Quality Management in Otolaryngology – An Assessment of the Current Situation

On Current View, how is the State of Quality Standards in German Hospitals and Practices, esp. in Otolaryngology? An Appraisal with Outlook

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ABSTRACT

To deal with medical malpractice, apart from sanctions an ethical code has been developed since ancient times which shapes our present expectation of a good physician. A century ago, industrialization and standardization initiated medical quality management in the USA. In the 1950s, the Japanese concept of total quality management arose, winning huge influence also in medicine. Every recent system of certification or accreditation originates from these roots.

In the last 15 years in Germany, minimum standards in health care have been enforced by law with increasing sophistication. Additionally, self-governed institutions of physicians have been clearly contributing to the quality of care.

Quality management has become an integral part of the German healthcare system, most notably in risk management and patient orientation. There are also a multitude of voluntary physician-driven initiatives to improve the quality of care, among others the guidelines of the medical societies.

A survey was conducted by the author to evaluate the implementation of quality management in otolaryngological departments and practices. The degree of implementation was predominately higher than for the national peers.

Currently there are substantial challenges to the health care system which impact the quality of care. Lack of funding, shortage of qualified staff, societal changes and effects of rapid scientific progress are a few to name.

To achieve a broad implementation of quality management in the future, wise political decisions and proper funding are crucial – the concept as such has long been accepted.

Contents

ABBREVIATIONS

APS	Patient Safety Alliance
ÄQSI	Database of Medical Quality Assurance Initiatives
ÄZQ	Medical Centre for Quality in Medicine
AWMF	Association of Scientific Medical Societies
BÄK	German Medical Association
BMI	German Ministry of Health
DAkkS	German Accreditation Body
DGHNO-KHC	German Society for Otolaryngology, Head and Neck Surgery
DKG	German Hospital Federation
DKG	German Cancer Society
DKH	German Cancer Aid
DNEbM	German Network for Evidence-Based Medicine
DNVF	German Network of Health Services Research
DPR	German Nursing Council
G-BA	Federal Joint Committee
GKV	Statutory Health Insurance Funds
GKV-SV	Umbrella Organization of Statutory Health Insurance Funds
IQM	Initiative for Quality Medicine
IQTIG	Institute for Quality and Transparency in Health Care
IQWIG	Institute for Quality and Efficiency in Health Care
KBV	Federal Association of Statutory Health Insurance Physicians
KTQ	Cooperation for Transparency and Quality in Health Care
KV	Association of Statutory Health Insurance Physicians (of a State)
LAG	State Working Groups
LÄK	Medical Association of the Federal State
LKG	State Hospital Federation

LQS	State Offices for Quality Assurance
MDK	Medical Service of Health Insurance
MDS	Medical Service of the National Association of Health Insurance Funds
MVZ	Medical Care Center
NVL	National Health Care Guidelines
SGB V	Social Code Book V
SVR	Expert Council (the Advisory Council for the Evaluation of Developments in the Health Care System)

1 Introduction

If perfection were inherent in human nature and actions, we would not need quality management. In reality, not only can the best possible quality be missed, but adverse events can cost the health and lives of patients.

Much attention has been given to a study published in 1991, in which 30 000 medical records from New York State were analysed. It found that 3.7 % of patients suffered adverse events, 13.6 % of which resulted in death. 58 % of events were considered preventable and 28 % were attributed to negligence [1]. In its report "To Err is Human", the Institute of Medicine extrapolated that 44 000 to 98 000 deaths could be avoided in US hospitals each year [2]. For Germany, the Patient Safety Alliance (APS, see 6.10.3) estimated that 2–4 % of avoidable adverse events, 1 % of treatment errors and a consecutive mortality rate of 0.1 % must be assumed for inpatients in 2007 [3]. In addition, employees, internal and external partners, economic results and the reputation of a health care institution can be affected by the impact of poor quality.

As a consequence, risk and error management is nowadays an integral part of every quality management system, and scientific research on human and systemic causes of errors [4, 5] has led to a new, more open culture of dealing with errors.

Despite all our imperfections, we also have a strong positive vision of the achievable quality of our actions, fed by intrinsic motivation, work ethics and ethics. This is expressed both in the clinical and research pursuit of improvement and progress and in the daily struggle to achieve the optimum under given circumstances and limitations. Methods of comprehensive quality management offer systematic support in achieving this goal.

2 Ethics – Obligation to Act Responsibly

The doctor-patient relationship is essentially characterized by the fact that the patient surrenders to the doctor with his person, his physical integrity, often with his entire weal and woe. This requires – depending on the circumstances – considerable trust in the doctor's professional competence and integrity. Earning and justifying this trust is an ethical imperative which is reaffirmed in declarations of commitment. The oldest of these documents date back to the beginnings of the written tradition of human history.

2.1 Historical vows

2.1.1 Hippocratic Oath

Probably the best known declaration of self-obligation is the Hippocratic Oath, which is attributed to the physician Hippocrates (ca. 460 to 370 B.C.) who practiced on the Greek island of Kos. The Hippocratic Oath already contains the essential elements of medical ethics: The promise to treat patients to the best of one's knowledge and ability and to avert harm from them is supplemented by the rejection of euthanasia and abortion. The pledge is made not to abuse the access gained through medical activity to the most intimate sphere of patients' lives, especially through sexual acts. Furthermore, there is an obligation to maintain medical confidentiality.

2.1.2 Primum non nocere

A condensed instruction for action focused on the therapeutic procedure, which is timeless in its conciseness, is often attributed to Hippocrates, but was possibly not coined until the 17th century [6]. The first sentence in particular is still common in clinical practice today:

> *"Primum non (nil/nihil) nocere, secundum cavere, tertium sanare".*

As the very first maxim, the physician should not cause the patient any (avoidable) harm through his actions; secondly, he should proceed carefully and prudently and only then begin with his healing efforts.

2.1.3 Vejjavatapada – India

From the same historic era as the Hippocratic Oath, the Vejjavatapada from India is dated to about 500 BC. Particular emphasis was placed on empathy, compassion and mindfulness, as is the case in Buddhist philosophy. This is motivation that the sick person should be treated, not greed. The doctor should not withdraw when his treatment is ineffective, and he should endure physically repulsive situations with equanimity.

2.1.4 Confucian tradition – China

The advanced Chinese civilization was influenced by the Confucian tradition and at the same time produced a comparable code of medical ethics. Physicians should treat patients with compassion and regardless of their social status, with care and to the best of their ability, while behaving with dignity. In particular, they are obliged to pursue medical training with the utmost seriousness [7].

2.1.5 The Seventeen Rules of Enjuin – Japan

At the Japanese Buddhist Ri-shu medical school, a commitment with 17 rules was developed for graduates in the 16th century. In particular, they were requested to avoid pride and craving for recognition, which are considered to be serious negative qualities of the mind. Instead, equanimity was requested, even towards ungrateful patients.

2.2 The Geneva Declaration of the World Medical Association

The Geneva Declaration of the World Medical Association, which was first adopted in 1948, is now available in its sixth revision in

2017 [8]. In contrast to the historical vows, all religious references have been removed and the absolute prohibition of killing and abortion has been relativized by a more general phrase ("utmost respect for human life"). New aspects are the explicit intention to preserve the patient's autonomy and not to make one's own expertise (directly or indirectly) available for repressive measures or even torture. One particularly relevant point of current interest is that physicians should take care of their own health and well-being, especially in the interest of the patients entrusted to them. This was also a focal point at the 122nd German Medical Assembly in 2019 (see 8.2.4).

2.3 The Declaration of Helsinki – Ethical principles for medical research

Medical progress, the further development of medical knowledge and medical techniques, is inextricably linked with the subject of medical research on sick or healthy people (including self-experiments). The fact that study participants might suffer harm can only be ethically justified by the fact that the aim is to improve the situation of all those affected by the same health disorder. The first recommendations on the ethical handling of medical research were documented as early as the beginning of the 19th century. In 1964, the World Medical Association adopted the Declaration of Helsinki, which defines the rights of patients who are to be included in studies, which contains a very elaborate code of conduct for the design of studies and the behaviour of researching physicians and which renders ethics committees binding [9].

2.4 Discussion – the "good doctor"

In the synopsis of all the vows and commitments mentioned above, one obtains a vision of a "good doctor" based on thousands of years of human experience. Since the physician plays a central role in the diagnosis and treatment process, he has a great influence on the quality of medical care. Observing medical ethics is therefore the oldest, directly effective measure of quality assurance.

3 Definitions of Quality

Quality can be understood as a term in two ways: firstly, it describes the nature of something, and secondly, it describes how good something is. In the context of medical quality management, the second meaning is referred to.

3.1 Quality

There are different approaches to define the term quality, especially in relation to health care. Quality is not an absolute but a relative measure. In industry, it is defined as the degree to which requirements (= target value) are met in the product (= actual value).

3.1.1 ISO

The DIN EN ISO 9000:2015 is relevant for quality management and is also applied in the health care sector. This defines quality as

> *"The degree to which a set of inherent characteristics of an object fulfills requirements"*

In DIN EN ISO 9001:2015, the definition is somewhat more detailed:

> *"The ability of a set of inherent characteristics of a product, system or process to fulfill the requirements of customers and other interested parties".*

In this definition, quality is assessed from the perspective of the customer, i.e. in the case of application to medicine, primarily from the perspective of the patient. In addition to these primary customers, internal and external partners can also be categorised as customers. Internal partners are, for example, medical colleagues in other departments, external partners are, for example, referring physicians, cost bearers or the legislature. So-called "customer orientation" in quality management should therefore include all 3 of the groups mentioned here.

3.1.2 Donabedian

The first known definition specifically related to health care and widely used was formulated by Avedis Donabedian in 1966 [10]. He segmented quality into 3 areas: structural, process and outcome quality. Structural quality refers to the available resources that can be used in the treatment of patients, in terms of the qualifications, type and quantity of staff as well as all technical and structural equipment. Process quality describes how the services are provided to the patient and covers the entire treatment process, not only in its clinical but also in its administrative aspects. The quality of outcomes refers primarily to the achievement of the expected treatment goals for the patient, but is not limited to this. In practice, structural and process quality are easier to measure than outcome quality; on the other hand, changes in structural and process quality do not necessarily have an effect on outcome quality. Despite these limitations, this definition has become widely used in health care, including health policy.

3.1.3 IOM

Another relatively widespread definition was published in 1990 by the Institute of Medicine (IOM) [11]:

> *"Quality of care 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".*

In extension of the ISO definition, explicit reference is made here to the current state of knowledge in the medical field. The fact that the term "probability" – unlike in the ISO definition mentioned above – is placed between the "degree" (of achievement) and the "outcomes" reflects the difficulty of measuring the quality of outcomes.

3.1.4 ÄZQ and GMDS

The „Medical Center for Quality in Medicine" (Ärztliches Zentrum für Qualität in der Medizin, ÄZQ, see 5.5.2) quotes the following definition of the „German Society for Medical Informatics, Biometry and Epidemiology" (Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie, GMDS) [12]:

"Quality in health care means sufficient and appropriate, i.e. patient- and needs-oriented, quality-of-life oriented, professionally qualified, but also economical medical care with the aim of increasing the probability of desired treatment outcomes in individuals and in the overall population".

It extends the IOM definition by the specifications "sufficient and appropriate", which are synonymous with "patient- and needs-oriented" and "economical". This introduces the core concepts of the Social Code §12 SGB V (see 5.1) regarding the benefit claims of the insured.

It is further explained that the (quality) requirements in medical quality can be differentiated into the explicit (the agreed), the implicit (the – implicitly – assumed) and the legally binding requirements [13].

3.1.5 IQTIG

In its "Methodological Foundations v1.1" (p. 16, [14]), the Institute for Quality and Transparency in Health Care (Institut für Qualität und Transparenz im Gesundheitswesen, IQTIG, see 5.3) defines quality in health care as follows:

"Quality of health care is the degree to which the care provided to individuals and populations meets requirements that are patient-centred and consistent with professional knowledge".

IQTIG explicitly refers to the definitions of ISO 9000:2015 and the Institute of Medicine.

3.2 Quality management

Quality management is a superordinate term that covers all aspects of securing and developing quality in relation to an organization. It comprises systematic and coordinated measures for planning, steering, controlling and improving processes and procedures with various specific instruments and is primarily the responsibility of the corporate management; however, it should be supported by all employees.

3.2.1 PDCA cycle according to Deming, TQM, and CIP

W. Edwards Deming was a mathematician, physicist and statistician who was invited to Japan in 1950 as a scientist and consultant to bring his ideas of quality management to Japan's post-war industry. His concept was extremely successful and made a fundamental contribution to the successful repositioning of Japanese industry [15]. This is now known as "Total Quality Management" (TQM) and "Continuous Improvement Process" (CIP). Deming propagated a holistic view of the entire organization, its internal and external relationships, and the continuous search for improvement opportunities. This is represented by the PDCA cycle (Plan-Do-Check-Act), which he himself attributed to his teacher Shewhart. It consists of a control loop in 4 steps for continuous quality improvement:

- Plan: A target and the required metrics are defined
- Do: Implementation through measures
- Check (or "Study"): Review of the results achieved
- Act: consecutive determination of the further procedure

3.2.2 Certification vs. accreditation

These terms, often used synonymously, differ significantly: an accreditation has higher requirements than a certification. A certification confirms the fulfilment of predefined requirements, also called conformity, e.g. of processes. An accreditation represents a formal recognition of the competence of the assessed organization.

3.3 Quality assurance

In a broader sense, quality assurance means that health care professionals take appropriate measures to ensure that the quality of their results does not fall below defined minimum standards. It also assures customers that quality standards will be adhered to. In the past, quality assurance was often used synonymously with the term "quality management". Today it is understood as a part of quality management. The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA, see 5.2) uses this term to describe all its quality-related tasks, especially the so-called external quality assurance.

3.3.1 Quality indicators

The IQTIG provides the following definition:

"Quality indicators are predefined criteria by which medical quality in a hospital or practice can be measured, described and compared"[16].

Quality indicators are quantitative measures, but they are not a direct measure of quality. The validation of quality indicators used in quality assurance by the Federal Joint Committee is carried out by the IQTIG.

3.4 PRO and quality of life

PRO (patient reported outcome) is defined as "any statement made by a patient about his or her health situation and related medical treatment" [17]. This has been extended to include the following (ordered by validity):

- Reports on symptoms (e.g. visual analogue pain scales)
- Reports on physical activity (e.g. ability to swallow)
- Patient satisfaction
- Patient Preferences
- Quality of life

The Robert Koch Institute defines health-related quality of life as follows [18]:

"Health-Related Quality of Life (HRQoL) is a multidimensional "construct" of physical, psychological and social dimensions and includes significantly more than just statements about the individual state of health. The essential orientation hereby is the subjective perception by the patient".

Quality of life is usually measured with validated questionnaire instruments.

In addition to the classic endpoints of morbidity and mortality and other physician-based outcome parameters, the PRO has been clearly revalued in recent years with respect to outcome quality, as it is now possible to measure "what the patient perceives", especially through quality of life (e.g. in rhinoplasty: [19, 20]).

3.5 Qaly

In order to differentiate from this, the Qaly should also be mentioned. This is an acronym for "Quality adjusted life years" and is a health economic instrument to quantify the benefit of interventions and to put these in relation to the costs. Quality of life is evaluated in the range from 1 (= completely healthy) to 0 (= dead). The methods used are "time trade-off" (how many years of life expectancy would one be prepared to give up for a remaining life in complete health), "standard gamble" (how much probability of death would one be prepared to accept for complete recovery) and rating scales. The quality of life measured in this way is multiplied by the life expectancy in years to obtain the Qaly. If an intervention has an effect on the quality of life and/or life expectancy, it results in a changed Qaly. The possibly positive difference can be related to the cost of the intervention, i.e. one receives an individual price per year of Qaly. This can be used for cost-benefit assessments and for rationing, be it for scarce therapies (organ transplantation) or resources. The Qaly is ethically and methodically not undisputed.

3.6 Discussion – is everything relative?

The comparison of these different definitions and approaches to the concept of quality shows that, depending on the perspective and reference framework, very different requirements and measurement methods are used to for evaluation - the quality of medical outcomes is not equal to the quality of life; the quality concept of the certifier does not include the political imperative of economic efficiency of the Social Code. As shown in Chapter 2, the perspective of the physician inevitably includes medical ethics as a criterion for quality.

4 Certification and Accreditation Models (Voluntary External Quality Assurance)

4.1 TJC – The Joint Commission

4.1.1 History and organization

"The Joint Commission" is by far the world's oldest accreditation organization specific to health care systems.

At the turn of the 20th century, as industrialization accelerated, the need for standardization in the USA materialized with the founding of the National Bureau of Standards in 1901 (nowadays called the National Institute of Standards and Technology, NIST). The engineers' ideas of increasing efficiency and reducing errors through standardization were also adopted by physicians. The prominent Chicago surgeon Franklin H. Martin hosted the first congresses of surgeons in Chicago 1910, Philadelphia 1911 and New York 1912. The latter was attended by 2600 participants. During this meeting, a resolution was passed on the "Introduction of a system for the standardization of hospitals". At the same time, the American College of Surgeons (ACS) was founded with the aim of guaranteeing the quality of surgeons by granting a conditional license. A permanent committee of the ACS was the Hospital Standardization Committee, chaired by the Boston surgeon Ernest A. Codman, who was a strong advocate of evaluating the outcome quality, in his words the "end result idea", and who even offered his patients a money-back guarantee. Codman could not prevail with his ideas. Instead, in 1917, as a result of a three-day congress, the first "Minimum Standard" for hospitals was drafted. It comprised 5 points:

1. All physicians and surgeons shall be organized as a definite group or staff.
2. Membership in this group should be made conditional on professional and ethical expertise.
3. The staff group must meet at least once a month and regularly analyze and review their clinical experience.
4. Accurate and complete medical records must be written for all patients.
5. Every hospital must have at least one clinical laboratory and an X-ray department.

Despite initial difficulties, 7 physicians were already on site in the hospitals in 1920 for the "Hospital Standardization Program" to assess compliance with the minimum standards by means of an evaluation ("survey"). In 1921, a list of all hospitals that met the standards was published for the first time. In the following 30 years, the standards were further developed and considerably expanded. They were finally summarized and published in "Standards Manuals" in order to serve the participating hospitals in their preparations.

The program was widely used and applied, and was also employed to distinguish hospitals that had successfully participated in a survey. As the ACS was no longer financially able to maintain the program, other organizations joined the circle of partners in 1951 and transformed the "Hospital Standardization Committee" into the "Joint Commission on Accreditation of Hospitals" (JCAH). Due to the increasing costs, the principle was first introduced in 1964 that hospitals have to bear the proportionate costs for evaluation ("survey" in JCAH terminology). In 1965, the Medicare Act was passed, which included a clause that hospitals wishing to participate in the Medicare and Medicaid programs would have demonstrated their qualification and eligibility by obtaining JCAH accreditation. This established the JCAH as a quasi-governmental body.

As a result of a reorientation and restructuring, the possibility of accreditation was extended to other healthcare organizations and the name was changed in 1987 to "Joint Commission on Accreditation of Healthcare Organizations" (JCAHO). In 1992, criteria for the assessment of outcomes were included in the accreditation manual for the first time, which was further institutionalized in 1997 by the so-called "ORYX" method for (partial) outcome quality measurement. Finally, in 1994 the "Joint Commission International" (JCI) was founded in order to offer accreditations worldwide [21]. Due to criticism and discussions about the effectiveness of the procedure, the possibility of unannounced surveys was also introduced in 2006. In 2007 the JCAHO shortened its name to "The Joint Commission". The field of measuring the quality of outcomes was significantly revised in 2015. Nearly half of the quality indicators were dropped because the reported outcomes were consistently excellent, and new ways of reporting were introduced (electronic clinical quality measures (eCQMs), and chart-abstracted measures) [22].

4.1.2 Procedures

Currently, the procedure is offered not only to hospitals but also to "Outpatient Healthcare", "Behavioral Healthcare", "Critical Access

Hospitals", "Laboratory", "Nursing Care Centre", "Office-Based Surgery", and – via the Joint Commission International (JCI) – also internationally.

To obtain and maintain accreditation, a health organization must undergo an on-site visit, which must be repeated at least every 3 years. Usually the date is known in advance and is normally prepared in detail, often even by a "trial survey". Since 2006, however, surprise surveys without prior notice are also possible.

Using comprehensive checklists based on the current published "Standards Manual", a team of full-time "surveyors" checks the conformity of the health organization with these standards. The overall scope of the survey covers 3 areas: Patient-related processes with focus on quality of care and patient safety, organizational processes including leadership and risk management, and organizational structures. The detection of so-called "sentinel events", i.e. incidents with a high potential to be hazardous to patients, can lead to the devaluation or even refusal of accreditation. Upon completion of the survey, the health care organization may receive either accreditation with distinction, regular accreditation, accreditation with type 1 recommendations (orders for rectification without restriction of the accreditation granted), conditional accreditation, temporary accreditation, provisional accreditation or no accreditation [23]. In the latter case, a follow-up survey is possible one year later at the earliest, in the 3 cases mentioned before, successful rectifications must be proven. In addition to the surveys, the Joint Commission has given high priority in recent years to the annual electronic transmission of quality indicators by the hospitals (see 4.1.1).

Currently, the Joint Commission has increased its focus on patient safety and is pursuing the motif of "primum non nocere" with the visionary campaign "Leading the way to ZERO" (harm), which aims to completely avoid adverse events [24].

In parallel to the accreditation program, the Joint Commission has also established a comprehensive certification program since 2005, which in addition to disease management programs also covers "Comprehensive Cardiac Centers", "Health Care Staffing Services", "Integrated Care", "Palliative Care", "Perinatal Care", "Primary Care Medical Home", "Patient Blood Management" and which is also offered internationally.

