or low, and how the further development in the follow-up period looks (QSR-Klinikbericht 2015).

6.1.2.1 Statistical Procedure – Confidence Interval (CI)"

In the QSR procedure, SMR values (standardized mortality or morbidity ratio) are calculated as the ratio of observed to expected events as a measure of the expression of a quality indicator. All SMR values are reported with 95 % confidence intervals.

The confidence interval describes the precision of the position estimate of a parameter (e.g. an SMR value). A 95 % confidence interval includes the range around the estimated value of the parameter that meets the actual position of the parameter with 95 % probability. A wide CI indicates a small sample size or a large spread of the parameter. In the QSR procedure, all SMR values as well as other statistical ratios are reported with 95 % confidence intervals. In the comparative quality assessment of hospitals, the problem of small numbers of cases and rare events is taken into account in that the assessment for public reporting in the AOK Hospital Navigator is based on the 95 % CI of the SMR values and not solely on the SMR value[44].

Example of the confidence interval:

Two clinics perform heart operations successfully in 96 % of all cases each. In contrast to Clinic A, which has already performed 500 heart operations, Clinic B, on the other hand, has only performed 50 heart operations. Statistically, the 96% success rate is more likely to occur in Clinic A than in Clinic B, as it has already performed significantly more heart operations (Held & Bové 2014: 56-57).

[44] http://www.qualitaetssicherung-mit-routinedaten.de/.

This is reflected in the calculated confidence intervals:

For Clinic A, the 95% confidence interval is between 94% and 98%. This means that there is a 95% probability that the rate of successful heart surgery is between 94% and 98%. For hospital B, the confidence interval is 84% to 100%.

6.1.2.2 Rating System

The quality of the hospitals with regard to the individual service areas is assessed on the basis of SMR values (standardized mortality or morbidity ratio) as well as the associated 95 % CI. For this purpose, the national comparative figures are calculated for each indicator of a service area in addition to the values of the individual hospital.

For public reporting in the AOK Hospital Navigator, the hospitals are evaluated both overall and according to individual indicators per service area. The results are presented using the following symbols:

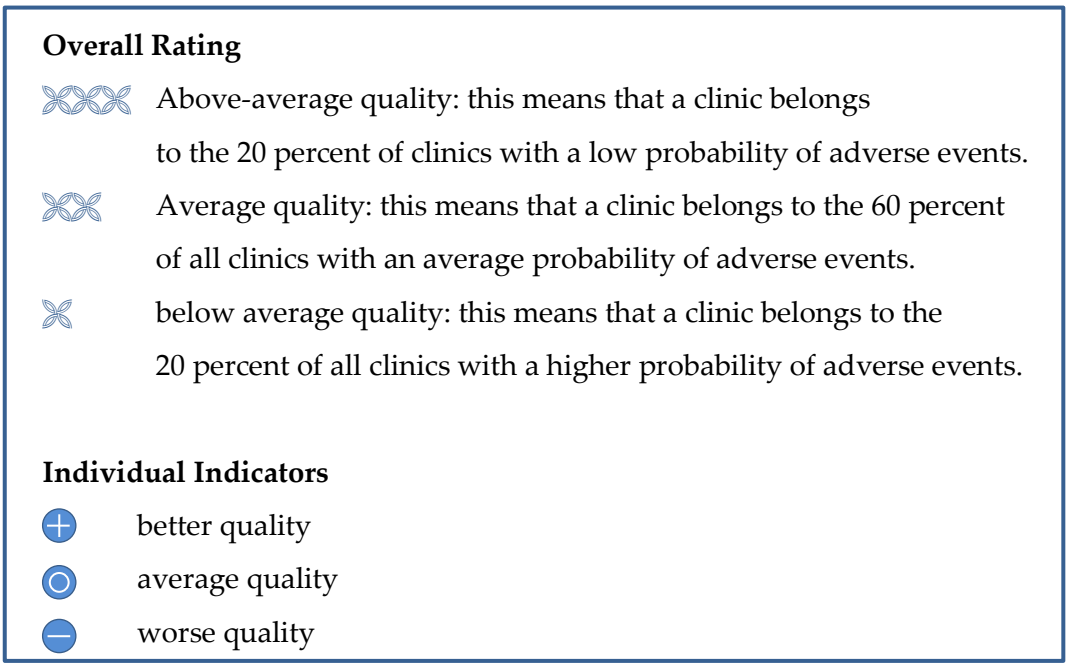

Figure 19: The Awarding of Stars follows the same Principle as the Evaluation of the Individual Indicators

The symbols are assigned on the basis of the 95 % CI of the SMR values. This ensures that the certainty of the statistical statement is taken into account in addition to the actual SMR figure.

The 20 percent of hospitals with the lowest upper AI limits receive three life trees or a plus symbol. These are the hospitals with a low probability of adverse events. The 20 percent with the highest AI lower limits are the hospitals with a higher probability of adverse events. They are rated with a tree of life or a minus symbol. All other hospitals with a medium probability of adverse events receive two life trees or an indicator symbol in the form of a circle in the overall assessment[45].

Hospitals with fewer than five events per indicator that would be classified as below average on the basis of the 95% CI of the SMR value are rated in the AOK Hospital Navigator from "average", i.e. with an indicator symbol in the form of a circle. This prevents hospitals from receiving a below-average rating due to random events.

The overall evaluation is based on the result of the overall indicator. The procedure for this indicator is analogous. However, the complications and adverse events that are included separately in the individual indicators are taken into account together, which increases the statistical significance.

It is possible that two hospitals nevertheless differ in the overall rating of a service area if the individual indicators are rated the same. Conversely, a comparatively worse or better rating for individual indicators does not necessarily lead to a worse or better overall result. This results from the methodological specifications for the calculations. The overall rating is not the average of the individual ratings, but is calculated separately. In this way, multiple counting of complication cases from different individual indicators is avoided in the overall evaluation. Also, an individual result can be of a rather random nature, which leads

[45] http://www.qualitaetssicherung-mit-routinedaten.de/.

to an average individual assessment because the individual indicator becomes statistically less easily conspicuous, while in the aggregation of all complications a more reliable overall assessment of the service area is made[46].

Example:

Hospital A has received an average rating for all individual indicators and also for the overall rating of a service area.

The SMR value for the overall rating is 1.4 (95% CI: 0.7 - 2.1) with 50 cases treated.

At Hospital B, the individual indicators have also all been assessed as average, but the overall assessment consists of a tree of life indicating comparatively below-average quality.

The SMR for the overall assessment is 1.6 (95% CI: 1.0 - 2.2) in 70 treated cases.

The higher SMR value with the higher CI lower limit of hospital B indicates that the total number of observed complications compared to the number of expected events was more increased in this hospital than in hospital A.

6.1.3 Quality and Treatment Costs

In the complication indices, in which various complication events are summarized, relevant quality differences in hospital treatments become more apparent. Between 2008 and 2010, in a total of around 150 thousand AOK patients who received an artificial hip joint for joint arthrosis, at least one complication occurred in more than one in ten cases (11.2%). In a hospital comparison, the overall complication rate was below 8.2% in the best quarter of all hospitals. At the other

[46] http://www.qualitaetssicherung-mit-routinedaten.de/.

end of the scale, a quarter of the clinics had a rate of 15% or higher (WIdO 2011a). In the reporting period 2013-2015 with follow-up until the end of 2016, there were similar results.

The overall evaluation includes (WIdO 2011b):

- Revisions (renewed operations on the same joint with or without replacement or removal of the endoprosthesis) within one year
- Surgical complications (dislocation of the joint or implant complications) within 90 days
- Thrombosis and pulmonary embolism within 90 days and death within 90 days
- Femur fracture within 90 days each after discharge after joint surgery and during initial stay

The differences in quality are accompanied by differences in costs. These presentations are based on the treatment results determined and published in 2011 by the QSR procedure. These are based on hospital treatments between 2007 and 2009, followed up with regard to late complications until the end of 2010. Patients with previous surgery on the same joint were excluded, as were treatments in hospitals with fewer than 30 cases in the three years, so that a total of 154,470 AOK patients in 930 hospitals could be evaluated. Data from patients who were treated in more than one clinic due to transfer were merged. The costs were based on the hospital bill amounts charged to the AOK (Malzahn et al. 2013).

A distinction is made between the complication-related follow-up costs of an individual indicator and the total complication-related follow-up costs across all indicators, in each case up to one year after joint surgery, as well as the total treatment costs of one year including the initial case and all follow-up treatments. This shows that revisions are the most expensive with €12,573.41 per patient and, with 1.97%, represent the most frequent follow-up complication besides surgical complications. Overall, follow-up complications occur with a frequency of 3.84%, and the follow-up costs per patient with a complication amount to an average of €9,106.40.

If one now compares the results of the above-average and below-average hospitals, it can first be determined that all individual follow-up complications

occur less frequently in the above-average hospitals than in the below-average hospitals (example revision 1.42% to 2.80%). Overall, the frequency of complication-related follow-up treatments is significantly lower at 2.84% in above-average hospitals compared to 5.21% in below-average hospitals. A look at the cost level shows that the complication-related follow-up costs in hospitals of below-average quality are higher than those of hospitals of above-average quality, both overall and in the individual indicators (Günster et al. 2013: 124-126).

Hospitals with above-average quality do not only trigger proven lower follow-up hospital costs. Patients who are treated there are also less likely to have their care level increased in the following year. There is clearly a connection between the quality of the primary hospital and the use of downstream services.

These results suggest that there is considerable potential for improving the quality of treatment, so that it makes sense to steer patients to high-quality hospitals. Against this background, contracts for quality-related payment would also make sense, in which costs saved through better treatment quality would partially benefit the hospitals, so that the investment in quality would also pay off for them. In such a system, poorer-quality service providers would be deliberately disadvantaged and would be faced with the alternative of either taking measures to improve quality or reducing their range of services.

6.2 QA ACCORDING TO PATIENTS' EXPERIENCE QUESTIONNAIRE (PEQ)

Patients' experiences with their hospital stay are also increasingly recognized in Germany as an independent and important source of information for the quality of hospital care. Until about the end of the last decade, patient satisfaction surveys initiated or commissioned by hospitals themselves were the focus of activities in this area. Since then, the issue of patient experience has increasingly been addressed by actors active outside the actual hospital care sector, and accordingly many new uses for this topic are emerging. For example, within the framework of inter-institutional QA, work is being done on the implementation of a procedure through which the patient perspective is to be made usable for the QA procedure Percutaneous Coronary Intervention and Coronary Angiography (QA PCI). The

focus is on the measurement and presentation of aspects of patient-related outcome quality and quality-relevant processes. Indication-related measurements of patient satisfaction during the hospital stay and follow-up surveys are already carried out by individual hospitals or hospital groups in particularly relevant service segments only in exceptional cases (Kraska et al. 2016).

In addition, patient experiences - without the possibility of a reference back to the reason for hospital admission - are surveyed without the possibility of referring back to the reason for hospital admission. Their results are primarily published in hospital search portals and can be used be a helpful support for the population in selecting a hospital, taking into account further portal information be a helpful support for the population. The largest patient survey, which has been five waves per year since 2011 is the patient survey conducted by the AOKs and BARMER[47] PEQ instrument. The results are published for all interested citizens on the White List (www.weisse-liste.de) and the portals of AOK and BARMER based on it. The professional discussion about patient satisfaction as an independent dimension describing the quality of care alongside clinical effectiveness and patient safety is intense. There is evidence that there is a positive correlation between patients' subjective assessment of their hospital stay and the other two dimensions for many diseases (Doyle et al. 2013). Kraska et al. (2016) summarize that feedback from patients on their satisfaction with their hospital stay can provide valuable and unique insights into day-to-day hospital care. Patient satisfaction is widely accepted as an independent quality dimension, as its evaluation includes internal (inward-looking) aspects of hospital care (e.g. communication, empathy or interaction) that often cannot be measured (otherwise). Patient satisfaction continues to be a field of ongoing research. Above all, the most diverse factors that influence each other are examined. These factors can be culturally determined

[47] Barmer Ersatzkasse (short name: Barmer; proper spelling: BARMER) is a German health insurance company from the Ersatzkassen group. With around 9.4 million insured persons, it is one of the two largest health insurance funds in Germany alongside Techniker Krankenkasse.

differences in patients' expectations. They can also be the emotional intelligence of the physicians, etc. (Pawils et al. 2012: 1183-1190). The dataset of the patient survey with the PEQ has already been used for individual research studies in recent years, which, however, have made no or hardly any statements on regional differences in patient satisfaction.

With a recent survey conducted by the IGES Institute on behalf of the Weisse Liste gGmbH in the second quarter of 2017, patients' feedback on their hospital experiences in 2015 and 2016 was used to investigate the following questions, for example:

- Are there regions in Germany where patient satisfaction with the hospital stay (willingness to recommend), with medical care and with nursing care is strikingly high or low? And how pronounced are the differences?
- What about the willingness of patients to recommend the two major medical fields of surgery and internal medicine?

The study shows that there are considerable differences in the willingness to recommend and in the satisfaction of patients with medical care and nursing care. Both between the federal states and on a small-scale level. The satisfaction information prominently displayed in the White List hospital search based on the extensive PEQ survey can provide helpful support when choosing a hospital. This is likely to apply above all to regions in which there is a stronger concentration of hospitals that are in principle suitable for the care of the respective clinical picture. If there is no indication-specific (published) quality information available, for example from the external QA procedure, for the disease on the basis of which someone is looking for a suitable hospital, the comparatively current satisfaction ratings of patients of the hospitals in question can be of particular importance (Doyle et al. 2013).

Even in the largest medical fields of surgery and internal medicine, which cover the majority of primary care, there are considerable differences in the observed willingness to recommend between the federal states and when viewed on a small scale.

Within the framework of the study, it was possible to identify influencing factors for surgery and internal medicine which, according to the current state of

discussion, predominantly affect the general assessment behaviour of patients, i.e. tend not to influence the assessment of the care experienced in the hospital. These include patient-associated factors (age, gender), hospital/department-specific factors (number of beds at the location, inpatient cases per full-time physician) and regional-structural characteristics (GP density, specialist internist density and partly the settlement-structural district type).

6.3 QUALITÄTSPRÜFUNGS-RICHTLINIE (QPR) – QUALITY REVIEW GUIDELINE

Statutory long-term care insurance ensures assistance for people who can no longer manage their everyday lives on their own. Residents of inpatient facilities are particularly dependent on support. Therefore, a systematic quality audit of the facilities is firmly prescribed by law. The regulations for this were revised at the end of 2019.

The Social Code (Das Sozialgesetzbuch SGB) XI formulates in § 114:

"In order to carry out a quality audit, the state associations of long-term care insurance funds shall issue an audit mandate to the Medical Service (...)". And in § 114a:

"The Medical Service and (...) are each entitled and obliged, within the framework of their inspection mandate pursuant to § 114, to verify on site whether the authorised long-term care facilities meet the performance and quality requirements pursuant to this Book."

The points of reference are jointly agreed quality standards according to § 113 SGB XI:

"Der Spitzenverband Bund der Pflegekassen and (...) agree on standards and principles for quality, quality assurance and quality presentation in outpatient and inpatient care as well as for the development of internal quality management in facilities (...) with the participation of the Federal Medical Service (...)."

The basis of the inspection was previously the guidelines of the central associations of the long-term care insurance funds on the inspection of the services provided in long-term care facilities and their quality (Quality Inspection Guideline - QPR) of 10 November 2005. The associated inspection protocol included ready-made information on the structural quality of the facility, on the handling of care standards and documentation, the instruction and supervision of the staff, etc. The inspection protocol also included questions on the general handling of complications. Questions were also asked about the general handling of people in need of care as well as relatives, about the general handling of complications, etc. The audit also included information about the quality of the care provided. Although personal contact between the auditors and the persons in need of care was foreseen, the audit in its general style asked more about the philosophy, the quality-oriented construct of the organization of the facility. And this mainly in the form of "yes/no" answers. Since the audit elements were not weighted against each other, strongly formalised documentation, for example, could act as a counterbalance to insufficient staffing. These circumstances in particular have led to criticism in the past.

The new quality audit guidelines for full inpatient care came into force on 1 November 2019. They were based on the results of a research project for the scientific development of instruments for quality assessment. The testing approach is intended to comprehensively map the quality of care and support. In addition to mobility and self-care, aspects of everyday life and social contacts are included in the quality assessment.

The regional associations of the long-term care insurance funds commission the MDK, PKV inspection service or special experts with the inspections. These are carried out as regular inspections, special inspections or repeat inspections. The inspection teams consist of nursing professionals or experts such as physicians. The team members must have nursing competence, leadership competence and knowledge in the field of QA. At least one member must have auditor training (see chapter 5.4) or an equivalent qualification.

The mainstay of the audit is the visit of nine randomly selected facility residents, whose consent must be obtained beforehand. For particularly small facilities or for purely short-term care facilities, special rules apply for drawing the sample. The situation of the nine residents is examined in relation to four quality areas. Subsequently, quality areas 5 and 6 ask about the conditions of the facility as a whole. An evaluative team discussion and the preparation of an audit report conclude the audit. The audit team bases its assessment of the situation of the nine residents on the following documents, among others:

- Interview with the person receiving care
- Technical discussion with the staff of the facility
- Observations during the examination
- Care documentation and other documents (entire personal file)
- Documentation of internal QM
- Facility-internal concepts or procedural instructions
- Information from the last results recording

The four patient-specific quality areas include:

- Quality area 1: Support with mobility and self-care (e.g. nutrition and hydration, personal hygiene)
- Quality area 2: Support in coping with disease and therapy related demands and burdens (e.g. drug therapy, pain management, wound care)
- Quality area 3: Support in organizing everyday life and social contacts (e.g. employment and communication, night-time care)
- Quality area 4: Support in special needs and care situations (e.g. transition after hospitalisation)

The two inter-facility quality areas are:

- Quality area 5: Interdisciplinary requirements (e.g. prevention of risks and hazards, compliance with hygiene requirements, provision of medical aids)

- Quality area 6: In-house organization and QM (e.g. support for dying patients and their relatives, measures to prevent and remedy quality deficits)

From the visit of the randomly selected residents, a representative picture of the residents' everyday situation should emerge in summary with the collected information. In contrast to the audit routine applied after 2005, the focus is no longer primarily on the construct of QM. Rather, the focus is now on the day-to-day reality as it presents itself at the time of the visit, both in positive and negative randomness. How the audits prove themselves in practice and how their results are assessed by the facilities on the one hand and commissioning associations on the other must be evaluated in the future[48].

6.4 QA FROM THE PERSPECTIVE OF THE MEDICAL ASSOCIATIONS

The obligation of the physician both to serve the health of the individual and to act responsibly in the interest of the common good is still the central social mandate that the medical profession has assumed today. This regulatory mandate is laid down in the professional code of conduct, the laws on the medical profession and the chamber laws of the Länder, as well as in the continuing education and training regulations. Through their specific problem-solving competence, the medical profession contributes in a central way to ensuring high-quality health care and humane care for patients. As corporations under public law, the medical

[48] Source: MDS (2019) Richtlinien des GKV-Spitzenverbandes für die Qualitätsprüfung in Pflegeeinrichtungen nach § 114 SGB XI. Full inpatient care. www.mdsev.de/fileadmin/dokumente/Publikationen/SPV/PV_Qualitaetspruefung/19-05-27_QPR_vollstationaer_2019.pdf. (accessed: 29.10.2020).

associations[49] monitor the fulfilment of professional duties and ensure the professional training of physicians (Jonitz 2008: 37).

The specific role of the medical associations in QA can be illustrated by looking at the causes of the current quality discussion. The thematization of quality in medicine arises from two fundamental developments: On the good side, there is the increase or explosion in performance, which has fundamentally changed the possibilities of patient care in recent years. Whereas, for example, the femoral neck fracture of a young person in the 1970s was almost a death sentence, as it could not be operated on or anesthetized, as was the case in Rudolf Virchow's50 time, who died of the consequences of a femoral neck fracture in 1902, in the present day both anesthesia and hip replacement operations are daily routine, even for older patients. While our grandparents' generation only had the choice between insulin or diet for diabetes, a type I diabetic can now assume that he or she has practically the same life expectancy as a healthy person. The increased efficiency of medicine is accompanied by the problem of its financial viability. The economic pressure, in turn, has an indirect effect on the quality of patient care through the declining job satisfaction of those working in the health care system as well as directly through the consequences of misguided incentives (Leidner 2009: 28-29). Experiences from the USA have shown that the introduction of flat rates per case has shortened treatment times in the inpatient sector, but that treatment outcomes have deteriorated.

[49] Ärztekammern (Medical Associations).

[50] Rudolf Ludwig Karl Virchow was born on 13 October 1821 in Schivelbein in Pomerania, in what is now Poland. He studied medicine in Berlin and, after completing his doctorate, worked as a physician at the university hospital, the Berlin Charité. He was mainly concerned with the development of diseases. He was the first to describe the clinical pictures of previously unexplored diseases such as thrombosis (formation of blood clots) and leukemia (blood cancer).

Influence of Flat Rates per Case on the Quality of Medical Treatment in Patients with Hip Fractures (USA 1987)			
	Without flat rates per case	**With flat rates per case**	**Difference %**
Length of stay	16,6 days	10,3 days	-37,6%
Number of physiotherapy treatments	9,7	4,9	-49,5%
Discharges to nursing homes	21%	48%	+129%
In need of home care	**13%**	**39%**	**+300%**

Table 3: Source: John F. Fitzgerald et al. (Indiana University School of Medicine/Indianapolis, USA)
Changing Patterns of Hip Fracture Care bevor and after Implementation of the Prospective 5 Payment System (JAMA 1987; 258: 218-221)

	1992	**1997**	**Difference %**
Inpatient length of stay? Days	11,9	7,7	-35,3%
Hospital costs per case	$9,228	$6,897	-25,3%
Mortality during the inpatient stay	14,1%	12%	-14,9%

Table 4: Source: Mark L. Metersky et al. (University School of Medicine/Connecticut, USA)
Temporal Trends in Outcomes of Older Patients with Pneumonia (Arch Intern Med. 2000; 160: 3385-3391)

Influence of per-case flat rates on the quality of medical treatment in elderly patients with pneumonia.

	1992	1997	Difference %
Death within 30 days after admission	15,7%	17,8%	13,4%
Death within 30 days after discharge			
∑ All patients	6,9%	9,3%	+34,8%
∑ Transfer to nursing home	14,9%	16,5%	+10,7%
Transfer to nursing home	30,3%	43,1%	+42,2%
Inpatient readmission due to relapse	3,0%	3,7%	+23,3%

Table 5: Source: Mark L. Metersky et al. (University School of Medicine/Connecticut, USA)
Temporal Trends in Outcomes of Older Patients with Pneumonia (Arch Intern Med. 2000; 160: 3385-3391)

The tension between economic aspects and medical decision-making criteria has also had a massive impact on physicians' activities in Germany for some years. Physicians are increasingly confronted with the conflict between their own medical concern to achieve the best possible medical treatment goal for the patient and the calculation of budgets.

Hagen Kühn already pointed out this problem in 1999:

The introduction of DRGs means that the economic success or survival of service providers depends on the extent to which they minimize costs or services. This sets in motion a dynamic that exposes patients to a risk of care. This can hardly be averted individually, especially if patients are limited due to illness or belong to less educated classes. Although this risk is largely undisputed in the international debate, no workable system currently exists that would be able to detect all the subtle mechanisms by which operational costs in such complex services are passed on to the patient and to the public in the form of risk selection, implicit rationing and quality restriction.

At approx. 65-70%, the personnel area represents the main block of costs. The hospital management can still influence the quality of staffing, the number of

positions and parts of the variable personnel costs (on-call duty). Compliance with the externally agreed personnel budget, reduced by a calculated safety rate, is the main starting point for cost management.

The negative effects on the quality of patient care are not hard to imagine. The staff shortage now affects not only the medical but also the nursing service.

The general realization that every system tends first to expand services, then to optimize them, also applies to the health system. There, the question of what optimization means arises fundamentally. Does optimization focus on profit or the return on investment of the various participants or does it aim at the quality of medical treatment? For ethical reasons, health care should only be about ensuring the highest possible quality of treatment and the most humane care possible for sick people. In many countries, this discussion is also conducted under value-based health care (Porter & Teisberg 2007: 1103-1111).

Good economists know that there is a connection between costs and quality: "if you only look at costs, you lower quality, but if you look at quality, you also save on costs" (BÄK, KBV, AWMF 2007).

So, what is good medicine?

The answer to this question is always also a question of point of view. For example, epidemiologists, physicians and patients can draw completely different conclusions or have different preferences for completely the same questions (BMI 1996):

"Epidemiologists love hard data. They want to know, whether people are dead or alive. They can count that with confidence."

"Physicians are less demanding, but still like to see evidence of objective improvement in their patients:

Indeed, they may be happy when a hypertensive patient´s blood pressure is coming down even if he or she is feeling worse."

"Patients, on the other hand, are much concerned with such things as how they feel, how well the physician communicates and whether they have confidence in their physicians – things that are annoyingly hard to measure."

"Epidemiologists physicians, and patients may thus all reach different conclusions about whether a medical activity is worthwhile."

So how is good medicine guaranteed by physicians?

Normally, personal responsibility is assumed by the members of the competent professional groups, in this case the medical profession. However, such a primarily person-oriented authority is no longer sufficient in the present. The physician is increasingly overburdened with an additional flood of administrative, economic and legal requirements in addition to his medical-medical tasks. He sees himself more and more forced into the role of the person ultimately responsible and confronted with problems that are triggered in a completely different place.

The health economist of Harvard University in Boston, USA, M. Roberts enriches the health policy discussion with the targets of systematization and optimization.

Systematizing here means, for example, dealing with the question of who takes care of patient groups with special risks such as diabetes mellitus. Optimization poses the question of which medical goals should actually be in the foreground (Harzband et al. 2009: 554-555).

Activities of the medical profession

Ensuring the quality of medical practice is a constitutive element of the medical profession's self-image. The following are examples of individual projects from the comprehensive activities of the medical profession.

The introduction of QA in connection with peri-neonatology in the 1960s and the almost simultaneous establishment of expert commissions and arbitration boards were and are equally exemplary and successful. In addition to the

institutionalization of the topic of quality through the establishment of the ÄZQ[51], in the area of further medical training, a quartet of curricula should be pointed out, which work towards treatment management and system control that is oriented towards the concrete benefit for the patient.

The curricula

- Medical QM
- Evidence-based medicine
- Patient Safety
- Medical leadership

provide the content-related basis for a medical practice in this sense.

The certification of medical facilities, especially in the inpatient sector by KTQ (chapter 5.4.1) is unique in Europe. More than one third of all German hospitals have already voluntarily obtained certification.

Politically, the German Medical Congress in 2000 made the first demands for a quality-oriented competitive order in order to put a stop to a development in the health care system dominated by economic aspects. The German Medical Congress in 2005 also passed a unanimous resolution to deal with the issue of patient safety objectively and constructively by establishing a network organization (DÄT 2000).

[51] The Medical Centre for Quality in Medicine (ÄZQ: Das Ärztliche Zentrum für Qualität in der Medizin) is the joint competence centre of the German Medical Association and the National Association of Statutory Health Insurance Physicians for medical guidelines, patient information, patient safety and evidence-based medicine.

QA from a medical perspective is not understood as something fundamentally new in all these activities, but rather represents the rediscovery of primary medical virtues on a systematic basis. Just as medicine has learned from other natural science subjects over decades and enriched its own actions, medical practitioners are now learning from the fields of labour and organizational sciences in the same sense.

In addition to the German Physicians' Congress in 2000, which called for quality-oriented competition, numerous allies were found. The Conference of Health Ministers also demanded quality-oriented competition in 2002, and the DKG voted for the motto "Quality leads" (Robbers, DKG 2003) in 2003. Even in the 2002 Bundestag election campaign, the demand for quality-oriented competition found its way into a party-political policy statement (FDP election campaign 2002).

The German Medical Association (Bundesärztekammer) considers in particular the benefit for patients as a priority basic principle for quality competition. This benefit must be differentiated according to patient groups, i.e. according to age-, gender- and culture-specific as well as social and status-related aspects. Other factors are to be emphasized as important moments for a quality-oriented development in the health care system:

- The cooperation of those involved is essential. The principle of shared responsibility - of common sense - helps to actually make quality possible for the patient. Top-down control with ultimate guidelines only leads to defence mechanisms and bureaucracy.
- Existing and proven procedures have to be further developed and the work already done has to be continued. Otherwise, there is a danger that with the implementation of more and more new approaches and institutions, the motivation of those involved will dwindle.
- The principle of voluntariness strengthens intrinsic motivation and prevents quality controls that cause costs without promoting quality in the end
- Mutual trust, an indispensable prerequisite for cooperation in patient care, is created through commitment and open communication.

- Valid, applicable QA procedures are of central importance. These include, for example, the collection, evaluation and feedback of quality indicators, as has been carried out in the procedure of external comparative QA in the inpatient sector practised to date (BQS procedure, chapter 9.2). Indispensable for the success of such procedures is the acceptance and thus the concrete implementation in practice. Without an actual consensus of all participants oriented towards the well-being of the patient, even the best QA procedures will be thwarted or misused.

Currently, such a consensus does not exist. The application of many procedures usually fails because politicians, health insurers, hospital owners or the medical profession associate different ideas with it. Currently, the medical profession is experiencing a culture of mistrust with the aim of decimation. Fewer physicians, fewer hospitals, fewer health insurers seems to be the declared goal of politics. In the current political discussion, there is even talk of merging private and statutory health insurance. In such a disharmonious environment, the successful application of QA procedures is difficult.

6.5 DAS PROGRAMM FÜR NATIONALE VERSORGUNGSLEITLINIEN (NVL) – REPRESENT THE APPROPRIATE PATIENT CARE

The Social Code stipulates that patients should receive appropriate care. But what is appropriate is not always easy to judge. And knowledge about this is constantly changing: on a daily basis, about 50 new studies are published per specialty, but not all of them provide reliable results on which physicians can base their treatments. The determination of appropriate care must therefore be based on the best available knowledge, meet the highest methodological standards and take into account the expertise of all those involved in the provision of care.

For this reason, the German Medical Association, the KBV and the Association of Scientific Medical Societies jointly launched the program for national health care guidelines[52] in 2003:

An interdisciplinary team consisting of representatives of all relevant professional associations, health and care professions as well as patient organizations develops scientifically based recommendations for action on priority health care problems. The coordination and moderation of the process as well as the methodological support are the responsibility of the Medical Centre for Quality in Medicine. National health care guidelines represent the entire health care process and take particular account of issues relating to interfaces at the transition between the sectors.

The recommendations are based on a systematic search and evaluation of the existing literature and also take into account high-quality current guidelines and clinical experience. All stakeholders adopt them by consensus. The development follows a high-quality methodology that is oriented towards international standards and is transparently documented:

For each National Health Care Guideline, there is a separate guideline report that describes the systematic approach in detail, documents the conflict of interest declarations of the participants and also provides information on the financing.

National health care guidelines serve, among other things, as a basis for disease management programs (DMPs) or for contracts for integrated care. They are updated regularly.

So far, there are national health care guidelines on the following topics:

- Asthma
- COPD

[52] The National Care Guidelines Program – Das Programm für Nationale VersorgungsLeitlinien (NVL).

- Type 2 diabetes (therapy and secondary diseases)
- Chronic CHD
- Heart failure
- Depression
- Low back pain

The new coalition agreement provides for the establishment of DMPs for depression and low back pain. Regardless of how the medical profession views the importance of these DMPs:

Should they be put in place, the German Medical Association, the KBV and the Association of the Scientific Medical Societies will be able to present recommendations for the appropriate care of these diseases with the National Health Care Guidelines for Low Back Pain and Depression, which have already been agreed upon by physicians and implemented in the meantime, and thus play a decisive role in shaping the process in terms of medical quality.

Procedure for the Development of a National Health Care Guideline	
1	Topic decision
2	Nominating mandate holders (professional organizations) Documentation conflicts of interest
3	Definition of key questions, research and evaluation of evidence
4	Formulating the NVL (draft stage)
5	Formal consensus conferences
6	Public consultation
7	Revision/consensus of the NVL
8	Publication (long version, method report, short version, patient guideline)
9	Continuous update

Table 6: Procedure for the Development of a National Health Care Guideline

QA is one of the core tasks of the Associations of Statutory Health Insurance Physicians and the KBV, with the patient at its centre. The associations of GKV-accredited physicians are the direct contacts of physicians and psychotherapists for

questions on all topics of quality. Among other things, they are responsible for issuing approvals for a number of procedures that are subject to approval in GKV-accredited medical care. This means that a physician may only provide and bill for certain services at the expense of the statutory health insurance funds if he has been granted the corresponding authorization by his Association of Statutory Health Insurance Physicians. In addition, the Association of Statutory Health Insurance Physicians checks compliance with the requirements of the guidelines and agreements concerning the maintenance of these authorizations. While the associations of GKV-accredited physicians are responsible for implementing the guidelines and agreements, the KBV represents the GKV-accredited physicians at federal level in negotiations with the contractual partners and in bodies such as the G-BA (Kiel et al. 2020: 275 ff.).