4.1.3 Relevance

In the USA, the Joint Commission is by far the market leader – with more than 20,000 accredited health care facilities, and its international subsidiary JCI has certified 939 hospitals in 66 countries worldwide (as of 2017) [25]. Only in Germany, the presence of KTQ (see 4.3) means that the market segment otherwise served by JCI is already occupied. This is probably the reason why only 2 hospitals in Germany are currently accredited according to JCI [26].

4.2 ISO – International Organization for Standardization

4.2.1 History and Organization

The ISO (International Organization for Standardization) is the world's largest developer of international standards. On a conference of 25 national standards organizations, held in London in October 1946, the decision was taken to found ISO, in which similar predecessor organizations were to be merged. As the acronym for the International Organization for Standardization is different in various languages, it was agreed that the Greek word "Isos" (Engl. "equal") should be basis of the naming.

As an independent, non-profit, non-governmental organization, it began operating in 1947 with its central office in Geneva. Since then it has published 22 729 international standards and now includes members from 164 countries. A total of 783 technical committees and subcommittees develop the standards. Germany has been represented by the German Institute for Standardization (Deutsches Institut für Normung, DIN) as a member of ISO since 1951. Standards adapted by DIN in Germany are called DIN EN (for European Standard) ISO [27].

4.2.2 Procedures

For quality management in healthcare institutions, the standards of the DIN EN ISO 9000-family are applied. It is used by more than one million organizations worldwide. The last revision of the ISO 9001 standard took place in 2015, which is expressed in the year added to the standard: DIN EN ISO 9001:2015.

Of the four standards in the 9000 family, ISO 9001 is the one that is applied for the actual certification process and which defines the requirements for a quality management system. In the DIN EN ISO 9000:2015 the basics and terminology are explained. The DIN EN ISO 9004:2012 provides a guideline for the development of an efficient and comprehensive quality management system and is not the basis for certification, but tries to integrate the concept of Total Quality Management (TQM) into the ISO universe. As a result, there is an even greater convergence with excellence models such as EFQM (see 4.4.2). Finally, there is the DIN EN ISO 19011:2018, in which the current certification process of management systems, called "audit" in the terminology of ISO, is described and defined in detail [28]. The previously existing standards ISO 9002 and ISO 9003 were withdrawn due to obsolescence and their content was integrated into the other standards as far as necessary.

4.2.2.1 DIN EN ISO 9001:2015

During the last revision of ISO 9001 the number of Chapters was increased to 10. Firstly, a new Chapter "6. Planning" was introduced and the previous Chapter 8 was divided into "9. Performance evaluation" and "10. Continual improvement".

The first 3 introductory Chapters are for clarification: 1. Scope, 2. Normative references and 3. Terms and definitions. The other Chapters of the standard are based on the Deming PDCA cycle. The next 3 Chapters correspond to the "Plan": 4. Context of the organization, 5. Leadership and 6. Planning. The subsequent 2 Chapters correspond to the "Do": 7. Support and 8. Operation. The penultimate Chapter corresponds to the "Check": 9. Performance evaluation. The last Chapter corresponds to the "Act": 10. Continual improvement.

As basic principles of quality management are mentioned:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

In summary, in addition to the clear process orientation, the ISO system has the objective of continuous improvement by including the evaluation of results, especially by aligning with the PDCA cycle. In addition to the strong focus on customer needs, the area of risk management has gained central importance [29].

4.2.2.2 Audit and certification

ISO has always offered the possibility of certifying not only entire organizations but also parts of organizations such as a department in a hospital or a laboratory.

As a first step, the organization must establish a quality management system, which should be aligned with ISO 9001:2015, and create a QM manual. It makes sense to have one's own employees trained for this purpose. Then a self-assessment has to be carried out by an internal evaluation according to ISO criteria, a so-called "audit", as well as various measurements and surveys (e.g. on patient satisfaction) and everything has to be documented in the "management review". The results of this self-assessment must be correlated with formulated objectives.

Subsequently, certification is contractually agreed with an external certification company, which has to be accredited by the German Accreditation Body (Deutsche Akkreditierungsstelle, DAkkS, s. 4.2.3). A so-called "pre-audit" is recommended, but not mandatory, which helps to identify areas that can be improved before the actual audit. The actual audit, the external assessment, is divided into 2 stages, whereby the first stage involves the auditors assessing the documentation and management, and the second stage involves checking the implementation of the quality management system at the employees' workplaces. Depending on the size of the organization, the audit can last one or more days. As a result of the audit, an audit report is written. If conformity to the standard is established, the organization receives a certificate that is valid for 3 years. If conformity is initially not achieved due to deviations of varying degrees, corrective measures are agreed upon, and the auditor monitors their implementation. He may then initiate the award of the certificate. If significant deficiencies are found, no certificate will be granted. Once a certificate has been issued, it is obligatory to have so-called surveillance audits carried out annually by external auditors who check the maintenance of the quality management system. After 3 years, re-certification is performed upon request.

4.2.3 DAkkS – German Accreditation Body

The DAkkS is the national accreditation body of the Federal Republic of Germany. It is a private-sector institution which was founded on the basis of an EU regulation that only one accreditation body per member state is permitted and which started its activities in 2010. By means of an ordinance of the Federal Government, the DAkkS is authorized to carry out sovereign accreditation activities. Shareholders are the Federal Government, the Federal States and the Federation of German Industries (Bundesverband der Deutschen Industrie, BDI) at one third each. The DAkkS is subject to the supervision of the Federal Ministry for Economy and Energy (Bundesministerium für Wirtschaft und Energie, BMWi).

The task of the DAkkS is to check conformity assessment bodies (laboratories, inspection bodies and certification bodies), as to whether they "perform their tasks competently and in accordance with applicable requirements. In short: The DAkkS audits the auditors" [30]. If the result of the examination is positive, the conformity assessment body is accredited. In practice, proof of accreditation is indispensable for the business activities of a conformity assessment body.

Accreditation can be granted to such bodies as laboratories (testing and calibration laboratories, medical laboratories), certification bodies (for persons, management systems and for products, processes and services) and providers of proficiency tests (interlaboratory comparisons).

In recent years, associations of the conformity assessment bodies to be accredited have expressed clear criticism of the DAkkS. The accreditation procedures was overloaded with bureaucracy, the processing times were unacceptably long and the prices were excessive. Especially for small and medium-sized enterprises, this posed a considerable burden [31–33].

4.2.4 Further development of the model

The ISO model has developed significantly in the past years. While 25 years ago there was the "running gag" that ISO could also be used to successfully certify "life jackets made of concrete " because of its pure process orientation, this has changed drastically, especially in ISO 9001 with its strong customer and result orientation and the approximation to excellence systems such as EFQM.

4.2.5 Relevance

ISO does not publish data on the number of health care facilities certified according to its standards. Consulting firms assume that ISO has overtaken KTQ (see 4.3) in recent years and is currently the most widespread certification system in German hospitals [34]. In practices, ISO is in second place behind the systems issued by the Associations of Statutory Health Insurance Physicians (Kassenärztlichen Vereinigungen, KV, see 4.6.2).

4.3 KTQ –Cooperation for Transparency and Quality in Health Care

4.3.1 History and organization

The "Cooperation for Transparency and Quality in Health Care" GmbH (Kooperation für Transparenz und Qualität im Gesundheitswesen, KTQ) was started in 1997 as a feasibility study with start-up financing by the Federal Ministry of Health. In 2001, the "Cooperation for Transparency and Quality in the Hospital" (Kooperation für Transparenz und Qualität im Krankenhaus) was founded. The shareholders were originally the German Medical Association (Bundesärztekammer, BÄK), the German Nursing Council (Deutscher Pflegerat, DPR), the German Hospital Federation (Deutsche Krankenhausgesellschaft, DKG), and the statutory health insurance funds. The aim was to develop a certification procedure tailored to the needs and specifics of the (German) health care system in order to prepare hospitals for the upcoming obligation of internal quality management (see 5.1). In 2002, the regular operation was started and the first certifications were performed. The type of certifiable facilities was gradually expanded. At present, in addition to hospitals, rehabilitation facilities, practices and MVZs (medical care centers), nursing facilities (outpatient and (semi-) inpatient) and hospices, emergency services, and, since catalogue version 6.0, also several connected facilities of the same type (combined certifica-

tion), several connected facilities of different types (networked certification) as well as organizational units, i.e. parts of large organizations, can be certified. For many years, the latter was a main point of criticism of the KTQ procedure, since previously only e.g. an entire university hospital could be certified, but not a single department. This was considered an advantage of the ISO procedure, which has always allowed the certification of subunits.

In 2017, the statutory health insurance funds withdrew from the circle of shareholders, and in 2019 the remaining original shareholders also withdrew. The shares were transferred to the new KTQ International GmbH, which was intended to expand its activities into (initially German speaking) foreign countries.

4.3.2. Procedure

The KTQ certification is clearly process oriented: its goal "was and is always the optimization of processes within patient care", and the certification process serves "to be able to make statements about the quality of the processes in care" [35].

The KTQ model is specified in the KTQ catalogues, which are adapted to the type of institution. 6 categories are always applied: Patient orientation, employee orientation, safety and risk management, communication and information management, corporate management and finally quality management. They are further differentiated by subcategories and so-called "criteria". In the current catalogue for Hospitals (Catalogue 2015) there are 55 criteria in total. Approximately half of the criteria are "core criteria", whose special importance for attaining good quality is expressed in the application of a multiplier to the scored points they are intended to achieve. Another essential feature of the catalogues is that they are structured according to the PDCA cycle. The evaluation of the individual criteria is divided – with different weightings – between the 4 steps of the PDCA cycle. "Plan" is the description of the target state with objectives and parameters, "Do" is the description of the actual state or the degree of implementation, "Check" is the description of the measurement procedures and "Act" the description of the improvement measures. For each individual step, half of the points to be achieved are then assigned for the so-called "degree of achievement" (measure of fulfilment of the requirements) and the other half for the so-called "penetration rate" (measure of implementation in breadth) [28].

The certification procedure is carried out in 4 steps: First there is a self-assessment, second the registration with one of the certification bodies, third the external assessment by KTQ visitors and finally the certification and publication of the KTQ quality report. The certificate is valid for 3 years

In detail, the procedure runs as follows [36]:

A hospital interested in KTQ certification first conducts a self-assessment based on the KTQ catalogue using a KTQ software tool. Furthermore, a short version of the self-assessment, the so-called KTQ-quality report, is prepared, which is intended for later publication. For this purpose it is usually necessary to have some employees trained on KTQ courses. If a promising result is achieved in this self-assessment (based on the minimum score of each category), the hospital can conclude a contract with a certification body authorized by KTQ for the next step and submit its self-assessment and KTQ quality report. The certification body appoints a team of so-called "visitors" and provides a "visitation attendant".

The visiting team consists of 3 members: a medical visitor (chief physician, deputy chief physician or senior physician), a nursing visitor (nursing director or deputy nursing director) and an economic visitor (leading position in the management of a hospital). They must not come from the same hospital in their respective team composition. Visitor activity is strictly a secondary activity and is limited in their annual number. The visiting team is provided with a visitation attendant by the certification body, who organizes the entire visitation process and ensures that the KTQ rules are observed, while maintaining neutrality with regard to the evaluation of the institution by the visitors.

Prior to the visit, the visiting team is provided with the hospital's documents. Each visitor first checks and evaluates the documents individually. The visitors then visit the hospital together, validate the self-assessment, inspect further documents and conduct the so-called "collegial dialogue", which provides the hospital with additional impulses and suggestions for its quality management. The visitation can last several days depending on the size of the hospital. At the end of the visit, the visitors summarize all information and assessments in the so-called KTQ visit report and submit a recommendation (positive or negative) regarding the granting of the certificate to KTQ.

The KTQ awards the certificate to the hospital if the recommendation of the visitors was positive, the hospital publishes the KTQ-quality report and participates in the legally required external quality assurance (according to DeQS-RL and/or QSKH-RL, see 5.2.6.3 and 5.2.6.4) For the validity period of 3 years, annual internal audits are mandatory, and re-certification after expiry of validity is possible and desirable. For particularly outstanding performance the KTQ awards the annual KTQ Award. On the website of KTQ, anonymized distribution graphs of the certified institutions are published displaying the scores in the single categories so that each institution has the opportunity of benchmarking.

The certification of organizations other than hospitals is basically the same, but the catalogue and the composition of the visiting teams are adapted to the specifics of the type of organization.

The institution is allowed to use the certificate for advertising purposes for the validity period.

4.3.3 KTQ-Plus

The KTQ-Plus procedure is a voluntary supplement to the certification, in which "dedicated feedback on the agreed criteria with the identification of strengths and improvement potential as oral feedback and in the form of a report" is intended to promote the development of the institution's internal quality management. Participation in KTQ-Plus may be communicated externally [37].

4.3.4 KTQ Best Practice

With the best-practice initiative, the KTQ wants to promote "excellence in quality management in the health care sector" and thus takes a step beyond mere process orientation. All KTQ-certified institutions are encouraged to present particularly good solutions, innovative projects, etc., in order to "contribute to the exchange between institutions and the dissemination of excellent solutions" [38].

4.3.5 Further development of the model

The KTQ model is continuously being developed further on the basis of experience and user feedback, partly also because of changed legal requirements in quality assurance.

For example, the current 2015 catalogue for hospitals reflects the increasing importance of risk management compared to the previous version 6.0, and the proof of guideline-compliant treatment has been introduced as a new requirement [39].

- In the current newsletters of April and July 2019, KTQ announces far-reaching changes to the model: The KTQ quality report must no longer be created by the institution, but would be optional in future, because there was already sufficient information on the legally required quality report (see 5.2.6.1). The objective was the "simplification of procedures and reduction of effort". The same goal continues to be pursued with reductions in the requirements for self-assessment. One optional offer is to conduct an intermediate inspection in the second year of validity of the certificate in order to evaluate progress on jointly agreed issues and to support timely further development. The duration of the re-certification after 3 years can thus be shortened.
- The importance of risk management and patient safety will again be significantly scaled up.
- The feedback element of the certification process shall be significantly strengthened and the formative element of the visitation examination should be emphasized: The feedback of the visitors should have consulting character. In the future, they should transparently communicate their assessment for each criterion of the self-assessment. Visitation attendants should in future participate in the consultation process – in addition to their neutral observer role.
- In line with this, the valuation structure is to be fundamentally revised. An overall percentage result, the corresponding benchmark and the KTQ Award will no longer be issued

The aim is rather "to promote the development of quality through collegial feedback", "to focus on our best practice initiative" and thus to promote "knowledge transfer of all KTQ-certified institutions".

The changes are to come into effect on 01.09.2019 [40, 41]. The emphasis on collegial counselling has analogies with the medical peer review procedure of the BÄK (see 6.10.1). The background for the recognizable, increased customer orientation could be the decreasing total number of certified institutions. Ten years ago, almost three times as many hospitals were certified as at present [42].

4.3.6 Pro cum cert (pCC) and pCC-KTQ-KH

Pro cum cert (pCC) is, according to its own statement, a "value-oriented certification company" for "companies and institutions in the health, social and educational sectors whose objectives are bound by values, charitable or ecclesiastical ". As a certification company, pCC offers a wide range of procedures, including ISO 9001 and KTQ.

Simultaneously with the development of the KTQ model, pCC has developed an extension of the KTQ catalogue for hospitals that takes into account the requirements of denominationally supported hospitals with regard to their "Christian value orientation". Therefore, the pCC KTQ-KH catalogue contains 3 additional categories in addition to the known 6 categories: Pastoral care in church owned hospitals, responsibility to society and responsibility of the owner. The certification according to pCC-KTQ-KH corresponds to a full KTQ certification and furthermore gives the hospital the opportunity to present its Christian profile internally and externally [43].

4.3.7 Relevance

KTQ is still relatively widespread in the German healthcare system. According to its own account, 244 hospitals (total number of certificates: 2275), 41 practices and MVZs (total number of certificates: 220), 46 rehabilitation facilities (total number of certificates: 275), 13 nursing homes (total number of certificates: 104) and an emergency medical service (total number of certificates: 12) are currently certified [44]. The difference between the number of currently certified facilities and the total number of certificates is due to the limited period of validity of the certificates. Facilities may be certified more than once or may no longer be certified. The overall number of certified institutions is declining (see 4.3.5).

4.4 EFQM – European Foundation for Quality Management

4.4.1 History and organization

At the end of the 1980s, European politicians and business leaders came to the conclusion that for "improving the competitiveness of European businesses and the sustainable economic development of Europe", it was no longer sufficient to apply the well-established ISO system alone, but that a European total quality management system should be developed and implemented in the style of the American Malcolm Baldrige National Quality Award (1987) or the Japanese Deming Prize (1951) [45]. On September 15th, 1988, 14 senior managers from major European companies met Jaques Delors, then President of the European Commission, and signed a declaration of intent to create a European foundation with the aim of improving European competitiveness. One year later, the European Foundation for Quality Management was created with the participation of 67 European companies. A development team was set up to create a holistic model applicable to all types of organizations, which was first applied when the first European Quality Award (EQA) was granted in Madrid in 1992. The EFQM model was reworked in the 1999, 2003, 2010 and 2013 revisions, sometimes significantly, sometimes cautiously, in order to develop it further and adapt it to the needs of the organizations. The next version will be released in 2020 (see 4.4.3). The EQA was renamed the European Excellence Award (EEA) in 2006. At the national level, it is complemented by the Ludwig Erhard Prize (ILEP [46]), which was first awarded in 1997. The EFQM model was expanded in 1996 to include the categories "public sector" and in 1997 "small and medium-sized enterprises" through corresponding awards. As a fourth group, organizational units can also apply for recognition. In 2001, an "EFQM Knowledge Base" was launched and a graduated certification system ("Levels of Excellence") was introduced to supplement the annual main prize [47].

The EFQM states that it currently has 450 members (companies and public institutions), 48 partner organizations (national quality organizations), 1500 assessors and 50 000 users.

4.4.2 Procedure

The idea of excellence is the central motive of the EFQM model, which regards itself as an instrument and fundamental structure for the management system of a successful organization.

It is intended to facilitate a holistic assessment and control of an organization by examining its relevant elements with regard to their function in the context of other elements and their interaction with them. The focus is always on long-term, sustainable excellence. The EFQM Excellence Model consists of 3 interlocking components: the "Basic Concepts of Excellence", the "Criteria Model" and the "RADAR Logic".

4.4.2.1 The eight basic concepts

The 8 basic concepts of excellence describe the fundamental conditions for achieving excellence as an organization, and provide important guidelines for organizational management. The 8 basic concepts are as follows:

- Adding value for customers
- Creating a sustainable future
- Developing organizational capability
- Harnessing creativity and innovation
- Leading with vision, inspiration and integrity
- Managing with agility
- Succeeding through the talent of people
- Sustaining outstanding results [48].

The two evaluation elements, i.e. the criteria model and the RADAR logic, are based on this canon of basic concepts. In principle, the evaluation is always initially carried out as a self-assessment and can be supplemented by an external evaluation when applying for an award.

4.4.2.2 The criteria model

According to the EFQM, the aim of the criteria model is to enable managers to "better understand the cause-and-effect relationships between what the organization does and the results it produces".

The criteria model is the superordinate assessment structure. It contains 9 criteria that relate to the activities and achievements of an organization. The 5 activity-related criteria are called "enabler criteria", the 4 achievement-related criteria "results criteria". A total of 32 subcriteria are assigned to the 9 criteria, and each subcriterion has several explanatory so-called "guidance points" which establish the reference to the eight basic concepts.

The 5 enabler criteria are as follows:

1. Leadership
2. Strategy
3. People
4. Partnerships and Resources
5. Processes, Products and Services

4 subcriteria are assigned to the criterion Strategy, to the others each 5.

The four results criteria are:

6. Customer Results
7. People Results
8. Society Results
9. Business Results

Two subcriteria are assigned to each of these.

The structure of this model allows the organization to be viewed as a whole from the PDCA perspective: The enabler criteria would correspond to the "Plan" and "Do", the result criteria to the "Check" and the feedback loop to the enablers, which is called "Learning, Creativity, Innovation" by EFQM, would correspond to the "Act".

In total, a maximum of 1000 points will be awarded for the evaluation of the 9 criteria, and these are largely evenly distributed among the criteria. The 2 result-related criteria Customer Results and Business Results are weighted more heavily with 15 % and 150 points respectively; all other criteria are weighted with 10 % or 100 maximally achievable points. Thus, the total score is divided equally between enabler and result criteria.

4.4.2.3 RADAR logic

The method of evaluating the individual criteria and assigning the respective percentage of points achieved is called "RADAR logic" in EFQM terminology. RADAR stands for Results, Approach, Deployment as well as Assessment and Refinement, is specifically adapted for the evaluation of enabler and result criteria and is derived overall from the PDCA cycle principle (with the addition of "result"). The underlying consideration is that an organization's objectives are first defined in terms of the desired outcomes ("R"), then the appropriate approaches are developed ("A" = "Plan") these are implemented ("D" = "Do"), subsequently evaluated and optimized if necessary ("AR" = "Check & Act").

For the evaluation, the "RADAR elements" are divided into the enabler and result criteria groups:

For the enabler criteria, Approach, Deployment and Assessment and Refinement are applied. For the results criteria, the Results element is divided into Relevance and Usability as well as Performance. All RADAR elements are individually allocated 2-4 attributes such as Sound, Implemented, Measurement, Scope, Trends etc.

At the level of the attributes, the actual assessment takes place using a matrix with a fivefold segmentation from "no evidence" (= 0 %) to "some evidence (= 25 %), "evidence" (= 50 %), "clear evidence" (= 75 %) until "exemplary throughout" (= 100 %).

4.4.2.4 Course of the procedure, application for recognition and prizes

The EFQM model focuses on the self-assessment process. With the necessary expertise for the model through training of internal employees and, if necessary, with the help of external consultants, the self-assessment can identify potential for improvement in all aspects of the internal management system. If these are addressed by appropriate measures, the quality of the entire organization can be increased in an iterative process.

If there is a desire to subject the achieved quality level to an external assessment and to communicate this to the outside world, it is possible to participate in the 4-stage "EFQM Recognition" programme [49]. The feedback of the external auditors (so-called "assessors") varies in detail depending on the level and the effort involved and can serve as a starting point for further improvement initiatives:

1. Committed to Excellence Validation
   At the entry level, after the self-assessment and the associated identification of improvement potential, 3 improvement projects are implemented. An EFQM Validator will assess the results of these 3 projects during a one day visit and prepare a feedback report. If clear progress can be identified, the recognition "Committed to Excellence 1 Star" will be awarded.
2. Committed to Excellence Assessment
   The next level examines the most important elements of management: strategy and key results, the management of people, customers and processes, and sustainability. In addition to the self-assessment, a short self-description is to be prepared. Two EFQM assessors evaluate the organization during a one day visit under the above-mentioned aspects. Afterwards, oral feedback is given as well as a detailed written report. If more than 200 points are achieved in the assessment, the recognition "Committed to Excellence 2 Star" is awarded.
3. Recognized for Excellence
   Advanced organizations can undergo a full external assessment by 3–5 assessors within 3–5 days. This is followed by comprehensive written feedback and the award of the certificate "Recognized for Excellence 3 Star, 4 Star or 5 Star". The award of the stars depends on whether the organization shows some (at least 300 points), good (at least 400 points) or very good (at least 500 points) change management activities and results.
4. EFQM Global Excellence Award
   Organizations that have been rated "Recognized for Excellence 5 Star" can apply for the annual Global Excellence Award. After a pre-meeting, an assessment by 5–9 assessors takes place over 5 days. Afterwards an EFQM jury decides on the annual award. A classification as "Highly Commended", "Prize Winner" in one or more fundamental quality concepts or as "Award Winner" can be granted. Furthermore, extensive written feedback is provided.

German organizations can also apply for the national Ludwig Erhard Prize [46].

4.4.3 Further development of the model

For the EFQM model, too, a very extensive redesign has been announced by autumn 2019 for the next model – version 2020. Instead of focusing only on continuous improvement, which had been the focus over the past 25 years, there was a need in organizations to be able to deal with transformations and disruptive events just as well as with continuous improvement through effective change management. The EFQM Model 2020 would adapt strongly to this and become more of a management tool than the previous assessment tool. Furthermore, the entire EFQM procedure would be completely digitalized. A curated version of the knowledge platform ("Knowledge Base") and an assessment platform ("Assessment Base") would be established for members. The latter would allow organizations to carry out a self-assessment and test whether the EFQM model is practicable for them. In addition, a separate, exclusive and app-based social network called "Totem" would be set up, in which members would not only be able to present themselves, but which would also serve as a best-practice platform and provide easy access to the Knowledge Base and the Assessment Base [50–52].

4.4.4 Relevance

Compared to the economic and administrative sectors, the EFQM model is relatively rarely used by health care providers. The "healthcare sector", which also includes administrative organizations, pharmaceutical industry etc., comprises only 6 % of all EFQM users. For the "Recognitions" of the different levels equivalent to a certificate, 14 hospitals, including one university hospital, 3 organizational units of hospitals, 2 practices and 1 MVZ are currently listed for Germany [53].

4.5 Comparison of ISO, KTQ, EFQM

Of the 3 models, ISO is most process-oriented and EFQM as a model of excellence is most results-oriented. KTQ lies between these two. All 3 systems start with a self-assessment and subsequently offer an external evaluation by auditors, visitors or assessors. Only ISO and KTQ issue a certificate and thus evaluate the current status, whereas EFQM focuses on the future and the interaction of the company divisions. The decisive difference is that quality indicators and certificates of conformity are retrospective, while models of excellence allow for forward-looking management in the organization.

All procedures emphasize a continuous improvement process. KTQ is the only healthcare system-specific procedure, while ISO and EFQM are generic [54]. Users and consultants regard ISO as a low-threshold system that offers a good introduction to setting up a quality management system. KTQ has the advantage of explicitly mapping the processes in hospitals or practices, but is more complex to implement. EFQM is the most abstract model of all; previous experience with quality management systems is recommended [28].

4.6 Certification of medical practices and MVZ – QEP, ISO, KPQM, KTQ, EPA and others

Like hospitals, SHI-accredited medical practices and MVZs (Medical Care Centers) are subject to the legal obligation to operate an internal quality management system (§135a SGB V). The Quality Management Guideline (QM-RL) issued by the Federal Joint Committee (G-BA) defines the details (see 5.2.5.1).

Voluntary certification can be very helpful in the improvement and continuous further development of a quality management system. In addition to the generic systems according to ISO, KTQ and EFQM described above, there are also certification systems specific to practices or MVZ. The most prevalent is QEP (Quality and Development in Practices, offered by the Federal Association of Statutory Health Insurance Physicians (KBV) [55, 56]), followed at a clear distance by KPQM (KV Practice Quality Management, offered by the Association of Statutory Health Insurance Physicians of Westphalia-Lippe [57]) and the EPA Practice Seal (European Practice

Assessment, offered by Aqua-Institute [58]). In addition there are a number of other suppliers with smaller market shares. The KBV indicates the percentage of users of the above mentioned procedures on the basis of the annual sample (see 4.6.2) of 2017 with QEP 32 %, DIN EN ISO 9001:2015 26 %, KPQM 4 %, KTQ PRAX-MVZ 3.0 2 % and EPA 2 %. EFQM does not play a role, with currently 3 participants from this segment throughout Germany (see 4.4.4).

4.6.1 Procedure

ISO is the only method that is purely generic. KTQ adapted its process through a specially adjusted catalogue. All other 3 procedures have been specially developed for the area of SHI-accredited practices.

In principle, all procedures are criteria-based self-assessment and external evaluation systems. After preparation and self-assessment, the external evaluation is carried out by an auditor or visitor and, if successful, a certificate valid for 3 years is awarded for all systems. For QEP, ISO and KTQ it is expected that re-certification will result in measurable improvements in performance. The costs for training and certification are comparable [59, 60].

4.6.2 Relevance

The annual "Report on the implementation status of quality management in SHI-accredited practices and MVZs in accordance with QM-RL Part A §7", which is to be submitted by the KBV, asked the participants, selected by random sampling, about the "Use of specific QM systems"; the answer was voluntary. 54 % of the respondents then stated that they use these systems (for distribution, see 4.6), and 13 % stated that they have already undergone voluntary certification (see 5.2.6.2), i.e. three quarters of the users remained with self-assessment.

4.7 Certification of centers

4.7.1 History and organization

The aim of creating centers is usually to create added value compared to conventional care. A center can be characterized as an "aggregation of expertise and resources" [61].

In principle, centers can be divided into those that are created by bundling resources (e.g. endoscopy centers), originate from health organizations and are usually not certified, and those that are certified for specific diseases by medical societies. In addition, there are state center designations, e.g. through hospital plans, tumor centers and oncological focus areas in Baden-Württemberg, breast centers in North Rhine-Westphalia or also for MVZs.

The center certifications by medical societies, which refer to disease-oriented centers, can be divided into centers in tumor care and centers in other specialist areas.

Centers in tumor care are certified according to "Onkozert", the certification procedure of the German Cancer Society (DKG) and the German Cancer Aid (DKH), as is the case with head and neck tumor centers in our specialty [62]. Depending on their size and importance, they are classified as "Organ Cancer Center (C)", "Oncological Center (CC)" or "Oncological Top Center (CCC)". In addition, there are other oncological certification procedures linked to medical societies. The centers for important non-oncological diseases are certified by the respective medical societies or medical organizations.

4.7.2 Procedures

According to the German Medical Association, a disease-oriented center should have the following characteristics:

- Disease-oriented specialization
- Patient focus
- Evidence-based care
- Interdisciplinary and professional cooperation and communication
- Close cooperation and communication with the referring and follow-up physicians as well as with all other parties involved in patient care
- Quality management [63]

The actual certification is usually carried out according to the principles of ISO certification with self-assessment based on a catalogue of requirements, external assessment through an audit and the granting of a certificate with a limited period of validity.

4.7.3 Relevance

In the field of certification as a center, in contrast to the above-mentioned procedures, there is a peer pressure dynamic, i.e. the need to participate, to certify "also" in order not to show a negative distinguishing feature.

The German Medical Association and the 112th German Medical Assembly have criticized the somewhat inflationary spread of the establishment of centers in the German hospital landscape [64]. In the public perception, the center concept is positively linked with competence, specialization and comprehensive treatment. Since it is not trademarked, any institution can ultimately call itself a center, for example, to take advantage of the associated marketing effect. Centers do not necessarily have to be certified, but often cite certification. The Institute for Quality and Transparency in Health Care (IQTIG) was commissioned by the legislature to develop "criteria for the evaluation of certificates and quality seals in both the outpatient and inpatient sectors" in this context (§135a para. 3 SGB V, see 5.3.2). In its evaluation of certifications, the German Medical Association agrees with the content of a policy paper of the Swiss Academy of Sciences, in which requirements for a medical certification process are set analogously to an ISO certification [65].

4.8 Discussion – measurable benefit?

Surprisingly, the obvious question of whether external certification produces a measurable benefit for patient- and organization-related processes and outcomes cannot be answered unequivocally, because there is no systematic, meaningful research on this, as was found in 2 Cochrane Reviews [66, 67].

A comparison of US hospitals accredited by the Joint Commission with state-accredited hospitals showed no difference in mortality and 30-day recovery rates [68]. A survey of patient satisfaction after inpatient treatment at German hospitals showed no difference between KTQ, pCC- and ISO-certified hospitals and non-certified hospitals [69]. Other, similar surveys also showed mixed results at best. However, the quality indicators used here do not meet higher standards in terms of their validity.

The Working Group on Centers of the German Medical Association (AG Zentren der Bundesärztekammer) was also unable to

identify any measurable effects on health care, given the poor study situation for disease-oriented center formation [70].

The Joint Commission points out that it is difficult to define reliable quality indicators of outcome quality, with the exception of mortality. The challenge of developing valid quality indicators is obviously considerable and also exists in the system of statutory external quality assurance in Germany (see 5.12).

Simple innovative approaches can enable valid statements to be made about quality deficiencies in hospitals, as was shown in Great Britain by a combination of classic patient surveys and evaluation of their statements on social media channels [71].

With regard to the effect within the organizations, there are numerous before-and-after studies which find that employee satisfaction, inter-professional cooperation, efficiency of the organization etc. improve significantly after certification or accreditation [72, 73].

It remains to be noted that certification or accreditation per se cannot make any statement about the quality of outcomes, but only about the conditions for achieving good quality. For this reason, all relevant systems today additionally include the querying of quality indicators and the necessity to demonstrate positive developments in the case of follow-up certifications [65].

The fact that commercial companies use certifications, accreditations and in particular models of excellence – despite the considerable effort involved – shows that there is evidently a perception that there is a real additional benefit to be gained from their use.

Nevertheless, it is deeply unsatisfactory that there is no solid evidence for the effects of external certification or accreditation on the quality of medical outcomes. Methodologically sound randomized controlled trials (RCT) would be highly desirable to answer this question (see 8.4).

5 Legal and Institutional Quality Assurance (Obligatory External Quality Assurance)

The health care system in Germany is not organized by the state throughout, but rather as a so-called "joint self-governance", with the main actors being constituted as public law corporations. On the service provider side, these are the representatives of the physicians and dentists and the hospital care sector, and on the funding side, these are primarily the statutory health insurance funds. Practically all institutions of the joint self-governance in the health care system are also concerned with quality issues or aspects thereof. Therefore, the presentation of institutional quality management is also an almost complete description of the structures of the joint self-governance in the health care system, its sub-organizations and spin-offs.

5.1 Quality-relevant laws

The majority of legal regulations concerning the issue of quality in the health care system are found in the fifth book of the Social Code (SGB V), which came into force in 1989 as a replacement for the second book of the German Imperial Insurance Code.

Three very relevant paragraphs define the entitlement to benefits of those insured by the statutory health insurance funds in Germany:

Firstly, the "efficiency requirement" §12 SGB V:

"(1) Benefits must be sufficient, appropriate and economical; they must not exceed the extent of what is necessary. Benefits that are not necessary or uneconomical cannot be claimed by insured persons, may not be provided by the service providers and may not be approved by the health insurance funds".

Secondly, the paragraph "Services" §2 SGB V defines, among other things, the level of benefits to be provided in consideration of the requirement for economic efficiency:

"(1) .... The quality and effectiveness of benefits must correspond to the generally accepted state of medical knowledge and take account of medical progress".

Thirdly, the section on "Quality, Humanity and Efficiency" in § 70 SGB V summarizes the interaction between equity of care, efficiency and ethics:

"(1) Health insurance funds and service providers must ensure that the insured persons receive care that is appropriate and consistent with their needs and in line with the generally recognized state of medical knowledge. The care of the insured persons must be sufficient and appropriate, may not exceed what is necessary and must be provided in the professionally required quality and economically.
(2) Health insurance funds and service providers shall take appropriate measures to ensure that their insured persons receive humane medical treatment."

The German Social Code, Book V (SGB V) also regulates the duty of continuous medical education for specialists in §§ 95d and 136b.

5.1.1 SHI Modernization Act (GKV-Modernisierungsgesetz)

Most quality-specific legal regulations were introduced at the beginning of the new millennium, especially with the enactment of the Statutory Health Insurance Modernization Act (GKV-Modernisierungsgesetz) [74] in 2004, which included a comprehensive reform and expansion of the Social Code Book V. The most important regulations concern

- The obligation of service providers to set up an internal quality management system and to participate in external quality assurance measures (§ 135a SGB V) and
- The establishment of the Joint Federal Committee (G-BA, §91 SGB V, see 5.2), the definition of its responsibilities (§§ 136 and 137 SGB V) and the establishment of the Institute for Quality and Efficiency in Health Care (IQWIG, §139a SGB V, see 5.4).

5.1.2 G-DRG

Even within the G-DRG system, which was made mandatory in 2004 (§ 85 Social Code Book V and § 17b Hospital Financing Act), regulations to ensure minimum quality standards were introduced, e.g. with the "lower limit length of stay".

5.1.3 SHI Competition Strengthening Act (GKV-Wettbewerbsstärkungsgesetz, GKV-WSG)

In 2007, the SHI Competition Strengthening Act introduced, among other things, the cost-benefit assessment (KNB) of drugs according to §35 SGB V.

5.1.4 Drug Market Restructuring Act (Arzneimittelmarktneuordnungsgesetz, AMNOG)

In 2011, the German Drug Market Restructuring Act (Arzneimittelmarktneuordnungsgesetz) introduced measures including the procedure of early benefit assessment of drugs under the responsibility of the Federal Joint Committee (G-BA) (Section 35a (1) SGB V [75]).

5.1.5 SHI Care Structure Act (GKV-Versorgungsstrukturgesetz, GKV-VStG)

In 2012, the Care Structure Act ("Versorgungsstrukturgesetz") introduced measures including trial regulations for examination and treatment methods. Both the G-BA and industry can initiate studies on this.

5.1.6 Patient Rights Act (Patientenrechtegesetz)

This law came into force in 2013 and summarizes the rights of patients

- With respect to the attending physicians – with regard to obligations for information and informed consent, documentation of the treatment and the patients' rights of inspection,
- Towards the cost bearers
- With regard to participation in self-governance bodies and
- With regard to risk and error management by the attending physicians [76].

5.1.7 SHI Financial Structure and Quality Development Act (GKV-Finanzstruktur- und Qualitätsweiterentwicklungsgesetz, GKV-FQWG)

In the SHI Financial Structure and Quality Development Act of 2015, the establishment of the Institute for Quality and Transparency in Health Care (IQTIG) was laid down (see 5.3).

5.1.8 SHI Care Improvement Act (GKV-Versorgungsstärkungsgesetz, GKV-VSG)

The SHI Care Improvement Act 2015 introduced measures including discharge management (Section 39 Para. 1a SGB V) and a procedure for new examination and treatment methods (NUB, Section 137h SGB V).

5.1.9 Hospital Structure Act (Krankenhausstrukturgesetz, KHSG)

In 2016, the Hospital Structure Act introduced quality standards as a criterion for hospital planning. The Federal Joint Committee was to develop relevant quality indicators for this purpose and make its findings available to those involved in hospital planning. The Federal States were granted the right to exclude consideration of the results in the hospital plan (see 5.2.6.8).

5.1.10 Nursing Staff Improvement Act (Personalpflege-Stärkungsgesetz, PpSG)

In the Nursing Staff Improvement Act in 2019, the financing of nursing staff costs was spun off from the DRG system and the full refinancing of tariff increases was established. Lower limits for nursing staff in care-sensitive areas were also established (Section 137i SGB V). A security surcharge was introduced to secure care provided by rural hospitals [77].

5.1.11 Appointment Service and Care Act (Terminservice- und Versorgungsgesetz, TSVG)

In 2019, the Appointment Service and Care Act raised the minimum number of consultation hours for SHI-accredited physicians to 25 per week. Certain groups of specialists, including ENT doctors, are obliged to offer 5 open (without appointment) consultation hours per week. The appointment service points (TSS) will in future be available nationwide under the telephone number 116117 and are to be further expanded and will also take over the management of emergency patients (see also 8.1.4). Treatments arranged via the TSS and treatments in open consultation hours are to be remunerated on an extra-budgetary basis.

5.1.12 Other laws relevant to quality

Other quality-relevant laws concern questions of patient safety (Infection Protection Act and recommendations of the "Commission for Hospital Hygiene and Infection Prevention" (KRINKO) at the Robert Koch Institute, Medicines Act, Medical Devices Act, Medical Device Operator Ordinance, etc.) and employee protection (Working Hours Act).

5.2 G-BA – Federal Joint Committee

The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) [78] is, in its own words, "the highest decision-making body of joint self-governance in the German health care system" [79], a public corporation and subject to the legal supervision of the Federal Ministry of Health (BMG). The term "legal supervision" must be clearly distinguished from "professional supervision". This means that the decisions of the G-BA cannot be corrected by the BMG, but only with regard to formal legal aspects. This is an essential aspect of the independence of self-governance in health care.

When it was introduced in 2004, the G-BA replaced 5 committees that had previously existed: the Federal Committees of Physicians, Dentists and Health Insurance Funds, the Hospital Committee and the Coordination Committee Working Group.

The central task of the G-BA is to determine which medical benefits must be borne by the statutory health insurance funds for the insured, taking into account the principle of economic efficiency in accordance with §12 SGB V and the entitlement to benefits in accordance with §2 SGB V. In order to enforce the claim formulated in §2 SGB V to high-quality treatment that takes account of medical progress, the Federal Joint Committee has created a number of instruments for both hospitals and practices with which the quality of the services provided can be measured and assured.

The Federal Ministry of Health describes the G-BA's mandate regarding quality assurance as follows:

"The definition of binding, concrete regulations both in the outpatient and inpatient sectors – i.e. in the provision of care by SHI-accredited physicians and in hospitals – is the responsibility of the Federal Joint Committee (G-BA). This means that the G-BA has the sovereignty to shape quality assurance in hospitals in particular. It therefore has the authority to decide for which areas quality requirements are to be determined, how detailed these requirements are and the effort involved in these regulations. Its specifications are binding for the service providers"[80].

5.2.1 Structure of the G-BA

The G-BA consists of the plenum, which is the decision-making body, and 9 subcommittees. The plenum and the subcommittees have the same structure: they are composed equally of representatives of the service providers and representatives of the cost-bearers (so-called "benches") and impartial members, who also provide the chairperson. The impartial members are appointed by consensus of the service providers and the cost-bearers or, if this is not possible, by directive of the Federal Ministry of Health. In detail, the plenum consists of 3 impartial members, including the chairman, 2 representatives of the National Association of Statutory Health Insurance Physicians (KBV), one representative of the National Association of Statutory Health Insurance Dentists (KZBV) and 2 representatives of the German Hospital Federation (DKG), as well as 5 representatives of the Central Association of Statutory Health Insurance Funds (GKV Spitzenverband). As an innovation compared to the committees existing before 2004, representatives of accredited patient and self-help organizations are also members of the plenum and the subcommittees, who have the right to make proposals and participate but who have no voting rights (so-called patient participation). The meetings of the plenum are public and, according to the current draft of the MDK Reform Act, will in future be broadcast live on the Internet and be accessible via the media library.

Subcommittees have been set up on the topics of outpatient specialist medical care, pharmaceuticals, demand planning, disease management programs, psychotherapy, method evaluation, quality assurance, services initiated and dental treatment. The subcommittees, which unlike the plenary, do not meet in public, summarize the results of their deliberations as recommendations for resolutions to the plenary.

5.2.2 Comments procedure and parties entitled to submit comments

The Federal Joint Committee is legally obliged to offer third parties the opportunity to comment on matters that concern them. Those entitled to submit comments include "organizations of service providers, chambers of health care professionals, medical device manufacturers, pharmaceutical companies, the Federal Commissioner for Data Protection and Freedom of Information, the Robert Koch Institute, the Commission on Radiological Protection or scientific associations".

5.2.3 Funding

The G-BA finances itself and the two institutes that work with it, IQTIG and IQWIG, via a so-called system surcharge that is levied by the cost-bearers and paid to the G-BA for each inpatient case (including self-pay patients) and for each outpatient SHI case [81].