For the practical work of the KBV, this means above all maintaining a sense of proportion, because the instruments and measures of QA are diverse, differentiated and effective. But they are all also associated with administrative effort - for the GKV-accredited physicians' associations, but above all for the physician. On the part of the KBV, there is a desire and demand for the verifiability of a medical service, which should be in reasonable proportion to the associated bureaucratic effort and the expected effect of an audit. This is a fine line and the patients' interests are always at the centre of all considerations.

Of course, it is desirable to be able to check the quality of the results of a medical service. However, a multitude of problems arise here. For example, the individual patient situation must be taken into account, the medical history and life situation as well as the patient's willingness to comply with medical therapy recommendations (compliance / adherence). The influences of these, but also other factors are manifold and it is difficult to make them measurable. The results of their work are reflected back to the physicians in different service areas, compared to their immediate group of colleagues (usually within the area of their Association of Statutory Health Insurance Physicians) through feedback reports. It seems easier to assess the process quality of a medical intervention. Examples of this are hygiene audits, indicator-based QA measures in colonoscopy (completeness of a colonoscopy), annual minimum numbers, obligatory education and training certificates and, of course, documentation reviews, usually by random sampling.

In GKV-accredited medical care, special attention is paid to instruments of structural quality. Before an authorization is granted, the physician must prove that he has sufficient qualifications, that the equipment and spatial conditions of his practice are appropriate and that medical and non-medical staff also have the necessary qualifications. This means that a uniform basic standard for a particular service is mandatory. This is particularly important because it is known that many medical methods and procedures are effective under research conditions within the framework of studies, but similar success can only be expected under everyday care conditions if the service is provided in a quality-assured manner. Ensuring this, is one of the central tasks of the KBV (Kiel et al. 2020: 275 ff.).

The associations of GKV-accredited physicians are responsible for implementing the QA agreements and guidelines that apply nationwide and also regionally. To support their work, the GKV-accredited physicians' associations set up service area-related QA commissions in which physicians with special experience in the relevant area are active. These assess, for example, the written and pictorial documentation requested in the context of random audits in a peer review process. With this system of QA, a dense QA network has been developed. Almost every panel physician has one or more authorizations based on QA agreements.

Granting of Approval	
Physician-generated requirement **Professional qualification:** Certificate / attestation and / or colloquium and / or preparation-related testing and / or case collection examination and / or submission of documentation and / or participation in training events, training conferences and training courses	**Premises related requirement** **Apparatus-technical, spatial, organizational and hygienic requirements:** Written evidence / declarations, warranty declarations, construction plans, hygiene plans, practice inspections **Professional capability of employees:** Education and training certificates, cooperation certificates
Notice on the granting of a permit	

Table 7: The Scheme for Granting Approval (own Representation)

Obtaining Approval Follow-up Obligations to Maintain a Permit
Condition Audits depending on the Contractual Regulation
Individual case examination by sampling / documentation examination and / or hygiene examination and / or frequency regulation and / or case collection examination and / or examination of preparation quality and / or annual statistics and / or continuous training and / or quality circles and / or evidence of practice organization and / or acceptance and constancy tests and / or maintenance evidence and / or ring tests
Individual Case Examination by Sampling / Documentation Examination
Dialysis: According to the QA Guideline Dialysis of the G-BA **Arthroscopy, conventional X-ray diagnostics, CT, MRI**: Criteria for quality assessment according to G-BA guidelines **Pacemaker control, long-term ECG, sleep-related respiratory disorders, outpatient surgery, nuclear medicine and others**: Criteria based on regional guidelines **Scope**: At least in accordance with the Quality Inspection Guideline for GKV-accredited medical care **Acupuncture, Histopathology in skin cancer screening, HIV/Aids, Hearing aid care, Hearing aid care for children, Intravitreal drug administration, Capsule endoscopy of small intestine, Colonoscopy, Magnetic resonance angiography, Mammography (curative), Molecular genetics, Phototherapeutic keratectomy, Pain management, Ultrasound diagnostics, Ultrasound diagnostics of infant hip, Vacuum biopsy of breast, Cytology of cervix uteri** Scope: Regulation in the respective agreements according to § 135 (2) SGB V

Apheresis, neuropsychological therapy, subsitution-based treatment of opiate addicts **Scope**: Regulation in the respective agreements according to § 135 (1) SGB V
Continuing education obligation according to § 95d SGB V
QM according to § 135a (2) SGB V

Table 8: Obtaining a Permit and Follow-up Obligations to Maintain a Permit (own Representation)

The largest part of all quality audits in GKV-accredited medical care concerns the structural quality of medical services. This is because ensuring suitable structures forms the basis for reliable process quality and the desired result quality. In addition, suitable inspection parameters of structural quality are relatively easy to determine. However, process and outcome-oriented aspects have been increasingly integrated into QA agreements and guidelines in recent years. In addition, the three levels of quality are not clearly separable, because the quality of outcomes, which is mainly what is in the public focus, is based on the reliable implementation of the specifications on the parameters of structural and process quality.

The work of the GKV-accredited physicians' associations essentially concerns two areas in all quality-assured procedures:

Work of the Kassenärztliche Vereinigung in all Quality-Assured Procedures
1. **Review in the context of granting a permit for a procedure (granting of a permit)**
2. **Reviews of the conditions on which the maintenance of a permit is based (permit maintenance)**
• QA commissions • Accreditation / examination of licensing requirements • Incoming inspection • Colloquium • Frequency regulations • Recertification / Maintenance records / Interlaboratory tests / Acceptance, constancy tests • Practice inspections / hygiene audits • Continuous training / quality circle • Case-by-case audits through sampling Documentation audits • Feedback systems / benchmark reports / evaluation • Consulting

Table 9: The Work of the GKV-Accredited Physicians' Associations

6.5.1 QA Committees

An essential feature of QA in medical self-administration is the linking of medical expertise with professional administration. The establishment of QA commissions staffed by physicians is therefore institutionally anchored in all GKV-accredited physicians' associations as a QA measure. The commissions have the task of reviewing the professional competence of the applicant for services with qualification reservations, by virtue of submitted certificates and attestations and/or through a professional discussion (colloquium), as well as preparing the decision of the GKV-accredited physicians' associations in the form of recommendations. The commissions also have special responsibility for the random documentation audits, which vary depending on the topic. As a rule, these audits are subject to follow-up. However, the focus is on intercollegiate exchange in the form of consultations with the audited physician. Recommendations by the

QA commissions to the associations of GKV-accredited physicians ranging from shorter inspection intervals to withdrawal of approval are also possible. A total of more than 3,600 physicians work in these commissions nationwide in addition to their practice. Members from the health insurance companies are rare.

6.5.2 Accreditation / Examination of Licensing Requirements

The main point of all QA measures is the conditional granting of approval by the associations of GKV-accredited physicians. This means that, depending on the agreement, the GKV-accredited physicians' associations check the specialist qualification of the physician, the specifications regarding technical equipment and spatial requirements as well as organizational and hygienic specifications, if applicable. In concrete terms, this means that a specialist qualification in GKV-accredited medical care is necessary for many areas, but not enough.

The expenditure of the GKV-accredited physicians' associations in this area varies from year to year and depends on the agreements that came into force or were amended in that year. These may, if necessary, necessitate a new authorization, for example also for partial areas. In 2015, about 44,000 such administrative acts were processed by the panel physicians' associations for this task alone.

6.5.3 Incoming Inspection

In particularly sensitive areas, an incoming test was agreed upon in addition to the examination of the accreditation requirements. In the area of panel physicians, this concerns curative mammography with a case collection examination and cervical cytology with a preparation examination. In 2015, this amounted to a total of about 232 examinations (without repeat examinations) for these two areas. Since 2012, for infant hip sonography, the documentation of the first twelve examinations after the granting of authorization has been reviewed by the commissions. In 2015, this was done for 390 physicians.

6.5.4 Colloquium / Consultation

The relevant QA commission is responsible for conducting colloquia. Among other things, it has the task of examining the professional competence of the applicant within the framework of a colloquium for service areas with qualification reservation This is carried out if either there are justified doubts despite the certificates presented, or a colloquium is obligatory. The GKV-accredited physician then has the opportunity to present and prove his professional competence in this collegial expert discussion. Furthermore, a colloquium, also in the form of a consultation, can serve to discuss the documentation objected to, for example, in a spot check with the physician concerned and, if necessary, to give advice on how to improve the provision of services. Colloquia within the framework of the granting of authorization took place about 2,100 times in 2015, whereby the largest number, about 1,600, was carried out in the area of ultrasound diagnostics. About 290 colloquia took place in the laboratory area.

6.5.5 Frequency Regulations

An essential quality factor can be the frequency and regularity with which a physician provides services that require a high degree of routine and / or manual skill. In GKV-accredited care, such minimum quantities have been defined for the following services:

- Histopathological examination in skin cancer screening
- HIV / Aids (patient numbers)
- Interventional radiology
- Invasive cardiology
- Capsule endoscopy of the small intestine (evaluator)
- Colonoscopy
- Magnetic resonance imaging examinations of the female breast
- Mammography screening
- Pain management
- Vacuum biopsy of the breast.

The associations of GKV-accredited physicians regularly check whether the physicians concerned fulfil the prescribed minimum number of examinations and treatments. If the minimum quantities are not performed within the specified period, the billing authorization can be revoked and the physician may no longer provide the examination at the expense of the statutory health insurance.

6.5.6 Recertification / Maintenance Records / Interlaboratory Tests / Acceptance Test, Constancy Test

For physicians who perform mammograms, a valid contract includes an additional recertification. Every two years, the physicians must undergo an examination in which the accuracy in the reporting of X-ray images is instructed and checked. If the physician does not meet the requirements, he or she is examined at shorter intervals and, if necessary, has to prove his or her qualification in collegial expert discussions (colloquia). If he or she does not succeed in this, he or she is no longer allowed to provide this service for GKV patients.

Maintenance certificates must be submitted regularly by physicians who perform balneo-phototherapies. The same applies to the provision of hearing aids.

Obligatory interlaboratory comparisons are part of the QA instruments in the agreements on molecular genetics and laboratory diagnostics.

By means of warranty declarations and regular constancy tests, which can also extend to maintenance certificates, ultrasound devices are checked with regard to compliance with technical specifications. This means that every single one of the almost 160,000 ultrasound scanners is inspected by each of the approximately 84,350 panel physicians in addition to the random inspections. The aim of this not inconsiderable effort is to maintain the quality of ultrasound at a high level and to further optimize it.

6.5.7 Practice Inspections / Hygiene Tests

Regular hygiene inspections have been mandatory for practices that perform colonoscopies since 2003. Hygiene is checked here twice a year, with no advanced

notice, by a hygiene institute commissioned by the Association of Statutory Health Insurance Physicians. If there are complaints, up to two repeat inspections are carried out. If there are repeated deficiencies, this can lead to the withdrawal of the billing authorization. After significantly higher complaint rates at the beginning, repeat inspections have been stable within a range of three to four percent for years.

Practice inspections (usually as part of the licensing process) can take place, for example, in practices where outpatient surgery is performed and which must have special building structures for this purpose.

6.5.8 Individual Case Studies by Random Sampling / Documentation Testing

The associations of GKV-accredited physicians examine the quality of services in individual cases on the basis of random samples in accordance both with the agreements and guidelines applicable nationwide and with their own regional decisions. Essentially, a distinction must be made between audits of agreements according to § 135 Para. 2 SGB V and of guidelines according to § 135b Para. 2 SGB V.

In the service areas

- Arthroscopy,
- Conventional X-ray diagnostics
- Computed tomography
- Magnetic resonance / nuclear spin tomography
- Neuropsychological therapy.

twelve documentations are checked by at least four percent of all billing physicians nationwide, in line with the Quality Control Guideline for Statutory Health Insurance Physicians.

This minimum audit scope is significantly exceeded in some panel physicians' associations. Furthermore, based on regional agreements, additional random audits were carried out in 2015 in the following areas:

- Outpatient surgery
- Pacemaker control
- Interventional radiology
- Long-term ECG examinations
- Magnetic resonance angiography
- Oncology
- Sleep-related breathing disorders
- Substitution-assisted treatment of opiate addicts
- Nuclear medicine.

These audits also take place in accordance with the Quality Audit Guideline for GKV-accredited medical care. The results of these obligatory and optional examinations are to be submitted annually by the KBV to the G-BA and are presented here on pages 58 and 59. Separate QA guidelines apply to dialysis, where a full review takes place. These results are also reported - with the involvement of an external data analyst - to the G-BA.

Further documentation audits, mainly according to agreements on § 135 Para. 2 SGB V, but also according to § 135 Para. 1 and others, regularly take place in the following areas:

- Acupuncture
- Histopathology in skin cancer screening
- HIV infections /Aids diseases
- Hearing aid prescription (adolescents / adults - children)
- Holmium laser for bPS (from 2016)
- Intravitreal drug administration
- Capsule endoscopy of the small intestine
- Colonoscopy
- Magnetic resonance angiography
- Mammography (curative - screening)
- Molecular genetics
- Oncology
- PET and PET/CT (from 2016)
- Photodynamic therapy at the back of the eye

- Phototherapeutic keratectomy
- Pain therapy
- Ultrasound diagnostics
- Ultrasound diagnostics - infant hip
- Substitution-assisted treatment of opiate addicts
- Vacuum biopsy
- Cervical cytology.

6.5.9 Feedback Systems / Benchmark Reports / Evaluation

By providing feedback reports, a physician can compare their own treatment quality with that of other practices. This is done in anonymized form. For this purpose, the documentation created by the other physicians is evaluated and reported back to the individual physician. This feedback system helps the individual physician to evaluate their own work and to improve it if necessary. Feedback systems are part of QA in dialysis, but also in disease management programs (DMPs). For all DMPs, the KBV has provided the GKV-accredited physicians' associations with easy-to-use software tools for creating these reports. The dialysis reports are centrally prepared by an external service provider (KBV 2019).

In addition, physicians who carry out receive annual feedback reports on their results from screening examinations through the Central Institute for Statutory Health Insurance Physicians (Zi), which is supported by the Associations of Statutory Health Insurance Physicians (Kassenärztliche Vereinigungen) and the KBV. Feedback reports will gradually be made available for further service areas. For this purpose, in order to ensure and further promote high quality in outpatient care, data on certain quality parameters are electronically documented by the GKV-accredited physicians on a case-by-case basis and transmitted to the Association of GKV-accredited Physicians or a body commissioned by it. Based on this information, feedback and other reports are created, which can be used by the physicians for internal QA (KBV 2019).

6.6 SUMMARY

In the presented chapter, the most relevant QA procedures that play an important role in the German healthcare system and are most frequently used were included.

QA procedures in the healthcare sector aim to ensure and continuously improve the quality of healthcare. They are intended to ensure that medical services are provided effectively, safely and in a patient-oriented manner. QA procedures are also intended to identify and correct errors and deficiencies in care. This can strengthen patients' trust in healthcare. In addition, QA procedures can achieve cost savings, as unnecessary treatments can be avoided and processes can be optimized.

However, QA procedures can also have some limitations and challenges. For example, they can be costly and time-consuming to implement and may not always align with the goals and priorities of different stakeholders in the healthcare system. Additionally, quality QA can sometimes be seen as bureaucratic and can potentially stifle innovation and creativity in healthcare delivery.

Benefits of QA procedures in healthcare include:

- Improving patient safety: monitoring and improving the quality of care minimizes errors and reduces the risk of complications or injuries to patients.
- Improving treatment outcomes: By implementing QA procedures, physicians and other healthcare professionals can work specifically to improve treatment outcomes and optimize their services.
- Increasing patient satisfaction: When treatment quality is high and patients are well cared for, they are more satisfied with their treatment and have greater trust in the healthcare system.
- Cost savings: When treatment quality is improved, it can lead to a reduction in complications and longer hospital stays, resulting in cost savings to the healthcare system.

Disadvantages of QA procedures in the healthcare system include:

- Additional bureaucracy: the implementation of QA procedures may lead to an increased administrative burden and additional bureaucracy.
- Potential financial burden: implementing QA procedures may involve costs that must be borne by hospitals or medical practices.
- Potential overregulation: some critics argue that the introduction of too many quality standards can lead to overregulation, which can have a negative impact on the effectiveness and efficiency of the healthcare system.
- Unclear benefit assessment: It is not always clear how much benefit the implementation of QA procedures actually provides to patients. Assessing the benefits is often difficult, and it is not always clear exactly how the introduction of quality standards will affect the quality of care.

7 METHODOLOGICAL APPROACH

The aim of the empirical study was to provide an estimate of the total costs of QA in the German health care market.

First, an attempt was made to address this question within the framework of systematic research.

Systematic search is a necessary step to identify the best available evidence (Gechter et al. 2013). It is one of the key components of the process of developing trustworthy, high-quality sources in accordance with international agreement, (Quaseem et al. 2012, IOM 2011).

Systematic literature review ensures that the current state of research can be recorded as comprehensively as possible.

The original intention was to examine and analyze articles and publications that dealt with this question, e.g. for subsectors of the German health system at national level.

In this analysis, however, it turned out that there is no corresponding publication or summary study dealing with the total costs of QA in the German health care market.

The methodology of this study is described in chapter 7.1.

The review, analysis and evaluation of the existing literature, with the help of systematic research, thus did not lead to any conclusive result, so the methodology had to be adapted.

In order to be able to estimate the total costs of QA of all parties involved in the German health care market for the first time, it was first of all necessary to

identify as many companies and organizations as possible that carry out QA measures.

After the identification, analysis and categorization of these companies, the cost structures were then examined.

The methodology of this analysis is discussed in chapter 7.2.

7.1 SYSTEMATIC LITERATURE RESEARCH

To answer the research question of estimating the total costs of QA in the German health care market, a systematic literature review was first conducted. The aim was to find previous publications that estimated the total costs of QA in Germany.

Systematic research according to the adapted methodology includes the following steps:

- Selection of suitable search sources
- Determining the search vocabulary and developing a strategy
- Conducting the search in the selected sources
- Reviewing the results and adapting the search strategy
- Conducting the search again
- Reviewing the hits for relevance and
- Documenting the search (Gechter et al. 2013).

The literature search conducted in the manner described (Higgins & Green 2011; Gechter et al. 2013) was carried out in the Medline databases via https://pubmed.ncbi.nlm.nih.gov/, in the Cochrane Library via http://www.cochranelibrary.com and additionally via other hand search sources (Higgins & Green 2011). These sources included references from the bibliographies of relevant publications, "related citations" of Medline hits and books. In order to be able to record further literature, including "grey literature", a search was also conducted on selected websites of topic-relevant national institutions that are responsible for QA/QM programs and by using Google Scholar as a search engine.

"Grey literature" includes reports and expert opinions that are not informally published sources, such as journals and books (Gechter et al. 2013). The search strategy and keywords were based on the possibilities of the relevant research source and were adapted accordingly. For Germany, a time limit of 2011-2020 was set for the search in Medline and Google Scholar. In the Cochrane Database of Systematic Reviews, the joint search for Germany was also limited to the years 2011-2020. On the one hand, a time limit enables a more detailed analysis of the individual sources and, on the other hand, avoids the consideration of evaluations and statistics that are outdated and therefore in all likelihood not applicable to the current economic and business situation.

Medline is the most important and popular database for searching original studies in the biomedical field. It is accessible via the PubMed and Ovid search interfaces, among others.

A systematic search also includes the use of MeSH Terms[53] and - depending on the research question - the use of filters for study designs.

In addition, searches can be narrowed down with the PubMed Clinical Queries function (therapy, guideline, diagnosis, etiology, prognosis).

The Cochrane Library is the online library of the international organization Cochrane. It is comprised of three scientific databases (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Cochrane Clinical Answers), which contain scientific evidence on questions from all areas of health care and on methodological aspects of evidence-based medicine or evidence-based health care.

[53] MeSH (Medical Subject Headings) is a polyhierarchical, concept-based thesaurus (subject index). It is used to catalogue book and media holdings, to index databases and to create search profiles. The MeSH Thesaurus is published by the National Library of Medicine (NLM).

The preparation of Cochrane Reviews follows strict methodological and qualitative requirements (Rheinisches Ärzteblatt 2009). The actual preparation of a review is preceded by the publication of a protocol. Using elaborate search strategies, studies relevant to the corresponding research question are then searched for and their quality and susceptibility to error are assessed (critical appraisal). The Cochrane Reviews provide a tabular overview of the included studies, information on their quality and, if applicable, point out existing differences between the individual studies.

Google Scholar is regularly used to obtain a first orientation on topics. The platform offers a convenient form of literature research. Google Scholar provides several functions that facilitate access to various forms of academic literature. In addition to published articles that have gone through the peer review process, other materials that are interesting and relevant from a scientific point of view are available, e.g. books, dissertations, white papers. Anything that is academically relevant in the broadest sense can find its way into the hit list.

After the literature databases and other research sources were selected, the search terms were defined. For this purpose, the research topic was broken down into equal-ranking blocks of terms. This approach is called the block-building method (Guba 2008: 62 ff.). The concept matrix, which lists the topic blocks and search terms according to a scheme, helps here too. The aim was to identify as many different synonyms, generic terms, sub-terms or related terms as possible.

The search terms that provided the best results for the research topic are presented in the tables below.

Research sources: Research for Germany

The following sources were selected for the systematic search:

1. Literature database Medline via https://pubmed.ncbi.nlm.nih.gov/
2. Cochrane Library: Cochrane Database of Systematic Reviews
3. Google Scholar

1. **Medline via https://pubmed.ncbi.nlm.nih.gov/**
   Search time: 05.01.2021

The search strategy documented in the table below included the keywords: “quality assurance healthcare“, “quality management healthcare“, and “administrative costs healthcare“. Medline already provided MeSH Terms for the selected keywords.

Due to the high hit rate and imprecise results in searches #1 and #2, the search keywords had to be combined. The hit rate was reduced considerably, but the result was not satisfactory.

Narrowing down by time and selecting German titles significantly reduced the hits and finally made the results more precise. Search #5 returned 176 results. The first 100 hits were used for the analysis.

Nr.	Search Keyword	Results
#5	#1 AND #2 Filters: Publication date from 2011/01/01 to 2020/12/31; German	176
#4	#1 AND #2 Filters: Publication date from 2011/01/01 to 2020/12/31; English; German	11,346
#3	#1 AND #2 (quality assurance healthcare [MeSH Terms] OR quality management healthcare [MeSH Terms] OR quality assurance program* OR quality management program*) AND ("costs" OR "administrative costs" healthcare [MeSH Terms])	24,531
#2	"costs" OR "administrative costs" healthcare [MeSH Terms]	132,171
#1	quality assurance healthcare [MeSH Terms] OR quality management healthcare [MeSH Terms] OR quality assurance program* OR quality management program*	523,772

Table 10: The Search Results via Medline (own Representation)

Detailed keyword resolution deposited by PubMed related to search no. #4:

(("quality assurance, health care"[MeSH Terms] OR ("quality"[All Fields] AND "assurance"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "health care quality assurance"[All Fields] OR ("quality"[All Fields] AND "assurance"[All Fields] AND "healthcare"[All Fields]) OR "quality assurance healthcare"[All Fields] OR (("qualities"[All Fields] OR "quality"[All Fields] OR "quality s"[All Fields]) AND ("manage"[All Fields] OR "managed"[All Fields] OR "management s"[All Fields] OR "managements"[All Fields] OR "manager"[All Fields] OR "manager s"[All Fields] OR "managers"[All Fields] OR "manages"[All Fields] OR "managing"[All Fields] OR "managment"[All Fields] OR "organization and administration"[MeSH Terms] OR ("organization"[All Fields] AND "administration"[All Fields]) OR "organization and administration"[All Fields] OR "management"[All Fields] OR "disease management"[MeSH Terms] OR ("disease"[All Fields] AND "management"[All Fields]) OR "disease management"[All Fields]) AND ("delivery of health care"[MeSH Terms] OR ("delivery"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "delivery of health care"[All Fields] OR "healthcare"[All Fields] OR "healthcare s"[All Fields] OR "healthcares"[All Fields])) OR (("quality assurance, health care"[MeSH Terms] OR ("quality"[All Fields] AND "assurance"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "health care quality assurance"[All Fields] OR ("quality"[All Fields] AND "assurance"[All Fields]) OR "quality assurance"[All Fields]) AND "program*"[All Fields]) OR (("qualities"[All Fields] OR "quality"[All Fields] OR "quality s"[All Fields]) AND ("manage"[All Fields] OR "managed"[All Fields] OR "management s"[All Fields] OR "managements"[All Fields] OR "manager"[All Fields] OR "manager s"[All Fields] OR "managers"[All Fields] OR "manages"[All Fields] OR "managing"[All Fields] OR "managment"[All Fields] OR "organization and administration"[MeSH Terms] OR ("organization"[All Fields] AND "administration"[All Fields]) OR "organization and administration"[All Fields] OR "management"[All Fields] OR "disease management"[MeSH Terms] OR ("disease"[All Fields] AND "management"[All Fields]) OR "disease management"[All Fields]) AND "program*"[All Fields])) AND (("costs"[All Fields] OR "administrative costs"[All Fields]) AND ("delivery of health care"[MeSH Terms] OR ("delivery"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "delivery of health care"[All Fields] OR "healthcare"[All

Fields] OR "healthcare s"[All Fields] OR "healthcares"[All Fields]))) AND ((english[Filter] OR german[Filter]) AND (2011:2020[pdat]))

Additional search in Medline via "Title/Abstract":

The additional function "Title/Abstract" can be used to reduce the many hits in Medline so that they can be examined more closely. Sometimes a good way to refine the search results is to limit results to those where the keywords show up in the title or abstract. In this case, the additional search did not yield any usable results either.

Time of search: 07.01.2021

Number of hits: 5

Selected keyword entry:

"costs" quality assurance healthcare* OR "costs" quality management healthcare*[Title/Abstract] AND (2011:2020[pdat])

Detailed keyword resolution deposited by PubMed:

(("costs"[All Fields] AND (("quality assurance, health care"[MeSH Terms] OR ("quality"[All Fields] AND "assurance"[All Fields] AND "health"[All Fields] AND "care"[All Fields]) OR "health care quality assurance"[All Fields] OR ("quality"[All Fields] AND "assurance"[All Fields]) OR "quality assurance"[All Fields]) AND "healthcare*"[All Fields])) OR "costs"[All Fields]) AND (("qualities"[All Fields] OR "quality"[All Fields] OR "quality s"[All Fields]) AND "management healthcare*"[Title/Abstract]) AND 2011/01/01:2020/12/31[Date - Publication]

2. Cochrane Library

Search date: 07.01.2021

Analogous to the search under Medline, the same procedure was applied, which is documented below. However, in order to achieve corresponding results,

the term “quality assurance program“ and “quality management program“ were added in addition to Medline.

Again, the terms from searches #1 and #2 had to be combined to achieve more consistent results.

Search #3 returned 406 hits. The first 100 hits were evaluated for the analysis.

Nr.	Search Keyword	Results
#3	#1 AND #2 Limit 2011 – 2020 Cochrane Database of Systematic Reviews	406
#2	"costs" OR "administrative costs" healthcare	1,464
#1	quality assurance healthcare OR quality management healthcare OR quality assurance program* OR quality management program*	692

Table 11: The Search Results via Cochrane Library (own Representation)

3. **Google Scholar**
   Date of search: 07.01.2021

Google Scholar is not a medical database like Medline, but a web crawler. Therefore, it is not possible to search along a thesaurus. It is also not recognizable which exact algorithms Google Scholar uses searching. Which search terms are successful can therefore only be matter of trial and error.

The appropriate terms for the search were: “quality assurance healthcare“ “quality management healthcare“ “certifications healthcare“ “costs“ and “administrative costs healthcare“.

As expected, there was an enormous hit rate with undesired results in searches #1 and #2. Only the combination of the two searches reduced the hit rate significantly and provided a better result.

Search #3 returned 422 hits. Of these, the first 100 hits were analyzed.

Nr.	Search Keyword	Results
#3	#1 AND #2 Filters: Publication date from 2011 to 2020; German	422
#2	allintitle: "costs" OR "administrative costs" healthcare	2,800,000
#1	allintitle: "costs" quality assurance healthcare OR "costs" quality management healthcare OR "costs" certifications healthcare	30,400

Table 12: The Search Results via Google Scholar (own Representation)

Despite the sensitive search strategy and the high number of hits, however, relevant studies could not be identified because the terms of QA, organization and costs are inconsistent in the common bibliographic databases. Due to the heterogeneous variety of individual QA programs, the vocabulary of keywords is very diverse and thus completeness is difficult to achieve. The difficulty of this type of search was also confirmed in a study by Hempel et al. (Hempel et al. 2011: 85) who compared different search strategies for finding QA projects and achieved insufficient results in terms of precision and sensitivity for all strategies. Due to the high number of hits in the search for QA in general, a restrictive linking of the selected keywords to QA programs with keywords of administration costs and QM was necessary, which may also have contributed to the lack of identification of relevant papers. Attempts were made to fill in the gaps in the search strategy by means of manual searches. Another limitation is the restriction of the search to literature databases such as Medline and the Cochrane Library (Cochrane Database of Systematic Reviews) without searching the databases Embase or CCMed (Current Contents Medicine), a database for German-language literature.

Furthermore, it should be critically noted that the systematic literature search for the topic of QA costs also has weaknesses in that the publications are not all available in databases such as Medline or the Cochrane Library, but are often only produced in the form of special reports commissioned by institutions of the health care system or by scientific institutes (Hempel et al. 2011: 85). The search for such publications poses a challenge in the systematic search, as they are published in a form that is only accessible to a limited extent and is difficult to find. In order to compensate for this weakness as far as possible and to be able to record this

literature, a search was carried out on selected websites of national institutions relevant to the topic and via the Google Scholar search engine.

Due to the rapid dynamics in both the establishment and fluctuation of the respective institutions in QA, it seems impossible for the literature to reflect the current state of development that would be usable for a study.

7.2 IDENTIFY AND SYSTEMATIZE THE ORGANIZATIONS THAT CARRY OUT QA AND ANALYSE THEIR COST STRUCTURE

As shown in the previous chapters, the systematic literature search did not deliver statistically robust results. At the time of this dissertation, no publication exists that deals with the total costs of QA in the German health care market.

In order to be able to estimate these total costs for the first time, it was necessary, as far as possible, to identify all organizations that carry out QA measures so as to subsequently be able to analyze their cost structure.

In order to obtain an overview of all parties with the highest possible level of completeness and to estimate the costs, the following procedure was used for the empirical study in hand:

1. Use of the data sets obtained after the systematic search from chapter 7.1, which were transferred to a database. Although the systematic literature search could not achieve the desired result, it was still possible to identify some organizations that are dealing with the topic of QA. These organizations were used for the subsequent analysis.
2. Completion of the created database - for the most part by web search - which is described in chapter 7.2.1. The final database can be found in annex 2.
3. Cost overview of all analysed organizations according to administrative costs and costs of QA (see chapter 8).

To be able to estimate the total costs of QA in the German health care market, the QA costs were surveyed using a bottom-up analysis. For this study, the research question was broken down into two further sub-topics:

1. Which organizations exist in the German healthcare market that deal with the topic of QA? The methodology is described in chapter 7.2.1.
2. What are the costs incurred for QA in these organizations? The methodology is discussed in chapter 7.2.3.

7.2.1 Identifying the Organizations that carry out QA Measures

The identification of organizations in the German health system that carry out QA measures was done exclusively by web search, which is described in more detail below.

Governmental organizations, health insurance companies or specific areas of the health care system, such as political bodies, which proactively promote the topic of QA, could be identified and documented systematically for the use of this study, via the relevant homepage.

Explanation of the procedure using the example of health insurance funds:

- Identification of all health insurance funds in Germany via various sources, e.g. www.krankenkassen.de
- Analysis of each individual health insurance fund via the relevant homepage with regard to QA measures
- Investigation of possible cooperation partners
- Documentation in case of a positive hit in the database

In the analysis of, for example, state organizations, health insurance funds or hospitals, a number of new companies and institutions were also identified.

Some of these companies are active as cooperation partners and carry out QA measures together, or they are often certification institutions that assess and certify specific areas of the German health system.

These new organizations then in turn served for further ongoing analyses. Thus, the database could be successively filled with new parties in the field of QA in the German health care market.

However, in order to identify as many organizations and companies as possible, especially those in private ownership, it was necessary to look more closely at the interaction and cooperation of these organizations.

The hand search was carried out via MetaGer of the University of Hanover. Furthermore, the Google's general search engine was used for the research.

MetaGer was used most frequently. In MetaGer, the search words entered are simultaneously searched in about 10 search engines (including Bing, Yahoo and YaCy). This includes a number of proprietary crawlers and indexers operated by MetaGer itself. MetaGer is therefore a hybrid search engine in which it is also possible to optionally set which search engines are to be included for the search. The results of the various search engines are summarized and presented in an edited form.

The keywords in all search engines were as follows:

"QA healthcare" AND "organizations" AND "administrative costs".

The number of hits on Google were: 936. The first 100 hits were used for the analysis. MetaGer returned a total of 96 hits. All results were analyzed here.

The period of the research was between 2018 and 2020.

All results are shown graphically in the following flowchart (chapter 7.2.2).

All companies or organizations that could be identified in the hand search were investigated in detail and analyzed for their business activities on the relevant homepage. Only those companies that were actually active in the field of QA in health care were included in the database for the subsequent cost analysis.

Due to the complex and partly non-transparent system, it is impossible to identify all companies implementing QA measures on the German health care market. This analysis is rather intended to create the basis for further empirical investigations in a field that is still largely unstudied and to provide new impulses for future discussions.

7.2.2 Flowchart about the achieved Hits as well as Inclusion and Exclusion Criteria

A graphic summary of the individual stages of the systematic literature search as well as the manual web search with the number of hits and documentation of the reasons for exclusion can be found in the flowchart according to the PRISMA statement (Moher, Liberati, Tetzlaff, Altmann 2009).

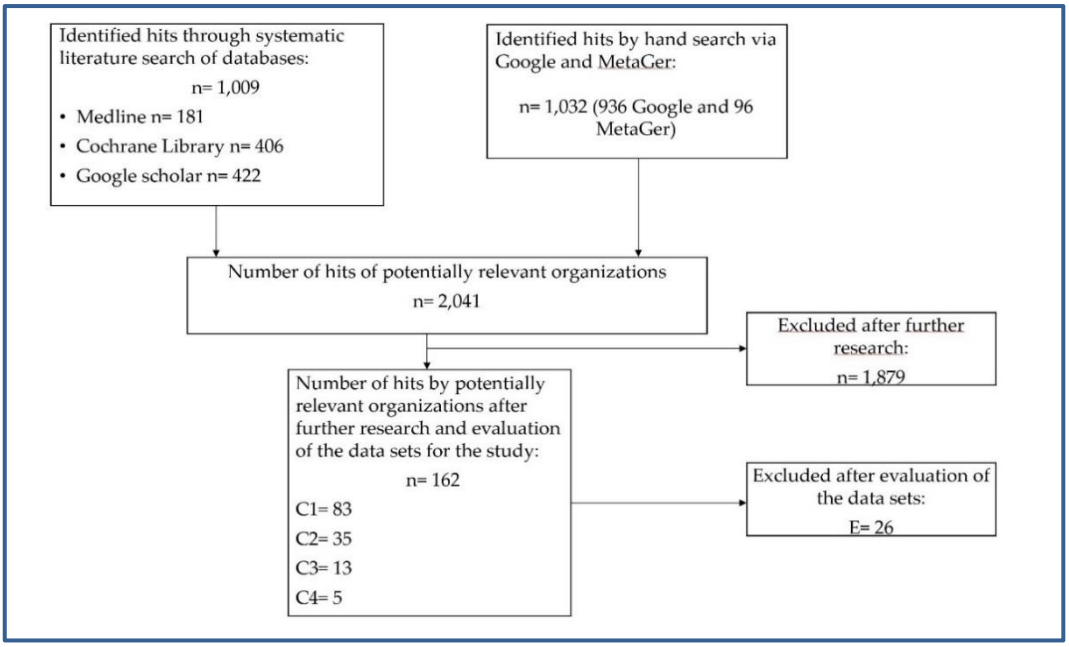

Figure 20: Flowchart about the scored Hits and the Number of Inclusions and Exclusions

Inclusion and exclusion criteria

After the systematic literature search as well as hand search, a total of 2,401 hits were available.

Included were the results for the German health care market that explicitly addressed costs of QA in health care and helped to identify organizations.

After reviewing and analyzing the results, 1,879 hits were excluded.

The reasons for the exclusion were:

- the systematic literature search did not find any publications or articles that addressed the costs of QA in the German health care sector
- articles that addressed the costs in only one specific area of the healthcare sector (e.g., the costs of QA in a single hospital)
- articles that did not address the German market
- hits that were not related to health care despite sensitive narrowing of terms

The analysis and clustering (C1-C4) of the potential hits obtained from 162 to identify organizations is described in chapter 8.

26 hits were excluded that did not provide any records.

7.2.3 Evaluation of Costs

As explained in the previous chapter, institutional and state-owned companies were identified for the empirical analysis in terms of the research question via web search.

The desired data and corresponding cost structures of these organizations were collected and documented with the help of Statistisches Bundesamt (The Federal Statistical Office).

Statistisches Bundesamt, now often referred to as Destatis (Deutsches Statistik-Informationssystem), is a German higher federal authority in the portfolio

of the Federal Ministry of the Interior. It collects, collates and analyses statistical information on the economy, society and the environment. The information processed is published daily in about 390 official statistics.

Numerous data offerings in the Federal Republic of Germany are provided by state institutions as official statistics. These include statistics on the fulfilment of state tasks by the Federal Government and the States, as well as municipal statistics. In addition, public authorities collect further data such as mobility and traffic data or geo-referenced information, which is made available to businesses, administrations and civil society.

GENESIS-Online is the main database of Statistisches Bundesamt. It contains a broad spectrum of subject-specific, soundly organized results of official statistics. The GENESIS databases offer search access in the form of a keyword search or as a hierarchical search by subject areas. Of the nine subject areas currently available, one is devoted to health, education, social services and law.

The search for desired key figures such as “number of employees” or “total costs of administration” for special institutions and state organizations, which are presented in chapter 7.2.1, were carried out with the help of this database.

For the study of other organizations and companies, the approach had to be adapted.

In order to obtain relevant information, two questions were formulated and the identified parties were contacted by mail:

1. How many employees are employed in your company to deal with the topic of QA?
2. How are the total costs incurred in your company for QA estimated?

These questions were sent to all identified organizations by mail. Response rate was unfortunately, but unexpectedly low. The documentation about the

contacting of the organizations as well as the systematization of the collected data can be found in the next chapter.

The mathematical calculation and the methodology for estimating the total costs of QA in the German health care market are shown in chapter results.

7.2.4 Systematization of the collected Data

In the first step, the researched and collected data material was documented, systematized and, as far as possible, checked for consistency.

The data was then transferred into a data matrix for better order and clarity.

After re-checking and validating the collected data, the dimensions to be analyzed were structured and divided into the four following clusters based on Thielscher (Thielscher 2012):

1. Political Bodies, ÖGD
2. Public Corporations and their Organizations
3. Companies
4. Liberal Professions and other

1. A committee specially as “political bodies” is a group of experts formed to perform a specific task. A synonymous term is “board”. Committees are sometimes formed for specific tasks with a time-limited focus of work and perform decision-making tasks, information tasks, advisory tasks or implementation tasks, for which specific functions are delegated to them. Committees can be formed in the private sector as well as in the public administration, both ad hoc and permanently. As a rule, they are characterised by a flat organization. Consequently, this cluster includes ministries or bodies that belong to a ministry or work entirely on behalf of a state institution.

2. A public corporation is a permanent association of persons that pursues a supra-individual purpose and whose existence is independent of the change of members. The corporation is a legal entity with legal capacity. There are corporations governed by private law and corporations governed by public law.
   Private law corporations such as stock corporations or limited liability companies participate in general economic life. Their free establishment and activity is constitutionally guaranteed in the Federal Republic of Germany, as is membership (Art. 19 para. 3 in conjunction with Art. 9 para. 1 GG). This also applies to legal entities governed by private law with their registered office in other EU countries.
   Public law corporations are part of the indirect state administration and perform public administrative tasks alongside institutions and foundations governed by public law as well as those in public trust. For certain people, membership in certain public-law corporations may be prescribed by law, for example, for members of the so-called chamber professions in professional organizations with a supervisory function such as the Medical Associations or Bar Associations.
   This cluster thus includes social insurance institutions, health insurance companies, long-term care insurance companies, G-BA, KBV, MDK and various corporate bodies such as AQUA, IQWiG and IQTIG.

3. An enterprise is an economically independent organizational unit that takes market and capital risks with the help of planning and decision-making instruments and makes use of one or more businesses in pursuit of the enterprise's purpose and objectives. The formal characteristic in all cases is the legal entity (e.g. GmbH, AG), through which the economic-financial unit comes into being in the first place in its specific structure of ownership and is defined by a purpose.

   Accordingly, all companies that must be assigned by definition are found in this cluster. In particular, certification companies or bodies that carry out QA are by definition part of this cluster. But clinics and

pharmaceutical companies, for example, have also been assigned to this cluster.
The Association of Private Health Insurers (PKV) plays a special role. In contrast to GKV, this is a private-law construct and therefore cannot be classified as a public corporation.

4. A liberal profession is an independently exercised scientific, artistic, writing, teaching or educational profession. A liberal activity is not a trade under German law and is therefore subject neither to the Trade Regulation Act nor to trade tax. Legal definitions can be found in the Income Tax Act and the Partnership Act, which define the following professions as liberal professions in the medical field in roughly identical terms: physicians, dentist, veterinary surgeon, pharmacist (at the same time a trader), midwife, therapeutic masseur, physiotherapist, non-medical practitioner.
   The liberal professions are generally concerned with the personal, autonomous and professionally independent provision of services of a higher nature in the interest of the clients and the general public on the basis of special professional qualifications or creative talent.

   According to this definition, all organizations of physicians, dentists, physiotherapists as well as independent associations of the medical profession have been grouped in this cluster.

   The mapping of the researched organizations according to the clustering as well as the documentation of the contacting is presented as follows:

Political Bodies

Organization	Communication Channel	Response
BfArM	Mail	No
BMG	Mail	No
BZgA	Mail	No

DIMDI	Mail	No
Gesundheitsämter*	Mail	No
Paul-Ehrlich-Institut	Mail	No
Robert-Koch-Institut	Mail	No
SVR	Mail	No

Table 13: Representation about the Political Bodies studied

*Gesundheitsämter (Health Departments): Due to the large number of health departments (375 in Germany) with different capacities reaching from 1-2 employees to large departments with double or 3-digit numbers of employees, it would have been counterproductive to contact each single department. Instead, the study focused on the central health departments of the biggest German cities Cologne, Munich, Hamburg, Berlin, Düsseldorf and Frankfurt.

Public Corporations

Organizations	Communication Channel	Response
AkdÄ	Mail	No
AQUA-Institute	Mail	No
ÄZQ	Mail	No
BAK	Mail	No
BÄK	Mail	No
BGW (qu.int.as)	Mail	No
BPtK	Mail	No
BZÄK	Mail	No
DQE	Mail	No
DRK Landesverband Baden-Württemberg e.V.	Mail	Yes
DRV	Mail	No
G-BA	Mail	No

GKV-Spitzenverband	Mail	Yes
IQN	Mail	No
IQTIG	Mail	Yes
IQWiG	Mail	No
KBV (KV)	Mail	No
KCQ	Mail	Yes
KV	Mail	No
KZBV	Mail	No
LQS	Mail	No
MDK	Mail	No
MDS e.V.	Mail	Yes
SQG	Mail	No
WIdO	Mail	No
ZI	Mail	No
ZQ	Mail	No

Table 14: Representation about the Public Corporations studied

Not included in this list:

- Gesetzliche Kranken- und Unfallversicherungen (Statutory Health and Accident Insurance). Due to the large number of statutory health insurers, only those that perform QA based on appropriate research (web search, telephone contact, mail) were contacted.
- These are: AOK, BKK, IKK and TK. A detailed list of these health insurance companies can be found in Appendix XY.
- Öffentliche Haushalte (Public Authorities). Corresponding data were collected by Statistisches Bundesamt
- Soziale Pflegeversicherungen (Social Care Insurance). Corresponding data were collected by Statistisches Bundesamt

Companies

Organizations	Communication Channel	Response
ANOA	Mail	No
AVG	Mail	No
AWO Bundesverband e.V.	Mail	No
BAGFW e.V.	Mail	No
BAR e.V.	Mail / Phone	Yes
BAV Institut	Mail / Phone	Yes
BPTK	Mail	No
BQS	Mail	No
BSI Group Deutschland GmbH	Mail	No
CAC	Mail / Phone	No
Cert iQ Zertifizierungsdienstleistungen GmbH	Mail / Phone	Yes
CertEuropA GmbH	Mail / Phone	Yes
ClarCert GmbH	Mail / Phone	Yes
DAG-KBT e.V.	Mail	No
dagnä e.V.	Mail	No
DEKRA Certification GmbH	Mail / Phone	No
Deutscher Verlag für Gesundheitsinformation GmbH	Mail	Yes
DIOcert GmbH	Mail	Yes
diqp	Mail	No
DNVF e.V.	Mail	No
DPA GmbH	Mail / Phone	No
DQS GmbH	Mail	No
ENPP-Boehm GmbH	Mail / Phone	No
EQ Zert	Mail / Phone	No

EQS	Mail	Yes
EurSagety Qualitätsverbund	Mail	No
GQMG	Mail / Phone	No
Gütegemeinschaft Pflege in stationären Einrichtungen e.V.	Mail / Phone	No
Heimverzeichnis GmbH	Mail / Phone	No
IGES Institut GmbH	Mail	No
IMC clinicon GmbH	Mail	No
i-med-cert GmbH	Mail / Phone	Yes
infaz GmbH	Mail / Phone	Yes
Institut für Pflegemanagement	Mail / Phone	Yes
IQD	Mail	Yes
IQH e.V.	Mail	No
IQM e.V.	Mail	Yes
IQMG	Mail	No
iqpr GmbH	Mail	No
ISGPN	Mail	No
Kneip-Bund	Mail	Yes
KTQ	Mail / Phone	Yes
LGA InterCert GmbH	Mail	No
MFT-Zert GmbH	Mail / Phone	No
MICADO HEALTH CARE GmbH	Mail / Phone	No
OnkoZert GmbH	Mail	No
pCC (proCum Cert GmbH)	Mail / Phone	Yes
QS-Reha	Mail	No
Qualitätspraxisverbund Humanitus GmbH	Mail	No
QuQuK	Mail / Phone	Yes

SQ Cert GmbH	Mail	No
TÜV Nord Cert GmbH	Mail	Yes
TÜV Rheinland Cert GmbH	Mail	No
TÜV Süd Management Service GmbH	Mail / Phone	Yes
VoltaMed GmbH	Mail	No
WIESO CERT GmbH	Mail	No
ZertSozial GmbH	Mail	No

Table 15: Representation about the Companies studied

Not included in this list:

- Ambulante Pflege (Outpatient Care)
- DKG
- Krankenhäuser (Hospitals)
- Pharmaunternehmen (Pharmaceutical Companies)
- PKV
- Rettungsdienste (Rescue Services)
- Stationäre / teilstationäre Einrichtungen (Inpatient / Partly Inpatient Facilities)
- Stationäre / teilstationäre Pflege (Inpatient / Semi-Inpatient Care)
- Vorsorge- / Rehabilitationseinrichtungen (Preventive / Rehabilitation Facilities)

For the organizations mentioned above, the corresponding data were collected by Statistisches Bundesamt.

Liberal Professions

Organizations	Communication Channel	Response
BHÄV e.V.	Mail	No
bpa e.V.	Mail	No
BVOU e.V.	Mail / Phone	Yes

DAKJ e.V.	Mail / Phone	Yes
DCV	Mail	No
DDG	Mail	Yes
DEGAM	Mail / Phone	Yes
DeGIR	Mail	No
Deutscher Paritätischer Wohlfahrtsverband-Gesamtverband e.V.	Mail / Phone	Yes
DGA e.V.	Mail / Phone	No
DGAV e.V.	Mail / Phone	No
DGE e.V.	Mail / Phone	Yes
DGfN e.V.	Mail	No
DGG e.V.	Mail	No
DGHO e.V.	Mail / Phone	Yes
DGI e.V.	Mail	No
DGIM e.V.	Mail	Yes
DGK e.V.	Mail	Yes
DGKCH e.V.	Mail	Yes
DGKJ e.V.	Mail / Phone	Yes
DGN e.V.	Mail / Phone	Yes
DGOU e.V.	Mail	Yes
DGPM	Mail	No
DGPR e.V.	Mail	No
DGQ e.V.	Mail	No
DGSM e.V.	Mail	No
DGSPJ e.V.	Mail	No
DGTHG e.V.	Mail	No
DHG e.V.	Mail / Phone	Yes
DIGAB e.V.	Mail	No

DKG e.V.	Mail / Phone	Yes
DMG e.V.	Mail	No
DOG e.V.	Mail	Yes
DSG	Mail / Phone	Yes
DTG e.V.	Mail	No
DVO e.V.	Mail / Phone	Yes
GMDS e.V.	Mail	No
ISQ e.V.	Mail	No
LAGO e.V.	Mail / Phone	Yes
Nikodemus-Werk e.V.	Mail	No
QgP	Mail	No
QSV	Mail	No
VDBD e.V.	Mail	Yes
VKAD e.V.	Mail	No
VLOU e.V.	Mail	No
VOD e.V.	Mail / Phone	Yes

Table 16: Representation about the Liberal Professions

Not included in this list:

- Ambulante Einrichtungen (Outpatient Facilities)
- Apotheken (Pharmacies)
- Arztpraxen (Medical Practices)
- Deutscher Hausärzteverband e.V. (German Association of General Practitioners)
- Gesundheitshandwerk/ -einzelhandel (Healthcare Trade/Retail)
- Krankenpfleger (Nurses)
- Physiotherapeuten (Physiotherapists)
- Praxen sonstiger medizinischer Berufe (Practices of other Medical Professions)

- Sonstige Einrichtungen medizinischer Berufe (Other Facilities of Medical Professions)
- Zahnarztpraxen (Dental Practices)

For the organizations mentioned above, the corresponding data were collected by Statistisches Bundesamt.

The research for this study has shown that most companies do not want to or are not able to present their business practices or necessary key figures in a transparent way and that they cannot be found in relevant documents such as balance sheets or annual reports. This may also be evidence of the fact that the response rate to the mails sent was below average.

In the second phase, all identified organizations were again critically reviewed, filtered and summarized.

Subsequently, the companies that did not respond in the first phase were written to again or followed up by telephone, in order to obtain the missing information. A significant increase in the success rate compared to the first phase could not be determined.

For a better understanding of the activities of the identified organizations, a separate data sheet was created, which specifically describes the field of activity of each organization. Furthermore, the data sheet contains the exact naming of the identified organizations, as they very often contain abbreviations. (see annex 2).

Overall, it can be stated that the organizations studied can contribute to improving the quality of patient care with the help of QA measures.

The instruments that can be used for this purpose are:

1. The alignment of organizational actions with a clearly defined quality objective.
2. Aligning organizational actions with evidence-based standards.
3. The implementation of systematic quality-supported measures, such as quality circles. peer review processes and others

4. The improvement of cooperation between the professional groups in everyday treatment as well as the general participation of all staff in the improvement process (Dean & Bowen 2000).

Employees in different organizations and with equally diverse tasks participate in medical care, its financing and regulation. The events are correspondingly complex (Thielscher, 2012: 12).

Based on the research of Christian Thielscher (Thielscher 2012), the following table with corresponding actors was developed and categorized from the results of the study in order to provide an orientation about the acting organizations in medical care on the German health care market.

The categorization of the identified parties is to be interpreted both as a methodology and as a partial result. For a better understanding and thematic separation, it was decided to deal with the following table and the corresponding explanations in the methodology chapter.

Chapter 8 “Results” contains only mathematical calculations that were used to determine the total costs of QA.

	Medical Care	Regulation and Funding	Education and Information
Political Bodies, ÖGD	Gesundheitsämter	BMG	SVR
		BfArm	BZgA
		RKI	DIMDI
		Paul-Ehrlich-Institut	
Public Corporations and their Organizations		GKV	Hochschulen und Akademien
		Soziale Pflegeversicherung	MDK
		DRV	WIdO
			bifg
		Gesetzliche Unfallversicherung	ZI
		Öffentliche Haushalte	G-BA
		KV	AQUA
		KBV	MDS
		BÄK	IQTIG
		BZÄK	AkdÄ
		BAK	ÄZQ
		LQS	DQE
		BGW	DRK
		BPtK	IQN
		GKV-Spitzenverband	IQWiG
		KZBV	KCQ
			SQG
			ZQ

Companies	Krankenhäuser	PKV	Verlage
			WIP
	Stationäre / teilstationäre Einrichtungen	DKG	Online Angebote
	Stationäre / teilstationäre Pflege	BDPK	Eingetragene Vereine
	Pharmaunternehmen		Qualitäts-sicherer
	Vorsorge- / Rehabilitations-einrichtungen		Zertifizierungs-stellen
	Ambulante Pflege		AWO
	Rettungsdienste		BAGFW
			BQS
			Kneip-Bund
			KTQ
			GQMG
			IQMG
			ZQP
Liberal Professions and other	Arztpraxen		Freie Verbände der Ärzteschaft
	Zahnarztpraxen		
	Apotheken		
	Krankenpfleger		
	Physiotherapeuten		
	Praxen sonstiger medizinischer Berufe		
	Gesundheits-handwerk / -einzelhandel		

	Sonstige Einrichtungen und private Haushalte		
	Ambulante Einrichtungen		

Table 17: Medical Care Stakeholders. Presentation and Categorization were done after Analysis of the Parties (Thielscher 2012: 12)

As the level of operation cannot be precisely segregated into e.g. macro, mesa and micro levels, a further categorization would not lead to any better results and was hence not performed.

All in all, this results in an extraordinarily complex system of tasks, responsibilities and competences, the interconnections of which are difficult to understand. Furthermore, they change over time, disappear from the market or merge into a new institution. Because of the importance of regulation in this sector, a very deep understanding of the involved organizations and the representatives involved is necessary to fully understand the health system in a whole.

"Health departments" can be named as examples for the complexity of the health system. Research into administrative costs or the number of employees has shown that even the health offices themselves do not know their key figures. The "Brandenburg Ministry of Health" writes in 2020:

"An overview of the number of employees working in the health offices and thus of the permanent and temporary positions is not available"[54].

[54] https://www.aerztezeitung.de/Nachrichten/Raetselraten-ueber-Anzahl-der-Amtsaerzte-in-Brandenburg-419304.html.

The welfare state has the task of ensuring the health of the population. The state fulfils this duty through its–health offices. Due to the federal system in Germany, the exercise of state powers and the fulfilment of state tasks is a matter for the States according to Article 30 of the Basic Law (Grundgesetz). This organizational principle also applies to the public health system, so that different organizational forms can be found in each federal state.

How complicated the structure and responsibilities of a single public health department can be is shown in the following diagram of the Frankfurt public health department.

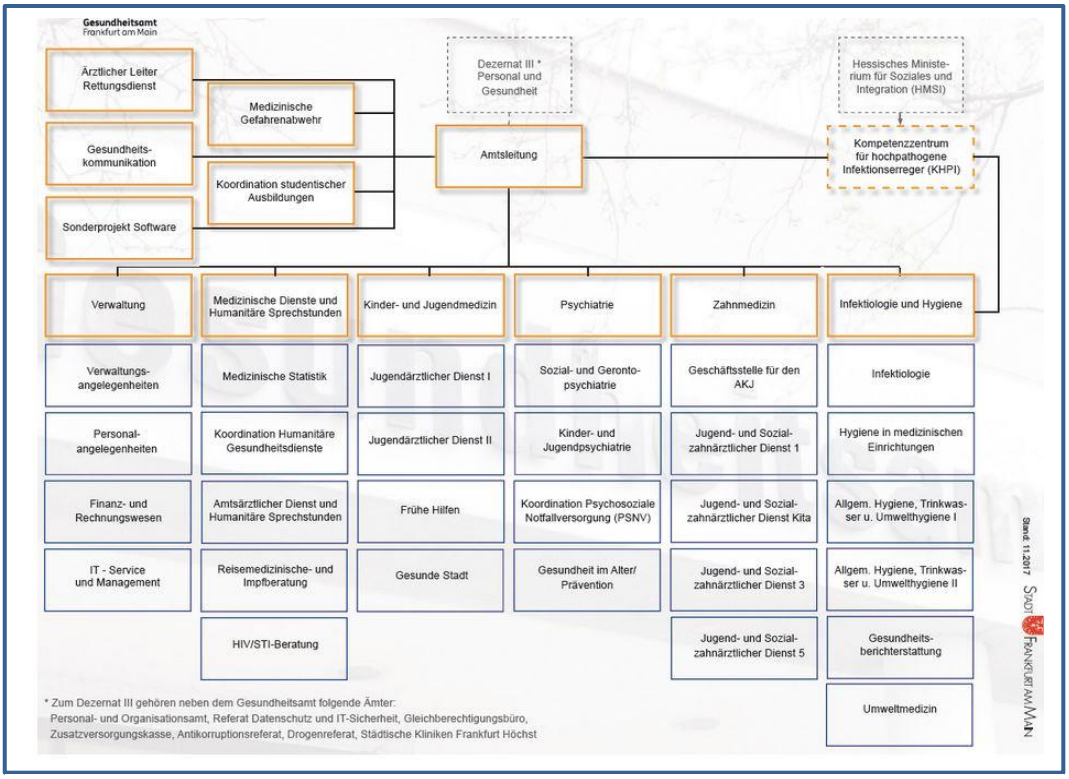

Figure 21: Representation of the Structure of the Frankfurt Public Health Department

It is not then surprising, that external research on certain key figures such as administrative costs or the number of employees in a government agency seems almost impossible. Furthermore, there is a sense that the barriers to research are deliberately complicated to make access more difficult.

The empirical study within this dissertation was able to identify many parties and assign them to main categories. Due to e.g. missing reporting standards in an environment of multiple parties with different tasks and targets, it must be noted that both the results and the structure of the parties in the respective categories only provide an overview and cannot claim to be complete. There are a number of organizations that assure their own quality (e.g. QA representatives of a hospital), while others assure the quality of others (e.g. certifiers). In addition, the functions and area of responsibility is not entirely comprehensible and evident for many parties, meaning that a holistic view and analysis of the market is not possible.

In the following chapters, the most important stakeholders in the German health care system were briefly introduced, which were included in table 17 due to their importance and function.

7.3 MEDICAL CARE

In Germany, medical care is divided into two areas: Outpatient care and inpatient care. Outpatient care includes all care services that are not provided by hospitals or clinics. By far the largest part of outpatient care is provided by physicians, psychotherapists and dentists in private practice. However, outpatient care also includes drugs prescribed by physicians and medical aids, such as hearing aids, as well as the provision of remedies such as physiotherapy and occupational therapy.

The clear separation of the two areas of care can be eliminated by cross-sectoral care under certain conditions. Examples of this are outpatient operations, which can be performed both by physicians in private practices and by employed physicians in hospitals. Another area will emerge in the future with so-called “outpatient specialist care (ASV: Ambulante Spezialfachärztliche Versorgung)”. In this context, treatment teams consisting of hospital physicians and/or contract physicians can become active under certain conditions and after obtaining the appropriate authorization. Conversely, physicians in private practice can use beds

in hospitals for their patients as so-called affiliated physicians and provide inpatient or day-care treatment.

7.3.1 ÖGD

The public health service (ÖGD) fulfils a variety of different tasks as a central actor in the care of the health of the population. It does this

- with various federal authorities
- with the state ministries as the supreme health authorities at the level of the federal states and, where applicable, state health offices
- at the local level with the local health offices.

It is organized at the state or municipal level and is oriented toward the needs of all people. Together with outpatient and inpatient individual medical care, the ÖGD forms the basis of the health care system. It makes a decisive contribution to the health care of every individual and the entire population in Germany, primarily in terms of population medicine and epidemiology.

The term ÖGD is not defined uniformly in the literature. In the sense of this dissertation, it should be understood as the tasks that are performed by state institutions and serve health care. These are thus activities of the state executive, whereas the state, for example, is only active in a regulatory, i.e. legislative, capacity in outpatient care (Troschke & Mühlbacher, 2005: 157 ff.).

Thus, on the one hand, federal authorities belong to the ÖGD, which have the following functions:

- Disease surveillance and prevention (RKI)
- Drug safety (Paul-Ehrlich-Institut)
- Clarification (BZgA)
- Documentation and information (DIMDI)

In a broader sense, this also includes authorities dealing with food safety, risk assessment, occupational, environmental and consumer protection. The structure

and responsibilities of the authorities have been changed and redefined several times in recent years.

Furthermore, the ÖGD includes institutions of the federal states or state health ministries e.g., Conference of Health Ministers and the Working Group of the Supreme State Health Authorities and, at the municipal level, the public health offices. More than 2,500 public health physicians work in the public health offices. Overall, the ÖGD deals with important issues, but measured by the number of employees, it is rather a small part of medical care.

7.3.2 BMG

The regulation of the German health care system is subject to the separation of powers between the federal and state governments, as well as institutions and interest groups at the level of self-government. At the federal level, the Bundestag, the Bundesrat and the BMG[55] are the main actors in the health care system. The self-administration is represented by G-BA and its affiliated institutes.

The supreme body for regulating medical care is the BMG. The ministry not only pursues a variety of objectives, but also has various steering instruments at its disposal, ranging from rules, commandments and regulations to financial regulations, information and education. Since it has to regulate medical care on the one hand, and the rights of those affected have to be taken into account on the other, conflicts arise that offer a diverse field of activity for legal scholars.

In its regulatory projects, the BMG seeks advice, among others from the SVR.

[55] Bundesministerium für Gesundheit (Federal Ministry of Health).

The state ministries of health essentially pursue the same goals as the BMG, but with different instruments. For example, the States regulate the number of inpatient hospital beds in the State bed plan.

7.4 REGULATION AND FUNDING

A special feature of the German medical system are corporate institutions. Particularly worthy of mention here are the health insurance funds, chambers and associations of panel physicians (e.g.: KV, KBV, KZBV). These institutions have state functions and can also use coercive measures. Under certain circumstances, membership in the body is regulated by law and not by choice.

7.4.1 GKV: Gesetzliche Krankenversicherung (SHI)

The main function of the GKV is to finance and contribute to the management of medical care for almost 90% of the German population. It is thus the largest payer of health care in Germany. About 10% of the German population is insured in the PKV. Its structure is hardly comparable to the GKV. It is essentially a private-sector construct. It is a contractual relationship between insurance company and policyholder.

The GKV and individual health insurance funds maintain other facilities:

- MDK advises the health and long-term care insurance funds on medical issues and also carries out individual assessments.
- WIdO sees itself as an institution for research for more quality and efficiency in the health care system

Analogous to WIdO, there is the institute bifg. It sees itself as a centre of competence for care and health system research and examines in particular questions of health care, financing and insurance systems.

In organizational terms, the bifg is an independent unit within BARMER.

Another institute of GKV, similar to WIdO and bifg, was WINEG of the TK. However, the institute is now completely integrated within the TK departments and has been dissolved.

The PKV also has its own scientific institute, the WIP.

The WIP regularly examines various aspects of the development of health expenditure, especially the influence of the ageing of the population. Another focus of the research is to examine the differences between PKV and GKV in health expenditure.

7.4.2 Kammern (Chambers)

The main function of the chambers of physicians, dentists, pharmacists, etc. is to monitor and develop profession-specific regulations. For example, the medical association represents the member physicians (every physician is a compulsory member of the chamber responsible for him or her) and assumes public tasks. In particular, it monitors compliance with professional regulations (professional code of conduct, equipment regulations, standards, etc.) and continuing education and training. While the state regulates medical training up to the state examination, further training to become a specialist is the responsibility of the chamber. This example also shows the smooth transition from state to corporate tasks and institutions. The individual state medical associations are united in the Federal Medical Association. The detailed discussion of this organization is covered in chapter 6.4.