5.2.4 Subject area quality assurance

The Federal Joint Committee divides its activities in the field of quality assurance, which are dealt with by the Quality Assurance Subcommittee, into three sections [82]:

1. Specifications for quality assurance
2. Data collection for quality assurance
3. Other areas of quality assurance

5.2.5 Section 1: Specifications for quality assurance

For quality assurance, the Federal Joint Committee has developed specifications concerning quality management, obligations for continuous medical education in hospitals, a cross-institutional error reporting system, minimum quantities, structural quality specifications and staffing in psychiatry and psychosomatics.

5.2.5.1 Quality management guideline (QM-RL)

The "quality management guideline" [83] issued by the Federal Joint Committee describes its requirements for a quality management – which must be distinguished from external quality assurance (see 3.2.1, 5.2.6.3 and 5.2.6.4.). This is an internal quality management system with systematic and coordinated measures for planning, steering, control and continuous improvement of processes and procedures. Quality management should also be an instrument for organizational development. The primary patient orientation and the special focus on patient safety are emphasized. In addition, the needs of all other actors in the treatment process should also be taken into account and their satisfaction should be increased. Furthermore, the reference to the PDCA cycle implicitly refers to procedures of Total Quality Management (TQM). Quality objectives should be defined, measured and reviewed for all relevant areas in order to be able to make any necessary adjustments as part of a continuous improvement process (CIP). The areas to be comprehensively included in quality management are patient orientation including patient safety, employee orientation including employee safety, process orientation, communication and cooperation, information security and data protection, responsibility and leadership – as in the TQM approach.

The following methods and instruments of quality management are mandatory: Measurement and evaluation of quality objectives, assessment of the current status and self-assessment, regulation of responsibilities and competencies, process and workflow descriptions, interface management, checklists and in particular surgical checklists (time-out), team meetings, further education and training measures, patient surveys, employee surveys, complaint management, patient information and education, risk management, error management and error reporting systems (Critical Incident Reporting Systems, CIRS, see 5.2.5.5, 6.6.2 and 6.10.2). In particular, the following areas of application should be regulated by quality management: Emergency management, hygiene management, drug therapy safety, pain management and measures to prevent falls or consequences of falls.

In summary, the Federal Joint Committee demands that practices and hospitals not only have a basic quality management system, but that they have a comprehensive quality management sys-

tem. The individual health care organizations are explicitly free to choose their own quality management system as long as it meets the requirements formulated by the Federal Joint Committee.

The implementation of a few of the quality management requirements is requested from hospitals via the annual quality report (see 5.2.6.1). In the SHI-accredited physician outpatient sector, the KVs or KZVs conduct surveys using a standardized questionnaire among a randomly selected group of SHI-accredited physicians whose size comprises at least 2.5 % (KVB) or 2 % (KZVB) of the total number of SHI-accredited physicians (see 5.2.6.2).

5.2.5.2 Obligation to provide evidence of continuous medical education in hospitals

The Federal Joint Committee has stipulated that since October 1, 2013, hospital specialists must also prove that they meet their obligation to undergo continuous medical education (§ 136 b SGB V) [84]. Within 5 years, continuous medical education courses must be attended that have been assessed by the State Medical Associations with a total of at least 250 continuing medical education points and that are predominantly subject-specific. The control and issue of continuous medical education certificates has been delegated to the State Medical Associations. The specialist physicians must present their certificates to the hospital administrations. These must then declare in their annual quality report how high the percentage of specialists with valid certificates is at their institution.

5.2.5.3 Specifications of structural quality

The Federal Joint Committee defines minimum structural quality requirements for the following treatments: treatment of abdominal aortic aneurysm, paediatric cardiac surgery, minimally invasive heart valve interventions, positron emission tomography for the treatment of non-small cell lung cancer, proton therapy for rectal cancer, care of premature and mature infants, and care of children and adolescents with haemato-oncological diseases.

5.2.5.4 Regulations of minimum quantities (Mm-R)

For elective inpatient services for which the Federal Joint Committee has stated that there is a correlation between the frequency of performance and the quality of treatment, the G-BA has introduced a minimum quantity regulation in order to ensure that the physicians performing these services have sufficient experience. A minimum quantity regulation currently applies to the following 8 services: liver transplantation (incl. partial liver donation), kidney transplantation (incl. living donation), complex interventions on the organ system oesophagus, complex interventions on the organ system pancreas, stem cell transplantation, total knee joint endoprostheses, coronary surgical interventions (currently without specification of a concrete minimum quantity) and care of premature and newborns with a birth weight of less than 1250 grams (see discussion 5.12.4).

5.2.5.5 Requirements for cross-institutional critical incident reporting systems (CIRS)

For a cross-institutional critical incident reporting systems (CIRS), i.e. not an internal CIRS, there are requirements for operation and participation. Cross-institutional error reporting systems should make a special contribution to the avoidance of adverse events by collecting experience about risks and sources of error from many different institutions. The reports must guarantee anonymity both with regard to the patient possibly affected and with regard to the reporting institution. Participation in a cross-institutional CIRS is certified by the operator, must be published in the annual quality report and is remunerated with a small amount per inpatient case (€ 0.20). Examples of a specialized cross-institutional CIRS are the "CIRSmedical Anesthesia" [85], of a regional CIRS the "CIRS Berlin Network" [86] and of a supra-regional, interdisciplinary CIRS the "Hospital-CIRS-Network Germany 2.0" [87].

5.2.6 Section 2: Data collection for quality assurance

The Federal Joint Committee has already established procedures for the declared goal of "measuring, presenting and comparing the quality of medical care" and is currently in the process of developing new procedures that will also influence remuneration (in the form of surcharges or discounts) and on hospital and demand planning.

Quality assurance measures are differentiated into "cross-institutional", i.e. allowing comparison between different service providers, "sector-specific", i.e. related to one of the sectors of the health care system such as the inpatient or outpatient sector, or "cross-sector", i.e. considering two or more sectors. Temporally longitudinal procedures are called "follow-up".

Current quality assurance procedures cover the fields of cardiology and cardiosurgery, gynaecology and obstetrics, transplantation medicine, orthopaedic surgery, and decubitus, pneumonia and nosocomial infections. There is currently no procedure for otolaryngology. An older procedure for tonsillectomy has been discontinued.

5.2.6.1 Quality reports of hospitals (Qb-R)

Since 2005, all hospitals have been legally obliged to provide information about their work in quality reports. The "Regulation on Hospital Quality Reports" [88] formulates the goal of this measure as an improvement in transparency, providing orientation and decision support for patients and a basis for comparative information and recommendations by the Associations of Statutory Health Insurance Physicians and Health Insurance Funds. Furthermore, hospitals are given the opportunity to present themselves to the public. In a detailed, structured form, the report requests information on the three areas "structural and performance data of the hospital", "structural and performance data of the organizational units/specialty departments" and "quality assurance". The total volume for a university hospital is about 1000 pages. In addition to statistical data, e.g. on the number of employed physicians, further information is collected on inpatient numbers of patients, type and number of diagnoses and services offered, on various aspects of risk management, on the implementation of internal quality management and participation in external quality assurance, as well as on the existence of target agreements with senior physicians and the implementation of the obligation to provide continuous medical education for specialists. The report is to be submitted annually to the joint acceptance office of the statutory health insurance funds, their associations and the Association of Private Health Insurance and is published by them, but can also be accessed via the

reference database of the Federal Joint Committee [89]. If the report is not delivered, the hospital is listed on a public list for the first year. As a financial penalty, a quality assurance discount of € 1.00 per inpatient case is levied in the second year, and € 2.00 per inpatient case in the following year.

5.2.6.2 Reporting on the implementation of quality management in SHI-accredited medical and dental care

In the SHI-accredited physician (incl. MVZ) and dentist outpatient sector, the implementation of the quality management requirements of the Federal Joint Committee is monitored by annual surveys conducted by the Associations of Statutory Health Insurance Physicians (KBV) and the Associations of Statutory Health Insurance Dentists (KBZV). A random sample of at least 2.5 % of the physicians and 2 % of the dental SHI-accredited partners is surveyed using a standardized questionnaire. The respondents are selected at random. The results are published by the KBV and KZBV in annual reports [90, 91].

5.2.6.3 Data-based quality assurance procedures (DeQS-RL)

The new procedure Data-based Cross-institutional Quality Assurance, which is based on the DeQS-RL guideline that came into force in 2019, will gradually replace several historically developed quality assurance procedures or combine them in a new structure [92]. In detail, this concerns the sector-specific inpatient and outpatient quality assurance (see below) and the cross-sectoral quality assurance. The collection and evaluation of patient treatment data is to be standardized and brought together across sectors in order to gain more reliable information about the areas in which there is potential for improvement – and thus support internal quality management and initiate a process of continuous quality development. The increased transparency of the procedure should serve both the participating institutions and patient safety and, through appropriate publication, the information and thus the self-determination of patients.

Three quality assurance procedures have so far been transferred to the new procedure: "Procedure 1: Percutaneous coronary intervention and coronary angiography" (QS PCI), "Procedure 2: Prevention of nosocomial infections – postoperative wound infections" (QS WI) and "Procedure 3: Cholecystectomy" (QS CHE). From 2020, three new procedures are to be introduced in accordance with a resolution of June 2019: "Procedure 4: Renal replacement therapy for chronic kidney failure including pancreatic transplantation" (QS NET), "Procedure 5: Transplantation medicine" (QS TX), which combines the previous transplantation medicine service areas of the QSKH-RL, and "Procedure 6: Coronary surgery and heart valve surgery" (QS KCHK) [93].

If a patient is treated who is subject to one of the above-mentioned quality assurance procedures, the service provider and the health insurance company must deliver the collected data in a specified electronic form to the data collection point, usually quarterly. The correct recording of the data must be confirmed annually with a declaration of conformity.

In addition to the actual quality-assurance-relevant information or quality data (QD), the data records contain further data for identifying the patient (PID), the service provider (LE) and the health insurance fund (KK) as well as administrative data (AD). As an example, details of the "QS PCI" procedure are listed below: the service provider is asked for 88 data characteristics per treatment case, which are incorporated into 20 quality indicators for evaluation. Of these, 2 are indication indicators, 11 process indicators and 7 outcome indicators. Administrative data, diagnoses, procedures and drug prescriptions are requested from the health insurance fund.

Data collection points for hospitals are the State Offices for Quality Assurance (LQS), which are located at the State Hospital Associations (LKG), for SHI-accredited physicians the responsible Associations of Statutory Health Insurance Physicians (KV) or Associations of Statutory Health Insurance Dentists (KZV), and for health insurance funds a commissioned institute. The data collection points check the data for plausibility, integrity and completeness and pseudonymize the service provider (LE). They then forward the data to the trust center.

The Federal Joint Committee has commissioned an independent "office of trust in accordance with § 299 SGB V", which was created for this purpose, to pseudonymize the patient identification (PID) in the data received. It then forwards the data to the Federal Review Board.

The Institute for Quality and Transparency in Health Care (IQTIG) acts as the Federal Review Board. If necessary, it brings together all existing data records of a pseudonymized patient and evaluates them uniformly according to the topic-specific criteria defined in the respective quality assurance procedure. This also enables cross-sectoral evaluations and progress reviews. These evaluations are forwarded to the State Working Groups (LAG), unless federal procedures are involved. In this case, the evaluation is forwarded to the federal agency, the Subcommittee on Quality Assurance of the Federal Joint Committee. As a rule, procedures are carried out on a state by state basis. Procedures are only conducted at the federal level if cases are rare or if the topic has unusual features.

In addition, IQTIG produces anonymized data evaluations for the Federal Joint Committee – in the form of the annual Federal Quality Report, which also contains information from the quality assurance results reports submitted by the LAGs (see below). Furthermore, IQITIG prepares so-called "feedback reports" to the service providers, which contain a statistical presentation of the results of the service provider and its comparison group. The transmission is carried out via the data collection points, which depseudonymize the recipient for dispatch.

The validity of the data is checked by the Federal Review Board or IQTIG and, in the case of service provider data, if necessary also by the LAGs (see below). The type of validation is regulated in a process-specific manner.

The State Working Groups (LAGs) are a new cross-sectoral structure introduced for the present purpose, which correspond to the federal system of self-governance and will gradually take over the function of the State Offices for Quality Assurance (LQS, see 5.2.6.4). They are formed in each federal state by the Association of Statutory Health Insurance Physicians (KV), the Association of Statutory Health Insurance Dentists (KZV), the State Hospital Association (LKG) and health insurance funds. The State Medical Associations (LÄK), the State Dental Associations (LZÄK), representatives of private health insurance companies and the nursing profession participate through the LAG, and patient representatives

have a right of consultation. The LAG sets up expert committees with suitable expertise for the respective quality assurance procedure. The expert committees examine the data from the Federal Evaluation Centre to determine whether there are any abnormalities. The LAG has the mandate to initiate quality assurance measures if abnormalities are detected (abnormalities can also be above average results). To this end, the data collection agency first depseudonymizes the service provider to the LAG (in federal procedures to the federal agency).

A multi-stage quality assurance procedure is subsequently initiated: Firstly, the service provider is given the opportunity to comment. This can in writing and, in addition, by means of discussions (the so-called "commenting procedure"). If the anomalies cannot be clarified in this way, an agreement is concluded with the service provider that contains level 1 measures – such as participation in suitable further training, expert discussions, colloquia, participation in quality circles, implementation of treatment pathways, conducting audits, conducting peer reviews, implementation of recommended actions based on guidelines, etc. If these measures do not succeed or are refused, or if there are "serious individual cases of malpractice", the service provider is asked to "comment". If the result is unsatisfactory, level 2 measures are decided upon. These include which a correction to the concluded agreement. The most severe sanctions are recommendations to the KV/KZV or the health insurance funds that remuneration should be reduced or that the billing option should be withdrawn. In the case of "particularly serious grievances", or if the obligation to transfer the data is (repeatedly) not fulfilled, the level 2 measures can be applied directly. Hospitals must publish the assessment of their conspicuous findings in the annual quality report.

In the "quality assurance results report", the LAGs summarize the results of the processing of abnormalities and the quality assurance measures that may result from this and prepare a report for the information of the public that can be understood by laymen.

5.2.6.4 External inpatient quality assurance (QSKH-RL)

The "external inpatient quality assurance" is the current external quality assurance procedure according to the directive on "Quality Assurance Measures in Hospitals" (QSKH-RL) [94]. This will gradually be replaced by the above-mentioned "Data-based Quality Assurance Procedures" (according to DeQS-RL). In contrast to the new procedure, the case data records according to the QSKH-RL do not include patient identification, but only information on the patient's year of birth and age at admission and discharge. This means that it is not possible to merge data across cases or sectors. On the other hand, the complex pseudonymization of the new procedure is not necessary. Moreover, no data have yet been collected from the health insurance funds. Analogously to the new procedure, there is a distinction between state- and federally related procedures, which, however, are described with a different terminology as "direct" (= federally related) or "indirect" (= state-related). Most procedures are in the group of indirect procedures. Direct procedures currently include e.g. transplantation procedures.

The State Offices for Quality Assurance (LQS) assigned to the State Hospital Associations (LKG) play a central role in the acceptance of data, which they forward to the IQTIG, and in the evaluation of arithmetical abnormalities [95]. The structures formed in these offices – steering committees, specialist groups, regional offices – are reflected in a similar way in the new State Working Groups (LAGs) created for the new procedure, which, unlike the LQS, are organizationally independent of the LKGs. The steering committee of the LQS is composed of representatives of the State Associations of Health Insurance Funds and compensation funds, the State Hospital Association, the State Medical Association, the State Nurses' Council and patient organizations. The specialist groups in the LQS are each assigned to a quality assurance procedure and staffed with medical and nursing experts sent by the State Medical Associations, the AWMF, the Nursing Council and the statutory and private health insurance funds.

Validation of the transmitted data is carried out by means of a basic statistical check, comparison of data with patient records and random samples coordinated with IQTIG in 3 service areas per year.

After the data have been accepted by the LQS in the "indirect procedures", they are passed on to the IQTIG, from which they are pseudonymized with regard to the site, in order to ensure an objective assessment by the LQS after they have been returned to them. If arithmetical anomalies arise in the LQS during the evaluation of the quality indicators reported by a hospital, the LQS initiates a so-called "structured dialogue". This is a multi-stage procedure that must always be triggered when anomalies occur and is an essential task of the LQS. If the expertise of the responsible specialist group is required, the conspicuous result can be assessed as implausible and thus without consequence, or it can lead to measures being taken. In the latter case, the hospital is de-pseudonymized by the IQTIG. The minimal measure is a "note" to the hospital where no response is expected. This is followed in stages by the request for a statement, a meeting, an inspection and an agreement on objectives. At any point of these escalating measures, the LQS can declare the structured dialogue as terminated if, in its opinion, the desired effect has already occurred. If a hospital refuses to participate in the structured dialogue, does not fulfil the target agreement or does not meet its obligation to transfer data ("substantial documentation deficiencies"), it is reported to the steering committee or, in the case of direct procedures, to the Quality Assurance Subcommittee of the Federal Joint Committee. The sanctions following failure of the structured dialogue are not specified in the directive. Only sanctions for documentation deficiencies are specified as so-called "quality assurance penalties", which can range from €150 to €5,000 per case, depending on the procedure and severity of the deficiency.

Quality assurance in hospitals and in the LQS at the state level is funded via a so-called quality assurance surcharge, which is levied from the cost-bearers in every inpatient case.

5.2.6.5 Quality report

IQTIG's current Quality Report from 2018 presents the results of the external quality assurance from 2017 and the results of the structured dialogue from 2016 [96]. In 26 different quality assurance procedures (24 inpatient and 2 intersectoral), about 25 % of all inpatient services were examined. For the 24 inpatient quality assurance procedures, 1516 hospitals transmitted about 2.5 million data sets, for the 2 cross-sectoral quality assurance procedures, 273 SHI-accredited medical practices or medical care centers and 1063 hospital sites transmitted about 0.8 million data sets, i.e. a

total of about 3.3 million data sets were acquired. In 4 % of the quality indicators collected in these procedures, a "special need for action" was identified due to "pronounced or continuing quality deficits".

The results of the structured dialogue relate to the year 2016. 116 163 results, i.e. the total number of procedures evaluated at all sites, were calculated from 2 482 141 data records submitted. Of these, 12 683 (10.9 %) were arithmetically significant. Of these, 7 607 (60 %) were reviewed in a structured dialogue, and for most of the remaining 40 % a note was sent. 1611 data sets were classified as qualitatively conspicuous after examination by LQS. This is 12.7 % of the mathematically conspicuous results or 1.0 % of all calculated results. The remaining results were rated as inconspicuous or could not be assessed due to poor documentation. 7607 statements were subsequently requested, 275 meetings were held, 13 inspections were carried out and 742 agreements were made.

5.2.6.6 External outpatient quality assurance

There is currently only one external quality assurance procedure for the outpatient sector. This refers to dialysis (Quality Assurance Directive Dialysis/QSD-RL) [97]. In the future, the outpatient procedure according to QSD-RL will be transferred to the new intersectoral "Procedure 4: Renal replacement therapy for chronic renal failure including pancreatic transplantation" according to NET-RL.

5.2.6.7 Secondary data use

For the purpose of research or the further development of quality assurance, third parties may use data from the data-based quality assurance upon request to the IQTIG.

5.2.6.8 Quality indicators for hospital planning (planQI-RL)

In 2016, the Hospital Structure Act (KHSG) stipulated for the first time that the quality of the services provided by a hospital should play a role in hospital planning. To this end, the Federal Joint Committee was commissioned to develop and apply quality indicators in order to provide political decision-making bodies at state level with decision-making aids for hospital planning through the resulting evaluation. However, the states are not obliged to apply these criteria, i.e. they can also be excluded by state law. Currently, Bavaria, North Rhine-Westphalia, Rhineland-Palatinate, Mecklenburg-Western Pomerania, Lower Saxony, Hessen and Baden-Württemberg have made use of this opt-out option; Thuringia intends to do so (see 5.12.2). This has been sharply criticized by the chairman of the Federal Joint Committee, Prof. Josef Hecken [98]. The procedure is laid down in the guideline on planning-relevant quality indicators (planQI-RL) [99]. In view of the scope of the procedure, special emphasis was placed on the selection of relevant, meaningful quality indicators. In contrast to external quality assurance according to the QSKH-RL, the data sets are evaluated directly by IQTIG nationwide. Computationally conspicuous results, i.e. results that lie outside the previously defined reference range, are checked to see whether they are also statistically significant. In this case, a commenting procedure is initiated and at the same time the LQS is asked whether there are results from a previous structured dialogue for the hospital concerned. The statement of the hospital and, if applicable, the response of the LQS are evaluated by an expert committee at IQTIG – which consists of pooled, appointed members of the expert groups established at the LQS -, in response to the question of whether an "exceptional case" exists that would avoid a negative evaluation. If this is not the case, the hospital is certified as having a "qualitatively inadequate performance" for the tested service. The hospital must publish this in its annual quality report. At the same time, the state authorities responsible for hospital planning and the state associations of the health insurance funds are informed, and the statement submitted by the hospital is forwarded. Furthermore, the nationwide results are published by the G-BA. At present, this procedure is already being applied in the 3 areas of gynecological operations, obstetrics and breast surgery, with evaluation of 11 quality indicators. The first report was published in 2018 [100]. As a result, some of the hospitals concerned have discontinued services that were assessed as "qualitatively insufficient" [101].

The AWMF is critical of the legal provisions for planning-relevant quality indicators and quality-based remuneration (see next section) in their current form [102] (see discussion 5.12).

5.2.6.9 Quality-based remuneration

The Federal Joint Committee was commissioned by the legislature to identify service areas with appropriate quality indicators for which hospitals and health insurance funds can agree performance bonuses for particularly good quality and performance discounts for insufficient quality. Here too, IQTIG is to play a central role. Such performance areas and quality indicators have not yet been identified. Only the performance bonuses to be claimed for participation in cross-institutional error reporting systems (CIRS, see 5.2.5.5) can be classified as a kind of quality-related remuneration (see discussion 5.2.6.9).