7.4.3 Kassenärztliche Vereinigungen (Associations of Statutory Health Insurance Physicians)

The Associations of Statutory Health Insurance Physicians (KV)[56] ensure that outpatient medical care functions smoothly: Every patient can be treated by a registered physician or psychotherapist of his or her choice close to home and at a high level of quality - regardless of which statutory health insurance fund he or she is insured with. At the same time, the associations of GKV-accredited physicians represent the rights, duties and economic interests of GKV-accredited physicians vis-à-vis the health insurance funds. They are subject to the legal supervision of the respective competent Land ministries (ministries of health or social affairs). The fields of activity of a KV are diverse. With requirement planning, they ensure that a sufficient number of physicians are available everywhere for outpatient care, that a medical on-call service is also available during off-hours, and that the quality of services is right.

The ZI serves scientific research. The fact that the KVs represent the interests of the physicians on the one hand, and on the other hand take over sovereign tasks and distribute funds between the physicians, their tasks are partly burdened with conflicts.

7.4.4 Die Deutsche Krankenhausgesellschaft (German Hospital Federation)

Hospitals and hospital chains are united in several organizations, the most important of which is the DKG (Deutsche Krankenhausgesellschaft). In addition, there are associations of private, Protestant, Catholic, etc. hospitals.

As a federal association, the DKG stands for 28 member associations of hospital owners: 16 state associations, 12 central associations. With this diversity of providers, the DKG represents the entire range of hospital interests. As the

[56] Kassenärztliche Vereinigungen: KV.

umbrella organization of hospital owners, it promotes the interests and concerns of hospitals. As the voice of the hospitals, the DKG represents the hospitals in all health policy decisions, which is why the careful analysis of current health policy and public relations work are further central tasks of the DKG.

7.5 EDUCATION AND INFORMATION

Health insurance funds, medical committees and others jointly operate a number of institutions. The first to be mentioned here is the G-BA, which is described in detail in chapter 9.1. The G-BA is the highest decision-making body of the joint self-government of physicians, dentists, psychotherapists, hospitals and health insurance funds in Germany and decides which medical care services are paid for by the GKV and which are not. The G-BA also decides on QA measures.

7.5.1 IQWiG

IQWiG[57] was founded in 2004 in the course of the implementation of the GKV Modernization Act as a special-purpose entity of the Foundation for Quality and Efficiency in Health Care to improve the quality and efficiency of patient care in Germany. The legal basis and tasks have since been adapted and expanded by several health care reforms. The main tasks of the professionally independent scientific institute are:

- Research, presentation and evaluation of the current state of medical knowledge on diagnostic and therapeutic procedures for selected diseases.

[57] Das Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (The Institute for Quality and Efficiency in Health Care).

- Preparation of scientific papers, expert opinions and statements on questions of quality and efficiency of the services provided within the framework of statutory health insurance.
- Evaluation of evidence-based guidelines for the epidemiologically most important diseases.
- Issuing recommendations on disease management programs (DMPs).
- Evaluation of the benefits of medicinal products.
- Evaluation of the trial potential of examination and treatment methods according to § 137e Para. 7 SGB V.
- Provision of general information on quality and efficiency in health care that is comprehensible to all citizens.

In accordance with the legal mandate, the assessments focus on the benefits and harms of medical interventions for patients. In particular, the improvement of the state of health, a shortening of the duration of the disease, a prolongation of life, a reduction of side effects as well as an improvement of the quality of life are taken into account. The evaluation results and further information on diseases and health topics are published – in a generally comprehensible form. The range of tasks of such institutions can change over time. For example, the BQS was founded in 2001 and commissioned with external QA in hospitals. However, it lost this function again in 2010.

7.5.2 Information Centres

Universities should also be mentioned as centres of education in, for example, medicine, management, public health, and so on. Publishers and online information services also help shape medical care

8 RESULTS FROM THE ANALYSIS OF CLUSTERS 1-4

With a cluster[58] analysis, as an explorative procedure, objects relevant to the investigation are divided into natural groups. This provides a better overview of large data sets. The objects of investigation can be people, countries, companies, etc., which are grouped according to certain characteristics.

Cluster analysis is segmentation and not sorting. This means that no categories are predefined for the grouping, but these are only formed on the basis of the patterns within the data.

Cluster analyses are used in almost all areas. For example, they are suitable in the field of medicine and psychology: if the behaviours or clinical pictures of patients are sorted into certain clusters, a targeted therapy approach can be developed (Frey & Dueck 2007).

The task of explorative data analysis is to condense the researched data with the help of statistical measures. This means, to transparently present the information hidden in the often relatively extensive data matrix, by means of a few key figures. In addition to calculating key figures, statistical graphics are used to

[58] At this point it must be mentioned that cluster analysis is interpreted differently in the field of mathematics or EDP. Cluster analyses are procedures for discovering similarity structures in (usually relatively large) data sets. The groups of "similar" objects found in this way are called clusters, and the group assignment is called clustering. The similarity groups found can be graph-theoretical, hierarchical, partitioning or optimizing. In cluster analysis, the goal is to identify new groups in the data (as opposed to classification, which assigns data to existing classes). It is referred to as an "uninformed procedure" because it does not rely on prior class knowledge.

identify and present conspicuous patterns and correlations in the data (Frey & Dueck 2007).

Due to the amount of data available and the complexity of calculating the key figures, the analysis was carried out with the support of the "Excel" tool.

Excel not only supports data evaluation, but also the preparation, planning, logging and graphical presentation of the results. In order to keep the amount of data which has been generated manageable, columns and rows can be hidden, filtered or colour-coded in Excel. Individual steps and intermediate results can be traced in Excel. In this way, changes can be made in the course of the analysis, adjustments can be made and various parameters can be tested. In contrast to Excel, the specialized applications of large providers such as SAS, IBM or SPSS, which are designed and specialized to process millions or even billions of data records, appear too complex (Frenzel 1987; Gogolok et al. 1992).

The data sets used for the analysis, which consist of responses from the organizations and self-researched data, are summarized in the table below.

The table is analogous to the structure defined in the methodology chapter and shows in each column how many data sets were available for the calculation.

Group	Number of Organizations	EMP	EMP in QA	AC	AC in QA
Political Bodies	8	5	0	6	1
Public Corporations	32	20	13	3	2
Companies	66	33	12	3	2
Liberal Professions	56	25	10	1	0
Overall	162	83	35	13	5

Table 18: The analysed Data Sets per Cluster that were used for the Calculation (own Representation)

- Number of Organizations: The column indicates how many organizations were contacted in the respective cluster. A total of 162 organizations were contacted and researched.
- EMP (Employees), EMP in QA: The columns indicate how many organizations could be researched in terms of total number of employees and employees in QA.
- AC (Administrative Costs), AC in QA: The columns indicate how many organizations could be researched in relation to administrative costs in general and in the area of QA.

A number of the usual tests, whose application have been recommended here, work with the statistical expected values and variances. They usually require a minimum number of data sets in order to be meaningfully interpretable. Examples include the Welch test and the T-test. These can be used to test whether the expected values of different groups differ (see e.g. Yates, Moore and Starnes, The Practice of Statistics, 3rd ed., p. 792. Copyright 2008 by W.H. Freeman and Company, 41 Madison Avenue, New York, NY 10010). After reviewing and validating all clusters, such an in-depth statistical analysis was rejected, as it would have implied a quality and quantity of data that is not available.

The statistical key figures that allow a valid calculation and extrapolation of the data sets in the formed clusters are “linear regression“, “standard deviation“ and “coefficients of variation“.

Thus, a representative value for the “cost per employee” can be determined using linear regression. When plotting the total costs against the number of employees, the slope reflects the value for the “costs per employee”. However, in order to be able to appropriately examine the deviations within the selected clusters, which come about through the results of the linear regression, and to ensure a valid comparison of the clusters, the coefficient of variation (deviation coefficient) was chosen as a supplementary key figure. The advantage of the coefficient of variation over the standard deviation is that the coefficient of variation is indifferent to the scale on which the data were measured (Duller 2018).

In this case, the coefficient of variation is calculated from the quotients of the standard deviation and costs per employee.

This described calculation basis was applied for clusters “Political Bodies”, “Public Corporations” and “Companies“. Insufficient data sets in the cluster "Liberal Professions" do not allow for a calculation of the coefficient of variation.

For the “Freelance Professions” cluster, the mean value of the other three clusters had to be used to calculate the “costs per employee” due to the lack of important data sets.

In each cluster, there is a preliminary projection calculated using the available data. A final extrapolation of QA administrative costs (AC) for clusters 1-4 are discussed subsequently in the section “Pooling QA administrative costs and extrapolation”.

Due to the fact that the collected data in each cluster were not available in the same amount, the description of the results is not analogous to the order of the clusters formed. For better presentation and clarification, the description starts with the second cluster “Public Corporations”.

8.1 ANALYSIS OF CLUSTER: PUBLIC CORPORATIONS

For the calculation “costs per employee“, two entities were used for which the data sets EMP total and total administrative costs were available. The result was used as a basis for the preliminary extrapolation of the missing data and for calculating the administrative costs of other entities in this cluster.

A closer look at this cluster reveals that a number of organizations have a low number of employees or the number of EMP-QA is exactly the same as the total number of EMP. A holistic view of the cluster with all available data in the matrix would therefore distort the statistical significance. In order to nevertheless obtain a

more valid result, an additional key figure "percentage weighting" was chosen so that the entities mentioned do not affect the overall result too drastically.

Despite the introduction of the percentage weighting, it was determined after several calculations that IQTIG, with its 100 employees all working in QA at the same time, could not be excluded from "diluting" the overall result. Thus, IQTIG was excluded from the calculation.

The result of the cluster can be mapped as follows:

- The slope from the linear regression yields a value of: €62,364.00 as "cost per employee".

Due to the missing data sets, the key figures standard deviation and coefficient of variation cannot be calculated.

With the existing data records, the key figure "percentage weighting" was used to create the basis for extrapolating the percentage of EMP-QA. Of a total of 2,338 employees, 291 work in QA. Thus, the ratio of employees working in QA is 12.4%.

With the assumption that 12.4% of the employees work in QA, the preliminary extrapolation for this cluster results in:

- 20,537 EMP-QA with a volume of €1,280,392,920.00 incurred for QA administration costs.
- The largest share of this sum is made up by the GKV with over €1,037,924,052.00.

Cluster: Public Corporations				
Organizations	**#EMP**	**#EMP in QA**	**AC**	**AC in QA**
AkdÄ	25	n/a (3)	n/a (€1,559,100.00)	n/a (€187,092.00)
AQUA-Institute	90	60	n/a (€5,612,760.00)	n/a (€3,741,840.00)
ÄZQ	30	8	n/a (€1,870,920.00)	n/a (€498,912.00)
BAK	88	17	€5,935,881.00	n/a (€1,060,188.00)
BÄK	1,429	122	n/a (€89,118,156.00)	n/a (€7,608,408.00)
BGW (qu.int.as)	2,000	n/a (248)	n/a (€124,728,000.00)	n/a (€15,466,272.00)
†BPtK	n/a	n/a	n/a	n/a
†BZÄK	n/a	n/a	n/a	n/a
†DQE	n/a	n/a	n/a	n/a
DRK Landesverband Baden-Württemberg e.V.	48	3	n/a (€2,993,472.00)	€60,000.00
DRV	17,336	n/a (2150)	€1,081,137,948.00	n/a (€134,082,600.00)
†G-BA	n/a	n/a	n/a	n/a
Gesetzliche Kranken-versicherungen	134,217	n/a (16,643)	€11,200,000,000.00	n/a (€1,037,924,052.00)
†Gesetzliche Unfallversicherungen	n/a	n/a	n/a	n/a

GKV-Spitzenverband (QS-Reha)	356	16	n/a (€22,204,584.00)	n/a (€997,824.00)
†Hochschulen	n/a	n/a	n/a	n/a
†IQN	n/a	n/a	n/a	n/a
IQTIG	110	110	n/a (€6,860,040.00)	n/a (€6,860,040.00)
IQWiG	185	n/a (23)	n/a (€11,537,340.00)	n/a (€1,434,372.00)
†KBV (KV)	n/a	n/a	n/a	n/a
KCQ	7	5	n/a (€436,548.00)	n/a (€311,820.00)
†KV	n/a	n/a	n/a	n/a
KZBV	120	4	n/a (€7,483,680.00)	€515,00.00
LQS	89	n/a (11)	n/a (€5,550,396.00)	n/a (€686,004.00)
MDK	8,406	n/a (1,042)	n/a (€524,231,784.00)	n/a (€64,983,288.00)
MDS e.V.	70	36	n/a (€4,365,480.00)	n/a (€2,245,104.00)
†Öffentliche Haushalte	n/a	n/a	n/a	n/a
†Soziale Pflegeversicherungen	n/a	n/a	n/a	n/a
†SQG	n/a	n/a	n/a	n/a
WIdO	89	14	n/a (€5,550,396.00)	n/a (€873,096.00)
ZI	56	16	n/a (€3,492,384.00)	n/a (€997,824.00)

ZQ	11	6	n/a (€686,004.00)	n/a (€374,184.00)
Overall	**164,762**	**20,537**	**€13,105,354,873.00**	**€1,280,392,920.00**

Table 19: Researched Data Sets and Extrapolation for Cluster Public Corporations

n/a = Values are not known

(...) = Values in brackets result from extrapolation

† = Not included in the calculation of the statistics because no data sets were

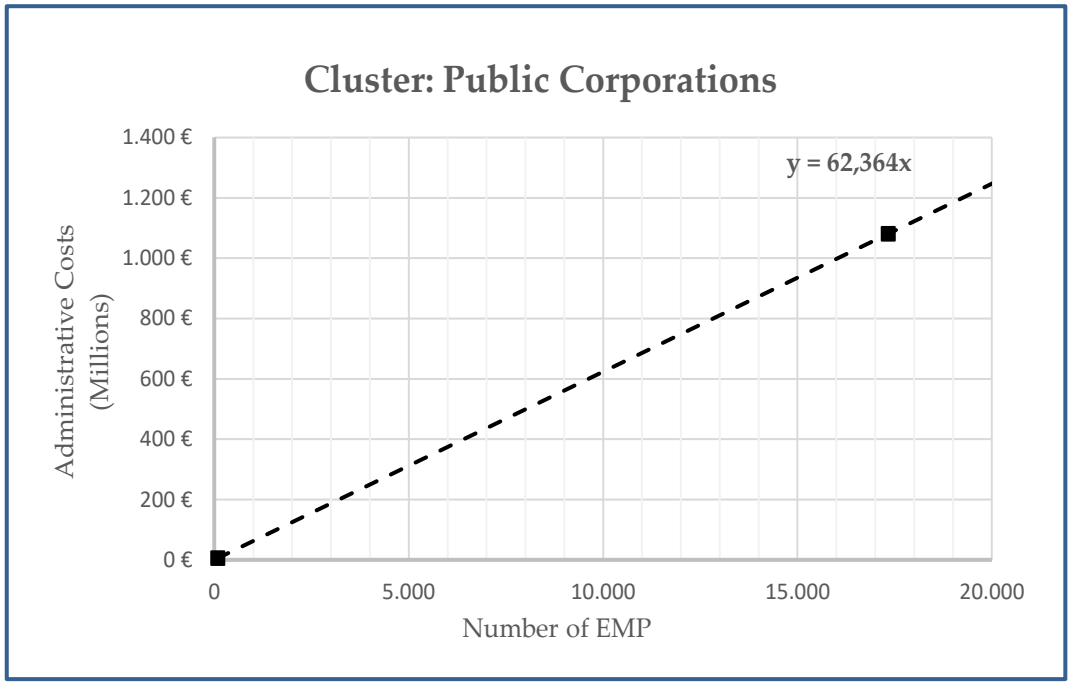

Figure 22: Linear Regression to determine "costs per employee" for Cluster Public Corporations

Cluster: Public Corporations				
Organizations	**#EMP**	**#EMP in QA**	**% of EMP in QA**	**Weighting [%]**
AQUA-Institute	90	60	66,7	3,8
ÄZQ	30	8	26,7	1,3
BAK	88	17	19,3	3,8
BÄK	1429	122	8,5	61,1
DRK – Landesverband Baden-Württemberg e.V.	48	3	6,3	2,1
GKV-Spitzenverband	356	16	4,5	15,2
KCQ	7	5	71,4	0,3
KZBV	120	4	3,3	5,1
MDS e.V.	70	36	51,4	3,0
WidO	89	14	15,7	3,8
ZQ	11	6	54,5	0,5
Overall	**2,338**	**291**	**Total product: 12,4%**	

Table 20: Calculation of the Percentage Weighting to determine the Number of Employees in QA for the Cluster Public Corporations

8.2 ANALYSIS OF CLUSTER: COMPANIES

The data matrix for this cluster contains quite a few companies, but they have incomplete or no data at all for a valid statistical evaluation. The complex research already described could not contribute any further data to complete the data for this cluster. The problem from all the clusters formed, namely:

- No reply to the mails
- Reference to already published data or documents
- No information because of data protection also applies to this cluster.

Consequently, only the data from three companies could be used for the evaluation and preliminary extrapolation.

Analogous to the cluster "Public Corporations" with the corresponding calculation basis, the "slope" was obtained from the linear regression.

The results of the cluster can be presented as follows:

- The slope yields €58,799.00 "cost per employee"

TÜV NORD had to be excluded from this calculation because the administrative costs per employee amount to approx. €165,000 and would thus have distorted the calculation.

In this cluster, as well, the necessary data sets are missing in order to calculate the standard deviation and the coefficient of variation.

The percentage share of EMP-QA, calculated according to percentage weighting, is:

- EMP-QA share: 9,3%
- Accordingly, according to preliminary extrapolation: 462,411 EMP-QA
- The total volume for QA administration costs is: €20,692,314,246.10

Due to the problem of significance already described and the associated dilution of the results, many of the institutions included and researched could not be included in the evaluation. These companies have accordingly been excluded from the data matrix for the calculation[59].

[59] At this point it must be noted (under the premise that the rejected companies are included in the calculation) that the total QA administration costs for this cluster are considerably higher than already calculated.

The very low rate of EMP-QA and the associated administrative costs in the hospitals is due to the fact that the hospitals usually commission external QA providers.

More in-depth research to explain the low rates has shown that most of the external QA officers who carry out the operational audits have themselves been physicians or senior physicians. Audits and visits have the task of assessing the quality currently provided, identifying system deficiencies, revealing inefficiencies and ultimately modifying professional behaviour at the individual level. This is done retrospectively or prospectively, in particular by analyzing process data e.g. medical records, prescription behaviour, but also practice structure and organization. In comparison with the underlying standard e.g. DIN EN ISO 9001:2000, specially trained auditors/inspectors assess whether the outpatient or inpatient facility has introduced QM that complies with the standard and, above all, is actually practiced. The use of "former colleagues" thus seems to be common practice in this sector. The calculated key figures support this assumption.

Cluster: Companies				
Organizations	**#EMP**	**#EMP in QA**	**AC**	**AC in QA**
Ambulante Pflege	407,000	n/a (37,851)	n/a (€23,931,193,000.00)	n/a (€2,225,600,949.00)
†ANOA	n/a	n/a	n/a	n/a
AVG	3,000	n/a (279)	n/a (€176,397,000.00)	n/a (€16,404,921.00)
AWO Bundesverband e.V.	212,000	n/a (19,716)	n/a (€12,465,388,000.00)	n/a (€1,159,281,084.00)
†BAGFW e.V.	n/a	n/a	n/a	n/a
BAR e.V.	32	5	n/a (€1,881,568.00)	n/a (€293,995.00)
BAV Institut	65	2	n/a (€3,821,935.00)	n/a (€117,598.00)

†BDPK	n/a	n/a	n/a	n/a
†BQS	n/a	n/a	n/a	n/a
†BSI Group Deutschland GmbH	n/a	n/a	n/a	n/a
†CAC	n/a	n/a	n/a	n/a
†Cert iQ Zertifizierungsdienst-leistungen GmbH	11	9	n/a (€646,789.00)	n/a (€529,191.00)
CertEuropA GmbH	10	6	n/a (€587,990.00)	n/a (€352,794.00)
ClarCert GmbH	n/a (54)	5	n/a (€3,175,146.00)	n/a (€293,995.00)
†DAG-KBT e.V.	n/a	n/a	n/a	n/a
†dagnä e.V.	n/a	n/a	n/a	n/a
†DEKRA Certification GmbH	n/a	n/a	n/a	n/a
Deutscher Verlag für Gesundheits-information GmbH	22	n/a (2)	n/a (€1,293,578.00)	n/a (€117,598.00)
DIOcert GmbH	6	n/a (1)	n/a (€352,794.00)	n/a (€58,799.00)
†diqp	n/a	n/a	n/a	n/a
DKG	100	n/a (9)	n/a (€5,879,900.00)	n/a (€529,191.00)
DNVF e.V.	7	n/a (1)	n/a (€411,593.00)	n/a (€58,799.00)
DPA GmbH	11	n/a (1)	n/a (€646,789.00)	n/a (€58,799.00)
DQS GmbH	200	n/a (19)	n/a (€11,759,800.00)	n/a (€1,117,181.00)

ENPP-Boehm GmbH	13	13	n/a (€764,387.00)	n/a (€764,387.00)
†EQ Zert	n/a	n/a	n/a	n/a
†EQS	n/a	n/a	n/a	n/a
†EurSagety Qualitätsverbund	n/a	n/a	n/a	n/a
†GQMG	n/a	n/a	n/a	n/a
†Gütegemeinschaft Pflege in stationären Einrichtungen e.V.	n/a	n/a	n/a	n/a
†Heimverzeichnis GmbH	n/a	n/a	n/a	n/a
†IGES Institut GmbH	n/a	n/a	n/a	n/a
†IMC clinicon GmbH	n/a	n/a	n/a	n/a
i-med-cert GmbH	4	4	n/a (€235,196.00)	n/a (€235,196.00)
infaz GmbH	3	n/a (1)	n/a (€176,397.00)	n/a (€58,799.00)
Institut für Pflegemanagement	5	n/a (1)	n/a (€293,995.00)	n/a (€58,799.00)
IQD	12	12	n/a (€705,588.00)	n/a (€708,588.00)
IQH e.V.	3	n/a (1)	n/a (€176,397.00)	n/a (€58,799.00)
IQM e.V.	7	3	n/a (€411,593.00)	n/a (€176,397.00)
†IQMG	n/a	n/a	n/a	n/a
†iqpr GmbH	n/a	n/a	n/a	n/a
†ISGPN	n/a	n/a	n/a	n/a

Kneip-Bund	66	5	n/a (€3,880,734.00)	n/a (€293,995.00)
Krankenhäuser	1,194,000	n/a (111,042)	€70,200,000,000.00	n/a (€6,29,158,558.00)
KTQ	6	3	n/a (€352,794.00)	n/a (€176,397.00)
†LGA InterCert GmbH	n/a	n/a	n/a	n/a
†MFT-Zert GmbH	n/a	n/a	n/a	n/a
†MICADO HEALTH CARE GmbH	n/a	n/a	n/a	n/a
†OnkoZert GmbH	n/a	n/a	n/a	n/a
pCC (proCum Cert GmbH)	8	n/a (1)	n/a (€470,392.00)	n/a (€58799.00)
Pharmaunternehmen	158,000	n/a (14,694)	n/a (€9,290,242,00.00)	n/a (€863,992,506.00)
†PKV	n/a	n/a	n/a	n/a
QS-Reha	n/a	n/a	n/a	n/a
Qualitätspraxisverb. Humanitus GmbH	3	n/a (1)	n/a (€176,397.00)	n/a (€58,799.00)
QuQuK	3	n/a (1)	n/a (€176,397.00)	n/a (€58,799.00)
Rettungsdienste	75,000	n/a (6,975)	n/a (€4,409,925,000.00)	n/a (€410,123,025.00)
†SQ Cert GmbH	n/a	n/a	n/a	n/a
Stationäre / teilstationäre Einrichtungen	2,055,000	n/a (191,115)	n/a (€120,831,945,000.00)	n/a (€11,237,370,885.00)
Stationäre / teilstationäre Pflege	739,000	n/a (68,727)	n/a (€43,452,461,000.00)	n/a (€4,041,078,873.00)

TÜV Nord Cert GmbH	3,653	300	€606,278,000.00	€49,790,145.10
†TÜV Rheinland Cert GmbH	n/a	n/a	n/a	n/a
TÜV Süd Management Service GmbH	23,024	n/a (260)	€1,572,900,000.00	€15,302,710.00
†VoltaMed GmbH	n/a	n/a	n/a	n/a
Vorsorge- / Rehabilitations-einrichtungen	122,000	n/a (11,346)	n/a (€7,173,479,000.00)	n/a (€667,133,454.00)
†WIESO CERT GmbH	n/a	n/a	n/a	n/a
†ZertSozial GmbH	n/a	n/a	n/a	n/a
Overall	**4,992,328**	**462,411**	**€284,858,244,149.00**	**€20,692,314,246.10**

Table 21: Researched Data Sets and Extrapolation for Cluster Companies

n/a = Values are not known

(...) = Values in brackets result from extrapolation

† = Not included in the calculation of the statistics because no data sets were available

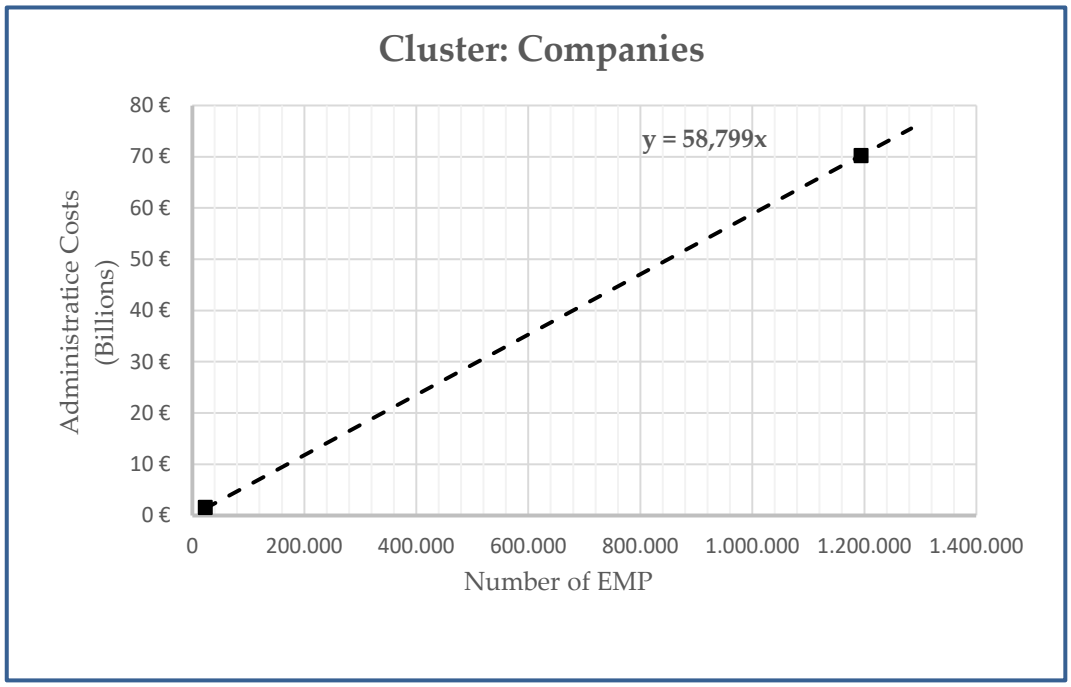

Figure 23: Linear Regression to determine "costs per employee" for Cluster Companies

Cluster: Companies				
Organizations	**#EMP**	**#EMP in QA**	**% of EMP in QA**	**Weighting [%]**
BAR e.V.	32	5	15,6	0,8
BAV Institut	65	2	3,1	1,7
Cert iQ Zertifizierungsdienst-leistungen e.V.	11	9	81,8	0,3
CertEuropA GmbH	10	6	60,0	0,3
ENPP-Boehm GmbH	13	13	100	0,3
i-med-cert GmbH	4	4	100	0,1
IQD	12	12	100	0,3
IQM e.V.	7	3	42,9	0,2
Kneipp-Bund e.V.	66	5	7,6	1,7
KTQ	6	3	50,0	0,2

TÜV Nord Cert GmbH	3653	300	8,2	93,8
VDBD e.V.	14	1	7,1	0,4
Overall	**3,893**	**363**	**Total product: 9,3%**	

Table 22: Calculation of the Percentage Weighting to determine the Number of Employees in QA for Cluster Companies

8.3 ANALYSIS OF CLUSTER: LIBERAL PROFESSIONS

In this cluster, important data sets are missing that would have been necessary for the calculation of the key figures of the linear regression and the coefficient of variation. For the calculation and preliminary extrapolation based on the percentage weighting, the data sets of eight companies in the freelance professions could be used.

The results are as follows:

- The calculated percentage share of QA employees in this cluster is: 11.6%.

To be able to determine the QS administrative costs, the average of the other three clusters was applied.

- Cluster 1: €51,121.00
- Cluster 2: €62,364.00
- Cluster 3: €58,799.00

Thus, the average administrative cost of QA-EMP in this cluster is €57,428.00. According to preliminary extrapolation a total of 553,199 employees work in QA with a volume of €31.769.102.172,00 as a preliminary result.

Cluster: Liberal Professions				
Organizations	**#EMP**	**#EMP in QA**	**AC**	**AC in QA**
Ambulante Einrichtungen	2,364,000	n/a (274,224)	n/a (€135,759,792,000.00)	n/a (€15,748,135,872.00)

Apotheken	160,465	n/a (18,614)	€31,459,440,000.00	n/a (€1,068,954,792.00)
Arztpraxen	708,000	n/a (82,128)	n/a (€40,659,024,000.00)	n/a (€4,716,446,784.00)
BHÄV e.V.	38	n/a (4)	n/a (€2,182,264.00)	n/a (€229,712.00)
bpa e.V.	n/a	n/a	n/a	n/a
BVOU e.V.	n/a	n/a	n/a	n/a
DAKJ e.V.	3	3	n/a (€172,284.00)	n/a (€172,284.00)
DCV	n/a	n/a	n/a	n/a
DDG	10	2	n/a (€574,280.00)	n/a (€114,856.00)
DEGAM	19	2	n/a (€1,091,132.00)	n/a (€114,856.00)
DeGIR	3	n/a (1)	n/a (€172,284.00)	n/a (€57,428.00)
Deutscher Hausärzteverband e.V.	n/a	n/a	n/a	n/a
Deutscher Paritätischer Wohlfahrtsverband-Gesamtverband e.V.	140	4	n/a (€8,039,920.00)	n/a (€229,712.00)
DGA e.V.	n/a	n/a	n/a	n/a
DGAV e.V.	n/a	n/a	n/a	n/a
DGE e.V.	n/a	n/a	n/a	n/a
DGfN e.V.	n/a	n/a	n/a	n/a
DGG e.V.	n/a	n/a	n/a	n/a

DGHO e.V.	12	7	n/a (€689,136.00)	n/a (€401,996.00)
DGI e.V.	n/a	n/a	n/a	n/a
DGIM e.V.	10	5	n/a (€574,280.00)	n/a (€287,140.00)
DGK e.V.	34	4	n/a (€1,952,552.00)	n/a (€229,712.00)
DGKCH e.V.	n/a (9)	1	n/a (€516,852.00)	n/a (€57,428.00)
DGKJ e.V.	7	n/a (1)	n/a (€401,996.00)	n/a (€57,428.00)
DGN e.V.	6	n/a (1)	n/a (€344,568.00)	n/a (€57,428.00)
DGOU e.V.	14	n/a (2)	n/a (€803,992.00)	n/a (€114,856.00)
DGPM	n/a	n/a	n/a	n/a
DGPR e.V.	n/a	n/a	n/a	n/a
DGQ e.V.	n/a	n/a	n/a	n/a
DGSM e.V.	n/a	n/a	n/a	n/a
DGSPJ e.V.	n/a	n/a	n/a	n/a
DGTHG e.V.	n/a	n/a	n/a	n/a
DHG e.V.	12	n/a (1)	n/a (€689,136.00)	n/a (€57,428.00)
DIGAB e.V.	n/a	n/a	n/a	n/a
DKG e.V.	81	n/a (9)	n/a (€4,651,668.00)	n/a (€516,852.00)
DMG e.V.	n/a	n/a	n/a	n/a
DOG e.V.	10	n/a (1)	n/a (€574,280.00)	n/a (€57,428.00)

DSG	14	n/a (2)	n/a (€803,992.00)	n/a (€114,856.00)
DTG e.V.	n/a	n/a	n/a	n/a
DVO e.V.	n/a (26)	3	n/a (€1,493,128.00)	n/a (€172,284.00)
Gesundheitshand-werk/-einzelhandel	n/a	n/a	n/a	n/a
GMDS e.V.	n/a	n/a	n/a	n/a
ISQ e.V.	n/a	n/a	n/a	n/a
Krankenpfleger	645,000	n/a (74,820)	n/a (€37,041,060,000.00)	n/a (€4,296,762,960.00)
LAGO e.V.	13	n/a (1)	n/a (€746,564.00)	n/a (€57,428.00)
Nikodemus-Werk e.V.	n/a	n/a	n/a	n/a
Physiotherapeuten	n/a	n/a	n/a	n/a
Praxen sonstiger medizinischer Berufe	532,000	n/a (61,712)	n/a (€30,551,696,000.00)	n/a (€3,543,996,736.00)
QgP	n/a	n/a	n/a	n/a
QSV	n/a	n/a	n/a	n/a
Sonstige Einrichtungen medizinischer Berufe	n/a	n/a	n/a	n/a
VDBD e.V.	14	1	n/a (€803,992.00)	n/a (€57,428.00)
VKAD e.V.	n/a	n/a	n/a	n/a
VLOU e.V.	n/a	n/a	n/a	n/a
VOD e.V.	15	n/a (2)	n/a (€861,420.00)	n/a (€114,856.00)
Zahnarztpraxen	359,000	n/a	n/a	n/a

		(41,644)	(€20,616,652,000.00)	(€2,391,531,632.00)
Overall	**4,768,955**	**553,199**	**€296,115,803,720.00**	**€31,769,102,172.00**

Table 23: Researched Data Sets and Extrapolation for Cluster Liberal Professions

n/a = Values are not known

(...) = Values in brackets result from extrapolation

Cluster: Liberal Professions				
Organizations	**#EMP**	**#EMP in QA**	**% of EMP in QA**	**Weighting [%]**
DAKJ e.V.	3	3	100	1,2
DDG	10	2	20,0	4,1
DEGAM	19	2	10,5	7,9
Deutscher Paritätischer	140	4	2,9	57,9
DGHO e.V.	12	7	58,3	5,0
DGIM e.V.	10	5	50,0	4,1
DGK e.V.	34	4	11,8	14,0
VDBD e.V.	14	1	7,1	5,8
Overall	**242**	**28**	**Total product: 11,6%**	

Table 24: Calculation of the Percentage Weighting to determine the Number of Employees in QA for the Cluster Liberal Professions

8.4 ANALYSIS OF CLUSTER: POLITICAL BODIES

Analogous to the previous two clusters, the results for this cluster can be presented as follows:

- "Cost per employee" based on linear regression: €51,121.00
- Standard deviation: €12,889.98
- Coefficient of variation: 25.3%

Based on administrative costs and administrative costs QA of the RKI, the percentage share of employees in QA can be calculated.

This percentage is: 4.5%.

For the calculation of the number of employees in QA, the calculated value of 4.5% can be applied to obtain the preliminary extrapolation of total administrative costs QA.

The extrapolated QA administrative costs are: €49,935,088.00 with an extrapolated share of employees in QA of 976.

Cluster: Political Bodies				
Organizations	**#EMP**	**#EMP in QA**	**AC**	**AC in QA**
BfArM	1,050	n/a (47)	€65,117,000.00	n/a (€2,402,687.00)
BMG	n/a (1,193)	n/a (54)	€60,979,000.00	n/a (€2,760,534.00)
BZgA	350	n/a (16)	€11,336,000.00	n/a (€817,936.00)
DIMDI	n/a (164)	n/a (7)	€8,403,000.00	n/a (€357,847.00)
Gesundheitsämter	17,000	n/a (763)	n/a (€869,057,000.00)	n/a (€39,005,323.00)
Paul-Ehrlich-Institut	900	n/a (41)	€35,894,000.00	n/a (€2,095,961.00)
Robert-Koch-Institut	1,100	n/a (48)	€55,601,000.00	€2,494,800.00
SVR	n/a	n/a	n/a	n/a
Overall	**21,757**	**976**	**€1,106,387,000.00**	**€49,935,088.00**

Table 25: Researched Data Sets and Extrapolation for Cluster Political Bodies

n/a = Values are not known

(...) = Values in brackets result from extrapolation

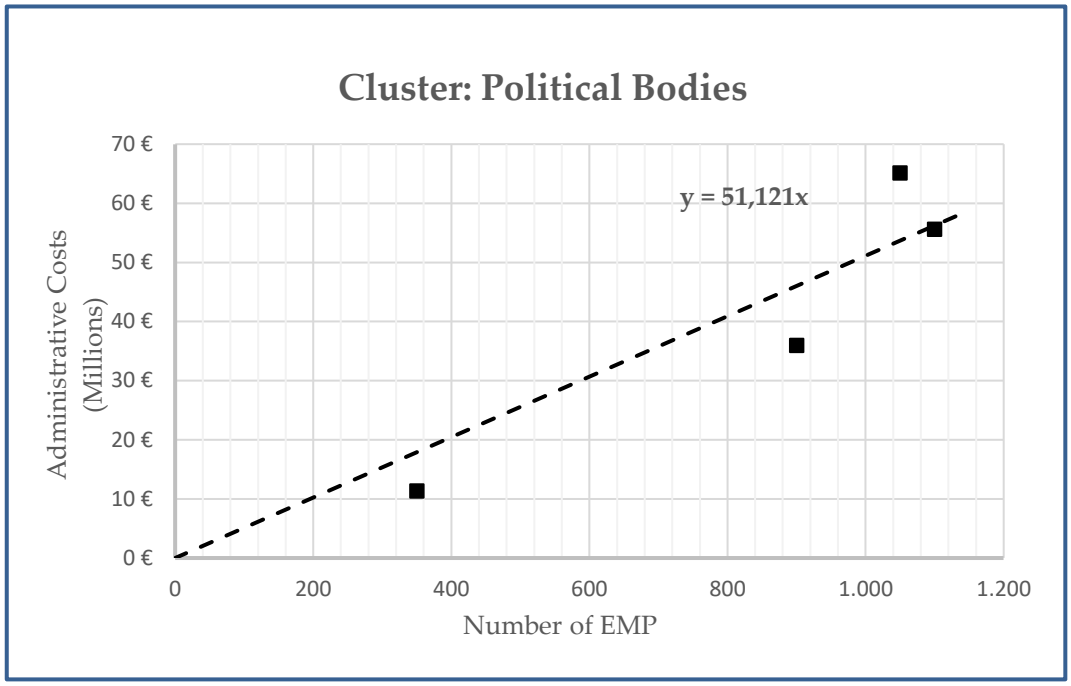

Figure 24: Linear Regression to determine "costs per employee" for Cluster Political Bodies

8.5 AGGREGATION OF QA ADMINISTRATIVE COSTS AND THE FINAL EXTRAPOLATION

A total of 87 datasets were available across four clusters, which acted as the basis for calculating QA administrative costs.

Explanation of the extrapolation with missing data sets based on the second cluster:

For this cluster, 34 out of 66 data sets were available to be used for the calculation of QA administrative costs.

On the premise that the 34 records account for $\frac{34}{66}$, the QA administrative costs can be extrapolated to 100%, namely from €20,692,314,246.10 to €40,167,433,536.55.

In this way, clusters one and four can also be extrapolated to 100%, so that the final result of the four clusters for QA administration costs is €110,698,889,404.86.

A detailed evaluation of the estimated total costs is discussed in chapter 10.2.

8.6 JACKKNIFE

In order to be able to better assess the randomness within the sample and thus the quality of the extrapolation, a method is used from the field of bootstrap methods that disregards assumptions about the underlying distribution. In bootstrap methods, different statistical data are repeatedly calculated on the basis of the existing sample, see e.g. Bradley Efron 1979 Bootstrap Methods: Another Look at the Jackknife. This is done with the aim of being able to derive further information from the existing data in a meaningful way. While the term bootstrap has become generally accepted, the term Münchhausen method is also used in German-speaking countries. The name comes from the idea of pulling oneself out of the swamp, once by one's own hair and once by one's own shoelaces. One of these methods is the delete-1-Jackknife method. The name - Jackknife - is meant to refer to the universal applicability of the method and no conditions are placed on the underlying distribution.

In this case, it is considered how the sample behaves when any value is dropped from the sample. To do this, we look at the mean values that result when one value is dropped from the sample. In the example of cluster Political Bodies, this means looking at the four mean values that result when PEI, RKI, BZgA and BfArM are each dropped. The mean value of the AC in QA in this cluster is €1,953 K; the standard deviation is €224 K or 12.5% of the mean value. The result can be

interpreted in several ways. Since almost all entities responded in this cluster, it is reasonable to conclude that the Political Bodies set different priorities in QA.

If the data are homogeneous, e.g., assuming that within a cluster the costs for QA follow the same distribution, a lower value for the standard deviation of the jackknife distribution would be expected than if the data were not homogeneous.

The method does not provide a clear explanation for the deviations.

However, it is conceivable, for example, that there are different valuations within a cluster. In each organization, QA, but also material and personnel costs are classified differently. The higher value is therefore an indicator for systematic differences.

9 A SELECTION OF RELEVANT POLITICAL BODIES AND PUBLIC CORPORATIONS OF THE GERMAN HEALTH CARE SYSTEM – OBJECT OF RESEARCH FOR THE STUDY

With the law on the GMG in 2004, the legislator created new institutions in the health sector. Some of these are old friends that have only been given a new name and assigned additional tasks, such as the Federal Committee of Physicians and Health Insurers, now the G-BA. But it is not only the legislator who has increased the number of health institutions through the various health reforms, but also the already well-known players such as the Federal Medical Association and the National Association of Statutory Health Insurance Physicians have contributed to the multitude of institutions by concluding cooperation agreements. Each of these institutions appears in public and presents results of expert discussions, research groups or statistical surveys in the form of statements, resolutions, guidelines or recommendations.

In this chapter, the political bodies and public corporations are examined and described in more detail due to their importance for the German health system.

The selection of these parties is based on table 17 from chapter 7.2.4.

By definition, BQS and KBV are not political bodies or public corporations. Nevertheless, due to their importance in the German healthcare system, they are discussed and presented in this chapter.

9.1 G-BA – DER GEMEINSAME BUNDESAUSSCHUSS

The best-known institution, which is almost exclusively referred to by the abbreviation G-BA, is the Joint Federal Committee. The G-BA was founded in the course of the reform of the statutory health insurance system on 01.01.2004.

According to § 91 SGB V, the G-BA is the highest "decision-making body of the joint self-administration" of physicians, dentists, psychotherapists, hospitals and health insurance companies in Germany. The G-BA has been given responsibility for guideline competence for the catalogue of services of the GKV by the legislator through § 91 SGB V. The G-BA is responsible for the decision-making process. The G-BA thus determines which medical care services are reimbursed by the GKV system for those with statutory health insurance. In addition, the G-BA decides on QA measures for the outpatient and inpatient sectors of the health care system.

The decision-making structures of the BQS procedure changed in 2004 with the GKV Modernisation Act (GMG). Pursuant to Section 137 (1) of the German Social Code, Book V, responsibility for the procedure of external comparative QA was transferred from the Federal Board of Trustees for QA to the G-BA. The G-BA thus became the central advisory and decision-making body for the external quality comparison of approved hospitals according to § 108 SGB V. With the health reform of 2007 (GKV-Wettbewerbsbestärkungsgesetz), the previously sectorally-organized structure of the G-BA changed. Since 1 July 2008, all decisions are made in a single cross-sectoral decision-making body for outpatient, medical, dental and inpatient matters.

The G-BA is formed from the four large self-governing organizations in the health system:

- The National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung: KBV)
- The Federal Association of Statutory Health Insurance Dentists (Kassenzahnärztliche Bundesvereinigung: KZBV)
- The German Hospital Federation (Deutsche Krankenhausgesellschaft: DKG)
- The National Association of Health Insurance Funds (Spitzenverband Bund der Krankenkassen: GKV-Spitzenverband)

Organizations that primarily represent the interests of patients and self-help groups of chronically ill and disabled people at a federal level have the right to

participate in consultations and submit proposals in the G-BA in accordance with the provisions of the Social Code Book V, but have no voting rights.

In addition to the plenum (which meets in public session), the committees of the G-BA currently include nine permanently established subcommittees for the areas:

- Medicines
- QA
- Disease management programs
- Outpatient specialist care
- Method evaluation
- Initiated services
- Demand planning
- Psychotherapy
- Dental treatment

These committees prepare the resolutions for the G-BA from a technical point of view. Within the framework of its legal mandate, the G-BA continuously adopts further resolutions, in particular for the revision and further development of each of the numerous guidelines.

The sub-committees consist of:

- An impartial member of the G-BA who also chairs the subcommittee
- Six members appointed by the GKV-Spitzenverband
- A total of six members appointed by the umbrella organizations of the service providers (DKG, KBV, KZBV)

The composition of the service provider side shall be based on parity, unless the plenary determines a different composition in view of the subcommittee's remit.

The working methods of the G-BA, the management and other organizational issues are regulated in rules of procedure, which are subject to the approval of the Federal Ministry of Health (BMG). The methodological requirements for the scientific assessment of the benefit, necessity and cost-effectiveness of services and measures by the G-BA and further procedural issues are regulated by the rules of procedure (also to be approved by the BMG).

In order to ensure transparency and opportunities for participation in the decision-making process in the G-BA, associations and institutions that are affected by the respective decisions of the G-BA have the right to submit their comments in writing and also to present them orally.[60]

9.2 BQS

BQS[61] (2001 to 2009: Bundesgeschäftsstelle Qualitätssicherung GmbH) is a company specialising, especially, in the presentation of quality of care on behalf of various partners in the health care system. BQS was responsible for statutory QA in German hospitals from 2001 to 2009.

The BQS was founded in 2000 by the German Medical Association, the German Hospital Association, the GKV-Spitzenverband and the Association of Private Health Insurers as an institution of self-administration and was initially active on behalf of the Federal Board of Trustees for QA.

With the GKV Modernisation Act on 1 January 2004, the responsibilities for regulations in the area of external QA were transferred from the Federal Board of Trustees to the new G-BA in accordance with § 91 Para. 7 SGB V. The G-BA then

[60] www.g-ba.de (accessed: 23.05.2019).

[61] Institut für Qualität & Patientensicherheit – Institute for Quality & Patient Safety.

commissioned the BQS to carry out data-based external QA for all German hospitals in 2005.

However, with the GKV Competition Strengthening Act of 2007, the G-BA was obliged under § 137a SGB V to commission a professional, independent institution to determine and present the quality of medical care. However, the BQS lost out in the Europe-wide call for tenders, and its work on behalf of the G-BA according to § 137a SGB V ended on 31 December 2009. As of 1 January 2010, the AQUA-Institute, based in Göttingen, took over these tasks. The office then renamed itself the Institute for Quality and Patient Safety GmbH (BQS) and expanded its range of services.

This company publishes scientific reports on medical and nursing quality in hospitals. For this purpose, it receives data from just less than 20 per cent of inpatient treatment cases.

It develops and operates medical registries. The focus of its activities is on medical and nursing topics, statistical methods, information technology for data management, presentation and evaluation of results, support for users and implementation of the structured dialogue in the indirect procedure.

In this context, the BQS moderates the work of specialist groups and project groups, supports data collection and data transmission by developing specifications for data sets, plausibility rules and export formats. It receives documented data records, checks them for plausibility and completeness of the data, carries out evaluations of the quality-relevant data on defined service areas and prepares reports on the quality situation in care.

In addition, the BQS coordinates the work of associations and institutions at a federal level and in the federal states, as well as that of manufacturers of hospital application software in hospitals and users in hospitals, physicians' practices and other healthcare facilities.

The BQS also has special expertise in the development of survey instruments. A focus in the area of comprehensive evaluation projects such as studies/expert reports, measurement procedures such as the QS-Reha procedure (chapter 9.2.1) or also in the area of Picker surveys (chapter 9.2.2). In this context, BQS has developed special technology platforms in order to not only be able to implement indication-

oriented, highly individualised surveys with large samples, but also offers its customers various dynamic reporting portals.[62]

9.2.1 QS-Reha®-Verfahren (QS-Reha® Procedure)

Against the background of the legal requirements, a cross-institutional and comparative QA procedure for medical prevention and rehabilitation facilities has been developed and implemented since 2000: the QS-Reha® procedure. Since 2012, the data collections, evaluations and results have been published every 3 years. At the same time, the procedure is constantly being further developed.

The former umbrella organizations of the health insurance funds had commissioned scientific institutes with the methodological development of the QA instruments for this purpose. This was done with the involvement of clinical experts from the preventive care and rehabilitation facilities as well as the then Medical Service of the National Associations of Health Insurance Funds (Medizinischen Dienst der Spitzenverbände der Krankenkassen: MDS) and the Medical Services of the Health Insurance Funds (Medizinischer Dienste der Krankenversicherung: MDK).

The QS-Reha® procedure includes an external, facility-comparative examination of the quality of structures, processes and results and patient satisfaction according to the concept of the quality profile.

Specific instruments were developed for each indication of preventive medical care and rehabilitation for which sufficiently high case numbers are available.

Participating facilities receive a two-part report of the results, in which both the summary evaluations for individual quality dimensions and individual results are presented. The summary assessments are compared with other facilities in the

[62] www.bqs.de (accessed: 18.03.2018).

same indication area (facility comparisons), so that each facility can compare itself both with the average of the other facilities and with individual, anonymised facilities.

The results from the QS-Reha® procedure can be viewed by all health insurance funds. They thus enable quality-oriented occupancy and contract design and sound advice for the insured.

The QS-Reha® procedure is constantly evolving. Thus, suggestions for changes to the structural criteria and the patient questionnaires can be made not only by the members of the committees, but also directly by those involved in the implementation of the QS-Reha® procedure, e.g. physicians or coordinators.[63]

9.2.2 Patient Experience as a Quality Indicator - The Picker Model[64]

Motivation and security have always been a reliable companion of a successful course of therapy. However, the basis for this is diverse and subject to constant monitoring. The most appropriate tools in order to be able to keep an eye on the complex care dimensions are surveys which determine the quality of patient care.

Picker works according to the concept of event-orientation. Unlike conventional satisfaction analyses, the Picker method focuses on problem

[63] www.qs-reha.de (accessed: 18.03.2018).

[64] Harvey Picker was an American businessman, teacher, inventor and philanthropist. In 1987, he founded the non-profit Picker Institute in Boston, USA, with the aim of promoting patient-centred healthcare. The Institute developed the first questionnaire to systematically measure patient satisfaction in hospitals. Picker surveys became the standard measure for surveying patient satisfaction worldwide.

frequencies and is therefore not a satisfaction analysis but a problem-oriented survey. The problem frequencies identified from the results serve as an indication of potential for improvement. The questions developed by Picker are based on priority quality indicators and key situations from e.g. the patient's point of view. Due to the event-orientation and the high level of specificity of the questions, person-dependent influencing factors (expectations, bias, conceivability effects, fear of personal disadvantages in case of criticism, etc.) can be largely left out. The event-oriented concept does not completely exclude the inclusion of some judgement questions. However, the report questions make up about 85-90% of the questionnaire here. In terms of content, the instruments are differentiated into interdisciplinary, discipline-specific, sector and diagnosis-related questionnaires, e.g. for inpatient care, for rehabilitation, obstetrics and other focal areas.

Since the beginning of 2000, a validated questionnaire for staff surveys has also been available. Based on the Picker data collected, a correlation between staff and patient satisfaction could be proven. If both types of surveys take place concurrently, a kind of "parallel" effect with revealing similarities and differences results with regard to the dimension-related results.

The problem frequencies identified from the results serve as an indication for potential improvements.

Since 2016, the BQS Institute in Hamburg has been conducting patient, staff and referrer surveys using the Picker method and is constantly developing the instruments further.[65]

9.3 IQTIG

Patients must be able to rely on the fact that a high quality of treatment is guaranteed in medical practices and hospitals. In order to make care even more

[65] www.bqs.de (accessed: 18.03.2018).

quality-oriented, measurable criteria are specifically needed that can be used to determine and compare the quality of diagnostics and therapy.

With the "Act on the Further Development of the Financial Structure and Quality in Statutory Health Insurance", the G-BA was therefore mandated to establish a quality institute to carry out the necessary development work for QA. QA in Germany is regulated and organized through the G-BA guidelines described in §§ 136 ff. of the SGB V. The IQTIG[66], which was founded as a result and is based in Berlin, began its work in 2015. It supports the G-BA in establishing scientifically and methodologically sound decision-making bases for QA measures.

IQTIG develops procedures and instruments for measuring and presenting the quality of care, mainly on behalf of the G-BA, and also participates in the implementation of measures to collect and assess quality outcomes, e.g. of hospitals. In doing so, it is legally obliged to further develop the documentation necessary for quality measurement under the precept of data economy. This is intended to limit the bureaucratic burden, e.g. for nursing staff and physicians, as much as possible.

One focus of the IQTIG's tasks is thus to contribute to better transparency of the quality of care. To this end, it is to publish, among other things, quality comparisons of hospital services so that patients, when, for example, choosing a hospital, can inform themselves more easily in advance about the quality of the services and facilities. This benefits patients, but is also an important aid for those providing treatment themselves. Their efforts to achieve good quality become visible and they receive indications of further possibilities for improvement.

In general, the focus of IQTIG's work can be described as in the following list.

According to § 137a SGB V, the Institute has the following core tasks:

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[66] Institut für Qualität und Transparenz im Gesundheitswesen – Institute for Quality and Transparency in Health Care.

- Development of QA instruments, presentation of the quality of care in the health care system and participation in their implementation (on behalf of the G-BA)
- Continuation and further development of the already existing QA procedures
- Development and implementation of procedures to better dovetail external QA in inpatient and outpatient care. At the same time, IQTIG is developing methodological principles on behalf of the G-BA to enable the state authorities to take the quality of care provided by hospitals into account in hospital planning
- Creation of criteria for the evaluation of certificates and quality seals in the outpatient as well as inpatient sector
- Publishing the results of the work in a form that can be understood by the general public. This also includes the development of a website that will enable patients to compare hospitals with regard to their quality

According to the Hospital Structure Act, IQTIG has, among other things, the task of developing concepts on behalf of the G-BA for

1. Planning-relevant quality indicators
2. Increases and reductions in the quality-oriented remuneration
3. The evaluation of the quality contracts according to § 110a SGB V

to be elaborated.

1. Planning-relevant quality indicators (plan. QI)

On 15.12.2016, the G-BA adopted the guideline on quality indicators relevant to plan. QI-RL. The aim of the guideline is to enable uniform quality-oriented decisions by the regional authorities responsible for hospital planning throughout Germany. In the plan. QI-RL, the plan. QI are defined and the procedure described.

In 2018, data on medical care in the three specialties of gynaecological surgery (15/1), obstetrics (16/1) and breast surgery (18/1) with a total of eleven quality indicators were recorded and defined as relevant for planning by the G-BA at a

total of 1063 hospital sites. An electronic case documentation was created for each patient treated.

These data are collected at a regional level and forwarded to IQTIG on a quarterly basis. At the IQTIG, the results of the plan. QI are calculated and evaluated for each hospital site.

QA Procedures	QI ID	QI-Designation
15/1 Gynecological Operations (QA GYN-OP)	10211	Complete removal of the ovary or adnexa without pathological findings
	12874	Missing histology after isolated ovariectomy with tissue removal
	51906	Ratio of observed to expected rate (O/E) of organ injury during laparoscopic surgery.
16/1 Obstetrics (QA PM-GEBH)	318	Presence of a paediatrician for premature births
	330	Antenatal corticosteroid therapy for preterm births with a prepartum inpatient stay of at least two calendar days
	1058	E-E (Urgent Sectio) time for emergency caesarean section over 20 minutes
	50045	Perioperative antibiotic prophylaxis for caesarean delivery
	51803	Critical Outcome Quality Index for Mature Infants
18/1 Breast Surgery (QA MC)	2163	Primary axillary dissection for DCIS
	52279	Intraoperative paediatric radiography or intraoperative preparation radiography with sonographic wire marking
	52330	Intraoperative paediatric radiography or intraoperative preparation radiography for mammographic wire marking

Table 26: Eleven Quality Indicators from the QA Procedures are defined as Relevant for Planning by the G-BA (own Representation)

In the plan. QI procedure, a distinction is made between mathematical and statistical abnormalities. An arithmetical abnormality is defined as a deviation of a result in a quality indicator from the defined reference range. Confidence intervals and case numbers are not taken into account when determining an arithmetical abnormality. A statistical abnormality has so far only been calculated for the plan QI.

Whether a result in a plan. QI is mathematically or statistically abnormal is only determined by the IQTIG in the annual evaluation. In the case of a mathematical abnormality in a plan. QI that is not statistically significant, a regular structured dialogue takes place according to the QSKH guidelines (chapter 4.4.3.3). In the case of a statistical abnormality in a plan. QI, the hospital concerned has the opportunity to assure the IQTIG that the statistical anomaly is not based on documentation errors. This needs to happen within two weeks of receipt of the annual evaluation. This eliminates the need for data validation for the cases that are statistically conspicuous. If a hospital does not assure the IQTIG of the correctness of the documentation in the case of a statistical anomaly, a data validation of the statistically conspicuous cases must be carried out by the regional office or the MDK by a specific deadline.

Within the framework of the plan. QI procedure, a file comparison must be carried out at corresponding hospitals:

- Which show at least one statistical anomaly;
- Which showed at least one statistical anomaly in the previous year;
- From a random sample;
- From a sample of hospitals that have supplied data.

After completion of the data validation, a recalculation is carried out at IQTIG. Afterwards, recalculated annual evaluations are made available to the regional offices for those hospitals for which a recalculation was necessary due to the results of the data validation.

If a hospital has assured the correctness of the documentation or if there is a statistical anomaly after data validation, a comment procedure with the IQTIG takes place. The IQTIG evaluates the comments of the hospitals after consultation with the expert commissions in accordance with § 12 plan. QI-RL. The result of the assessments is communicated by the G-BA to the regional authorities responsible for hospital planning, the regional associations of health insurance companies, the substitute health insurance companies and the regional offices. The G-BA then publishes the results of the assessments on its website.[67]

9.4 KBV

As the umbrella organization of the individual Associations of Statutory Health Insurance Physicians, KBV[68] [69]occupies a key position in the statutory health insurance system. Around 73 million people with statutory health insurance receive the same medical care throughout Germany. This is probably the most visible result of the KBV's daily work.

In addition to this so-called guarantee mandate, its main task is the political representation of the interests of the approximately 183,000 physicians and psychotherapists working in outpatient practices: When it comes to legislative procedures or health policy decisions at the federal level, the KBV puts forward the position of physicians and psychotherapists in private practice. In the same way, it is always at the table when it comes to negotiations on the range of services

[67] www.iqtig.org (accessed: 19.03.2018).

[68] https://www.kbv.de/html/.

[69] KBV: Kassenärztliche Bundesvereinigung – National Association of Statutory Health Insurance Physicians.

provided by the statutory health insurance funds and the remuneration of physicians (KBV 2020).

One of the most important self-set goals is to improve conditions so that the bodies can actually take on the legal mandate and responsibility to ensure care. The KBV is also committed to restoring diagnostic and therapeutic freedom.

Bureaucracy and cost-cutting constraints should not burden the sensitive relationship between patient and physician. In addition, the KBV wants to achieve adequate, secure and comprehensible remuneration for physicians and psychotherapists in private practice.

The main tasks of the KBV can be summarised under the following headings (KBV 2020):

Representation of interests

- The KBV represents the interests of the approximately 181,000 self-employed physicians and psychotherapists working in outpatient practices. It gives them a voice vis-à-vis politicians and the public and contributes its expertise to health policy discussions. At the federal level, it not only works to ensure that self-employment, freedom of establishment and the free choice of physician are preserved.
- Above all, it fights to improve the framework conditions in order to make the profession more attractive again. The fact that KBV is a corporate body makes it unique among all forms of medical interest representation: no other physicians' organization can exert such direct influence on politics and legislation.
- The KBV regularly lends weight to its demands for adequate remuneration of medical and psychotherapeutic services in negotiations with the GKV funds: when concluding contracts with the umbrella organization of the statutory health insurance and in bodies of joint self-administration, such as the G-BA, Federal Arbitration Board and Evaluation Committee.

Securing

- The Associations of Statutory Health Insurance Physicians (Kassenärztliche Vereinigungen: KV) and the KBV are legally obliged to

ensure outpatient medical care for all statutorily insured persons in Germany. This legal mandate dates back to fierce disputes between the medical profession and the health insurance funds at the end of the 19th century. The physicians' goal was not simply better working conditions or fee increases, but collective agreements with the health insurance funds and the free choice of physician for the insured.

- With the so-called Berlin Agreement, which celebrated its centenary in 2013, significant progress was made that is still decisive for the relationship between physicians and health insurance funds today. These include the free choice of the physician - albeit still limited at the time - the physicians' guaranteed right to compensation that is appropriate in form and amount, and the establishment of arbitration bodies.
- This was the birth of the joint self-administration of physicians and health insurance funds, in which both sides agreed on the basic consensus that they would be responsible for the care of patients together, but each with their own responsibilities. Although assurance was not yet explicitly mentioned in the agreement, it was implicitly included in it. The demand for organizational equality of physicians with the health insurance funds eventually led to the foundation of the KV.
- The historical compromise at that time was: the self-government of physicians, in the form of the associations of panel physicians, which negotiates the contracts with the health insurance funds collectively. The aim was to free the individual physician from direct individual dependence and thus from the arbitrariness of the health insurance funds.
- Because the physicians who were on the leash of the health insurance funds were no longer in a position to run their practices economically. In return for the collective contract, the associations of GKV-accredited physicians had to provide care for the insured, i.e. ensure it. In return, the physicians waived their right to strike - but with the guarantee of adequate compensation.
- Under today's conditions, however, what the physicians fought for back then and what they received with the founding of the associations of GKV-accredited physicians is no longer the guarantee mandate that they

assumed back then. The erosion of the guarantee mandate took place over a long period of time in small, sometimes almost imperceptible steps. The KBV is fighting in many areas to restore the conditions of the former consensus.

Care

- It is important for patients to be able to reach physicians close to their place of residence. In order to ensure good access throughout the country, requirement planning regulates how many physicians per inhabitant of which of the individual specialist groups are appropriate.
- Demand planning is regulated by the KBV with the GKV funds in the G-BA in a guideline. The Demand Planning Guideline describes a fully comprehensive functional planning system that leaves room for regional deviation possibilities.
- In the G-BA, the KBV is involved in assessing the benefits of new medicines and services. This enables the statutory health insurance funds, for example, to include a new treatment option in their range of services.
- An essential instrument for shaping this are contracts such as the Federal Mantle Agreement and also contracts with special payers (such as accident insurance providers, the Postal Civil Service Health Insurance Fund, the Federal Armed Forces, the Federal Police). In addition, there are framework recommendations for tripartite contracts between health insurance funds, hospitals and panel physicians, agreements on data exchange between associations of panel physicians and health insurance funds as well as agreements on uniform qualification requirements for medical examination and treatment methods.
- The KBV's contract workshop develops templates that the GKV-accredited physicians' associations and the health insurance funds can implement regionally: for certain clinical pictures, treatment can thus be better coordinated and a closer trusting relationship between physicians and patients can be promoted.
- Health services research is also playing an increasingly important role in identifying the need for action. The KBV and the Central Institute for Statutory Health Insurance Physicians in Germany (ZI), for example,

have created a public internet platform www.versorgungsatlas.de. Physicians, scientists, health policy actors and the interested public can gain insight into scientific results that are presented here in a way that is suitable for everyday use. Regional differences in the utilisation and quality of GKV-accredited medical care can be seen here.

10 FINAL CONSIDERATION

10.1 SUMMARY EVALUATIONS

The focus of this study was to investigate the total costs of quality assurance in the German health care market. In order to be able to estimate these costs for the first time, it was first necessary to identify the parties that perform quality assurance.

After identifying the relevant organizations and collecting necessary data, the costs were estimated mathematically.

In advance, an understanding of the terms “quality“ and “quality assurance“ was developed, which were defined and discussed accordingly.

First, the concept of “quality“ was discussed, starting from national and international standards (Schubert et al. 2007) to general and specific medical definitions (Gruhl & Klemperer 2008) and further to Donabedian's model. It became clear that quality can refer to diverse circumstances, e.g., to the performance of an action, to its outcome, to the totality of preventive actions in a society, and to other areas.

These definitions were tested using a specific example (chapter 2.3). It was shown that none of the quality definitions allows a generally valid assessment of treatment quality. Depending on the purpose of the study, other definitions are useful. For the quality of treatment of individual cases, Donabedian's definition proved to be particularly suitable.