5.2.6.10 Quality control and assessment in the outpatient sector (QP-RL)

In accordance with Guideline QP-RL, the examination of the quality of office-based SHI-accredited physicians in the fields of radiological diagnostics and computed tomography, magnetic resonance imaging and arthroscopy is carried out by the Associations of Statutory Health Insurance Physicians (KV) by means of spot checks. In doing so, the panel physicians must submit complete documentation of the above-mentioned areas for review, which is laid down in individual directives. In the case of arthroscopy, for example, the endoscopic findings must be fully documented before and after therapeutic intervention. The KVs transmit the results of their examinations annually to the Federal Association of Statutory Health Insurance Physicians (KBV), which in turn summarizes them in a report to the Joint Federal Committee.

Since the QP-RL has just been fundamentally revised due to a court decision concerning the lack of pseudonymization of patient identification and the guidelines for the three areas mentioned above have not yet been adapted, the spot check has been suspended since the second quarter of 2019 [103].

5.2.7 Section 3: Other areas of quality assurance

5.2.7.1 Quality controls by the Medical Service of the Health Insurance Funds (MDK)

Under the Hospital Structure Act (KHSG), the MDK has been commissioned by the Federal Joint Committee to carry out any inspec-

tions of hospitals that may be necessary in quality assurance procedures. The procedure is regulated by the MDK quality control guideline (MDK-QK-RL) [104] of the Federal Joint Committee. It is used to check compliance with quality requirements and correct documentation and can be initiated directly by the G-BA, or the committees concerned with quality assurance at federal and state level or the health insurance funds. The MDK may be commissioned to carry out quality control in the context of external quality assurance procedures or the collection of quality indicators in similar procedures, as a consequence of anomalies in the quality report or in the accounting to the health insurance funds, or of documentation deficiencies or serious, possibly repeated references from third parties such as insured persons. The procedure is usually carried out as an announced on-site inspection. In well-founded exceptional cases, it can also be carried out as an unannounced on-site inspection, or in writing if it is of less importance. The hospital has an obligation to cooperate. The MDK issues the results as a control report to the commissioning body. If it discovers grave, e.g. life-threatening, quality defects, it is obliged to notify not only the ordering party but also third parties (responsible health authorities of the states and municipal health authorities) immediately. At the same time, reports and notifications are always sent to the hospital concerned.

5.2.7.2 Regulations of consequences in case of non-compliance with quality specifications (QFD-RL)

According to §137 SGB V, the G-BA is charged with developing a system of consequences of non-compliance with quality requirements. This system is to include, in an increasing chain of escalation, "remuneration deductions, the discontinuation of the right to remuneration for services for which minimum requirements are not met, information to third parties about the violations and the institution-related publication of information on non-compliance with quality requirements". The mandate also includes the requirement that the "measures are to be designed and applied in a proportionate manner". To this end, the Federal Joint Committee adopted a general Quality Promotion and Enforcement Guideline (QFD-RL) [105] in 2019. The enforcement section, which includes the above-mentioned consequences, is preceded by a support section. In the event of quality deficiencies, the first step is to attempt to eliminate the quality deficiencies by means of a written agreement on participation in measures. The following 12 measures are mentioned in the guideline: "1. written recommendation, 2. agreement on objectives, 3. participation in suitable further training, technical discussions, colloquia, 4. participation in quality circles, 5. participation in audits, 6. inspections/visits, 7. participation in peer reviews, 8. implementation of specifications for internal quality management, 9. implementation of treatment pathways, 10. implementation of standard operating procedures (SOPs), 11. implementation of recommendations for action on the basis of guidelines and 12. review of evaluation results during the year". According to the Federal Joint Committee, the implementation of this general guideline depends on the implementation in the topic-specific guidelines and therefore only comes into force when this step has been taken.

5.2.7.3 Service areas for testing quality contracts

Pursuant to § 136b, Subsection 1, Sentence 1, No. 4, SGB V, the G-BA has the mandate to designate 4 areas for which hospitals and health insurance funds can conclude fixed-term contracts with an incentive system for special quality requirements. According to its own statement, the G-BA has selected one area with recognizable potential for improvement, endoprosthetic joint care, and 3 areas with "particularly vulnerable patients", namely "prevention of postoperative delirium in the care of elderly patients, respiratory cessation in long-term ventilated patients, and the care of people with mental retardation or severe multiple disabilities in hospital" [106]. Neither the G-BA, the DKG nor the National Association of Statutory Health Insurance Funds have provided any information on specific contracts.

5.2.8 Other subject areas and subcommittees of the G-BA

All other subcommittees of the Federal Joint Committee (see 5.2.1) also deal with topics that at least implicitly have quality aspects, since in addition to the economic efficiency requirement according to §12 Social Code, Book V, the claim to a qualitatively good service that incorporates medical progress should always be considered, in accordance with §2 Social Code, Book V.

5.2.8.1 Early benefit assessment

The best-known subcommittee of the G-BA is the subcommittee on medicinal products and in particular on the "early benefit assessment" of new drugs on the basis of §35a SGB V (Social Code, Book V) and the Law on the Reorganization of the Pharmaceutical Market (AMNOG) of 2011. In the evaluation of the benefit of new drugs, in which the "Institute for Quality and Efficiency in Health Care" (IQWIG) is intensively involved, the four aspects of morbidity, mortality, adverse drug reactions and quality of life – as the most valid form of a Patient Reported Outcome (PRO, see 3.4) – are taken into account. The last point in particular is the subject of intensive discussions, as the pharmaceutical industry and third parties question the insistence on quality of life measured with validated instruments while other PRO methods such as subjective patient benefit assessments, pain scales, etc. are presented as equivalent [107]. In a recent statement, the AWMF criticized the fact that drugs for chronic diseases are rated worse than drugs for patients with diseases with short life expectancy and orphan drugs. A "stronger consideration of morbidity parameters for chronic diseases" would be necessary. In contrast, the "sensitive, comprehensive recording of quality of life changes in all approval studies" is explicitly supported [108] (see also 5.4.2 and [109]).

5.2.8.2 Trial guideline for tonsillotomy

In 2018, the Subcommittee on Methods Evaluation adopted the "Guideline for the Testing of Tonsillotomy in Recurrent Acute Tonsillitis" (ErpRL Tonsillotomy) [110], in which a multi-center study was commissioned to compare the effectiveness and side effects of tonsillotomy and tonsillectomy in recurrent acute tonsillitis. It is argued that tonsillotomy has the potential to be a treatment alternative to tonsillectomy if "the periprocedural strain is reduced compared to tonsillectomy", but that there is currently not enough data available for a definitive evaluation of this question.

5.3 IQTIG – Institute for Quality and Transparency in Health Care

Of the two institutes that are affiliated with the Federal Joint Committee, the Institute for Quality and Transparency in Health Care (IQTIG) is the more important in quality issues.

5.3.1 Organization

The Statutory Health Insurance Financial Structure and Quality Development Act (GKV-FQWG) came into force on 1 January 2015 and introduced §137a [111] into the Social Code Book V (SGB V). This lead to the foundation of the IQTIG as a professionally independent scientific institute. The Federal Joint Committee was commissioned to carry out the project and to establish a foundation under private law for this purpose, which is the founder and responsible body of the Institute. The committees of the foundation and IQTIG are composed equally of representatives of the service providers and the health insurance funds.

IQTIG took over the tasks of the private AQUA Institute [112], which it succeeded on January 1st, 2016.

5.3.2 Tasks

IQTIG's tasks have already been described in detail in some cases in the previous sections (see 5.2.4). The Institute summarizes the legal text according to §135a, paragraph 3, SGB V, which describes the tasks of the IQTIG as follows:

- *"Development of quality assurance instruments, presentation of the quality of care in the health care system and participation in its implementation – on behalf of the GBA.*
- *Continuation and further development of existing quality assurance procedures.*
- *Development and implementation of procedures to better integrate external quality assurance in inpatient and outpatient care. At the same time, IQTIG is developing methodological fundamentals on behalf of the G-BA to enable the state authorities to take the quality of care in hospitals into account in hospital planning.*
- *Creation of criteria for the evaluation of certificates and quality seals in the outpatient and inpatient sectors.*
- *Publication of the results of work in a form comprehensible to the general public. This also includes the creation of an Internet site which should enable patients to compare hospitals with regard to their quality.*
- *According to the Hospital Structure Act, IQTIG's tasks include the development of concepts for*
  - *Quality indicators relevant to planning,*
  - *Premiums and deductions in the quality-oriented remuneration and*
  - *The evaluation of quality contracts according to § 110a SGBV"* [113].

The legislator explicitly stipulates that "in the development of the contents" all relevant representatives of the German health care system must be involved (§ 137a, paragraph 7, SGB V). In addition to direct participation in procedures of external quality assurance, demand planning and quality-related remuneration, another important task of the IQTIG is to further develop the methods for the above-mentioned applications on a scientific basis. This is an iterative process in which a draft of IQTIG is sent to the organizations entitled to comment, which are then revised on the basis of these comments and sent again for comments [14, 114–118].

A special aspect of IQTIG's work is the development of instruments for patient surveys, which should incorporate the perspective of the "patient reported outcome" (PRO, see 3.4) into the quality assessment. In the description of the "methodological principles", PROs are differentiated into "PROM" (patient reported outcome measures) and "PREM" (patient reported experience measures) [14], i.e. they are not instruments for the standardized assessment of quality of life (QoL, see 3.4). These patient surveys already exist for the areas of cardiac catheters/stents and schizophrenia, and are currently being developed for the areas of renal replacement therapy and outpatient psychotherapy.

IQTIG fulfils its publication obligations through a series of publications, e.g. the Quality Report [96] (see 5.2.6.5), the Federal Evaluation, the Federal Quality Report, the Structured Dialogue Report, the Data Validation Report, the Structured Quality Report, the validation procedure NICU (Neonatal Intensive Care Unit), development reports, evaluation reports, special evaluations and finally its annual activity report [119].

5.4 IQWIG – Institute for Quality and Efficiency in Health Care

The Institute for Quality and Efficiency in Health Care (IQWIG) is a so-called HTA (Health Technology Assessment) institute [120]. After HTA institutes had existed for more than 10 years in other European countries, especially Scandinavia, IQWIG was founded in Germany in 2004.

5.4.1 Organization

On the basis of the SHI Modernization Act (see 5.1.1) and the resulting § 139a, § 139b, § 139c Social Code Book V, a foundation of the same name was established in 2004 with the mandate to establish IQWIG. The Executive Board consists of five members, one of whom is provided by the Federal Ministry of Health, two by the umbrella organization SHI, and one each by KBV and DKG. The Board is supervised by the Foundation Board, which is composed of equal numbers of representatives of the service providers and the National Association of Statutory Health Insurance Funds. In addition to the Scientific Advisory Board, the Executive Board is assisted by a Board of Trustees, which includes representatives of direct stakeholders in the health care system as well as representatives of social groups and the pharmaceutical industry. The Board of Trustees can submit comments on IQWIG's decisions. The Institute is managed by the chair and his or her deputy, who are supported by so-called staff departments. The "reporting departments" in the areas of drug evaluation, non-drug procedures, health care and health economics, and medical biometry provide the basis for IQWIG's recommendations.

5.4.2 Tasks

Since its foundation, the current range of tasks has been continuously expanded and modified by a series of laws and regulations. In general, IQWIG's task is to review and evaluate the advantages and disadvantages of medical services as objectively as possible, using the methodology of evidence-based medicine.

IQWIG is commissioned to do this by the Federal Joint Committee or the Federal Ministry of Health; it can also act on its own initiative or at the suggestion of the general public. The Institute forwards assessments that it has prepared on behalf of the G-BA to the G-BA as recommendations, which the G-BA is required by law to take into account in its decision-making. The subject of the assessment includes drugs, and non-drug methods of treatment, such as surgical procedures, screening procedures and disease management programs (DMPs). The Institute also produces evidence-based health information for laypersons. The exact procedure is published in a methods paper version 5.0 [121].

In the legal text, the tasks in § 139a SGB V are described in detail:

- *"Research, presentation and evaluation of the current state of medical knowledge on diagnostic and therapeutic procedures for selected diseases,*
- *Preparation of scientific elaborations, expert opinions and statements on questions of quality and efficiency of the services provided within the framework of the statutory health insurance, taking into account age, gender and life situation specific characteristics,*
- *Evaluations of evidence-based guidelines for the epidemiologically most important diseases,*
- *Making recommendations on disease management programs, assessing the benefits and costs of drugs, providing general information on the quality and efficiency of health care and on the diagnosis and treatment of diseases of major epidemiological importance in a way that is comprehensible to all citizens,*
- *Participation in international projects for cooperation and further development in the field of evidence-based medicine".*

The SHI Competition Reinforcement Act of 2007 (GKV-WSG, see 5.1.2) introduced the cost-benefit assessment (KNB) for drugs according to §35b SGB V. With the help of international experts, IQWIG developed the instrument "Analysis of the efficiency threshold" [122], which made it possible to estimate appropriate prices for new drugs with additional benefits. The Drug Market Restructuring Act (AMNOG, see 5.1.4) in 2011 shifted pricing to a new procedure, the so-called "early benefit assessment". Since then, the KNB has been a reserve procedure if no agreement can be reached in the new procedure. In the early benefit assessment according to §35a SGB V, IQWIG is commissioned by the G-BA to scientifically evaluate the dossiers that the manufacturer is obliged to submit for the desired market launch. The additional benefit described therein has a direct effect on the pricing negotiations at the G-BA (see 5.2.8.1). In a press release of 11.07.2019, the Institute points out that since the introduction of the procedure, no additional benefit has been demonstrated in about half of the 216 dossiers analyzed for the launch of new drugs, mostly due to methodological weaknesses. This result was published in the BMJ [109].

The SHI Care Structure Act (GKV-VStG, see 5.1.5) introduced "trial regulation" according to §137e SGB V in 2012. It states that the G-BA can approve new examination and treatment methods that have the "potential of a required treatment alternative" by means of a testing guideline – combined with clinical studies – in order to be able to obtain the necessary findings for a benefit assessment. IGWIG is commissioned to evaluate the applications of manufacturers for this procedure (so-called potentials evaluation). The SHI Care Improvement Act (GKV-VSG, see 5.1.8) introduced the evaluation of new examination and treatment methods (NUB) for "medical devices of high-risk classes" in 2015 by § 137h SGB V. This applies to methods that pursue a new theoretical scientific concept, have a particularly invasive character, and for which reimbursement according to §6 of the Hospital Fee Act (NUB procedure) is applied for. In this case, IQWIG is also commissioned by the G-BA to assess the potential of the applications of manufacturers and hospitals.

In our field of expertise, for example, implantable hypoglossic nerve stimulators for sleep apnea are subject to the NUB procedure.

The procedure for the right of individuals to propose research topics (so-called HTA procedure) and IQWIG's participation in international scientific organizations were also regulated by the law.

5.5. BÄK – German Medical Association and LÄK – State Medical Associations

The German Medical Association (Bundesärztekammer, BÄK) is not a public corporation, but a working group of the 17 state medical associations, which in turn are public corporations [123].

5.5.1 German Medical Association (Bundesärztekammer)

The BÄK is the umbrella organization of physicians' self-governance and as such represents the professional political interests of physicians in Germany, thereby exerting influence on the health policy opinion-forming process of society. The German Medical Assembly (Deutscher Ärztetag) is the annual general meeting of the BÄK.

The activities of the BÄK relate in many aspects to quality in the health care system, which are mainly coordinated by its "Quality Assurance Committee" and, together with the LÄK, the "Standing Conference on Quality Assurance".

As a body entitled to comment, the BÄK participates intensively in procedures that are the responsibility of the G-BA, or comments on IQTIG and IQWIG papers or drafts of the legislature. Through the Drug Commission of the Medical Profession (AkdÄ), the BÄK is involved in the early benefit assessment procedure according to AMNOG (see 5.2.8.1) and is a member of IQWIG's Board of Trustees. The BÄK also actively promotes health services research. In addition, the BÄK maintains the "Database of medical quality assurance initiatives" (ÄQSI, see 6.10) and thus supports voluntary quality initiatives, which also include the promotion of the medical peer review procedure.

Through special legal regulations, the BÄK has guideline competence in determining the current state of the art of medical science in the field of transplantation medicine (§16 TPG) and transfusion medicine (§18 TFG) and is involved in the fields of radiology and laboratory medicine. Ethical guidelines are established by the ethics committee of the BÄK, but also in the Model Professional Code of Conduct [124], which is preceded by the Geneva Declaration (see 2.2).

On a cross-organizational level, the BÄK is involved in the "Medical Center for Quality in Medicine" (ÄZQ), in the "Patient Safety Alliance" (APS [125]) and until 2019 as a shareholder in the "Cooperation for Transparency and Quality in Health Care" (KTQ, see 4.2). In this context, "patient safety", "Program for National Health

Care Guidelines" and the curriculum "Advanced Training for Quality Assurance" are named as focal points.

5.5.2 ÄZQ – Medical Center for Quality in Medicine

The Medical Center for Quality in MedicineQ (Ärztliches Zentrum für Qualität in der Medizin, ÄZQ) is jointly supported by the BÄK and the National Association of Statutory Health Insurance Physicians (KBV). It was founded in 1995 as the "Central Office of the German Medical Association for Quality Assurance in Medicine" („Zentralstelle der deutschen Ärzteschaft zur Qualitätssicherung in der Medizin") and was renamed in 2003. The task of the ÄZQ is to support the BÄK and KBV in their efforts in the field of quality assurance of medical professional practice. The objectives for quality improvement in the health care system as defined in the mission statement are

- Quality assurance/quality management (QA/QM) across all areas of care
- Further development of QA/QM in line with the requirements
- Setting priorities
- Getting it right: Integrating guidelines and principles of evidence-based medicine into care
- Involving the patient
- Creating appropriate personnel and organizational structures for QA/QM
- Further professionalization in the field of QA/QM
- Further development of QA/QM in cooperation with all parties involved

The principles of the Institute's work are evidence-based medicine, patient safety, patient orientation and transparency [126].

The ÄZQ designates 4 main areas of activity: Medical guidelines, patient information, patient safety and error prevention, and finally quality development in medicine. In addition, the ÄZQ offers a comprehensive training program and is linked internationally with partner organizations.

In the field of guidelines, cooperation with the AWMF has been established to produce so-called "National Health Care Guidelines" (Nationale Versorgungsleitlinien, NVL). These are intended to support integrated care as cross-sectoral guidelines on high prevalence diseases. Currently, 7 NVLs have been completed for asthma, COPD, CHD, heart failure, lower back pain, depression, diabetes, and the eighth for hypertension will follow soon [127]. According to the BÄK, the NVLs are "a concept based solely on medical expertise and scientific evidence, with explicit inclusion of the areas of prevention and rehabilitation" in "distinction to statutory treatment programs according to § 137f SGB V (i.e. DMPs)" [128].

Furthermore, in the same cooperation, the ÄZQ has developed the German guideline evaluation instrument (DELBI), which can be used in parallel to the internationally used AGREE II for the clearing of guidelines. Since its foundation, the IQWIG has assumed responsibility for guideline clearing.

For patient information, the website "Patienten-Information.de" is available with a wide range of information that can be understood by laypersons.

In addition to detailed information on patient safety and error management, the ÄZQ has been operating the "CIRSmedical.de network" since 2005, which as an umbrella organization that brings together the largest and most important specialist, supraregional or regional error reporting systems (CIRS, see 5.2.5.5) and currently networks 126 hospitals [129].

Finally, the ÄZQ offers a comprehensive information and training program for quality management concepts, e.g. in outpatient care (Q-M-A).

5.5.3 State Medical Assoziation

The State Medical Associations (Landesärztekammer, LÄK) are primarily responsible for the quality assurance of the physicians organized in them. For this purpose, binding regulations for professional conduct, specialist training and continuous medical education are drawn up, which regulate not only the physician's practice but also his professional qualifications. The specialist training regulations are adapted in a continuous process to the development of medical progress and the medical profession. Continuous medical education is guaranteed by the award of certificates upon proof of attendance at certified continuous medical education events. The basis for this is § 95d for SHI-accredited physicians and § 136 b SGB V for hospital physicians.

In addition, all LÄK operate quality projects on their own initiative and are involved in committees for external quality assurance at state level (e.g. LAG, see 5.2.6.3; LQS, see 5.2.6.4).

5.6 AWMF – Association of the Scientific Medical Societies in Germany

The Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V., AWMF) comprises 179 medical societies (and 3 associated societies) from all areas of medicine. The AWMF was founded in 1962, initiated by the German Society of Surgery, with initially 16 members in Frankfurt in order to better represent common interests vis-à-vis the legislator and organs of medical self-governance. Organs of the AWMF are the delegates' conference and the executive committee. If necessary, ad-hoc commissions are formed from the delegates and, if necessary, experts from the member societies. The AWMF has established 2 permanent interdisciplinary working groups (physicians and lawyers, hospital and practice hygiene), operates the "AWMF Institute for Medical Knowledge Management (AWMF-IMWi)" and publishes the journals "German Medical Science" (GMS), "Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen" (ZEFQ, co-editor) and "Hygiene und Medizin" (via the working group Hospital and Practice Hygiene).

The AWMF describes its objectives as follows:

"The AWMF advises on fundamental and interdisciplinary issues in scientific medicine, promotes the cooperation of its member societies in the performance of their scientific-medical tasks and objectives, and the transfer of scientific findings into medical practice. Furthermore, in cooperation with other medical organizations, it represents the interests of scientific medicine vis-à-vis the responsible political bodies and the public, strives for close cooperation with comparable organizations and thus represents an important pillar in the medical organization of Germany"[130].