Overall, it can be stated:

1. Quality can refer to the actual treatment of an individual patient, but also to treatment procedures for groups of patients and the quality of treatment providers.

In other words, there is a quality per treatment situation and quality per disease and patient group, as well as quality as a characteristic of the practitioner (Unterrieder 2004: 33).Exclusive guidelines allow a generally valid estimation of quality (Selbmann 1998: 199 ff.). In their case, it is relatively easy to compare the actual course of treatment with the optimal procedure. However, this only applies to the technical side of quality; the specific subjective view of the individual patient is not taken into account in guidelines.

2. Insofar as quality is considered for a patient, its assessment is based on the needs of that patient. Since the patient's needs are disease-specific, this also applies to quality. It also applies to groups of patients with the same disease. Since the needs also depend on the personality of the patient(s), the quality assessment includes a component that is patient-specific and subjective.

   The needs can range from:

   - the search for immediate help, e.g., when there is severe pain whose cause the patient does not know (heart attack, gallstones, etc.)
   - the need for further disease-specific information, e.g., when there is diagnosis of chronic diseases (diabetes, cancers, etc.)
   - the search for non-specific information, e.g., when a healthy insured person is looking for information about hospitals in his or her area in case of need

3. While the patient is aware of his or her needs, he or she is not always aware of the advantages and disadvantages of all possible treatment options. In such cases, the physician and patient must work together to select the right treatment.
4. The assessment of quality can vary in complexity (Eichhorn 1994; Seelos 1997; Müller-Osten 1980; Faber 2002). In some procedures it is evident (prescription of vitamin preparations), in others not (surgery on an Achilles tendon). It follows that, depending on the condition, the requirements for assessing quality may vary. For simple procedures, questioning the patient is sufficient; for difficult ones, the assessor must have considerable background knowledge.

The concept of quality assurance, its instruments, and concepts and tools in the context of health care were then described.

In general, quality assurance is a part of the actions of all professional groups and institutions working in the healthcare sector. It corresponds to the self-image of the medical profession and its social mandate to place the patients entrusted to them at the center of their actions.

The professions have developed forms of internal QA in different ways (e.g. case discussions in hospitals, quality circles between physicians in private practice, dentists and pharmacists). The institutions are involved - beyond the legal requirements applicable to them - in quality assurance related to the organization as a whole.

External quality assurance programs aim to optimize results-oriented learning through systematic comparisons, transparency of treatment options and by demonstrating therapy results, and in this way to accelerate internal quality assurance efforts. The obligations for physicians to participate in quality assurance programs are legally anchored in the professional code of conduct, the responsibility of the chambers in the Heilberufsgesetz (German Health Professions Act), and the obligations of other service providers in the SGB (German Social Code), among others.

Thus, medical institutions have been using QM, QA and patient safety instruments for decades and continue to develop them with the aim of constantly improving high-quality patient care: quality improvement or quality development.

Overall, it can be stated:

1. The main approaches to quality assurance procedures are based on standards and guidelines whose effects in the health care system and in relation to the outputs and outcomes of health care services have not yet been sufficiently validated empirically (Grol 2001; Øvretveit 2003; Simoes et al. 2004). Salzer et al. (1997) point out the associated danger that dysfunctional effects can be expected for the health care system as a whole from quality promotion models that are based only on the reduction of consensus-based structural and process indicators: "Additionally, the focus on structure and process quality indicators in a system of quality management is highly corruptible, especially when

monetary resources are involved. Care must be taken to assure that data are not manipulated or gamed in an accountability system“ (Salzer et al. 1997: 303).

2. The question of the extent to which the use of quality assurance procedures achieves the goal of increasing efficiency and improving patient-related health care services is not answered unambiguously. If the models used in evaluation research are based on invalid indicators of structural and process aspects in which no connection to patient-related outcomes is visible, the efforts made in the introduction of quality assurance procedures can be described as futile (Øvretveit 2002). Another problem seems to be that the introduction of procedures for evaluating the quality of care by funders dissolves the fundamentally existing tension between quality control and quality promotion in favor of control (Øvretveit 2002: 244).
3. The common features of the described quality assurance approaches within the health care system are that seemingly rational principles of "good organization" are prescribed for health care facilities on the legal basis of more or less empirically validly proven standards. What is unclear about this approach so far, is what consequences are triggered by the introduction of these seemingly rational principles in practice.

   The existing literature also provides a very mixed picture regarding the magnitude, direction and significance of the relationship between outcome transparency and quality improvement. The impact of individual structural factors on outcome quality has been insufficiently studied, and existing papers sometimes provide contradictory results. These divergent results can be explained, in part, by different research approaches and outcomes data that are often unsuitable for scientific analysis. In addition, existing empirical research focuses mainly on US and UK data (eg, New York State and Pennsylvania and NHS coronary artery bypass graft registries). Therefore, there is a strong need for a detailed investigation of the relationship between outcome transparency, structural requirements, and quality improvement in medical care and for an extension of empirical analyses to other countries outside the

United States and the United Kingdom (Pross, Schöner, Geissler, Busse 2021: 276-282).

4. In the terminology of QA, the multitude of which can hardly be reproduced here, the corresponding procedures and principles are as follows:
   - Alignment with a clearly defined set of quality objectives
   - The control of structural resources and organizational processes through consistent focus on measurable and standardized structures and procedures
   - The orientation towards customer or patient needs
   - The identification and participation of employees with and in the organization - especially with regard to motivation for QA - the need for cooperation between professional groups, and
   - The permanent or ongoing willingness to change (Pietsch-Breitfeld et al. 2002: 241, Kastenholz 2002; Selbmann 2004).
5. It has not yet been possible to integrate comprehensive QA as a natural part of professional action into the thinking and everyday actions of all those involved. The success of QA crucially depends on this.
   Furthermore, QA measures across professional groups and cross-sectoral QA - particularly necessary at the interfaces of the health care sectors - are not yet sufficiently established. The clarification required for this purpose must include, for example, the nursing service areas necessary to ensure optimal health care. In this context, it is necessary to ensure the quality of care provided by laypersons (especially relatives) in addition to the work of public and private care services.
6. The stocktaking and analysis of instruments and procedures shows that a wide range of offers now exists, but the question of proof of effectiveness has hardly been answered so far.
   The question of the extent to which the use of tools and procedures can contribute to the further development of QA was evaluated, for example, by research carried out by the BZgA in 2013: this research revealed that some developers design materials and make them available, for example brochures or websites, but do not follow up on whether the target group

also uses the tools and procedures, what experiences are made with them, and how they can be further developed if necessary.

The lack of documentation of the application and systematic evaluations make it difficult to further develop instruments and procedures and to make recommendations to potential users. It would be desirable for sponsors to invest not only in the development of what is on offer, but also in the documentation and evaluation of experiences. On the other hand, they should only recommend instruments and procedures that have proven benefits and/or effects (Kawski & Koch 2004).

In this context, it would also be desirable for experience with the various instruments and procedures to be systematically compiled and evaluated. At present, Germany still lacks a central office to take on such a task. Such a transfer and coordination office at the federal level, which the German Council of Economic Experts also considers necessary, could make a significant contribution to strengthening quality development in health promotion and prevention. It could take over the following tasks by documenting and evaluating existing procedures and instruments, also from related subject areas:

- Inventory of the need for quality development in prevention and health promotion in cooperation with scientists
- Identification, description and criterion-guided comparison of existing procedures and instruments for quality development in health promotion and prevention as well as dissemination of suitable procedures and instruments.
- Development of qualification offers and training concepts for practitioners
- Strategic consulting of parties in different fields of work in questions of quality development

7. An important question is the quality level of the quality assessments.

   Of particular importance is how the individual procedures determine quality and how they take into account the subjectivity of assessors and thus of assessments. Is subjectivity deliberately allowed, or is an attempt made to minimize the influence of individual assessors' preferences in quality assessments - that is, to record quality as "objectively" as possible

and thus independently of the individual? To what extent these different quality concepts influence the effects of QA and what contribution they make to impact-oriented quality development is a question to be answered empirically. Currently, the assumption is formulated - theoretically well founded - that with good planning, structural and process quality, outcome quality increases. However, the empirical evidence for this assumption is still largely lacking. Empirical investigation of the effectiveness of QA therefore represents an important future research task for which sufficient financial resources must be made available.

There is a further need for research and development which arises from the requirement that in the development of offers an element of planning quality is needed

a) to draw on the previous experience of others

b) to draw on scientific theories

The first demand can only be met if the experiences from other interventions are also systematically described - here the documentation situation in Germany is very patchy. Although a wealth of projects are documented on the website www.gesundheitliche-chancengleichheit.de, only a few have been evaluated; moreover, there is no overview of which interventions are effective.

Other countries, such as the USA, provide a database that, similar to a Cochrane review, shows users and funders as to which interventions have good evidence (http://www.thecommunityguide.org/index.html).

Such databases exist in Germany only in a rudimentary form and only for a few topic areas. There is a considerable need for development here, which requires a not inconsiderable expenditure of resources. Reference to scientific theories is also always called for, but the concrete implementation of theory-based work has so far been scarcely highlighted.

After developing a common understanding of the terms quality and QA and presenting the approaches, instruments and procedures of QA in the context of

health care, the total costs of QA for the German health care market have finally been estimated mathematically (chapter 8.5).

In order to be able to estimate the total costs, the QA costs were surveyed for the first time in the sense of a bottom-up analysis. For this study, the research question (costs of quality assurance in the German medical market) was broken down into two further sub-topics:

1. Which organizations exist in the German healthcare market that deal with the topic of QA?
2. What are the costs incurred for QA in these organizations?

The collection of data:

1. There are no articles or publications that address the topic of total cost of quality assurance. A continuation/update of existing studies was therefore not possible.
2. There are selective, cost investigations and measurements, such as for medical practices (Frank 2005: 72) or the costs of acute inpatient care at the university hospital of Ulm, Germany, but these are only for certain subsegments of the health care sector (Klose, Herlemann, Leidl 1999). However, the measurements are generally quite outdated and could not be used for a holistic view due to their limitation to specific segments.
3. There is currently no database listing the companies or organizations that perform quality assurance. The database created for this study was largely created using web search and is intended to provide a reference point for future studies.
4. The readiness of the identified organizations to provide information can be described as very poor overall. This is shown by the response rate across all clusters (see chapter methodology). Both the information provided by telephone and the response by mail were unsatisfactory. Although a number of companies expressed great interest in the results of the study, they were not prepared to provide the relevant data themselves.
5. A detailed evaluation of the estimated total costs is discussed in detail in the next chapter.

Quality assurance represents an important building block in the German healthcare system. Nevertheless, there is little to no transparency and publicly accessible sources of information dealing primarily with the cost structure in this subject area.

The lack of transparency and the quiet suspicion that installed quality assurance cannot necessarily contribute to increasing and improving quality, reinforces the impression that the identified companies would like to provide little to no information if possible. Even the state-run institutions, which have made quality assurance their priority, were “consciously“ or “unconsciously“ unable to name the specific costs requested and referred to the legally standardized annual reports.

The authors of the 2012 study “Ressourcenverbrauch durch Verwaltung im deutschen Gesundheitssystem“ had similar experiences. It states:

“This report is based almost exclusively on publicly available sources. Information on health expenditure accounting comes from the Federal Health Reporting System. Research on administrative data from associations, federations, chambers and foundations proved to be incomparably more difficult. While some parties in the health care system publish their activities in a more or less detailed form as annual or business reports on the Internet, other institutions are unwilling to provide information about their budgets even when asked in person.“

The research and analysis of public documents, such as annual reports or balance sheets, conducted here has shown that the costs of quality assurance are not declared as a separate, important part of the company's operations. Rather, the costs of quality assurance, and thus the administrative costs for it, are considered and presented as part of the general administrative costs. Controlling and transparent presentation of the costs is therefore not possible.

If the legislator does not define any legal and binding requirements for this, this trend will not change significantly in the foreseeable future.

An established model from the reinsurance sector could be used to increase the level of information and the associated transparency.

There, for example, data on invalidations are requested from several companies. The data is processed and analysed accordingly. The overall result is then anonymized. Each participating company receives a detailed report on how its portfolio compares with the cumulative portfolio. Anonymization means that no conclusions can be drawn about individual companies. The success of this method naturally depends on trust in the confidentiality of the reinsurance.

For the establishment of this system in the healthcare sector, a superordinate, governmental body could be considered, which collects, analyses, processes and anonymizes corresponding key figures and makes them available to the participating organizations or companies.

The advantages of the system would be:

- Increase of transparency
- Comparability of costs
- benchmarking
- Market overview

10.2 INTERPRETATION OF THE ESTIMATED TOTAL COSTS OF QA

Per capita spending on healthcare in Germany is higher than in all other member states of the European Union. In 2017, 4,300 euros were spent on the care of a patient in this country. This was 1,400 euros more than the EU average. Life expectancy in Germany, on the other hand, is 81.1 years, only slightly above the European average of 80.9 years[70].

The above-average costs in the German healthcare system are attributed on the one hand to the fragmentation of the system and the insufficient coordination of patient treatment. The Ärzteblatt report states that because a gatekeeping

[70] https://www.aerzteblatt.de/archiv/211193/Deutsches-Gesundheitssystem-Hohe-Kosten-durchschnittliche-Ergebnisse.

system[71] is lacking, there is not only a high utilization of medical services, but also breaks between general and specialist care. Inefficiencies due to loss of information and duplication of examinations also occur at the interface between physicians in private practice and hospitals. In addition, there are deficits in digitization, such as the lack of electronic patient files.

On the other hand, the high costs in the inpatient sector are held responsible for Germany's poor performance in the European spending comparison. The number of hospital beds, for example, is 60 percent higher than the EU average. At 7.2 days, the length of stay is also longer than in some European countries such as the Netherlands or Denmark, which are at 4.5 days.

Declaration of the cost of health and presentation of selected studies for QA cost measurement:

According to the Federal Statistical Office, spending on health - i.e., prevention, treatment, rehabilitation and care - rose steadily between 1992 and 2019 from 159.5 to 413.8 billion Euros. This corresponds to an increase of 3.6 percent per year. Due to the Corona pandemic, spending increased at an above-average rate from 2019 to 2020 - by almost 6.5 percent to 440.6 billion Euros.

The estimated total QA costs of over 110 billion Euros (see chapter 8.5) accordingly account for around a quarter of total costs.

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[71] General practitioner-centered care (gatekeeping) is an important instrument of managed care or integrated care and comprises targeted service management by a specially qualified physician. The physician (especially general practitioners, practicing internists or gynecologists are suitable here; hereafter referred to as the family doctor) is the first point of contact for the patient in the event of illness and assumes a kind of pilot function (gatekeeper) along the supply chain.

For example, more than 1.5 million Euros were spent on the external quality assurance program of the statutory health insurance in "inpatient medical rehabilitation" (Glattacker, Jackel 2007: 277-283). The estimated bureaucratic costs for cross-sectoral quality assurance in the field of "cataract surgery" amounted to up to 7.6 million Euros (Albrecht, Loos, Otten 2013: 528-533).

According to a study by management consultants A. T. Kearney, administrative costs in the German healthcare system are apparently much higher than previously assumed. According to the study, bureaucracy accounted for 23 percent of the GKV system's total expenditure of 176 billion Euros in 2011.

The 23 percent administrative cost ratio of the healthcare system is - the study notes - 3.8 times higher than the average value in German industrial companies, which is 6.1 percent. In addition, the study concludes that 68 percent of the total administrative costs, or 27.5 billion Euros, are caused precisely by the GKV system. This corresponds to an actual administrative cost of 15.6 percent in relation to the 176 billion Euros in total expenditure. This share of administrative costs is 2.9 times higher than the 5.4 percent or 9.5 billion Euros of administrative costs officially reported by the GKV.

Accordingly, the health insurance funds generate bureaucracy not only in their own companies, but also in the entire sector, for example at pharmacies, doctors' practices or hospitals[72].

One of the main problems identified by the authors of the study is the large number of inspection bodies that have been created over the years. Legislators are constantly imposing new bureaucratic auditing tasks on the health insurers. No one has yet demonstrated so clearly that the obsession with saving money, which is focused on efficiency gains, could actually be a cause of the cost-driving.

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[72] https://www.aerzteblatt.de/nachrichten/48585/Verwaltungskosten-im-Gesundheitswesen-Milliarden-koennen-eingespart-werden/.

In cooperation with the Stiftung Gesundheit (Health Foundation), a study by Obermann & Müller in 2006 selected a representative sample of 15,383 physicians and asked them to participate in an Internet-based survey. The survey covered sources of information and experience with QM, costs of QM, and general attitudes toward QM (Obermann, Müller 2007: 851-863). In addition to the direct costs for process support and certification, the time spent by practice owners and employees was also taken into account. In the implementation phase, total costs arose on average in the amount of €5,960. Of importance are the nevertheless substantial differences between the individual QM systems. In the case of ISO, it must be taken into account that particularly in the years before 2002 quite high costs (approx. €20,000) were incurred. The average workload over 37 weeks was 5.7 h/week for the practice owner and 7.8 h/week for the staff.

A similar study by Matthias Frank in 2005 showed a similar picture to Obermann & Müller:

Cost Cause	Implementation by	Estimated Costs
Implementation of a QM system according to DIN EN ISO 9001: 2000 and preparation of the manual	External consultancy	€5.000 plus VAT, travel and accommodation expenses
Certification of the QM system	Accredited certification body	€2.500 plus VAT, travel and accommodation expenses
	Internally by the quality representative of the medical practice	€0,00
Mandatory repeat audit every three years	Accredited certification body	€1.500 plus VAT, travel and accommodation expenses

Table 27: Implementation of a QM System according to DIN EN ISO 9001: 2000 and Preparation of the Manual

The studies by Obermann & Müller and Frank did not report an absolute final amount. However, an extrapolated final sum of the above-mentioned hourly rates as well as the attribution of the one-time costs for the implementation of the quality assurance system is likely to reflect the true dimension of the costs, which in this study is quantified for the medical practices at €4,716,446,784.00 (adminstrative costs in QA).

Obermann and Müller, as well as the authors of the A. T. Kearney study, assume that the actual result of administrative costs in the GKV sector should be significantly higher than the figures that can be read, for example, at the Federal Statistical Office. This assumption is consistent with the results presented and extrapolated here from all identified areas of health care.

According to calculations made in 2018 by Friedrich Breyer, holder of the Chair of Economic and Social Policy at the University of Konstanz, technical progress ensures an annual cost increase of two percent.

In general, it can be stated that when health care spending increases, quality assurance costs can also be assumed to increase proportionally (Breyer 2018).

He explains:

“Medical progress in the healthcare sector consists predominantly of new and expensive forms of treatment." He said the aging population is causing costs to rise by one percentage point per year, so total costs will increase by three percent per year. "Health care spending will continue to rise sharply, with population aging contributing little and medical advances contributing much.“

As a solution to the cost dilemma, the economist argues that the effectiveness of modern treatment methods should be scrutinized more closely through the use of quality assurance. Any treatment that significantly increases a patient's quality of life and lifespan is desirable and should therefore be financed by the community. However, many expensive drugs and treatments have little or no effect on the patient's state of health. Nevertheless, they are often carried out. A stronger systemic comparison of the costs and benefits of a treatment is the only way to prevent a cost explosion in the healthcare system.

The methodology used in the above-mentioned studies to collect the data sets is comparable to the approach used here, which was described in chapter 7.

As already described, Obermann & Frank and the authors of "Ressourcenverbrauch durch Verwaltung im deutschen Gesundheitssystem", for example, report limitations in the collection of their data sets. The authors also had to make statistical assumptions to calculate their data, which were incorporated into the final results.

Thus, the mathematical assumptions, extrapolations with given limitations (see chapter 8), which led to the final result of this study, are comparable to previous studies of this kind.

With this estimated order of magnitude of 110 billion Euros, it is remarkable that to date there has been no study of the total costs of QA in the German healthcare market.

One reason for this may be the "complexity of the German health care system" (e.g. figure 21). To obtain concrete valid data, which would be necessary to evaluate such an investigation, seems to be almost impossible. The corresponding limitations and lack of transparency have already been pointed out in chapter 10.1.

The reasons for the complexity of the system are:

a) **Federalism**

   The complexity begins with the fact that governmental responsibilities for the health care system are divided between the federal and state governments: The federal government, primarily the BMG, and the Bundestag are responsible for the overarching regulations. Such as health legislation, which is then the same in all federal states. The concrete organization of the public health system in Germany is the responsibility of the federal states. They are responsible for hospital planning, for example, but also for monitoring the manufacture of medicines. How the tasks are distributed between different state authorities and what exactly the organization looks like can then vary from state to state. To make

things even more complex: Some healthcare tasks are also assigned to the municipalities, such as the public health offices.

b) Self-governance

While state players are responsible for the framework conditions, the concrete organization of tasks lies with so-called "self-administration". This means that those who pay for and provide healthcare services regulate many things among themselves and on behalf of the state, without the state intervening in specific issues. This is a German peculiarity that does not exist in such a form in other countries.

In concrete terms, this principle manifests itself in the most important body of self-governance, the G-BA. The following are represented in the G-BA:

- KBV and KZBV, representing physicians, dentists and psychotherapists in private practice who bill the statutory health insurance funds.
- DKG
- GKV-Spitzenverband

The committee can draw on the expertise of two scientific institutes for its tasks: IQWiG (chapter 7.5.1) and IQTiG (chapter 9.3). But this is not enough for self-administration: Some tasks, such as the organization of continuing education and training for physicians and pharmacists or professional supervision, are carried out by other institutions: the professional chambers, which are organized at the state level. For example, each federal state has its own chamber of pharmacists.

c) Sectors

Further complexity arises in the German healthcare system from the sectors of outpatient care on the one hand, for example by physicians in private practice, and inpatient care on the other, which includes hospitals, for example.

However, not all treatments in hospitals are actually part of inpatient care: for example, larger hospitals often have specialized areas where patients are also treated on an outpatient basis. This has an impact on

which documents patients need in the hospital: a yellow referral slip for treatment in the outpatient department, and a pink hospital admission slip for inpatient admission. The background to this is that there are different regulations for billing and reimbursement for the outpatient and inpatient sectors.

Such difficulties are also pointed out, for example, in the report of the German Council of Economic Experts on the Development of the Healthcare System, which was published in 2018 with many suggestions for improvement.

The complexity presented, as well as the reasons mentioned in chapter 10.1, lead to the fact that all cost measurements of QA that have taken place to date either refer only to a specific sector (e.g. physician practices) of the health care system or cover only a specific subfield of medicine (e.g. cataract surgery). Early studies that looked at cost measurements concluded that total costs should be significantly higher than assumed:

The authors of the study "Ressourcenverbrauch durch Verwaltung im Deutschen Gesundheitssystem" from 2012 for the German Medical Association describe, for example, in their conclusion:

"At this point, however, it should be pointed out that this report naturally could not examine all players in the health care system with regard to their administrative tasks. The actual expenditure on administration is likely to be *considerably higher* if pharmaceutical and medical technology manufacturers and their associations are also taken into account."

The estimated administrative burden of over 110 billion euros can thus essentially be attributed to increasing lack of transparency and complexity in the German healthcare system. As already outlined, a number of complexity drivers contribute to this, such as the large number of different players, an oversupply of products and services, a wide variety of IT systems, frequently changing reforms and laws, and interface problems due to processes that are not coordinated (Breyer 2018).

The parties involved are organized in silo-like structures with lone wolf interests and are represented by more than 300 lobby and interest groups in order to maintain or make their own services billable at the expense of the community and at the highest possible prices.

The system would benefit, for example, from an overall coordinated reduction in the number of statutory health insurance funds and optimization of the administrative apparatus of the associations of statutory health insurance physicians.

In addition, the complex portfolio of products and services and the associated administrative burden should be reduced to a level that makes sense for the overall system. It is also important to have lean, direct and continuous information flows that save costs and reduce interfaces.

11 CONCLUSION AND OUTLOOK

QA remains a controversial topic. Proponents cite increased transparency, informed patient decision making, and cost savings as benefits of the procedures for patient care and patient safety (Riskin, Campagna 2009: 237). On the other hand, counter-arguments are cited such as the emergence of unfavorable competition between clinics, a selection of a certain patient clientele that is detrimental to care, restricted freedom of treatment for physicians, and the inhibition of innovations (Riskin, Campagna 2009: 240).

In recent years, a large number of different procedures and measures for quality assurance or improvement strategies have been developed in Germany. The same development can also be seen in the international arena (Grol, Baker, Moss 2002: 110). Different health care stakeholders from clinical care, health policy and academia considered that quality had to be further improved by many kinds of measures. Program initiatives were started with different fundamental perspectives and introduced procedures such as certification, TQM, external QA with measurement of quality, risk management, patient safety and disease management programs (DMP). All initiatives set the same goal of improving patient care (Grol, Baker, Moss 2002: 111).

The introduction of new drugs[73], for example, follows a rigorous process with testing and evaluation of sub-steps[74]. Such approaches are also necessary in the area of QA procedures before and after the introduction of such measures (Grol, Baker,

[73] Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM).

[74] European Medicines Agency. Marketing authorization.

Moss 2002; Helou 2002; SVR). Thus, publications on the evaluation of QA measures can be found with descriptions of positive effects as a result of these quality assurance procedures in both the outpatient and inpatient sectors.

In one evaluation, for example, it was shown that the quality assurance measures of the statutory pension insurance in cardiological rehabilitation facilities led to significant improvements in the results of process quality with regard to the quality and duration of the discharge reports in the course of 2001 to 2004 (Beckmann, Klosterhuis, Mitschele 2005: 431).

In addition, positive associations with improved process indicators were reported internationally in a pan-European and cross-health system research project on quality improvement strategies such as TQM, certification, patient safety projects, guidelines, and quality indicator measurements in eight participating EU countries (Sunol et al. 2009: 65).

However, the effectiveness of QA programs has been widely criticized, as the to some extent limited methodological approach of the analyses and the underlying data validity have increasingly called into question evidence of effectiveness in improving patient care (Albrecht 2013; Glattacker 2007; Linder 2011; Offermanns 2011; Petzold 2013; Schafer et al. 2010).

Another major point of criticism in the context of QA procedures in hospitals, for example, is the measurement of quality, which is limited to inpatient stays, so that a sufficiently long follow-up[75] for an adequate assessment of quality would be lacking (Albrecht, Loos, Otten 2013: 528-533). Intersectoral quality assurance was seen as a possible solution. In the context of the many conceptual challenges of

[75] Follow up are follow-up examinations, e.g. physical examinations, measurements or surveys, which take place after the clinical trial intervention and the results of which are included in the study evaluation.

cross-sectoral quality assurance, there has also been increasing discussion about the relationship between effort and effectiveness (Albrecht, Loos, Otten 2013: 528-533).

Due to the legal obligation to introduce internal quality management in hospitals, hospitals are forced to choose the most suitable among the quality management models for themselves. Since there are few concrete specifications from the legislature, this is a challenge for most hospitals against the backdrop of uncertain data on effectiveness (Offermanns 2011: 173). The choice is left to the hospital. The legislature and the states merely have to create the framework conditions (Offermanns 2011: 173-249).

The following considerations are intended to provide an outlook on the future development of QS:

Catch up on development backlog in external QA

The "classic" external QA was aimed at promoting quality and wanted to enable all service providers to achieve the same minimum quality level through internal benchmarking - learning from the better ones in a protected space. Fortunately, this goal was achieved some time ago for a large number of quality indicators (QIs) in inpatient QS. However, this also means that the quality improvement potential of these QIs has been exhausted. The continuous development of external QA has been neglected. Today's external QA provides only a fragmentary picture of the care provided and only questionably fulfills its original purpose of supporting quality management within the facility.

The new tasks of external QA for purposes of quality-oriented hospital planning and other care management purposes, as well as for financial incentive systems, can only be implemented to a very limited extent with the existing quality indicators, which are geared to quality promotion. Apart from the need for new development in this regard, it must be made clear that QS instruments cannot replace necessary changes in the financing or regulatory policy framework (Geraedts 2020).

QS can only support the desirable quality-oriented structural change and other purposes of care management. To this end, the gradual establishment of a nationwide, public quality monitoring system could be helpful, for example in the form of a quality barometer based on routine data. The indicators of this quality barometer should not only focus on individual procedures, but also on patient-relevant outcomes such as complications, unplanned readmissions and quality at the interfaces of care (Geraedts 2020).

To this end, the RKI Department of Epidemiology and Health Monitoring, for example, has been researching the "external quality assurance of the NAKO Health Study" as a project assignment since 2013. The aim of the NAKO Health Study is to investigate the development of chronic diseases such as cardiovascular diseases, diabetes, cancer, dementia and infectious diseases, as well as their subclinical precursors and functional changes. The study is being conducted by an interdisciplinary network of German research institutions. Its results are expected to enable or improve prevention, prediction and early detection based on a solid database.

Rebalancing the interplay between quality promotion and quality competition

QA procedures for quality promotion should be targeted to exploit ex ante defined quality improvement potential. QIs for quality promotion have the character of pick-up criteria for the initiation of a P D C A cycle and may not require as elaborate a development as the risk-adjusted QIs needed for selection decisions. In the context of the ongoing development of its methodological foundations (IQTIG 2019), one task for IQTIG will be to rebalance the relationship between QI for quality promotion on the one hand and quality-based selection decisions on the part of funders, the insured and referrers on the other hand, as well as their interplay with quality-changing effects through the publication of QI.

Since the 1980s, the interplay of "quality improvement", "competition and accountability", and "public reporting" has posed an ongoing methodological

challenge to quality developers in a wide variety of health care systems (Huster 2018).

Since 2017, for example, the scientific team of the DNQP has been examining healthcare facilities that want to put their current quality level for pressure ulcer prophylaxis[76] to the test and develop it further. In addition, the participating facilities are to test a set of indicators for its practicality, especially with regard to the effort of data collection and the resulting gain in knowledge for the facility.

Enhance internal quality management

Measures of cross-institutional, external quality assurance must actually form a functional unit with measures of internal quality management, otherwise no quality-improving change in behavior can be expected from QI. However, since the preparation of the KHSG, which came into force in 2016, only external QA has been at the center of both professional and public discussion. In this context, for example, the new quality indicators relevant for hospital planning pursuant to Section 136c (1) SGB V will not have any significant consequences for the hospital landscape for the foreseeable future for various reasons. Instead of the steady increase in cross-facility special procedures for quality measurement and quality control, internal facility quality management must regain greater importance.

[76] Since a pressure sore develops as a result of reduced blood flow to the skin or tissue, the most important prophylaxis is the promotion of movement, mobilization and an adequate supply of oxygen to the skin and tissue. Through targeted positioning, movement promotion and mobilization of people at risk, the desired stress and relief of skin and tissue can be achieved. This can prevent too much pressure being exerted on a section of skin and tissue and the development of a pressure sore.

The Patient Rights Act of 2014 actually recognized the signs of the times and made risk and error management binding minimum quality requirements for both inpatient and outpatient care.

This basic focus of external QA on supporting internal QM must be urgently resumed as soon as possible since the challenges posed by the Corona pandemic.

Various current studies or legislative initiatives on "further" digitization can make a significant contribution to upgrading internal QM/QA. Positive effects can also be mapped and demonstrated in the logic of concrete, existing quality concepts for structural, process and outcome quality (Huber & Gärtner 2018). This applies, for example, to the introduction of the electronic patient record and other applications of the telematics infrastructure with the Patient Data Protection Act, but also to the introduction of digital health applications with the Digital Care Act and the strengthening of hospital IT with the Hospital Future Act.

Further develop QA and care structures across sectors

If one takes the claim of patient orientation seriously, the quality of care cannot be viewed in any other way than across sectors. Instead of looking at individual procedures with tunnel vision, the QA of the future must focus on the interfaces of care and patient-relevant endpoints. These are well-known demands on QA, the implementation of which has so far failed due to the de facto sectoring of care.

Cross-sectoral quality assurance remains at the level of sectoral procedures. Cross-sectoral follow-up procedures or procedures involving a topic in which at least two sectors have a significant share in the treatment outcome have not yet been introduced. Regardless of the fundamental slowness of the introduction of new QA procedures, an important reason for this is that questions about the attributability of quality deficits remain unresolved. Which practitioner in the supply chain is responsible for which (partial) outcome and to what extent? Which service provider involved in the treatment may have to accept a reduction in remuneration or other consequences in the event of insufficient quality? And who must be held liable in the event of avoidable harm that has occurred? These open

questions, which hinder the introduction of cross-sectoral patient-centered care concepts into standard care, will not be solved with the possibilities of cross-sectoral quality assurance under the given framework conditions (Klakow-Franck 2020).

It would be possible to mitigate this well-known problem if either the assumption of joint responsibility for the treatment chain were promoted, for example, in the context of integrated quality contracts, or at any rate the coordination of the treatment process were upgraded, which takes place at least in the context of DMPs for chronic diseases or for complex and rare diseases - theoretically - in the context of outpatient specialist care (ASV) in accordance with § 116b SGB V. Not every patient needs a complex treatment concept for every diagnosis. However, in view of demographic developments and the increasing complexity of medicine, the need for this is growing. The future lies in the formation of interdisciplinary and interprofessional teams with clear responsibilities for the coordination of the treatment process as well as for the quality of the sub-processes.

The Innovation Fund was an attempt to promote innovative cross-sectoral care concepts. The results and, in particular, the roll-out of successful model projects to standard care remain to be seen (Klakow-Franck 2020).

Quality development as a "learning system" – between aspiration and reality

In connection with the further development of the health care system, the image of the "learning system" is often invoked. However, we are still a long way from implementing this fiction, which is due to different, but partly overlapping reasons at the various levels of the healthcare system. The limited willingness of expert organizations, such as hospitals, to change has a long tradition.

Schrappe (2018) elaborated, in his expert report commissioned by the Aktionsbündnis Patientensicherheit (Patient Safety Action Alliance) in 2018, on which causes can be assumed for the sluggishness of change processes in medical operations:

Quite counterintuitively, the high level of standardization in expert organizations leads to a pronounced tolerance of uncertainty, which Schrappe calls intrinsic uncertainty. In addition, an innovation paradox can be observed: There is a high degree of openness to product innovations, but little openness to process and structural innovations, especially when they are demanded from outside. In addition, an apersonal rule-boundness persists, even when undesirable events occur. This combination of tolerance of uncertainty, paradoxical behavior toward innovations and rule-boundness leads to an inadequately high stability of expert organizations in the face of changes that are actually necessary (Schrappe 2018).

However, problems related to the fundamental readiness for change required for a quality push in health care also affect the meso level:

At the sector boundary, the clashes of interests and distributional struggles between panel physicians and hospitals are so massive that it is difficult for self-governance to initiate cross-sector QA measures here of all places (Huster 2018).

Consumer protection function of QA

In retrospect, the introduction of more competition and deregulation of the health care system can be described as one of the most persistent myths of health policy (Reiners 2011). Nevertheless, in a health care system that sees itself as a health care market, QS assumes an original consumer protection function. The criticism that a patient is not a consumer like any other, which is repeatedly voiced by the medical profession, is fundamentally correct, but not really helpful and sometimes seems to serve more to maintain the paternalistic relationship to the patient (Klie 2019).

Sick patients have only limited choice and decision-making sovereignty of a healthy insured person. In addition, compared to Stiftung Warentest, which evaluates product quality, the requirements for the development of, for example, a quality portal on hospitals are more complex. This is since medical care is not a product, but rather complex services, for whose quality assessment different quality dimensions, structure, process and outcome quality, among others, must be used. The quality of outcomes depends on a large number of factors, including those on the patient side. This makes informed patient decisions through shared

decision making, competition-neutral quality information (see also the article by Klaus Koch in this publication), the promotion of health literacy, and also the use of patient surveys (Klie 2019) all the more important. Not least because supply-induced demand on the Web via personalized health service and health insurance offerings from commercial providers is foreseeably going to increase, should the development of health-related consumer competencies be promoted.

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ANNEXES

Annex 1: Development of Medical Service Areas Subject to QA

The aim of quality assurance is to provide patient care that corresponds to the current state of scientific knowledge. Therefore, the tasks of QA are constantly adapted to new medical findings and the increasingly complex workflows in practice.

The following charts show the development from 1990-2016.

1990 - 2005	
Aids Agreement	Mammography screening
Outpatient surgery including structural contracts	Retinal and vitreous surgery
Arthroscopy	Oncology
Dialysis	Otoacoustic emissions
DMP Breast Cancer	Photodynamic therapy
DMP Diabetes Type 2	Psychotherapy
DMP Coronary heart disease	Radiology
General practitioner contracts PKK/EKK	Rehabilitation
Pacemaker controls	Sleep apnoea
Immunapheresis	Pain management
Invasive cardiology	Sonography of the infant hip
Cataract contracts AOK/EKK	Social psychiatry
Magnetic resonance mammogram	Sociotherapy
MRI	Radiation therapy
	Substitution
	Ultrasound

Colonoscopy Lab services Long-term ECG LDL-apheresis Lithotripsy Mammography	Environmental Medicine Cytology

2006	
DMP Asthma /COPD DMP Diabetes Type 1 skin cancer screening Interventional radiology Palliative care contract Quality Inspection Policy Random samples	Long-term ECG LDL-apheresis Lithotripsy Mammography Mammography screening Retinal and vitreous surgery Oncology Otoacoustic emissions Photodynamic therapy Psychotherapy Radiology Rehabilitation Sleep apnoea Pain management Sonography of the infant hip
Aids Agreement Outpatient surgery including structural contracts Arthroscopy Dialysis DMP Breast Cancer	

2007	
Acupuncture Ampulant Surgery Centre Contract General practitioner contract BKK Homeopathy contract Cataract contracts BKK/IKK Magnetic resonance angiography Palliative care contract EKK Prevention U7a/U10 BKK	Lab services Long-term ECG LDL-apheresis Lithotripsy Mammography Mammography screening Retinal and vitreous surgery Oncology Otoacoustic emissions Photodynamic therapy Psychotherapy Radiology Rehabilitation Sleep apnoea Pain management
Aids Agreement Outpatient surgery including	

DMP Diabetes Type 2	Social psychiatry
DMP Coronary heart disease	Sociotherapy
General practitioner contracts PKK/EKK	Radiation therapy
Pacemaker controls	Substitution
Immunapheresis	Ultrasound
Invasive cardiology	Environmental Medicine
Cataract contracts AOK/EKK	Cytology
Magnetic resonance mammogram	
MRI	
Colonoscopy	
Lab services	

structural contracts	Sonography of the infant hip
Arthroscopy	Social psychiatry
Dialysis	Sociotherapy
DMP Breast Cancer	Radiation therapy
DMP Diabetes Type 2	Substitution
DMP Coronary heart disease	Ultrasound
General practitioner contracts PKK/EKK	Environmental Medicine
Pacemaker controls	Cytology
Immunapheresis	
Invasive cardiology	
Cataract contracts AOK/EKK	
Magnetic resonance mammogram	
MRI	
Colonoscopy	

2008		2009	
Apheresis for isolated LP(a) nutrition	MRI	Histopathology i.R.	MRI
Carrying out additional early diagnosis examinations within the framework of paediatric and adolescent medicine	Colonoscopy	Skin cancer screening	Colonoscopy
General practitioner contract IKK/BIG	Lab services	Macular degeneration LKK/BKK	Lab services
Macular degeneration	Long-term ECG	Specialised outpatient palliative care	Long-term ECG
AOK, BKN	LDL-apheresis	Ultrasound agreement	LDL-apheresis
Phototherapeutic keractomy	Lithotripsy	Breast vacuum biopsy	Lithotripsy
Preventive examinations for children U10/U11 AOK	Mammography	Aids Agreement	Mammography
Aids Agreement	Mammography screening	Outpatient surgery including structural contracts	Mammography screening
Outpatient surgery including structural contracts	Retinal and vitreous surgery	Arthroscopy	Retinal and vitreous surgery
Arthroscopy	Oncology	Dialysis	Oncology
Dialysis	Otoacoustic emissions	DMP Breast Cancer	Otoacoustic emissions
	Photodynamic therapy	DMP Diabetes Type 2	Photodynamic therapy
	Psychotherapy	DMP Coronary heart disease	Psychotherapy
	Radiology	General practitioner contracts PKK/EKK	Radiology
	Rehabilitation	Pacemaker controls	Rehabilitation
	Sleep apnoea	Immunapheresis	Sleep apnoea
	Pain management	Invasive cardiology	Pain management
	Sonography of the infant hip		Sonography of the infant hip
	Social psychiatry		Social psychiatry
	Sociotherapy		Sociotherapy

DMP Breast Cancer	Radiation therapy
DMP Diabetes Type 2	Substitution
DMP Coronary heart disease	Ultrasound
General practitioner contracts PKK/EKK	Environmental Medicine
Pacemaker controls	Cytology
Immunapheresis	
Invasive cardiology	
Cataract contracts AOK/EKK	
Magnetic resonance mammogra	

Cataract contracts AOK/EKK	Radiation therapy
Magnetic resonance mammogra	Substitution
	Ultrasound
	Environmental Medicine
	Cytology

2010	
ADHD	Lab services
Balneophototherapy	Long-term ECG
HIV-Aids (nationwide agreement)	LDL-apheresis
Tonsillotomy	Lithotripsy
	Mammography

2011	
Affiliated physicians	Long-term ECG
J2	LDL-apheresis
Aids Agreement	Lithotripsy
Outpatient surgery	Mammography
	Mammography screening

Vitreoretinal surgery
Aids Agreement
Outpatient surgery including structural contracts
Arthroscopy
Dialysis
DMP Breast Cancer
DMP Diabetes Type 2
DMP Coronary heart disease
General practitioner contracts PKK/EKK
Pacemaker controls
Immunapheresis
Invasive cardiology
Cataract contracts AOK/EKK
Magnetic resonance mammogram
MRI
Colonoscopy

Mammography screening
Retinal and vitreous surgery
Oncology
Otoacoustic emissions
Photodynamic therapy
Psychotherapy
Radiology
Rehabilitation
Sleep apnoea
Pain management
Sonography of the infant hip
Social psychiatry
Sociotherapy
Radiation therapy
Substitution
Ultrasound
Environmental Medicine
Cytology

including structural contracts
Arthroscopy
Dialysis
DMP Breast Cancer
DMP Diabetes Type 2
DMP Coronary heart disease
General practitioner contracts PKK/EKK
Pacemaker controls
Immunapheresis
Invasive cardiology
Cataract contracts AOK/EKK
Magnetic resonance mammogram
MRI
Colonoscopy..
Lab services

Retinal and vitreous surgery
Oncology
Otoacoustic emissions
Photodynamic therapy
Psychotherapy
Radiology
Rehabilitation
Sleep apnoea
Pain management
Sonography of the infant hip
Social psychiatry
Sociotherapy
Radiation therapy
Substitution
Ultrasound
Environmental Medicine
Cytology

2012	
Hearing aid provision	Magnetic resonance mammogram
Molecular genetics	MRI
MRSA	Colonoscopy..
Nursing home contract	Lab services
Care of patients with diabetic foot syndrome	Long-term ECG
Aids Agreement	LDL-apheresis
Outpatient surgery including structural contracts	Lithotripsy
Arthroscopy	Mammography
Dialysis	Mammography screening
DMP Breast Cancer	Retinal and vitreous surgery
DMP Diabetes Type 2	Oncology
DMP Coronary heart disease	Otoacoustic emissions
General practitioner contracts PKK/EKK	Photodynamic therapy
Pacemaker controls	Psychotherapy
Immunapheresis	Radiology
	Rehabilitation
	Sleep apnoea
	Pain management
	Sonography of the infant hip

2013	
Schizophrenia	Long-term ECG
Aids Agreement	LDL-apheresis
Outpatient surgery including structural contracts	Lithotripsy
Arthroscopy	Mammography
Dialysis	Mammography screening
DMP Breast Cancer	Retinal and vitreous surgery
DMP Diabetes Type 2	Oncology
DMP Coronary heart disease	Otoacoustic emissions
General practitioner contracts PKK/EKK	Photodynamic therapy
Pacemaker controls	Psychotherapy
Immunapheresis	Radiology
Invasive cardiology	Rehabilitation
Cataract contracts AOK/EKK	Sleep apnoea
Magnetic resonance mammogram	Pain management
MRI	Sonography of the infant hip
Colonoscopy..	Social psychiatry
	Sociotherapy
	Radiation therapy
	Substitution
	Ultrasound
	Environmental Medicine

Invasive cardiology Cataract contracts AOK/EKK	Social psychiatry Sociotherapy Radiation therapy Substitution Ultrasound Environmental Medicine Cytology

Lab services	Cytology

2014	
Allergology contract Small intestine capsule endoscopy IVM contract Rheumatoid arthritis Halmium laser therapy Hepatitis C structure contract	Lab services Long-term ECG LDL-apheresis Lithotripsy Mammography Mammography screening Retinal and vitreous surgery Oncology
Aids Agreement Outpatient surgery including structural contracts Arthroscopy	Otoacoustic emissions Photodynamic therapy Psychotherapy Radiology

2015	
Amblyopia screening contract Refugee contract	Lab services Long-term ECG
Aids Agreement Outpatient surgery including structural contracts Arthroscopy Dialysis DMP Breast Cancer DMP Diabetes Type 2 DMP Coronary heart disease General practitioner contracts PKK/EKK	LDL-apheresis Lithotripsy Mammography Mammography screening Retinal and vitreous surgery Oncology Otoacoustic emissions Photodynamic therapy Psychotherapy

Dialysis	Rehabilitation
DMP Breast Cancer	Sleep apnoea
DMP Diabetes Type 2	Pain management
DMP Coronary heart disease	Sonography of the infant hip
General practitioner contracts PKK/EKK	Social psychiatry
Pacemaker controls	Sociotherapy
Immunapheresis	Radiation therapy
Invasive cardiology	Substitution
Cataract contracts AOK/EKK	Ultrasound
Magnetic resonance mammogram	Environmental Medicine
MRI	Cytology
Colonoscopy	

Pacemaker controls	Radiology
Immunapheresis	Rehabilitation
Invasive cardiology	Sleep apnoea
Cataract contracts AOK/EKK	Pain management
Magnetic resonance mammogram	Sonography of the infant hip
MRI	Social psychiatry
Colonoscopy	Sociotherapy
	Radiation therapy
	Substitution
	Ultrasound
	Environmental Medicine
	Cytology

2016	
Geriatrics	MRI
PET/PET-CT	Colonoscopy
Healthy pregnant	Lab services
Aids Agreement	Long-term ECG
Outpatient surgery including	LDL-apheresis

structural contracts Arthroscopy Dialysis DMP Breast Cancer DMP Diabetes Type 2 DMP Coronary heart disease General practitioner contracts PKK/EKK Pacemaker controls Immunapheresis Invasive cardiology Cataract contracts AOK/EKK Magnetic resonance mammogram	Lithotripsy Mammography Mammography screening Retinal and vitreous surgery Oncology Otoacoustic emissions Photodynamic therapy Psychotherapy Radiology Rehabilitation Sleep apnoea Pain management Sonography of the infant hip Social psychiatry Sociotherapy Radiation therapy Substitution Ultrasound Environmental Medicine Cytology

Annex 2: Entire Database of the analysed Organizations

This database contains all identified organizations that were examined for the evaluation of the study. Furthermore, the database contains a detailed listing of the respective fields of activity.

AkdÄ (Arzneimittelkommission der deutschen Ärzteschaft)
• Since 2015, the AkdÄ has been conducting a project to record and evaluate medication errors
ANOA (Die Arbeitsgemeinschaft nicht operativer orthopädischer Akut-Kliniken) in cooperation with: ClarCert
• The ANOA is a medical-scientific association of acute clinics providing non-surgical orthopaedic trauma surgery, manual medicine and pain therapy • Certification
AOK-Bundesverband GbR (Allgemeine Ortskrankenkasse) in cooperation with:
➢ WIdO (Wissenschaftliches Institut der AOK) ➢ AOK Baden-Württemberg ➢ AOK Bayern ➢ AOK Bremen/Bremerhaven ➢ AOK Hessen ➢ AOK Niedersachsen 6,800 EMP ➢ AOK Nordost ➢ AOK Nordwest ➢ AOK Plus 6,700 EMP ➢ AOK Rheinland/Hamburg 7,934 EMP ➢ AOK Rheinland-Pfalz/Saarland ➢ AOK Sachsen-Anhalt
• Initiation of the AOK Hospital Navigator • Development of the procedure QA with routine data (QSR) • Patient surveys using the Patients' Experience Questionnaire (PEQ) • Participation as a member of the Endoprostheses Register Germany

AQUA-Institute (Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen GmbH)
• The AQUA-Institute is an independent partner for quality in the health care system • QA • Implementation of large-scale projects for QA/promotion in health sector • European Practice Assessment (EPO) - quality management for the medical practice
AVG (AnbieterVerband qualitätsorientierter Gesundheitspflege-Einrichtungen e.V.
• Further development of home nursing • Expansion and assurance of quality in the facilities
AWO Bundesverband e.V. (Spitzenverband der Freien Wohlfahrtspflege)
• The Arbeiterwohlfahrt (AWO) is a decentralised German welfare association. Its main task is to support socially less advantaged people • Further training and qualification opportunities • QM
ÄZQ (Ärztliches Zentrum für Qualität in der Medizin)
• ÄZQ is the joint competence centre of the German Medical Association (BÄK) and the National Association of Statutory Health Insurance Physicians (KBV) for quality and knowledge transfer in the health care system • QA of the medical profession • Development and evaluation of medical guidelines • Further development of QM and QA
BAGFW e.V. (Bundesarbeitsgemeinschaft der Freien Wohlfahrtspflege)
• QM • Concept for future quality reporting in inpatient care
BAK (Bundesapothekerkammer) is divided into the following state chambers of pharmacists
➢ Landesapothekerkammer Baden-Württemberg ➢ Bayerische Landesapothekerkammer ➢ Apothekerkammer Berlin

- Landesapothekerkammer Brandenburg
- Apothekerkammer Bremen
- Apothekerkammer Hamburg
- Landesapothekerkammer Hessen
- Apothekerkammer Mecklenburg-Vorpommern
- Apothekerkammer Niedersachsen
- Apothekerkammer Nordrhein
- Landesapothekerkammer Rheinland-Pfalz
- Apothekerkammer des Saarlandes
- Apothekerkammer Sachsen-Anhalt
- Sächsische Landesapothekerkammer
- Apothekerkammer Schleswig-Holstein
- Landesapothekerkammer Thüringen
- Apothekerkammer Westfalen-Lippe

- The Federal Chamber of Pharmacists (BAK) represents the interests of the profession and is responsible for issues of education, training and continuing education, for professional law and for issues of drug safety
- QA for recipes
- Guidelines and working aids

BÄK (Bundesärztekammer)

- Landesärztekammer Baden-Württemberg 47 EMP / 4 in QA, Administrative costs: 283,000€, Budget 2015
- Bayerische Landesärztekammer 200 EMP / Total administrative expenses: 12.100.000€
- Ärztekammer Berlin: 90 EMP / 9 in QA (3 EMP via an external office)
- Landesärztekammer Brandenburg 55 EMP / 11 in QA
- Ärztekammer Bremen 25 EMP / 10 in QA
- Ärztekammer Hamburg 90 EMP / 12 in QA
- Landesärztekammer Hessen 32 EMP / 1 in QA
- Ärztekammer Mecklenburg-Vorpommern 51 EMP / 3 in QA
- Ärztekammer Niedersachsen in cooperation with ZG (Zentrum für Qualität, is integrated with Medical Association!) 65 EMP / 11 in QA
- Ärztekammer Nordrhein 242 EMP / 10 in QA
- Landesärztekammer Rheinland-Pfalz 27 EMP / 2 in QA
- Ärztekammer des Saarlandes 47 EMP / 1 in QA
- Sächsische Landesärztekammer 136 EMP / 7 in QA
- Ärztekammer Sachsen-Anhalt 47 EMP / 3 in QA

➢ Ärztekammer Schleswig-Holstein 16 EMP / 1 in QA ➢ Landesärztekammer Thüringen 79 EMP / 4 in QA ➢ Ärztekammer Westfalen-Lippe 180 EMP / 46 in QA
• QA - uniform federal procedure for reproductive medicine • Optimising care for the seriously ill and dying • Promotion of QA measures • Certification
BAR e.V. (Bundesarbeitsgemeinschaft für Rehabilitation e.V.)
• QM and Certification • Quality Development and QA in rehabilitation
BAV Institut (Institut für Hygiene und Qualitätssicherung GmbH)
• The BAV Institute is an accredited contract laboratory and offers hygiene and quality control services to companies in the food, cosmetics and pharmaceutical industries
BGW (Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege) in cooperation with: qu.int.as (Qualitätsmanagement mit integriertem Arbeitsschutz)
• BGW is the provider of statutory accident insurance for non-governmental institutions in the health service and welfare care sector • Prevention and rehabilitation
bifg (Das BARMER Institut für Gesundheitssystemforschung)
➢ The BARMER Institute for Health Systems Research (bifg) is the scientific institute of BARMER. It sees itself as a centre of competence for care and health system research and examines, in particular, questions of health care, financing and insurance systems.
• It creates and develops analyses and concepts itself and in partnerships • Competitive analyses • QA • Medical evaluation
BHÄV e.V. (Bayerischer Hausärzteverband e.V.) in cooperation with Hausärztlicher Service- und Wirtschaftsgesellschaft mbH (HSW GmbH) awards the: **HÄQS (Hausärztliches Qualitätssiegel: General Practitioner Quality Seal)**
• Certification • QM

- Further education

BKK (Betriebskrankenkassen) is divided into four BKK regional associations:

BKK Landesverband Bayern

- Audi BKK Administrative costs: 44,756,394€ / 600 EMP
- BKK Akzo Nobel Bayern Administrative costs: 3,462,916€ / 53 EMP
- BKK Faber-Castell & Partner Administrative costs: 4,129,880€
- BKK KBA (Koenig & Bauer AG) Administrative costs: 1,046,985€
- BKK Krones Administrative costs: 982,857€
- BKK Mobil Oil Administrative costs: 77,048,107€ / 1700 EMP
- BKK ProVita Administrative costs: 9,015,669€
- BKK Stadt Augsburg Administrative costs: 1,491,392€ / 29 EMP
- BKK Textilgruppe Hof Administrative costs: 556,533€
- BKK VerbundPlus Administrative costs: 7,098,740€
- BKK Wirtschaft & Finanzen Administrative costs: 2,583,964€ / 19 EMP
- BMW BKK Administrative costs: 11,635,402€
- mhplus Krankenkasse Administrative costs: 45,893,660€ / 970 EMP
- Salus BKK Administrative costs: 12,896,272€ / 320 EMP
- SKD BKK (Svenska Kullagerfabriken GmbH und Düker GmbH & Co. KGaA) Administrative costs: 4,376,211€

BKK Landesverband Mitte

- BKK 24 Administrative costs: 8,367,058€ / 168 EMP
- BKK advita Administrative costs: 4,020,218€ / 85 EMP
- BKK EWE (Energieversorgung Weser-Ems AG) Administrative costs: 70.400.000€ / 8,465 EMP
- BKK exklusiv Administrative costs: 2,003,438€
- BKK Pfaff Administrative costs: 2,289,611€ / 40 EMP
- BKK Pfalz Administrative costs: 18,709,786€ / 250 EMP
- BKK Public Administrative costs: 410,688€
- BKK RWE (Rheinisch-Westfälisches Elektrizitätswerk AG)
- BKK Salzgitter Administrative costs: 6,000,652€
- BKK Technoform Administrative costs: 1,624,508€
- BKK VBU (BKK Verkehrsbau Union) Administrative costs: 38,927,000€ / 850 EMP
- BKK Vital Administrative costs: 1,160,285€
- BKK ZF & Partner Administrative costs: 10,360,208€
- Brandenburgische BKK Administrative costs: 1,252,695€ / 20 EMP

- Debeka BKK Administrative costs: 3,910,668€
- energie-BKK Administrative costs: 8,633,420€ / 136 EMP
- pronova BKK Administrative costs: 75,408,500€ / 1,300 EMP

- TBK (Thüringer Betriebskrankenkasse) Administrative costs: 1.715.166€ / 25 EMP
- TUI BKK (Touristik Union International AG) Administrative costs: 1,389,327€

BKK Landesverband Nordwest

- actimonda Krankenkasse Administrative costs: 11,091,451€ / 220 EMP
- Bergische Krankenkasse Administrative costs: 6,870,912€ / 125 EMP
- Bertelsmann BKK Administrative costs: 2,037,876€ / 78 EMP
- BKK Achenbach Buschhütten Administrative costs: 2,551,289€ / 50 EMP
- BKK Diakonie Administrative costs: 3,102,868€
- BKK DürkoppAdler Administrative costs: 2,699,321€
- BKK Herford Minden Ravensberg Administrative costs: 2,665,547€ / 35 EMP
- BKK Melitta Plus Administrative costs: 4,381,793€ / 56 EMP
- BKK Miele Administrative costs: 2,620,913€
- Continentale BKK Administrative costs: 5,676,732€
- Heimat Krankenkasse Administrative costs: 11,354,319€ / 176 EMP
- KK BPW Bergische Achsen KG 9 EMP
- Novitas BKK Administrative costs: 43,626,380€
- SECURVITA Krankenkasse Administrative costs: 22,285,000€

Landesverband der Betriebskrankenkassen Süd

- Bahn-BKK Administrative costs: 46,790,012€
- BKK Aesculap Administrative costs: 936,407€
- BKK B. Braun Melsungen Administrative costs: 1,877,022€ / 29 EMP
- BKK Freudenberg Administrative costs: 2,015,827€
- BKK Groz-Beckert Administrative costs: 874,635€
- BKK Henschel Plus Administrative costs: 1,897,671€
- BKK Herkules Administrative costs: 2,757,910€
- BKK PwC (PricewaterhouseCoopers AG) 30EMP
- BKK Rieker.Ricosta.Weisser

- BKK SBH (Schwarzwald-Baar-Heuberg) Administrative costs: 1,521,173€
- BKK Scheufelen Administrative costs: 3,941,905€
- BKK Werra-Meissner Administrative costs: 3,078,552€
- BKK Würth Administrative costs: 772,718€
- Bosch BKK Administrative costs: 19,698,046€ / 300 EMP
- Daimler BKK Administrative costs: 23,148,500€ / 230 EMP
- Die Schwenninger Krankenkasse Administrative costs: 30,101,155€ / 600 EMP
- Metzinger BKK Administrative costs: 544,710€
- SBK (Siemens-Betriebskrankenkasse) Administrative costs: 90,455,360€ / 1,554 EMP
- Südzucker-BKK
- Wieland BKK
- WMF BKK (Württembergische Metallwarenfabrik AG) Administrative costs: 2,045,728€

- Health care in regional state
- Development of individual supplementary offers for the company health insurance funds
- BKK representation of interests in field of politics and the (specialist) public
- QM
- QA

bpa e.V. (Bundesverband privater Anbieter sozialer Dienste e.V.) in cooperation with: TÜV Nord Cert GmbH

- Establishment and further development of the quality of care
- Further education and training
- Seminars

BPtK (Bundespsychotherapeutenkammer)

There are currently 12 state chambers for psychotherapists in Germany:

- Landespsychotherapeutenkammer Baden-Württemberg (LPK Baden-Württemberg)
- Bayerische Landeskammer der Psychologischen Psychotherapeuten und der Kinder- und Jugendlichenpsychotherapeuten (PTK Bayern)
- Psychotherapeutenkammer Berlin (PTK Berlin)
- Psychotherapeutenkammer Bremen (PTK Bremen)

➢ Psychotherapeutenkammer Hamburg (PTK Hamburg) ➢ Landeskammer für Psychologische Psychotherapeutinnen und -therapeuten und Kinder- und Jugendlichenpsychotherapeutinnen und -therapeuten in Hessen (LPPKJP Hessen) ➢ Psychotherapeutenkammer Niedersachsen (PKN) ➢ Landespsychotherapeutenkammer Rheinland-Pfalz (LPK RLP) ➢ Kammer für Psychologische Psychotherapeuten und Kinder- und Jugendlichenpsychotherapeuten Nordrhein-Westfalen (PTK NRW) ➢ Ostdeutsche Psychotherapeutenkammern (OPK) ➢ Psychotherapeutenkammer des Saarlandes (PKS) ➢ Psychotherapeutenkammer Schleswig-Holstein (PKSH)
• The purpose of the BPtK is the constant exchange of experience among the chambers of psychotherapists, the mutual coordination of their goals and activities and the joint representation of their concerns • QA
BQS GmbH (Bundesgeschäftsstelle Qualitätssicherung, Institut für Qualität & Patientensicherheit GmbH)
• Benchmarking and quality comparisons • Consulting and scientific studies
BVOU e.V. (Berufsverband für Orthopädie und Unfallchirurgie e.V.)
• The BVOU enforces the professional interests of its members by developing the standard of orthopaedic trauma surgical care together with the scientific societies for the benefit of patients and the common good
BSI Group Deutschland GmbH (The British Standards Institution)
• Auditing • Certification • Further training • QM
BZÄK (Bundeszahnärztekammer)
• The BZÄK represents the health and professional policy interests of the dental profession • Creation of framework conditions for the provision and recognition of dental services • Education and further training • Strengthening prevention and health promotion

• In-house QM
CAC (Comprehensive Allergy Center) in cooperation with:
➢ DDG (Deutsche Dermatologische Gesellschaft) ➢ DGAKI (Deutsche Gesellschaft für Allergologie und Klinische Immunologie e.V.) ➢ DGP e.V. (Deutsche Gesellschaft für Pneumologie und Beatmungsmedizin e.V.)
• Certification • Training and research
CertEuropA GmbH
• CertEuropA GmbH is a nationally active, accredited certification body as well as a recognised expert body for QM systems
Cert iQ Zertifizierungsdienstleistungen GmbH
• Certification • Accreditation • Seminars
Charité Berlin (Universitätsmedizin Berlin)
• Satisfaction measurement • Clinical care • Clinical risk management • Certifications, accreditations and audits • QA
ClarCert GmbH
➢ Vergibt unter anderem das Zertifikat “Babyfreundlich“ im Auftrag von BFHI e.V. (Verein zur Unterstützung der WHO/UNICEF-Initiative “Babyfreundliches Krankenhaus“ (BFHI) e. V.)
• Certification • Trainings and seminars • QM Certification
DAG-KBT e.V. (Deutsche Arbeitsgemeinschaft für Knochenmark- und Blutstammzell-transplantation e.V.)
• Certification • Research

• Continuing education
dagnä e.V. (Deutsche Arbeitsgemeinschaft niedergelassener Ärzte in der Versorgung HIV-Infizierter e.V.)
• Optimisation of quality-assured care for HIV-infected people in Germany • QM • Certification • Scientific studies and evaluations of the HIV treatment reality in Germany • Further training
DAKJ e.V. (Deutsche Akademie für Kinder- und Jugendmedizin e.V.) is the umbrella organization of the three major paediatric societies in Germany:
➢ Deutsche Gesellschaft für Kinder- und Jugendmedizin e.V. (DGKJ) ➢ Berufsverband der Kinder- und Jugendärzte e.V. (BVKJ) ➢ Deutsche Gesellschaft für Sozialpädiatrie und Jugendmedizin e.V. (DGSPJ)
The DAKJ e.V. awards the certificate "Ausgezeichnet. Für Kinder" in cooperation with: • BaKuK e.V. (Bundesarbeitsgemeinschaft Kind und Krankenhaus e.V.) • GKinD e.V. (Gesellschaft der Kinderkrankenhäuser und Kinderabteilungen in Deutschland e.V.)
DCV (Deutscher Caritasverband e.V.)
• External/internal QA measures • Further training of the staff • The German Caritas Association sees itself as an advocate and partner of the disadvantaged • The Caritas association helps to shape social and societal policy • The German Caritas Association contributes to the qualification of social work
DDG (Deutsche Diabetes Gesellschaft)
• Further education • Certification • Research
DEGAM (Deutsche Gesellschaft für Allgemeinmedizin und Familien-medizin)
• Testing of different methods and tools for QM in the practice • Assessment of the quality of GP work by patients

• Monitoring and evaluation of the quality of care in new care models
DeGIR (Deutsche Gesellschaft für Interventionelle Radiologie und minimal-invasive Therapie) in DRG e.V. (Deutsche Röntgengesellschaft e.V.)
• Research • Certification • Supporting the QA of interventional procedures through an appropriate system
DEKRA Certification GmbH
• Certification • Auditing
Deutscher Hausärzteverband e.V. awards HÄQS (Hausärztliches Qualitätssiegel: General Practitioner Quality Seal)
• Certification • QM • Further training
Deutscher Paritätischer Wohlfahrtsverband-Gesamtverband e.V.
• QA • QM • Training and advice
Deutscher Verlag für Gesundheitsinformation GmbH (Medführer)
• Development, expansion and optimisation of sound solutions for the field of medical transparency and health information
DGA e.V. (Deutsche Gesellschaft für Angiologie - Gesellschaft für Gefäßmedizin e.V.) in cooperation with:
➢ DGG (Deutsche Gesellschaft für Gefäßchirurgie) ➢ DRG (Deutsche Röntgengesellschaft)
• Research • Certification
DGAV e.V. (Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie e.V.) in cooperation with:
➢ CAEK (Chirurgische Arbeitsgemeinschaft Endokrinologie)

➢ CALGP (Chirurgische Arbeitsgemeinschaft für Leber-, Galle- und Pankreaserkrankungen) ➢ CAMIC (Chirurgische Arbeitsgemeinschaft für Minimal-Invasive Chirurgie)
• Systematic basic, further and advanced training • Participation in QA measures
DGE e.V. (Deutsche Gesellschaft für Ernährung e.V.)
• Offers for QA in nutrition counselling and communal catering by designing framework conditions, setting standards, certifications and inspections, counselling and training, etc. • Design training programs for multipliers, including the development of curricula, organization and implementation of training courses and seminars • Determination of the need for nutritional research and ideational support • Development of scientific recommendations
DGfN e.V. (Deutsche Gesellschaft für Nephrologie e.V.) in cooperation with: ClarCert
• DGfN has created a certification procedure by which specialised nephrology departments can undergo a quality development and review process
DGG e.V. (Deutsche Gesellschaft für Gefäßchirurgie und Gefäßmedizin e.V.) in cooperation with "Private Akademie" und DIGG (Deutsches Institut für Gefäßmedizinische Gesundheitsforschung gGmbH)
• Recording, documentation and evaluation of quality indicators of vascular medical care • QA • Certification • Further training
DGHO e.V. (Deutsche Gesellschaft für Hämatologie und Medizinische Onkologie e.V.)
• Certification • Research, diagnosis and treatment of blood diseases • Education and training
DGIM e.V. (Deutsche Gesellschaft für Innere Medizin e.V.)