Important activities concern:

- Publication of the medical guidelines of the medical societies
- Collaboration on the National Health Care Guidelines
- Participation in the Oncology Guidelines Program
- Training, advanced training and continuous education in medicine
- Interdisciplinary cooperation of the specialities
- Collaboration on classification systems in medicine (e.g. ICD, OPS)
- Accessibility of scientific literature

The AWMF is directly involved in specific committees of self-governance in the health care system (e.g. the Board of Trustees of IQWIG) and is entitled to make comments to the Federal Joint Committee on the methods and development of quality indicators by IQTIG and on disease management programs. The AWMF cooperates with the BÄK and KBV (via the ÄZQ, see 5.5.2), with the German Cancer Society and German Cancer Aid and with the German Network for Health Services Research (DNVF).

The AWMF comments on quality management as follows:

"High-quality guidelines and the indicators for process quality derived from them, surveys of citizens, patients, staff and external co-suppliers, readable quality explanations, medically oriented certifications and benchmark techniques ("learning from the good") are among other quality management instruments that are co-developed, taught and used by the scientific medical societies. The AWMF sees further important tasks in the implementation and evaluation of medical quality management"[131].

The AWMF is thus much more than the institution that provides the professional and organizational framework for medical guidelines, even though this is a very important task for ensuring quality of treatment that is totally or partially specific to a particular field: It is the distilled expertise of the German medical profession. It is an important integrating actor that uses the expert knowledge of the member societies for scientific and health care policy issues – and thus also for quality in the health care system. The AWMF has an important, critical voice in health policy and contributes to the political and professional development of the health care system through its statements, some of which it is legally authorized to make.

5.7 KBV – National Association of Statutory Health Insurance Physicians and KV – Associations of Statutory Health Insurance Physicians

The National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KBV) is a public corporation and the umbrella organization of 17 Associations of Statutory Health Insurance Physicians (Kassenärztliche Vereinigungen, KV). Its tasks cover 3 areas: Representation of the interests of the currently approximately 172 000 freelance doctors and psychotherapists in dealing with the statutory health insurance funds and in health policy matters, ensuring outpatient medical care for the insured and cooperation in the planning and design of care.

The KBV and, at the state level, the KV, are firmly anchored in the system of statutory quality assurance and, together with representatives of the German Hospital Federation (DKG), represent the interests of the so-called service providers. They occupy positions on committees of the G-BA, IQTIG, IQWIG and the LAG. The possibility of being involved in decision-making in these committees gives them great scope for shaping quality aspects in health policy.

In addition to "Reporting on the implementation status of quality management in SHI-accredited physicians' practices, SHI-accredited psychotherapists' practices and medical care centers (MVZs)" according to the quality management guideline of the G-BA (QM-RL, see 5.2.5.1, 5.2.6.2), the implementation of quality assurance measures (according to §135 para. 2, §135 para. 1 and §135b para. 2 SGB V) are the central task of the KVs in the area of quality assurance and patient orientation.

As a result of these regulations, a continuously growing number of service areas have been placed under a licensing requirement. In 2018, these were a total of 52 service areas, 5 of which were disease management programs. In otolaryngology, the service areas "Hearing Aid Care" and "Hearing Aid Care (Children)" are relevant. When an application for a license is made, the KV, with the support of the quality assurance commission set up at the KV, checks whether the conditions for the license are met, both in terms of the applicant's professional qualifications and other characteristics of the structural quality of his practice. According to the "Quality Report 2018", in 2017, "283 218 licenses for various service areas and an additional 38 357 licenses for psychotherapy were granted with the participation of 3199 members of the quality commissions". The continued existence of the conditions for licensing will be subsequently examined through various procedures. As a result of these reviews, "In a total of 410 cases … the license was revoked" [132].

Furthermore, the KVs support and promote quality circles that are not limited to one practice and are described in the KBV quality assurance guidelines as a recognized quality instrument. Continuous medical education points can be earned by participating in certified quality circles.

Finally, the KVs offer a quality management system for practices and MVZs, the "QEP – Quality and Development in Practices" (see 4.6).

5.8 DKG – German Hospital Federation and LKG – State Hospital Association

The German Hospital Federation (Deutsche Krankenhausgesellschaft e.V., DKG) is the umbrella organization of hospital owners, i.e. of a total of 28 member associations, 16 of which are state hospital associations and 12 central associations such as the "Association of German University Hospitals" (Verband der Universitätsklinika Deutschlands, VUD) [133].

The DKG represents the interests of its member associations in the system of legally prescribed quality assurance and, together with representatives of the National Association of Statutory Health Insurance Physicians (KBV), represents the interests of so-called service providers. It fills positions in committees of the G-BA, IQTIG, IQWIG and the LAG. The possibility of being involved in decision-making in these committees gives it great scope for shaping quality aspects in health policy.

The state offices for quality assurance (LQS, [95]), which play a central role in inpatient quality assurance according to the QSKH-RL, are assigned to the state hospital associations (see 5.2.6.4).

Furthermore, the DKG conducts active public relations work to present the positions of its members as the "voice of the hospitals" in current health policy discussions. In the recent position paper "Patient Welfare and Services of General Interest", the following points are highlighted among others:

1. Strengthen quality, create transparency,
2. Supporting staff, countering the shortage of skilled workers,
3. More time for the patient, cutting bureaucracy,
4. Financing investments sustainably, enabling modern structures
5. Accelerating digitization, expanding eHealth,
6. Strengthening innovation, ensuring medical progress [134].

5.9 GKV-SV – Central Association of Statutory Health Insurance Funds

The Central Association of Statutory Health Insurance Funds (Spitzenverband GKV, GKV-SV) is a public corporation whose members are all statutory health insurance funds [135]. It regards itself as the central representation of the interests of all health and nursing care insurance funds. In organizational terms, it consists of a general meeting, administrative board and executive board, to which a specialist advisory board is assigned. According to its own statement, the goal of the umbrella association of statutory health insurance funds is "to shape the framework conditions for intensive competition for quality and efficiency in health and nursing care".

The GKV-SV and the state associations of the health insurance funds are the counterbalance to the so-called service providers in the system of legally obligatory external quality assurance as the cost-bearers. They usually send an equal number of representatives to the committees of the Federal Joint Committee, IQTIG, IQWIG and the LAG or LQS. Through the possibility of participating in decision-making in these bodies, they have considerable influence on the design of health policy, including its quality dimensions.

With regard to quality assurance in the health insurance sector, the Central Association of Statutory Health Insurance Funds names 6 areas: minimum volume regulation (see 5.2.5.4), quality reports by hospitals (see 5.2.6.1), financial support for clinical cancer registries, cross-institutional quality assurance for preventive and rehabilitation facilities, physicians' work processes and G-BA guidelines for SHI-accredited physicians (see 5.7, KV-based outpatient quality assurance) and a study on the quality of outcomes in midwives and birth centers.

Finally, the GKV-SV conducts active public relations work in order to take a stand on current health policy issues in its capacity as "advocate of the contributors".

5.10 MDK – Medical Service of Health Insurance

The Medical Service of Health Insurance (Medizinischer Dienst der Krankenversicherung, MDK) is the socio-medical and nursing advice and assessment service for statutory health and nursing insurance funds [136]. There are 15 MDKs, some of which operate across federal states, and a "Medical Service of the National Association of Health Insurance Funds" (Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen, MDS), which coordinates the work of the MDKs and supports them, for example, by issuing guidelines for a uniform assessment [137]. The MDKs and MDS together form the so-called MDK Community.

A total of four centers of excellence support the MDK Community in the fields of geriatrics, oncology, psychiatry and psychotherapy, as well as quality assurance and quality management (KCQ). The latter center of excellence is located at the MDK Baden-Württemberg. It sees its role primarily in the scientific systemic consulting of the MDK community [138]. Furthermore, 6 socio-medical expert groups (SEG) support the MDK community on issues of nationwide assessments of consistency.

The MDK is financed on the basis of § 281 para. 1 SGB V by a levy on the health and nursing care insurance funds.

Its mission is to ensure that health and nursing insurance are beneficial to all insured persons on equal terms and conditions according to objective medical criteria. In accordance with the essential regulation in paragraphs §2, §12 and §70 of the SGB V – the principle of economic efficiency and the right to benefits in accordance with the generally accepted state of medical knowledge (see 5.1) -, the MDK decides which benefits are necessary for the care of the insured.

In its publication "Figures, Data, Facts 2018", the MDS/MDK reports a total of 5 729 000 social-medical recommendations for the health insurance funds for the reporting year 2018, the largest item being 2 580 000 hospital bill audits, which corresponds to an audit quota of approx. 17 %. There are intensive discussions on the scope of these audits and the amount of work they demand from hospitals. The lowest number of recommendations was 14 000 for the item "treatment errors" [139]. According to the MDK-QK-RL of the Federal Joint Committee, the MDK is responsible for carrying out on-site inspections of hospitals as part of the external quality assurance of hospitals (see 5.2.7.1).

The Federal Ministry of Health is currently preparing legislation that will drastically reconfigure the MDK (MDK Reform Act).

5.11 SVR Gesundheit – Expert Council on Health

The Advisory Council for the Evaluation of Developments in the Health Care System (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen, SVR Gesundheit) exists on the basis of §142 SGB V and its members are appointed for 4 years by the Federal Minister of Health. It has the task of submitting an expert opinion every 2 years in order

- *"to analyze the development in health care with its medical and economic effects,*
- *to develop priorities for the reduction of supply deficits and existing overprovision, taking into account the financial framework conditions and existing efficiency reserves,*
- *to submit proposals for medical and economic orientation data, and*
- *to show possibilities and ways to further develop the health care system"* [140].

In its current report and in statements and press releases, the SRV Gesundheit argues that a significant restructuring of the hospital landscape is necessary, which was currently characterized by both over- and underprovision [141, 142] (see also 8.1.6).

5.12 Discussion – how to measure quality?

Over the past 15 years, the legislature and the Federal Joint Committee and its institutes have developed an increasingly differentiated and complex system of external quality assurance. The physicians' institutions of the joint self-governance contribute to external quality assurance by their participation in committees. Apart from this, they have taken on other important tasks, some – such as in transfusion medicine – date back to before the start of statutory quality assurance.

External quality assurance is based mainly on the evaluation of quality indicators relating to process quality and, to a lesser extent, specifications for structural quality (equipment and qualification). These two quality dimensions are easier to measure than the quality of outcomes, which can often only be measured across sectors and contains both objective and subjective elements.

5.12.1 Quality indicators in external inpatient quality assurance (according to the QSKH-RL)

With regard to the statutory external quality assurance, the AWMF states that it is incomplete, including the quality indicators used, because it only covers small sub-sectors. Therefore, it could not make a statement about the entire health care system. It demands that it be extended to all hospital areas [143]. Furthermore, in a statement on IQTIG's position paper, the AWMF criticizes the fact that the "tracer concept" (= quality indicators) is still exclusively used to assess quality. However, there was no evidence that this could be used to draw conclusions about the quality of an entire organization. Apart from the consideration of the "micro level" of direct service provision (through quality indicators), the "meso level"(the hospital) and the "macro level" (the health care system) should also be included. The meso-level included institution-related requirements such as leadership, staff orientation and internal quality management, while the macro-level included, for example, ensuring equity of care. If, however, the tracer concept pursued by IQTIG were to be maintained, and if the focus were not placed on the internal structures and quality management of the institutions providing patient care, an organizational culture oriented towards patient centricity could not succeed [102]. In essence, the AWMF thus demands that legal quality assurance be expanded in the direction of an accreditation system (!).

The BÄK agrees with the criticism. The quality indicators used in external quality assurance would often not be able to identify real quality deficiencies. For this reason, new instruments would be developed by IQTIG including patient surveys, use of billing data and random facility inspections. The collection of long-term results beyond sectoral boundaries would be useful [144]. The German Society for Internal Medicine (DGIM) also demands this. It expects the preferred use of outcome parameters to have positive steering effects on service providers [145].

5.12.2 Quality indicators for hospital planning (planQI-RL)

Both the BÄK and the AWMF consider that the IQTIG approach is inadequate, as it only uses quality indicators from external quality assurance for inpatients. Other essential requirements would have to be considered, including interdepartmental improvements in patient safety, provision of basic care close to the patient's home and sufficient availability of qualified staff. With the increasing shift towards outpatient care and planning of cross-sectoral care, quality assurance would also have to be cross-sectoral. Adequate control could not be achieved by simply assessing the quality of structures, processes and, if necessary, outcomes; therefore, the planQI guideline was not a comprehensive, sustainable concept for quality-oriented hospital planning [144, 145] (see also 8.1.6). Eight federal states apparently share this view and have decided not to use this method for their hospital planning (see also 5.2.6.8).

5.12.3 Quality indicators for quality-related payment

Studies in other health care systems could not find a positive correlation between bonus payments and outcomes with regard to the effectiveness of quality-related pay increases or reductions, the so-called "pay for performance" (P4P) [146–149]. In contrast, P4P provides strong incentives for patient selection or patient misdirection [144].

5.12.4 Regulation of minimum quantities (Mindestmengenregelung [Mm-R])

Minimum quantities for cochlear implants have also been discussed in otolaryngology. They are generally highly controversial within the medical community. Before they are introduced, there should be clear evidence that differences in quality are related to quantity (e.g. [150, 151]). In the opinion of the BÄK, it was particularly problematic to equate a minimum quantity with quality and this might be a false incentive for a hospital to reach a threshold against the background of unbiased medical indications [144]. The BGM plans to extend minimum quantities and use them as an instrument of structural policy [152].

6 Internal and Cross-Institutional Quality Management

None of the above-mentioned mandatory legal and institutional regulations and voluntary certification, accreditation and excellence systems can directly generate quality in health organizations; they can only have a supporting or stimulating effect on the actors in immediate patient care. The actual quality of the treatment process is created anew every day as a result of the joint efforts of doctors and nurses, managers, those indirectly involved in health care, internal and external partners and the administration. The areas that have a relevant influence on this are listed below.

6.1 Leadership

The leadership is not only confronted with the challenge of the responsibility for organizing functioning processes with limited human and material resources, but also with the challenge of permanently adjusting and realigning the organization in a constantly changing environment.

The contribution of the leadership to quality management is considerable. Apart from exemplifying an attitude of integrity and the ability to inspire employees, quality management measures can neither be introduced nor sustainably maintained without the top-down support of the leadership. The introduction of a comprehensive quality management system is of great benefit to the leadership itself, as its application provides valuable information on

areas for improvement, the development of the entire organization and any necessary reorientation.

6.2 Quality management system

The function of a quality management system has already been described in detail in previous Chapters (see 4.2, 4.3, 4.4 and 5.2.5.1).

Its main function is to support all aspects of sustaining and improving the quality of an organization in a systematic way.

6.3 Objectives, results, and development

The goal-oriented development of an organization is considerably more difficult without defining goals, measuring the degree of target attainment at intervals and, if necessary, implementing corrections, i.e. applying the PDCA cycle. A high degree of implementation of this method can be found in the economic or business objectives of an organization, expressed, for example, in case-mix points and budget compliance. In the case of medical and patient-related goals, the degree of implementation and penetration of the PDCA method is much more heterogeneous and depends strongly on whether a quality management system is used. However, it is not any less helpful there than in managing economic parameters.

6.4 Research and innovation

The human mind is characterized by its ability to recognize; this is indeed one of its core qualities. The curiosity to understanding the world is the driving force for research, creativity and innovation.

In medicine, the interaction between academic research, clinical innovations and technological progress in industry benefit the quality of medical care, and thus the patients.

The rapid innovation of medical knowledge and thus its shortened period of validity period – as well as the continuous increase in its volume – render active knowledge management indispensable. This includes the transfer of knowledge to the next generation in student teaching and specialist training, as well as updating the state of knowledge through continuous medical education and its application in clinical practice.

6.5 Processes

6.5.1 Standardization of processes

Standardization is an effective means of avoiding errors and is therefore particularly useful in areas where errors can have serious consequences (e.g. in aviation). Processes can be well standardized if they always run the same way in principle, so that standardization can prevent undesirable deviations from an ideal process sequence:

- Processes covered by risk management
  - This includes, for example, the time-out before surgery in order to avoid confusion of patients, procedures and sides.
- Treatment processes
  - SOPs (Standard Operating Procedures), care standards, treatment paths, application of guidelines and, if available, EBM (Evidence Based Medicine) findings are intended to ensure consistent treatment quality in line with the current state of medical knowledge.
- Written instructions
  - Work instructions, procedural instructions and quality manuals describe processes in varying degrees of detail and define their sequence in a binding manner.

6.5.2 Process improvement

Processes can be improved in various ways, be it through ad-hoc quality circles and projects, supported by internal or external consultants if necessary, permanent quality circles, or within the framework of the application of a quality management system.

6.6 Risk and error management

6.6.1 Administrative risk management

In order to avert avoidable harm to patients, but also to employees, precautions and regulations for emergencies, hygiene, drug safety, and information and data security are taken on the basis of statutory provisions. Furthermore, persons in charge are appointed and regular training courses are held.

6.6.2 Error management

Error management is a part of risk management. Various methods are used to reflect in a transparent manner on clinical experience and to present incidents that could potentially have caused harm to a patient or have actually caused it. This is not only to heighten the awareness of individual causes of errors, but also to identify organizational or technical reasons that may be jointly responsible.

A fundamental contribution to the theory of errors, especially in relation to medicine, was made by James Reason. He first distinguished between active errors and pre-existing latent conditions. While active errors are manifested immediately, it can take years for latent conditions to have an effect. Therefore their involvement is less obvious. Active errors are based, for example, on inattention, lack of information, ignorance, or deliberate deviation from the usual procedure. Latent conditions can be error-provoking working conditions such as time pressure, understaffing, insufficient technical equipment, etc., or permanent weaknesses such as poorly designed work processes and premises or unreliability of technical equipment and material.

Manifest (near-) errors can usually be traced back to a sequence of failures of various safety measures, including the final active mishandling. Reason has vividly described this with his “Swiss cheese slice model”: Each slice of cheese represents a security level, including the last person to act. The holes in the cheese slices vary dynamically in size and position. Only when a hazard beam (i.e. the potential for a damaging event) can pass straight through all cheese slice levels (as the holes overlap by chance), does it come into effect. Normally, if one level fails, the hazard potential is absorbed by the next level.

He differentiates 2 approaches to human error:

- Personal approach
  - This is the traditional approach and focuses only on the person responsible for the active mistake. It reacts with (follow-up) training, naming, blaming, shaming and, if necessary, disciplinary measures. Near misses will mostly not be reported in this culture. The potential to learn from them is wasted.

- Systemic approach
  - This accepts that people are not infallible and therefore active errors must be expected. It creates a culture of trust in order to enable the most complete possible flow of reports of adverse events. The analysis of these reports allows the identification of latent conditions which, in contrast to the human propensity for error, can be permanently and sustainably corrected [4, 5, 153].

  In the following, applications of the systemic approach are listed:
- Error Conferences
  - Usually anonymous presentation of (near-) errors in the treatment process within the framework of a team meeting
- M&M Conferences
  - Morbidity and mortality conferences are hardly used in otolaryngology as the patients are usually less severely ill than in other specialties
- Error reporting systems
  - Critical Incident Reporting Systems (CIRS) allow each employee to report an incident with the potential to harm patients anonymously and promptly to a central office. In addition to the internal CIRS in each institution, there are also cross-institutional CCIRSs (see 6.10.2, 5.2.5.5). The reports are evaluated centrally, checked for possible relevance for action and finally commented publicly in the system.

6.6.3 Opus primum and assistance systems – clinical methods of risk management

Especially in surgical specialties or in other invasive procedures, manual skills and surgical strategies must be learned, and their acquisition follows a learning curve. Supervision by an experienced person can mitigate but not eliminate this effect. The degree to which a learner achieves the goals of the intervention and avoids collateral damage will usually differ from that of an experienced person, no matter how serious and cautious the learner may be – often with minor but, depending on the type of intervention, also serious consequences [154, 155]. The ethical justification for this is that our life span and thus also the duration of our activity in the medical profession is limited. If there were no permanent training of the next generation, the quality of medical care would degenerate within a short time.

The following methods are used in surgical training for quality assurance:

- Formative examination interview (so-called "audition") before the initial intervention to ensure the conceptual understanding of the intervention and knowledge of surgical anatomy
- Simulation models or phantom models, available in otorhinolaryngology e.g. for the temporal bone, possibly embedded in a Surgical Skills Labs
- Operation courses with cadaver preparations, preparation exercises on explanted human petrous bones
- In contrast to 2 decades ago, access to the bodies of deceased persons in pathology, on which surgical steps could be practiced without externally visible mutilation, is practically barred by the current legal situation
- Intraoperative assistance and supervision by a specialist or attending physician, until the so-called specialist standard is attained.

Beyond the training situation, methods are generally applied that are not required by law but are "good clinical practice":

- Surgical assistance systems – such as neuromonitoring and navigation systems – support the surgeon in sparing the important anatomical structures that may be endangered, as well as in achieving the surgical goal in difficult anatomical conditions.
- Clinical follow-ups allow at least a partial assessment of the quality of outcomes and provide valuable feedback to the surgeon.

6.6.4 Ethics committees

Ethics committees are approach to prevent harm to patients. Their activities are based on the Declaration of Helsinki (see 2.3).

6.7 Patient orientation

A clear patient orientation is not only in line with medical ethics, but is also a prominent requirement of all legal regulations (e.g. 5.1.6), as well as systems for voluntary accreditation and certification, and is an indispensable prerequisite for achieving good quality.