• QA in drug therapy through the establishment of drug therapy management (AMTM: Arzneimitteltherapie-Management) and drug therapy safety (AMTS: Arzneimitteltherapie-Sicherheit) • Research and teaching
DGK e.V. (Deutsche Gesellschaft für Kardiologie – Herz- und Kreislaufforschung e.V.)
• Certification • Prevention • Further education
DGKCH e.V. (Deutsche Gesellschaft für Kinderchirurgie e.V.)
• QA and patient satisfaction
DGKJ e.V. (Deutsche Gesellschaft für Kinder- und Jugendmedizin e.V.)
• Research • Education and training
DGN e.V. (Deutsche Gesellschaft für Nuklearmedizin e.V.)
• Research • Certification
DGOU e.V. (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie e.V.) is the umbrella organization of:
➢ DGOOC e.V. (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie) ➢ DGU e.V. (Deutsche Gesellschaft für Unfallchirurgie e.V.) DGOU e.V. cooperates with: ➢ AE e.V. (Deutsche Gesellschaft für Endoprothetik e.V.) ➢ D.A.F. e.V. (Deutsche Assoziation für Fuß und Sprunggelenk e.V.) DGOOC e.V. cooperates with: ➢ EndoCert GmbH (Endoprothetik) ➢ EPRD gGmbH (Das Endoprothesenregister Deutschland gGmbH)
The areas of responsibility of these organizations: • Research and certification • QA and assessment of artificial joints • Education, training and continuing education

• QA • Society for Prevention and Diagnostics
DGPR e.V. (Deutsche Gesellschaft für Prävention und Rehabilitation von Herz-Kreislauferkrankungen e.V.)
• Medical-scientific umbrella organization for all areas of prevention • Research, development, implementation and dissemination of new methods in the treatment of cardiovascular diseases • Further education • Development and updating of quality standards
DGQ e.V. (Deutsche Gesellschaft für Qualität e.V.)
• Certification • Consulting and further education • Research • Auditing • QA • QM
DGSM e.V. (Deutsche Gesellschaft für Schlafforschung und Schlafmedizin e.V.)
• Accreditation • QA • Further training
DGSPJ e.V. (Deutsche Gesellschaft für Sozialpädiatrie und Jugendmedizin e.V.)
• Promotion of research, teaching and further and advanced training in the field of social paediatrics and adolescent medicine. • QA in social paediatrics
DGTHG e.V. (Deutsche Gesellschaft für Thorax-, Herz- und Gefäßchirurgie e.V.)
• Research and certification • Continuing education
DHG e.V. (Die Deutsche Hernien Gesellschaft e.V.)
• Quality control development • Further training

DIGAB e.V. (Deutsche Interdisziplinäre Gesellschaft für außerklinische Beatmung e.V.)
• Certification • Further training • Establishment of new and improvement of existing organizational structures in out-of-hospital ventilation
DIOcert GmbH in cooperation with:
➢ DGINA Zert e.V. (Deutsche Gesellschaft Interdisziplinäre Notfall- und Akutmedizin e.V.)
• Certification • Risk Management • Training
diqp (Deutsches Institut für Qualität in der Physiotherapie)
• Consulting and coaching • Research • Quality development
DKG e.V. (Deutsche Krankenhausgesellschaft)
• Maintaining and improving the performance of hospitals • Scientific research in the field of health care • QM
DKG e.V. (Deutsche Krebsgesellschaft e.V.) in cooperation with:
➢ ClarCert GmbH ➢ OnkoZert GmbH ➢ XML-OncoBox
• Certification • Health services research • Development of medical guidelines
DNVF e.V. (Deutsches Netzwerk Versorgungsforschung e.V.)
• Further development and communication of methods in health services research • Quality and patient safety research

DOG e.V. (Deutsche Ophthalmologische Gesellschaft / Gesellschaft für Augenheilkunde e.V.) in cooperation with:
➢ RG (Retinologische Gesellschaft)
• Certification of IVOM (Intravitreal Operative Medication) - and PDT (Photodynamic Therapy) courses by RG and DOG
DPA GmbH (Deutsche Psychologen Akademie GmbH) is the educational institution of Berufsverband Deutscher Psychologinnen und Psychologen e.V. (BDP)
• Certification • Further education and training
DQE (Diakonisches Institut für Qualitätsentwicklung Diakonie Deutschland – Evangelischer Bundesverband Evangelisches Werk für Diakonie und Entwicklung)
• DQE develops quality principles for a diaconal profile • The special results are the QM systems Diakonie-Siegel Pflege, KiTa/Evangelisches Gütesiegel BETA (Bundesvereinigung Evangelischer Tageseinrichtungen für Kinder e.V.) • Further training • Certification
DQS GmbH (Deutsche Gesellschaft zur Zertifizierung von Managementsystemen)
• Certification • Auditing • Risk Management in the health sector • QM
DRK (Deutsches Rotes Kreuz, here: DRK-Landesverband Baden-Württemberg e. V.)
• QM in rescue services • Outpatient and inpatient QM
DRV (Deutsche Rentenversicherung)
The institutions of the German Pension Insurance are: ➢ Deutsche Rentenversicherung Bund 17,336 EMP Administrative costs: 1,081,137,948 €

- Deutsche Rentenversicherung Knappschaft-Bahn-See 28,367 EMP Administrative costs: 36,300,000
- Deutsche Rentenversicherung Baden-Württemberg 3,600 EMP
- Deutsche Rentenversicherung Bayern Süd 3,000 EMP
- Deutsche Rentenversicherung Berlin-Brandenburg
- Deutsche Rentenversicherung Braunschweig-Hannover
- Deutsche Rentenversicherung Hessen
- Deutsche Rentenversicherung Mitteldeutschland
- Deutsche Rentenversicherung Nord 1,894 EMP, 7 EMP incl. one physician for QA, costs: 410,000€
- Deutsche Rentenversicherung Nordbayern
- Deutsche Rentenversicherung Oldenburg-Bremen
- Deutsche Rentenversicherung Rheinland
- Deutsche Rentenversicherung Rheinland-Pfalz
- Deutsche Rentenversicherung Saarland
- Deutsche Rentenversicherung Schwaben
- Deutsche Rentenversicherung Westfalen

- For continuous improvement of medical rehabilitation services, the German Pension Insurance uses instruments and procedures of rehabilitation QA
- The aim is to improve the quality of medical rehabilitation
- QA for services for participation in working life (LTA: Leistungen zur Teilhabe am Arbeitsleben)

DSG (Deutsche Schlaganfall-Gesellschaft)

- Coordinate, qualify and promote research and further education in the field of stroke
- Certification

DTG e.V. (Deutsche Transplantationsgesellschaft e.V.)

- QA in transplant medicine

DVO e.V. (Dachverband Osteologie e.V.)

- Development of new approaches and communication tools in the field of osteology
- Further development of osteology
- Research
- Certification

ENPP-Boehm GmbH (Europäisches Netzwerk für psychobiographische Pflegeforschung)
• Certification • Training and research
EQS (Hamburg Landesgeschäftsstelle Qualitätssicherung)
• Creation and maintenance of an information and advisory platform for hospitals involved in QA measures in accordance with § 4 Para. 1 of the Directive on QA Measures in Hospitals (QSKH-RL: Richtlinie über Maßnahmen der Qualitätssicherung in Krankenhäuser) • Implementation of the Structured Dialogue for the evaluation of statistical anomalies according to § 10 ff of the QSKH-RL pursuant to § 136 SGB V • Validation of the transmitted data records according to § 9 Para. 1 to 3, 5 and 6 of the QSKH-RL pursuant to § 136 SGB V
EQ Zert (Europäisches Institut zur Zertifizierung von Managementsystemen und Personal)
• Certification • Auditing • Further training
EurSafety Qualitätsverbund (EurSafety Health Net)
• Certification • QM
G-BA (der Gemeinsame Bundesausschuss)
• Working Group for Promotion of QA in Medicine (AQS: Arbeitsgemeinschaft zur Förderung der Qualitätssicherung in der Medizin) • G-BA is the highest decision-making body of the joint self-administration of physicians, dentists, psychotherapists, hospitals and health insurance funds in Germany • It determines the catalogue of services provided by the statutory health insurance system in guidelines • The G-BA decides on QA measures for the outpatient and inpatient health care sector
GKV-Spitzenverband, Bund der Krankenkassen
➢ Supporters of the QS-Reha Institute

• The GKV-Spitzenverband is the central representative body of the statutory health and long-term care insurance funds in Germany • It shapes the framework conditions for intensive competition for quality and efficiency in health care and long-term care • The GKV-Spitzenverband is also the umbrella organization of the long-term care insurance funds • QA in all areas of health insurance
GMDS e.V. (Die Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie e.V.) is an independent scientific-medical professional society. GMDS arbeitet in cooperates with:
➢ BVMI e.V. (Berufsverband Medizinischer Informatik e.V.) ➢ DGSMP e.V. (Deutsche Gesellschaft für Sozialmedizin und Prävention e.V.) ➢ DVMD e.V. (Der Fachverband für Dokumentation und Informations-management in der Medizin e.V.) ➢ GI e.V. (Gesellschaft für Informatik e.V.)
• GMDS makes its medical-informational, biometric and epidemiological methods available to all medical subfields. These methods are further developed with computer science, mathematics, statistics, economics, clinical research, bioinformatics and health services research • Certification • Education and training
GQMG e.V. (Gesellschaft für Qualitätsmanagement in der Gesundheitsversorgung e.V.)
• QM • Improving health care
Gütegemeinschaft Pflege in stationären Einrichtungen e. V.
• Awarding and securing the RAL quality mark RAL-GZ 113: Quality-tested care in inpatient and outpatient facilities
Heimverzeichnis gGmbH
• Assessment • Promotion and improvement of inpatient long-term care facilities • Quality check
HELIOS Kliniken GmbH
• Quality measurement using quality indicators

• Proprietary patient survey methodology • Peer review process • Improvement of long-term results (QSR)
IGES Institut GmbH
• Conceptual design of quality improvement systems • System analysis of comprehensive quality reporting systems
IKK (Innungskrankenkassen)
• IKK Brandenburg und Berlin — Administrative costs: 21,174,650€ • IKK classic — Administrative costs: 325,427,807€ • IKK gesund plus — Administrative costs: 32,715,067€ • IKK Nord — Administrative costs: 21,831,652€ • IKK Südwest — Administrative costs: 62,274,456€
IMC clinicon GmbH
• Benchmarking, analyses and consulting for hospitals • Consulting and service institute in the health care sector • QM • Process optimisation
i-med-cert GmbH
• QM • Certification
infaz GmbH (Institut für Auditierung und Zertifizierung GmbH)
• Certification • Auditing
Institut für Pflegemanagement
• Checklists and procedures e.g. professional guidance, nursing rounds, induction training • Nursing documentation • Training • QM
IQD (Institut für Qualitätskennzeichnung von sozialen Dienstleistungen GmbH)
• Certification

• Assessment • Examination of nursing documentation for conclusiveness of content, completeness and legal security
IQH e.V. (Institut für Qualitätssicherung in der Heilmittelversorgung e.V.)
• QA in the provision of therapeutic products • Certification • QM
IQM e.V. (Initiative Qualitätsmedizin e.V.)
• Provides a platform for exchange and shared learning for currently over 400 hospitals • Quality measurement based on routine data • Transparency of results through their publication • Quality improvements through peer reviews (examining treatment processes with conspicuous results for possible errors in the processes, structures and interfaces)
IQMG (Institut für Qualitätsmanagement im Gesundheitswesen) is a 100% subsidiary of Bundesverband Deutscher Privatkliniken e.V. (BDPK)
• IQMP-Reha (Qualitätsmanagement-Programm-Reha) • The IQMG's task is to develop and disseminate quality development instruments for rehabilitation facilities and hospitals. • Seminars and training courses • Development and maintenance of certifiable QM systems such as IQMP Reha, IQMP health and related services • Certification
IQN (Institut für Qualität im Gesundheitswesen Nordrhein)
➢ IQN was founded in 1996 and is jointly supported by the North Rhine Medical Association (ÄkNo: Ärztekammer Nordrhein) and the North Rhine Association of Statutory Health Insurance Physicians (KV: Kassenärztlicher Vereinigung)
• Supporting physicians in realising quality of care and patient safety • Observation of health policy trends
iqpr GmbH (Institut für Qualitätssicherung in Prävention und Rehabilitation)

• The Institute's objective is the evaluation and further development of preventive and rehabilitative services. • QA
IQTIG (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen)
• IQTIG develops concepts and instruments for external QA and participates in the implementation of procedures • The Institute is commissioned by the G-BA
IQWiG (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen)
• Reviewing the quality and cost-effectiveness of medical services • Evaluation of evidence-based (evidence-supported) guidelines • Recommendations on Disease Management Programs
ISGPN (Internationale Stiftung für Gesundheits- und Pflegenetze)
• Certification • Transparency of quality in care • Electronic nursing file
ISQ e.V. (Interessenverband zur Sicherung der Qualität der Ausbildung an den deutschen Schulen für Physiotherapie e.V.) Interest group to ensure the quality of training at German schools for physiotherapy
• Assurance and promotion of quality in the training of physiotherapists • Certification
KBV (Kassenärztliche Bundesvereinigung) **KV (Kassenärztliche Vereinigung) The KBV is the umbrella organization of the 17 associations of panel physicians:**
➢ Kassenärztliche Vereinigung Baden-Württemberg (KVBW) ➢ Kassenärztliche Vereinigung Bayerns (KVB) ➢ Kassenärztliche Vereinigung Berlin (KV Berlin) 40 EMP ➢ Kassenärztliche Vereinigung Brandenburg (KVBB) ➢ Kassenärztliche Vereinigung Bremen (KVHB) ➢ Kassenärztliche Vereinigung Hamburg (KVH) 360-380 EMP, 29 EMP in QA / Administration costs: 1,572,511€ ➢ Kassenärztliche Vereinigung Hessen (KV Hessen) ➢ Kassenärztliche Vereinigung Mecklenburg-Vorpommern (KVMV) ➢ Kassenärztliche Vereinigung Niedersachsen (KVN) 35 EMP

➢ Kassenärztliche Vereinigung Nordrhein (KVNO) ➢ Kassenärztliche Vereinigung Rheinland-Pfalz (KV RLP) ➢ Kassenärztliche Vereinigung Saarland (KV Saarland) 10 EMP ➢ Kassenärztliche Vereinigung Sachsen (KVS) ➢ Kassenärztliche Vereinigung Sachsen-Anhalt (KVSA) ➢ Kassenärztliche Vereinigung Schleswig-Holstein (KVSH) ➢ Kassenärztliche Vereinigung Thüringen (KV Thüringen) ➢ Kassenärztliche Vereinigung Westfalen-Lippe (KVWL)
• QEP (Qualität und Entwicklung in Praxen) - Quality and Development in Practices is the QM system of the Association of Statutory Health Insurance Physicians (KV) with the Federal Association of Statutory Health Insurance Physicians (KBV) for GKV-accredited medical and psychotherapeutic practices and medical care centres (MVZ) • QEP Certification • Outpatient and cross-sector QA
KCQ (Kompetenz-Centrum Qualitätssicherung/Qualitätsmanagement) is an institution of Medical Service of Health Insurance Baden-Württemberg (MDKBW: Medizinischer Dienst der Krankenversicherung Baden-Württemberg)
• Supporting the MDK community and the MDS in QA assessments and special expert reports • Advice on QA and quality promotion measures in the health care system • Conceptual advice, monitoring and evaluation of pilot projects and new forms of care with regard to Quality Assurance • Advising the GKV-Spitzenverband in committees of the G-BA and the GKV at national level
Kneipp-Bund e.V. (Bundesverband für Gesundheitsförderung und Prävention)
• Health promotion and health education • Certification
KTQ (Kooperation für Transparenz und Qualität im Gesundheitswesen)
• Maintenance and further development of the KTQ certification procedure • Approval of KTQ certification bodies • Training
KZBV (Kassenzahnärztliche Bundesvereinigung)

- In 2012, the KZBV set up the "Quality Promotion" department to further systematise the handling of issues related to the management and assurance of the quality of dental care. The department's focus in the broad spectrum of dental QA is on supporting dentists and KZVs in implementing quality promotion measures, for example, supporting quality circles as well as education, training and continuing education, QM and the preparation of quality reports
- Collaboration on dental guidelines
- 4.5 EMP in QA, Administration costs: 515.000€

LAGO e.V. (Landesarbeitsgemeinschaft Onkologische Versorgung Brandenburg e.V.)

- Certification
- Screening - Early detection - Prevention
- Advanced training

LGA InterCert GmbH

- A company of the TÜV Rheinland Group with location in Nuremberg
- Certification
- QM
- Validation

LQS: Landesgeschäftsstellen für Qualitätssicherung is divided into:

- BAQ: Geschäftsstelle Bayerische Arbeitsgemeinschaft für Qualitätssicherung in der stationären Versorgung bei der Bayerischen Krankenhausgesellschaft e.V. (Office of the Bavarian Working Group for QA in Inpatient Care at the Bavarian Hospital Association e.V.), 5 EMP
  - The basic aim of external QA is to support the internal QA in the individual hospitals, which is at different levels
- EQS: Externe Qualitätssicherung Hamburg, 2 EMP, Administration cost: 115,000€
  - Measures for QA and further development of quality in the hospital
  - Support of hospital's internal QM
- GeQik: Geschäftsstelle Qualitätssicherung im Krankenhaus bei der Baden-Württembergischen Krankenhausgesellschaft e.V. (Office of QA in Hospitals at the Baden-Württemberg Hospital Association e.V.), 9 EMP
  - Implementation and supervision of QA measures in inpatient hospital treatment
  - Data management for QA procedures

- Geschäftsstelle Qualitätssicherung Regionalvertretung Nordrhein und Westfalen-Lippe, 17 EMP
  - The Westphalia-Lippe Regional Office awards the "ÄKzert" certificate
- GQH: Geschäftsstelle Qualitätssicherung Hessen bei der Hessischen Krankenhausgesellschaft e.V., 9 EMP
- Krankenhausgesellschaft Mecklenburg-Vorpommern e.V. (KGMV), 11 EMP, 4 EMP in QA
- Landesgeschäftsstelle Qualitätssicherung Brandenburg bei der Landesärztekammer Brandenburg, 11 EMP in QA
- Projektgeschäftsstelle Qualitätssicherung bei der Niedersächsischen Krankenhausgesellschaft e.V., 7 EMP
  - Data processing of the QA data collected in the hospital for indirect procedures
  - Preparation of the annual evaluations for indirect procedures
- Projektgeschäftsstelle Qualitätssicherung bei der Ärztekammer Sachsen-Anhalt, 3 EMP
- Projektgeschäftsstelle Qualitätssicherung bei der Landesärztekammer Thüringen, 4 EMP
- Projektgeschäftsstelle Qualitätssicherung bei der Sächsischen Landesärztekammer, 7 EMP
- Projektgeschäftsstelle Qualitätssicherung, Krankenhausgesellschaft Schleswig-Holstein e.V.
- QBS: Qualitätsbüro Saarland
  - Planning, organizing and implementing QA measures across facilities and specifying criteria for quality audits
- Qualitätsbüro Berlin, 9 EMP in QA (3 EMP via an external office)
- Qualitätsbüro Bremen, 2 EMP
- SQMed gGmbH: Geschäftsstelle Qualitätssicherung Rheinland-Pfalz, 4 EMP

MDK: Medizinischer Dienst der Krankenversicherung is the medical, dental and nursing advisory and assessment service for statutory health and long-term care insurance in Germany. MDK operates regionally and is usually represented in every federal state:

- MDK Baden-Württemberg, 1,132 EMP
  - The Office for Interagency QA in the Baden-Württemberg Ambulance Service (SQR-BW: Die Stelle zur träger-übergreifenden Qualitätssicherung im Rettungsdienst Baden-Württemberg) is

responsible for the development and implementation of external QA in Baden-Württemberg ambulance service

- MDK Bayern, 1,172 EMP
  - Nationwide, the MDK Bavaria is the largest medical service of the health insurances
- MDK Berlin-Brandenburg, 673 EMP
- MDK Bremen
- MDK Hamburg / Schleswig-Holstein, 480 EMP
- MDK Hessen, 615 EMP
- MDK Mecklenburg-Vorpommern
- MDK Niedersachsen
- MDK Nordrhein, 1.000 EMP, 40 in QA
- MDK Rheinland-Pfalz
- MDK Saarland, 100 EMP
- MDK Sachsen
- MDK Sachsen-Anhalt
- MDK Thüringen
- MDK Westfalen-Lippe, 808 EMP

- Advisor on medical care issues
- Quality assessment and QA of care facilities
- Advising the state associations of long-term care insurance funds

MDS e.V. (Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen e.V.)

- MDS is a medical and care expert organization
- It advises the statutory health and long-term care insurance at the federal level - in particular the GKV-Spitzenverband - on questions of care, services, quality and structure
- 36 EMP in QA / Administration cost: 250,000€

MFT-Zert GmbH

- For clinics:
  - Bürgerhospital Frankfurt a.M.
  - Clementine Kinderhospital gGmbH (Frankfurt a.M.)
  - St. Bernward Krankenhaus GmbH (Hildesheim)
  - Rotes Kreuz Krankenhaus Kassel gGmbH
  - Brüderkrankenhaus St. Josef Paderborn
  - St. Vincenz Krankenhaus GmbH (Paderborn)
  - AGAPLESION ELISABETHENSTIFT gGmbH (Darmstadt)

• Städtisches Klinikum Wolfenbüttel • Sana Klinikum Offenbach • Hufeland Klinikum GmbH (Bad Langensalza Mühlhausen/Thüringen) • Ev. Krankenhaus Göttingen-Weende gGmbH
• Certification • The seal of quality documents the special performance of the certified academic teaching hospital in the training of medical students
MICADO HEALTH CARE GmbH (Minimal- Invasive Chirurgie & Ambulant Durchführbare Operationen GmbH)
• Establishment of integrative cooperations as a basis for quality-assured performance of hospital-replacement operations
Nikodemus-Werk e.V. (Bund für gemeinnützige Altenhilfe aus Anthroposophie und Christengemeinschaft) Federation for Charitable Care for the Elderly from Anthroposophy and the Christian Community
• Quality seal • Education and training
OnkoZert GmbH
• Certification
pCC (proCum Cert GmbH)
• QKA (Qualitätskatalog für katholische Einrichtungen der stationären Altenhilfe), Quality catalogue for Catholic facilities for in-patient care for the elderly • QKS-Zertifikat ambulante Dienste, Qualitätskatalog für kirchliche Sozialstationen: Certificate for Outpatient Services, Quality Catalogue for Church Social Wards • Certification
PBeaK (Postbeamtenkrankenkasse)
• The Postal Civil Servants' Health Insurance Fund (PBeaK) is a social institution of the former German Federal Post Office • QA (COMPASS nursing advice)
QgP (Qualitätsgemeinschaft Pflege (QgP) der LIGA der Spitzenverbände der freien Wohlfahrtspflege Brandenburg)
• Certification • Training and further education of QM officers in the member institutions

QS-Reha (Qualitätssicherung in der medizinischen Rehabilitation)
• The QS-Reha procedure includes an external, facility-comparative examination of the quality of structures, processes and results, including patient satisfaction
QSV (Qualitätssicherungsverbund stationärer Pflegeeinrichtungen im Landkreis Heilbronn)
• Elaboration and further development of quality criteria for the nursing homes • Carrying out regular mutual reviews • Certification
Qualitätspraxisverbund Humanitus GmbH
• Certification • QM • Further training
QuQuK (Institut für Qualifizierung und Qualitätssicherung in der Kinder- und Jugendpsychiatrie)
• The QuQuK Institute at Klinikum Bremen-Ost gGmbH works for qualification and QA in child and adolescent psychiatry • Further training • Seminars
SVLFG (Sozialversicherung für Landwirtschaft, Forsten und Gartenbau)
➢ It is the provider of agricultural social insurance for the following insurance branches: • *Die Gesetzliche Unfallversicherung als Landwirtschaftliche Berufsgenossenschaft*. Statutory accident insurance as the Agricultural Employer's Liability Insurance Association (Landwirtschaftliche Berufsgenossenschaft) • *Die Alterssicherung der Landwirte als Landwirtschaftliche Alterskasse*, Old-age insurance for farmers as the Agricultural Old-age Insurance Fund (Landwirtschaftliche Alterskasse) • *Die Gesetzliche Kranken- und Pflegeversicherung als Landwirtschaftliche Kranken- und Pflegekasse (LKK)*, The statutory health and long-term care insurance as the Agricultural Health and Long-Term Care Insurance Fund (LKK is the only branch treated in this context) • 4,382 EMP

• Occupational health and safety management system, Arbeitsschutzmanagementsystem (AMS) • Certification
SQ Cert GmbH (Paritätischer Wohlfahrtsverband Landesverband NRW)
• SQ Cert GmbH is a certification company of Paritätischer Gesamtverband e.V. and Union Versicherungsdienst GmbH • Certification • Assessment of technical regulations
SQG (Sektorenübergreifende Qualität im Gesundheitswesen)
• The SQG brings together the previously separate QA of the outpatient and inpatient sectors • Data validation • Quality report
TÜV Nord Cert GmbH
• Certification • Workplace health promotion • QM in health and social care
TÜV Rheinland Cert GmbH
• Certification • Certification Acute Pain Therapy • Reprocessing of medical devices
TÜV Süd Management Service GmbH
• Certification • Auditing • Validation
Universitätsklinikum Köln
• The Central Division Medical Synergies is responsible for the QM of the University Hospital Cologne, organizes and controls clinical risk audits
VDBD e.V. (Verband der Diabetesberatungs- und Schulungsberufe in Deutschland e.V.) in cooperation with VDBD Akademie GmbH
• QA of diabetes training through own studies and quality circles • Certification

VKAD (Verband katholischer Altenhilfe in Deutschland e.V.)
• QM Framework Manual for Elderly Care and Nursing • Quality standards for geriatric care training in practice and school
VLOU e.V. (Verband leitender Orthopäden und Unfallchirurgen Deutschlands e.V. Bundesverband)
• Merging orthopaedics and trauma surgery • Improving further education and training opportunities and ensuring the professional quality of future specialists
VOD e.V. (Verband der Osteopathen Deutschland e.V.)
• Certification • The VOD is committed to a uniform standard and assured quality in the field of osteopathy, supports teaching and continuing education, research and further development
VoltaMed GmbH
• Hygiene management • Equipment and facility management • Validation of autoclaves (moist heat sterilisation process) and thermal disinfectors
WIESO CERT GmbH
• Certification • Audits
WIP (Wissenschaftliches Institut der PKV)
• The WIP develops designs for studies and pilot projects of the PKV Association and evaluates the projects on a scientific basis • Evaluation of processes and projects
ZertSozial GmbH
• Certification • Audit service provider for QA and management in the health care sector
ZI (Zentralinstitut für die kassenärztliche Versorgung in der BRD)
• Disease Management Programs • Analysis tools • Which diseases are diagnosed how often? • Which medicines are prescribed and to what extent?

• How can care be provided as economically as possible?
ZQ (Zentrum für Qualität und Management im Gesundheitswesen)
➢ ZQ is established as an institute of Ärztekammer Niedersachsen (Lower Saxony Medical Association)
• Strategically position health care facilities • Use management tools in a targeted manner • Implementing efficient management systems sustainably • QA
ZQP (Das Zentrum für Qualität in der Pflege)
➢ The Centre for Quality in Care (ZQP) is a non-profit operational foundation established in 2009 by the Association of Private Health Insurers.
• Improving the quality of care in Germany • Further development of care for older people and those in need of care • Research, studies and analyses

Annex 3: ISO QM Document and QM Drafts

Criteria catalog with chapters 1-8 of the DIN EN ISO standards in the version of the NQSZ 2008

ISO 9001:2000
1. Scope of application 1.1 General 1.2 Application
2. References to other standards
3. Terms
4. Quality management system 1.1 General requirements 4.2 Documentation requirements 4.2.1 General 4.2.2 Quality Management Manual 4.2.3 Document steering 4.2.4 Control of quality records

5. Management responsibility 5.1 Management commitment 5.2 Customer focus
5.3 Quality policy 5.4 Planning 5.4.1 Quality objectives 5.4.2 Planning of the quality management system 5.5 Responsibility, authority and communication 5.5.1 Responsibility and authority 5.5.2 Representative of the top management 5.4 Internal communication 5.6 Management Evaluation 5.6.1 General 5.6.2 Inputs for the evaluation 5.6.3 Evaluation results

6. Resource management

6.1 Provision of resources

6.2 Human resources

6.2.1 General

6.2.2 Ability, awareness and training

6.3 Infrastructure

6.4 Working environment

7. **Product realization**

7.1 Planning of the product realization

7.2 Customer-related processes

7.2.1 Determination of the requirements in relation to the product

7.2.2 Evaluation of the requirements in relation to the product

7.2.3 Communication with customers

7.3 Development

7.3.1 Development planning

7.3.2 Development inputs

7.3.3 Development results

7.3.4 Development evaluation

7.3.5 Development verification

7.3.6 Development validation

7.3.7 Steering of development changes

7.4 Procurement

7.4.1 Procurement process

7.4.2 Procurement details

7.4.3 Verification of procured products

7.5 Production and service provision

7.5.1 Control of production and service provision

7.5.2 Validation of the processes for production and service provision

7.5.3 Labeling and traceability

7.5.4 Customer property

7.5.5 Product preservation

7.6 Control of monitoring and measuring equipment

8. Measurement, analysis and improvement

8.1 General

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

8.2.2 Internal audit

8.2.3 Monitoring and measurement of processes

8.2.4 Monitoring and measurement of the product

8.3 Steering missing products

8.4 Data analysis

8.5 Improvement

8.5.1 Continuous improvement

8.5.2 Corrective Action

8.5.3 Preventive measures

Annex 4: QSR Performance Areas

The QSR process is fundamentally open and is continuously developed with reference to the specified selection criteria (chapter 6.1). The following table provides an overview of the current QSR performance areas.

1	Heart failure
2	Myocardial infarction
3	Cerebral infarction or intracerebral hemorrhage
4	Colon or rectal surgery for colorectal cancer
5	Implantation of a hip joint endoprosthesis for coxarthrosis
6	Implantation of a hip joint endoprosthesis or osteosynthesis for hip fracture
7	Implantation of a knee joint endoprosthesis for gonarthrosis
8	Cholecystectomy
9	Therapeutic cardiac catheterization (PCI) in patients without myocardial infarction
10	Therapeutic cardiac catheterization (PCI) in patients with myocardial infarction
11	Appendectomy
12	Prostate surgery for benign prostatic syndrome (BPS)
13	Radical prostatectomy (RPE) for prostate cancer
14	Care of premature infants

15	Surgery for benign thyroid disease
16	Coronary angiography
17	Vaginal delivery
18	Sectio