6.7.1 Patient information and education

It is accepted good practice to inform patients in layman's language about diseases, the hospital and treatment procedures. The information of patients to consent to invasive procedures has reached a high standard, not least due to the rigid jurisdiction of recent years.

6.7.2 Participatory decision making

The so-called "participatory decision-making" is based on the international "shared decision making" (SDM) initiative. The aim is to train doctors and medical students in such a way that they proactively involve patients in the decision making process for therapeutic procedures, and to enable patients to weigh up the advantages and disadvantages by providing information. Such portals for patient education can be found, for example, at the ÄZQ (see 5.5.2) and IQWIG (see 5.4.2). For example, on its website "Gesundheitsinformation.de", IQWIG offers a decision support tool on tonsillitis and tonsillectomy in children [156]. However, there is still room for improvement in the implementation of participatory decision-making [157].

6.7.3 Process optimization

These often aim to increase safety for patients or reduce inconvenience such as waiting times.

6.7.4 Feedback

Patient satisfaction can be measured with feedback forms that can be filled out on site or alternatively by means of systematic postal surveys. This is just as much a part of the repertoire of most health organizations as is complaint management – which is clearly visible as such to the outside world and ensures a timely response.

Regular evaluation of patient feedback generates result parameters for quality management.

6.8 Employee orientation

"Employee-oriented management" means taking the needs and wishes of employees seriously and incorporating them in management decisions. This includes recognition and appreciation for contributions made, an explanatory and interactive leadership style with team meetings, town-hall meetings, etc., the opportunity to expand professional expertise through internal and external training, and the promotion of independent work by delegating responsibility ("empowerment"). This increases employee satisfaction, which in turn maintains and enhances the quality of the results and helps to retain qualified employees. Regular monitoring of employee satisfaction and the fluctuation rate generates indicators for the quality of results.

6.9 Communication, cooperation, and interdisciplinarity

Good communication and cooperation ensures that treatment-relevant information is transmitted in full at interfaces and that the best possible decisions can be made by pooling expertise in interdisciplinary standing committees, such as tumor boards or in disease-oriented centers (see 4.7.2). Best practice initiatives continue to provide suggestions for improving quality.

6.10 Cross-institutional initiatives

There are a large number of voluntary, cross-institutional initiatives that use different approaches to try to improve the quality of the care.

6.10.1 Collegial counselling – quality circles and medical peer review

Collegial counselling can include both cross-practice quality circles and so-called "medical peer review". The latter is carried out by peers trained according to BÄK criteria, who provide feedback without judgement or sanctions after an on-site visit within the framework of a collegial dialogue. The procedure includes standardized self-assessment and external evaluation and resembles a certification procedure, with a focus on counselling [158].

6.10.2 Cross-institutional error reporting systems

Cross-institutional error reporting systems and critical incident reporting systems (CIRS) under the umbrella of the "Network CIRS-medical.de" have already been described (see 5.5.2 and 5.2.5.5) [129]. The CIRS "Every error counts" has been set up for GP practices [159]. CIRSs contribute significantly to the identification of system-related possibilities for error (i.e. so-called "latent conditions" according to Reason, see 6.6.2).

6.10.3 APS –Patient Safety Alliance

The Patient Safety Alliance (Aktionsbündnis Patientensicherheit, APS) is an initiative of professional associations, patient representatives, and self-governance organizations of the health care system and industry to increase patient safety in medical care by attempting to minimize the possibility of systemic errors (i.e. so-called latent conditions according to Reason, see 6.6.2) through so-called procedural recommendations [125].

6.10.4 IQM – Initiative for Quality Medicine

6.10.4.1 History and organization

The Initiative for Quality Medicine (Initiative Qualitätsmedizin, IQM) is a voluntary initiative of hospitals from Germany and Switzerland with the aim of improving quality in the affiliated hospitals. It was founded in 2008 by private and by non-profit hospital chains, several university hospitals and the Berlin Medical Association.

In cooperation with the scientific institute of the AOK health insurance fund (WIdO), quality indicators were developed from routine data, i.e. the ICD and OPS transmitted for DRG billing (so-called Inpatient Quality Indicators, IQI). Due to the cooperation with the AOK, cross-sectoral follow-up data can also be evaluated. The advantage in the IQM is that these data are available without additional effort, in contrast to external certification procedures.

6.10.4.2 Procedure

A total of 40 quality indicators have been defined. The results are published in annual reports by the hospitals and contain, for example, information on mortality in relation to the mean of IQM hospitals and the risk-adjusted expected value for specific diagnoses or procedures. Otolaryngology is not represented by a quality indicator, but by the average length of stay after tonsillectomy. The cross-sectoral QSR results are published in the AOK Hospital Navigator.

If there are conspicuous deviations, a peer review is initiated to improve quality. In Germany, this employs the BÄK procedure (see 6.10.1), No certificates or similar documents are issued [160].

6.10.4.3 Relevance

The IQM website currently lists 447 participating hospitals from Germany, including several university hospitals. One study found a statistically significant improvement in the quality of IQM clinics that had undergone peer review for conspicuous IQIs [161]. This gives IQM a unique selling point compared to other external procedures (see 4.8, 5.12 and 8.4).

6.10.5 ÄQSI – Database of medical quality assurance initiatives

The German Medical Association has set up an online database that records voluntary initiatives in medical quality assurance that aimed to measure and improve the quality of treatment. It also includes registers on specific diseases and implants. The database is intended to provide an overview of these initiatives and to give interested parties the opportunity to join an initiative in their field [162]. 147 initiatives are listed in total, 2 of which are from the professional association of ENT physicians ("Audiology/Neurotology" and "Quality Seal Allergology"). A register for cochlear implants is in preparation and should be listed in the ÄQSI in the future.

6.10.6 Guidelines

Guidelines are an essential part of knowledge management in medicine. They have been developed according to a dedicated set of rules and reflect the current state of knowledge on a topic, in order to support physicians as well as patients in decision-making. They

are therefore an important instrument for securing and further developing the quality of medical care. Guidelines are characterized by the fact that they are action-oriented, i.e. they specify "action and decision corridors", although justified deviations are permitted or even required in individual cases.

The AWMF publishes the guidelines of the medical societies. It has drawn up a set of standards for the development of guidelines and ensures their implementation through administrative support and supervision. The "German Instrument for Methodological Guideline Evaluation" (DELBI) is used to assess the quality of new guidelines. Guidelines are provided with an expiry date on publication [163].

Guidelines are divided into 4 classes:

- S1: Recommendation for action by experts (consensus finding in an informal procedure)
- S2k (formerly S2): Consensus-based guideline (representative body, structured consensus)
- S2e: Evidence-based guideline (systematic search, selection, evaluation of references)
- S3: Evidence-based and consensus-based guidance (combined requirements of S2k and S2e)

The German Society for Otolaryngology, Head and Neck Surgery (DGHNO-KHC) has currently published 19 of its own recent guidelines and is involved in 57 guidelines of other medical societies.

While there are indications that guidelines have a positive influence on the quality of medical outcomes [164, 165], they may take years to prepare and may therefore sometimes be out-dated, or their content may deviate from those of other countries. The quality of German guidelines was significantly raised by a clearing procedure at the beginning of the millennium [166].

In addition to the guidelines of the medical societies published by the AWMF, there are also the National Health Care Guidelines (see 5.5.2) and the Oncological Guidelines published jointly with the German Cancer Society and German Cancer Aid [167].

6.10.7 CWI – Choosing Wisely Initiative

The "Choosing Wisely Initiative" (CWI) has its origins in the USA. In response to calculations that at least 20 % of medical services with an annual volume of up to 200 billion US dollars were superfluous ("waste" and "no value") [168], the general practitioner Howard Brody formulated the CWI: each discipline should compile a top 5 list of superfluous procedures and attach a negative recommendation to each. The criteria for inclusion in the list were frequency, cost and lack of evidence. As an additional justification, it was later stated that CWI could also prevent avoidable harm to the patient (e.g. radiation exposure). With the support of the American Board of Internal Medicine (ABIM), this has become a national and international movement with more than 20 participating nations.

There has been considerable criticism of the international CWI. In the sense of a "mission creep", "low value" procedures are now to be included on the negative lists instead of only those with "no value". This has given new impetus to the highly controversial discussion on rationing. This is glossed over by using the terms of "prioritisation" or "posteriorisation", but is not communicated transparently. On the contrary, the well-being of patients is cited as the sole motivation. Supply policy aspects that could be legitimately discussed are, however, ignored. Furthermore, the recommendations fall far short of the standards that apply to the development of guidelines. Finally, there are currently no indications of the effectiveness of the initiative, particularly as regards the motivation of the physicians who are encouraged to follow the recommendations [169, 170]. In a recent study in the USA, it was shown that procedures from other disciplines were given preference on the negative lists [171].

In Germany, the CWI is operated as "Klug Entscheiden" (KE) by the German Society for Internal Medicine (DGIM), with the participation of 12 medical societies [172]. It is the only international organization involved that also formulates positive recommendations in cases of identified underprovision. The AWMF has produced a manual with minimum qualitative requirements for the development of KE recommendations [173]. The German Society for Otolaryngology, Head and Neck Surgery (DGHNO-KHC) has not yet participated in the KE initiative.

Possible reasons for medical decisions leading to overprovision and underprovision are discussed below (see 8.1.5)

6.10.8 EBM – German Network for Evidence-based Medicine

6.10.8.1 Evidence-Based Medicine

Evidence Based Medicine (EBM) is a movement that originated in the mid-nineties of the last century. David Sackett gave a concise description of what EBM is – and what it is not – in an editorial in 1996:

> *"Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research."*

He therefore emphasizes that clinical expertise is to be regarded as equally important to external evidence and that the best quality of care can only be achieved by combining the two. EBM is therefore not a sort of medicine that can be carried out exclusively according to external evidence "like a cookbook". He also clearly stated that EBM is not and must not be limited to the "gold standard" of evaluation of randomized controlled trials (RCT). Cross-sectional studies, follow-up studies, findings from basic sciences or the "next best external evidence" can also be meaningful and appropriate – and controlled trials are of course superfluous for interventions that would prevent an otherwise fatal outcome [174]. The application of EBM to surgical interventions is discussed below (see 8.3.2).

6.10.8.2 Cochrane

An important contribution to EBM is made by the Cochrane Collaboration, a worldwide network of scientists who produce "systematic reviews of primary research on human health care" [176]. Reviews can be searched for questions and topics in the publicly accessible database. 187 reviews are currently listed for otolaryngology [177].

6.10.8.3 DNEbM – German Network for Evidence-based Medicine

The German Network for Evidence-Based Medicine (Deutsches Netzwerk Evidenzbasierte Medizin, DNEbM) is the German-speaking center of excellence and reference center for all aspects of evidence-based medicine. Its declared goal is to spread and further develop concepts and methods of EBM in practice, teaching and research [178].

6.10.9 DNVF – German Network for Health Service Research

The German Network for Health Service Research (Deutsches Netzwerk Versorgungsforschung, DNVF) is "a platform of professional societies, institutions and individuals with the special concern of researching health and patient care" in order to create "important prerequisites for evidence-based decisions in the health care system as well as improved care and health of the population". A particular focus is on the patient perspective [179].

6.11 Discussion – an extensive quality landscape

Ensuring a high quality of medical care is part of the professional ethos of the German medical profession. Long before the start of legal obligations and far beyond these, this is expressed not only in day-to-day practice but also in numerous voluntary initiatives, some of which are independently organized and some of which are supported by the institutions of the medical profession. This has created an extensive quality landscape beyond the obligatory statutory quality assurance.

7 State of Quality Management in German Hospitals and Practices, Especially in Otolaryngology

In the area of external quality assurance and quality reports, the legal requirements and those specified by the Federal Joint Committee (G-BA) are enforced in hospitals under threat of sanctions. This is different in the case of the G-BA's quality management guideline (QM-RL), which has obliged hospitals, practices and medical care centers to run a comprehensive internal quality management system for almost 15 years. This is not monitored in hospitals. Only single aspects of risk management have to be disclosed in the annual quality report. In the area of SHI-accredited physicians, a random sample-based annual survey is conducted on this topic.

In times of great challenges (see Chapter 8), the question arose to what extent this inherently meaningful requirement is actually being implemented, especially as it ties up human and financial resources.

For this purpose, questionnaires were sent in June 2019 to all German ENT departments and to ENT physicians in practices in the Rhein-Neckar region. The evaluation included returns until the end of August 2019. The questionnaires were deliberately kept compact, with the aim of obtaining a high response rate.

7.1 Hospitals – external quality assurance

The current IQTIG quality report for the year 2017 shows that more than 99 % of hospitals meet their obligation to submit data for external quality assurance according to the QSKH-RL. Of the quality indicators (QI) used for this, 17 % showed improvement, 5 % deterioration and 67 % no change compared to the previous year; the rest were not comparable. In 4 % of the QIs there was a "pronounced or persistent quality deficit" in the national average. Only in one percent of the results calculated from the QIs there was currently an important abnormality in respect of individual hospitals (for further details see 5.2.6.4) [96]. In summary, these results demonstrate a very high level of quality in hospitals – with regard to the criteria examined, which, however, only cover a limited area. As already mentioned above, otolaryngology itself is not affected by external quality assurance according to QSKH-RL, because there are no quality indicators for our specialty.

For voluntary external quality assurance procedures the following information is available:

Currently 447 hospitals participate in the IQM procedure, 244 hospitals are certified according to KTQ, 14 according to EFQM and 2 according to JCI. ISO does not publish figures; there are estimates of about 400 certified hospitals or organizational units of hospitals.

7.2 ENT departments – results of the survey

168 hospitals or main departments were surveyed and the return rate was 128 questionnaires (76 %). The hospitals were divided into 3 groups: Hospitals with less than 30 beds (response 34), hospitals with more than 30 beds (response 61) and university hospitals (response 33).

The 11 questions on content were divided into 5 groups: External certification, standardization, organizational development, risk management and patient and employee orientation (▶ **Table 1**):

2 opposing trends emerged in the answers about certification: the percentage of total certifications decreases with increasing size, but the percentage of center certifications increases. The former can be explained by the (disproportionately) increasing effort with the increase in size and complexity of a hospital; the latter is due to the increasing expertise in maximum care.

The questions on the standardization of specific treatment processes are consistently answered positively to a high degree, and the result of the question on quality manuals coincides with that of certification, i.e. almost 80 % of the participants in the survey obviously apply elements of an internal quality management system.

This is also confirmed by the question about process optimization (quality circles), which is answered positively by a comparable percentage.

The main component of a quality management system is risk management. As expected, the areas of risk management for which the hospitals are responsible show high implementation rates of more than 95 %.

The results for patient orientation are in the same area, whereas employee orientation is slightly lower.

In summary, it can be stated that a very high and almost homogeneous implementation of quality management in ENT hospitals has been reported ("degree of achievement"), but with the exception of certifications. Of course, no statement can be made about the extent of the so-called "degree of penetration" (degree of implementation across the board) with the means of this survey.

7.3 Practices – KBV report on the implementation state of quality management

The current report of the KBV on the implementation status of quality management in SHI-accredited physicians' practices and MVZs was based on a sample of 2017 and found that the implementation of quality management methods and instruments is high – almost 90 %. This was followed by patient surveys (54 %) and, to a lesser extent, employee surveys, checklists and self-assessments based on quality objectives.

The KBV provides the following information on voluntary external quality assurance procedures:

54 % of practices used instruments of external certification in their quality management system but only 13 % underwent additional external certification (see 5.2.6.2), i.e. three quarters of the users left it at self-assessment.

7.4 ENT practices – Results of the survey

56 practices in the Rhein-Necker region were sent questionnaires, of which 29 were returned (53 %) in .

The 14 contents-related questions were divided into 5 groups: External certification, standardization, organizational development, risk management and patient and employee orientation (▶ **Table 2**):

A quarter of the survey respondents stated that they were certified. The standardization of processes through checklists and quality manuals shows a very high degree of implementation. As regards surgical checklists, it should be remembered that many practices do not perform surgical procedures.

The question about quality circles for process optimization was answered positively by almost 40 %. It should be born in mind that process optimization can also be initiated in staff meetings within the relatively small group of people in a practice.

Questions concerning patient safety showed a high degree of implementation throughout. This concerns the definition of responsibilities, team meetings, equipment briefings and dedicated risk and error management. About half of the practices have already undergone an external hygiene inspection.

Instruments for patient and staff orientation showed a lower degree of implementation than in hospitals, but were still used in most practices. Within a single practice, however, there is more likelihood of direct feedback from patients and staff than in a hospital, and this would not be detected through a survey.

In summary, it can be said that despite the significantly lower certification rate compared to the hospitals, instruments of quality management are applied to a high degree within the practices.

7.5 Discussion – Good results in otorhinolaryngology

7.5.1 Comparison of ENT departments with the German hospital landscape

There is only one parameter to compare the state of quality management of ENT departments with the entire German hospital landscape: The extent of external certification .

The Federal Statistical Office gives the total number of all German hospitals in 2017 as 1942. Of these, 1834 offered a range of services that required them to participate in external quality assurance (QSKH-RL) [96]. If the sum of the certified hospitals accor-

▶ **Table 1** Results of the survey of hospitals. Note on line 1: Since the number of non-university hospitals was only known in total, but not their distribution between the two groups with less or more than 30 beds, the percentage of the return as a group as a whole was calculated to be 72 %.

	All hospitals	%	<30 beds	%	>30 beds	%	University hospitals	%
Returned questionnaires	128	75.7 %	34	72 %[1]	61	72.0 %[1]	33	89.2 %
Certification								
1. Is your entire hospital certified (e.g. KTQ, ISO, JCI)?	99	77.3 %	29	85.3 %	50	82.0 %	20	60.6 %
2. Is your hospital certified as part of a center (e.g. skull base center)?	85	66.4 %	13	38.2 %	42	68.9 %	30	90.9 %
Standardization								
3. Do you use SOPs?	119	93.0 %	28	82.4 %	60	98.4 %	31	93.9 %
4. Do you use treatment pathways?	117	91.4 %	30	88.2 %	58	95.1 %	29	87.9 %
5. Have you created one or more quality manuals?	102	79.7 %	27	79.4 %	47	77.0 %	28	84.8 %
Organizational development								
6. Do you use quality circles for specific projects?	105	82.0 %	26	76.5 %	49	80.3 %	30	90.9 %
Risk management								
7. Are there error conferences (or M&M conferences) in your hospital?	122	95.3 %	33	97.1 %	58	95.1 %	31	93.9 %
8. Is there a CIRS (Critical Incident Reporting System) in your hospital?	124	96.9 %	33	97.1 %	59	96.7 %	32	97.0 %
Patient and employee orientation								
9. Do you use a complaint management system?	128	100,0 %	34	100,0 %	61	100.0 %	33	100.0 %
10. Do you conduct patient surveys?	124	96.9 %	32	94.1 %	60	98.4 %	32	97.0 %
11. Do you conduct employee surveys?	107	83.6 %	28	82.4 %	53	86.9 %	26	78.8 %

▶ **Table 2** Results of the survey of practices. Comment to question 3: Since there was no separate question on whether the practice performs surgical procedures, the result of this question is not representative.

	Practices	%
Returned questionaires	29	52.7 %
Certification		
1. Is your practice certified?	7	24.1 %
Standardization		
2. Do you use checklists?	28	96.6 %
3. Do you use surgical safety checklists (time-out)? (see annotation)	12	41.4 %
4. Do you have a quality manual?	28	96.6 %
Organizational development		
5. Are responsibilities clearly defined or defined in writing?	26	89.7 %
6. Do you have regular team meetings?	27	93.1 %
7. Do you use quality circles for certain projects?	11	37.9 %
Risk management		
8. Have you ever had an external hygiene inspection?	16	55.2 %
9. Do you perform documented device instructions?	28	96.6 %
10. Is there a risk management in your practice?	24	82.8 %
11. Is there an error management in your practice?	24	82.8 %
Patient and staff orientation		
12. Do you use a complaint management system?	15	51.7 %
13. Do you conduct patient surveys?	19	65.5 %
14. Do you conduct employee surveys?	16	55.2 %

ding to KTQ (244), EFQM (14), JCI (2) and ISO (approx. 400) is put in relation to the total number of all hospitals that are subject to the QSKH-RL, the degree of certification is approx. 36 %. This does not take into account the fact that double certifications according to 2 systems are not uncommon (e.g. ISO and KTQ) and that ISO is often only rolled out to organizational units, but not entire hospitals. Realistically speaking, one can therefore probably assume that one third of all German hospitals are externally certified. With 447 participants, IQM meanwhile already covers a quarter of all hospitals, but does not issue certificates and is therefore not relevant for this consideration.

In relation to this, the proportion of certified ENT departments is considerably higher: Almost twice as high at university hospitals at 60 %, and 2.5 times at non-university hospitals at 80 %. This is certainly also due to the fact that ENT departments are only represented in hospitals above a certain level of care: statistically, they are only present in about 9 % of all German hospitals.

7.5.2 Trend: ISO wins, KTQ loses drastically

KTQ has experienced a meteoric increase in the number of participating hospitals in the years up to 2009; a maximum of almost 700 hospitals were certified according to KTQ. Since then, KTQ has suffered a constant, drastic decline to currently just under 250. ISO, which does not publish figures, is conversely more successful, according to certifiers. The reasons given are the better scalability of the ISO procedure, the high documentation effort required by KTQ and the higher costs of re-certification by KTQ.

7.5.3 Trend: Quality minus quality management system and certificate

Interesting changes are emerging with regard to the use of procedures with voluntary self-assessment and external assessment: The IQM procedure is apparently experiencing considerable growth, while KTQ is suffering a slump, as already described. The impact on ISO cannot be assessed. The advantage of the IQM procedure is the reduction to the essential: The quality indicators that are used are data that already had to be created in the billing process. For this purpose, restrictions in the validity of the indicators are accepted if necessary. Time-consuming training of employees for an external certification system, time-consuming preparation of self-assessments, quality manuals, etc. are no longer necessary, and the costs for external certification are also avoided.

A dedicated quality management system that is internal to the institution also does not have to be proven. An audit system is only used if the quality indicators are abnormal and the lean but qualified peer review procedure of the BÄK or some LÄK is used for this purpose. This ensures competent, problem-centered and practice-oriented advice, which is highly relevant to the measures to be introduced. An official certificate is deliberately not provided. Instead, membership in IQM is published and the evaluation of the quality indicators is made transparent through annual publications.

The course correction of the KTQ (see 4.3.5) aims in the same direction as the IQM concept, and emphasizes the aspect of guidance and reducing the documentation effort.

7.5.4 Two groups: with and without a certified quality management system

In summary, even 15 years after the passing of the QM-RL directive, two thirds of all German hospitals and a quarter of all ENT departments do not have a certified quality management system. The degree of implementation of risk management and patient-related parts of a quality management system will certainly be high in this group as well, while it is probably rather heterogeneous in the other areas.

7.5.5 Comparison of ENT practices with a random sample of German practices

In contrast to hospitals, the survey data collected by the KBV allow an easier comparison of ENT practices with the German average.

Similarly to the ENT departments, many ENT practices are also certified, namely 24 % compared to 13 % of the national average. With checklists, the degree of implementation in ENT practices was 10 % higher; the other parameters of risk and error management were in comparable ranges. Quality circles were used in ENT practices only about half as often as in the nationwide comparison. A heterogeneous picture resulted in patient and employee orientation: ENT practices carry out 10 % more patient surveys, but 30 % fewer employee surveys and they are 30 % less equipped with complaint management.

As regards the comparability of the two surveys, the samples were about the same size (approx. 2 %), but the response rate of the KBV survey was almost twice as high (97 %) as the ENT survey. The biggest difference is that ENT specialist practices had to be compared against a cross-section of GP practices and specialist practices of all medical disciplines. In its reporting, the KBV does not differentiate between GP and specialist practices or even individual specialist disciplines.

8 Current Challenges for Quality Assurance and Quality Management

As already mentioned, the actual quality level of treatment is created at the place of care in hospitals and medical practices. Challenges and risks to the quality of care are therefore closely related to anything that strains, overburdens or disincentives service providers, or jeopardizes equitable access to health care for patients.

8.1 Resource allocation and patient well-being

With regard to the key areas of resource allocation and patient well-being, the following deliberations refer to the statement of the AWMF "Medicine and Economics – Measures for scientifically based, patient-centered and resource-conscious care" of 2018 [143], the expert opinion of the Expert Council on Health (Sachverständigenrat Gesundheit, SVR) "Demand-oriented management of the health care system" of 2018 [180] and the statement of the German Ethics Council "Patient well-being as an ethical standard for hospitals" of 2016 [181].

8.1.1 Economics versus patient well-being

In the opinion of both the AWMF and the German Ethics Council, the current general conditions create conflicts between business management requirements and evidence-based, patient-oriented care that meets professional ethical standards. Patient selection and an increase in the number of standardizable procedures were noted. This not only raised questions about the individual justification of the indication, but would also be at the expense of patient groups with high care expenditure, pediatrics and obstetrics. The equity of care and the well-being of patients were at risk [143, 181].

In a survey conducted in 2017, hospital physicians reported growing pressure and indirect and direct influences to consider business interests in patient-related decisions. This would lead to under-, over- and missupply of care for patients, ethical conflicts, stress situations and frustration [182].

The reasons for this situation are discussed in the following 2 Chapters.

8.1.2 Diagnosis Related Groups (DRG) – from talking to documenting medicine

The DRGs were introduced on a mandatory basis in 2004 and are the system through which the operating costs of German hospitals are mainly financed. The adaptation of this system to the whole of the country has revealed considerable shortcomings.

8.1.2.1 Effects of the DRG system

Since the introduction of DRGs, there has been a significant increase in the overall number of cases, almost exclusively involving elective procedures (e.g. [183]). At the same time, the average length of stay has been correspondingly decreased. Since the basic costs incurred by hospitals are not covered, there is a disincentive to change services or portfolios, to "pick and choose" and to split complex cases [143]. The originally intended savings effect of the DRGs was cancelled out by the expansion of volume. Financially unattractive patient groups (multimorbid, pediatric, etc.) suffered from this development. Talking medicine and interdisciplinarity were not remunerated, nor were extremely expensive cases and innovations in high-performance medicine [181]. In the field of otolaryngology, for example, the presence of 2 highly qualified surgeons for the interdisciplinary endoscopic 4-hand surgery of the anterior skull base is not taken into account.

According to the SVR, the undesirable developments are particularly serious for university hospitals and maximum care providers: The German DRG implementation followed the "one-house approach", i.e. unlike in neighboring countries, no distinction was made between hospital care levels, although the services offered vary considerably in terms of complexity, quantity and provision costs. The current DRG system tried to compensate for this by means of intense differentiation of the DRG system, supplemented by surcharges and discounts, and strong procedure orientation, which assumed the character of an individual service remuneration system and thus created incentives for the expansion of the number of cases [180].

However, it still does not manage to correctly map the cost structures of maximum care providers. As a result, university hospitals and maximum care providers are systematically underfunded, which pushes even high-performance hospitals into a negative balance.

8.1.2.2 Proposals for corrections of the financing of the operating costs

Within the DRG system, according to the SVR, surcharges or multipliers according to hospital care levels should be introduced on a departmental basis to reflect the cost structures of university hospitals and maximum care providers. This would allow the DRG system to be modified in the direction of diagnosis-related reimbursement and would reduce disincentives. This is in line with the demands of the AWMF and the German Ethics Council for surcharges for university hospitals and maximum care providers, but is a more far-reaching and welcome proposal from a systemic point of view. For volume-sensitive elective interventions, a binding second opinion procedure by medical officers is being demanded. Patient information ("talking medicine") and the effort for interdisciplinarity should be mapped in the system. Segmentation of cases of multimorbid patients should be prevented by "package DRGs". There should be surcharges for particularly complex patient groups and extreme cost cases should be reimbursed. The AWMF demands that DRG revenues should not be taken for investments or profits and that private hospitals should therefore only be operated as non-profit companies.

According to the SVR and the German Ethics Council, the proportion of flat-rate remuneration elements, e.g. for the need to maintain reserves, outside the DRG system should be significantly increased. In university hospitals, a balanced ratio of basic and third-party funds should be established for research [143, 180, 181].

8.1.2.3 MDK – questionable accounting audits

In 2018, the MDK carried out more than two and a half million billing audits at hospitals, which corresponds to an audit quota of approx. 20 % in ENT departments. The vast majority of these audits are not about incorrect coding, but about generating reimbursement discounts in favor of the insurance companies by reducing the recognized length of stay, although the medical services provided are undisputed. The administrative effort of the audit procedures and the effort of the medical "defensive documentation" are considerable – and in essence superfluous. Fortunately, this questionable practice is announced to be corrected by the legislator (MDK Reform Act, see 5.10).

8.1.3 Investment funds: too little, too late

Under the so-called dual financing system, the operating costs of hospitals are borne by the health insurance funds and the investment costs by the federal states. In a joint press release of March 21st , 2019, the DKG, the Umbrella Association of Statutory Health Insurance Funds (GKV-SV) and the Association of Private Health Insurances stated that, according to an investment analysis by the Institute for the Remuneration System in Hospitals (InEK), the investment funds required by German hospitals in 2019 would amount to more than 6 billion euros, but that the federal states only covered just under half of this amount with their funding, as there were no binding legal regulation on the volume of investment funds [184].

This major deficit in investment funding, which has existed in the same way for years, is partially responsible for the lack of process efficiency, including the lack of digitisation concepts and outdated infrastructure in hospitals. As a consequence, and contrary to the system, cross-financing from DRG revenues is occurring, to some extent because further developments in medicine render investments indispensable.

While the AWMF calls for dual financing to be maintained in principle, only in appropriate amounts and with federal participation, the SVR proposes sole financing by the health insurance funds, which should be compensated with tax refunds [143, 180].

The current state is unbearable. Despite scientific evidence for the actual investment needs, the federal states have stoically withheld the necessary funds from hospitals for years – with considerable consequences for the structural quality. It is regrettable that they are thus not living up to their responsibility.

8.1.4 Emergency care – patients going astray

Emergency care is based on 3 pillars: The emergency medical service is provided by SHI-accredited physicians, the ambulance service and the emergency outpatient departments at hospitals. For years, there has been a trend to reduce the emergency medical service provided by SHI-accredited physicians, e.g. by discontinuing the ENT emergency service; while on the other hand, patients increasingly make direct use of the emergency outpatient departments. The SVR points out that the reasons given for consulting the emergency outpatient departments for non-urgent treatment are the 24-hour availability, the outpatient care provided by specialists or the hoped-for good quality of treatment in interdisciplinary care [180].

As a result, specialized capacities for patients who are really in need are often blocked by harmless complaints and waiting times may be overly long. The irritated, sometimes aggressive mood of the waiting patients is a strain on the staff. For the hospitals, the increased staff commitment and the use of resources are loss-making because the care of emergency patients is not reimbursed in a cost-covering manner [185].

The SVR proposes that integrated control centers should be set up to manage emergency patients and that telephone services under the numbers 116117 and 112 should be merged. With a "Structured Initial Medical Assessment in Germany" (SmeD), as proposed jointly by the Marburger Bund (MB) and the KBV, patients could then be recommended by telephone to visit a practice, the emergency medical service or an emergency outpatient department or, if necessary, the ambulance service could be ordered directly [186]. The BMG has taken a step in this direction by announcing the future 24-hour availability of the 116117 number.

The SVR also follows the proposal of the German Interdisciplinary Association for Intensive and Emergency Medicine (DIVI) [185] to set up integrated emergency centers (INZ) at hospitals, in which the emergency outpatient departments and, if possible, the emergency medical service of SHI-accredited physicians are combined (so-called portal practices). Depending on the severity of the illness, patients could be treated as outpatients or be transferred to inpatient care. The INZs are to be remunerated on an extra-budgetary basis. The Marburger Bund and KBV support this proposal [187]. These proposals appear to be extremely reasonable for solving a long-term problem of hospitals and should be accompanied by a broad patient information campaign on their introduction.

8.1.5 Overprovision – defensive medicine and patients' desire

In 2017, the German Society for Internal Medicine (DGIM) carried out a member survey as part of its Choosing Wisely Initiative (see 6.10.7) to investigate the reasons for overprovision or underprovision.

The majority of those members answering were aware of the negative consequences of overprovision, namely an increase in health expenditure, possible patients' feelings of insecurity and possible harm to patients. The frequency of unnecessary diagnostic or therapeutic procedures was reported by a quarter of the respondents as daily and almost a half as several times a week. The reasons given with decreasing frequency were concern about treatment errors (79 %), pressure from patients (63 %), achievement of additional revenues (48 %), ignorance of the guideline (44 %), lack of time for the patient (24 %), etc. Further training measures were mentioned as the best countermeasure. Omitted but indicated services were perceived as a much smaller problem [188].

A recent study by the American Medical Association (AMA) found similar results with regard to the justification for overprovision with fear of treatment errors (85 %) and pressure from patients (59 %), and reported the volume of unnecessary procedures at 20 % [189].

The conclusion of the DGIM was that targeted further education measures and improved access to the content of the guidelines, e.g. by means of an executive summary, should be initiated as countermeasures, and this seems very sensible.

8.1.6 Distributive justice and participation

According to the German Ethics Council, patients' well-being is determined by the quality of treatment, self-determination and distributive justice.

Self-determination should be strengthened by participatory decision-making (see 6.7.2) and by strengthening the role of talking medicine in hospitals through remuneration models within the DRG system [181].

Distributive justice, which is established through equal access to and fair distribution of resources, is based on the principle of care according to need, irrespective of social status. On the other hand, there is a close relation to the way in which the resources provided by society are used for the health care system. Overuse or misuse, inefficient and ineffective use of resources are unfair because wasted resources are not available elsewhere where they could have been more meaningfully used [180].

There is a consensus that resource allocation is currently not sufficiently needs-oriented. Misuse of resources should be corrected by counteracting disincentives in the DRG system. Overprovision and underprovision should be remedied by means of need-based, cross-sectoral planning with a regional focus that is geared to the services to be provided and less to organizational structures. Patient well-being should be ensured throughout Germany by means of outpatient and inpatient primary care close to the patient's home on the one hand and specialized centers on the other. All members of the medical joint self-governance involved should be included in the regional planning.

The interface problems should be addressed by a cross-sectoral electronic patient file. The current state of care should be reviewed regularly and be subject to cross-sectoral quality assurance. The structural fund to reduce hospital overcapacity should be continued, as should the support of rural hospitals through the so-called guarantee supplement fund (Sicherstellungszuschlag) [143, 180, 181]. This staggered system of care is in clear contradiction to the Bertelsmann Foundation's proposal to centralize hospital care at one third of the sites [190].

8.2 Hospital leadership and employees

8.2.1 Leadership – balancing medicine and economics

In order to correct the focus of hospital management on economics, the AWMF proposes to put medical directors on an equal footing with commercial directors and to introduce value management – including a right of veto for medical and nursing directors in decisions that could affect the quality of care or safety. Performance bonuses in chief physician contracts should be abolished for good nationwide [143]. The German Ethics Council recommends the introduction of clinical ethics committees.

8.2.2 Employees – In a downward spiral

Due to the DRG-related shortening of layover times, increased patient turn-over resulted despite almost unchanged personnel numbers. Together with changes in working hours due to the Working Hours Act, increased part-time jobs and a shortage of nursing staff, this led to a shortage of time and chronic overwork, increased staff turnover and sickness rates. Work intensification and increasing bureaucracy leave less and less time for direct patient contact. All this has not only resulted in decreasing attractiveness of the health care sector and a consequential shortage of skilled workers, but also in an increased risk to patients [143, 181]. The new measures introduced to finance nursing care and to guarantee minimum nurse-patient-ratios are a step in the right direction because they will make the nursing profession more attractive again in the medium term by improving working conditions.

Under the conditions of economic primacy and work intensification, communication skills are also becoming increasingly relevant. The language expertise of non-native-speaking medical and nursing staff should be guaranteed throughout by German courses and specialist language examinations [181].

8.2.3 The climate is getting rougher

What is difficult to grasp or objectify, is the social change that has taken place in recent years, which is expressed in a changed patient attitude. Self-centeredness and a sense of entitlement are on the rise, and patients are less willing to wait and be understanding in the event of inconvenience. Irritability and aggression culminate especially in emergency departments. Verbal abuse, damage to property and even physical violence against employees are unfortunately no longer exotic exceptions, but have become a global phenomenon. This is also reflected in the increasing number of publications in this area, most of which were only authored after 2010. The Joint Commission published a "Sentinel Alert" [191] on this topic.

It is to be hoped for Germany that the reform of emergency care can defuse the situation in emergency outpatient departments. Communication training for de-escalation strategies and, if necessary, the presence of security guards is useful in hot spots. The

122nd German Medical Assembly called on the legislature to extend criminal law protection for persons providing medical assistance [192].

8.2.4 Physicians' well-being is also patients' well-being

The Lancet proclaims "Physician burnout: a global crisis" [193]. In a recent study on German physicians, the prevalence of burnout is estimated to be between 4 and 20 % and that of depression between 6 and 13 %. In addition, there is evidence of impairments due to anxiety disorders, suicidal tendencies and substance abuse. Work-related stress factors play an important role in the development of these disorders [194].

The obligation to take care of one's own health and well-being, as contained in the Declaration of Geneva, may be just pure theory, according to the report of the "Deutsches Ärzteblatt" of the 122nd German Medical Assembly [195]. Under the conditions of economic primacy with time pressure, work intensification, increase of non-occupational tasks, especially high documentation efforts, work with unergonomic IT systems, and the loss of autonomy of action, self-care would be difficult to implement. There was no culture of setting limits and standing up for physicians' health. The Working Hours Act is still not being implemented consistently, although overtired physicians can pose a considerable risk to patients.

In its absurdity, an attempt in the USA to reduce the prevalence of burn-out among physicians by "mindfulness training" instead of improving working conditions seems almost comical. As expected, the intervention left the frequency of burnout unchanged [196].

The 122nd German Medical Assembly calls on employers, the relevant authorities and legislators to create healthy working conditions for physicians. In particular, the Working Hours Act should be observed [192].

The shortage of medical personnel is due to the high number of medical school graduates who, in the light of the above-mentioned conditions, do not choose a clinical career (relative shortage of education). This shortage is further aggravated structurally by the fact that, with the increasing number of female physicians and the nowadays fortunately possible combination of family and career, the lifetime working hours of female physicians have been significantly reduced by several years of parental leave and part-time work. The situation will be further aggravated when the baby boomer generation retires. The 122nd German Medical Assembly therefore called for the full implementation of the Master Plan for Medical Studies 2020 and a 10 % increase in the capacities of medical schools [192].

The training of residents and the – especially surgical – further training of specialists is not refinanced in the current system of financing operating costs. It is mainly conducted at university hospitals and maximum care hospitals. The structured training of residents particularly suffers under the conditions of economic primacy described above. The SVR therefore recommends setting up a resident training fund from which the hospitals providing training will be paid on a personal basis (so-called rucksack principle – the trainee brings his or her own funding) [180].

8.2.5 Is the license to practice medicine meaningless?

There have recently been attempts to devalue the license to practice medicine by declaring only specialists as sufficiently competent. Examples are the discharge management regulation that only a specialist may issue a prescription, or the market-radical hospital study by the Bertelsmann Foundation, which cites the fact that specialists are always available at night as an advantage in reducing the number of hospitals.

Our professional associations should resolutely oppose this development.

8.3 Research, science and progress

In times of rapid and at times disruptive progress in the fields of "omics" (genomics, proteinomics, microbiomics etc.), the announcement of imminent personalizable or individualizable therapy [197], a digital twin simulated from DNA data and new active implants, it is a challenge to evaluate these developments with regard to their clinical benefit. A study on so-called "medical reversals" [198] has shown that this is a process with twists and turns, even apart from the cases of crude scientific fraud in which the peer review process has failed. A critical approach to innovation and awaiting the first evidence either pro or contra a benefit therefore seems to be generally sensible.

8.3.1 EBM vs. Real World Data and Big Data

The transferability of evidence-based medicine (EBM) findings from randomized controlled trials (RCTs) to the real world must take into account the fact that there may be differences between a strictly selected and homogeneous study population and the application population [199]. This so-called extrapolation of EBM is currently the subject of intense discussion [200]. A relativization of the relevance of EBM and RCTs is not only promoted by advocates of the preference for "real world data" [201], but also in the context of accelerated drug approvals as so-called "adaptive pathways", where observational studies are to be given greater weight than RCTs [202].

In addition, "Big Data" question the scientific quality standards developed over the last decades for the evaluation of causality: In "Big Data", causality is replaced by correlation [201]. The results should therefore be interpreted with the appropriate caution.

8.3.2 Evidence-based surgery

New surgical procedures are being developed by a small number of surgeons, often in connection with advances in medical technology. They are tested on their own patients and then presented with the perceived added value. In contrast to non-surgical interventions, placebo-controlled RCTs for surgical interventions are rare and unusual. It is debatable whether it is ethically justifiable to expose a patient in the placebo group to a possible complication, the risk of anesthesia and the skin scar of the sham surgery.

The outcome of a surgical procedure depends on 3 factors: the crucial element of the surgical procedure, the placebo effect and unspecific effects. The placebo effect is rather strong in surgical interventions because of the suggestive setting.

In particular, placebo-controlled RCTs are regarded as ethically justified for elective interventions to improve quality of life, whose added value compared to a conservative approach is considered questionable in professional circles [203]. A current review has evaluated 53 studies. In almost half of the studies, no significant benefit was found in comparison to the placebo arm. In the trials with

superior active treatment, a smaller benefit was also measured in the placebo arm [204]. The best-known study in our field is that of Thomsen, who was able to show as early as 1981 for the decompression of the saccus endolymphaticus in Ménière's disease that surgery and sham surgery lead to equally good results that remained stable over a follow-up period of 3 years and must therefore be regarded as a pure placebo effect [205, 206].

As unusual as the idea of evidence-based surgery might be, it certainly makes sense to think about what part the placebo effect plays in the PRO (patient reported outcome) of our surgical therapies – and whether instead of a saccus decompression only a retroauricular skin incision should be performed.

Less controversial and extremely useful is the comparison of two surgical procedures with the same goal in the form of an RCT. An example is the planned study comparing tonsillectomy and tonsillotomy (see 5.2.8.2).

8.4 Quality management: Financing overdue – with accompanying RCT

The fact that 2/3 of all German hospitals or 23 % of all ENT departments and 87 % of all practices or 76 % of all ENT practices do not have a proven, internal quality management system is unfortunately not in the focus of the current health policy discussion.

The operation of a quality management system generates costs [207], which, under the general conditions of economic primacy and underfunding, are apparently being avoided by the majority. The rapid growth in participation in IQM, which is largely cost-neutral, also points to this. However, IQM is a reduced approach and does not assess the existence and conformity of an internal quality management system (see 6.10.4).

Analogous to the SVR proposal on the financing of resident training, the introduction of a quality fund is to be demanded, from which the operating costs of a proven internal quality management system are to be reimbursed. In return, hospitals and practices should prove that they have an internal quality management system (which they have been legally obliged to for the last 15 years).

This could be done by participating in a certification procedure such as KTQ or ISO, which have established procedures for verifying the existence and proper operation of a quality management system. Alternative verification procedures via an extension of the external quality assurance are conceivable. Any costs for certification would also have to be reimbursed.

When implementing this measure, which is likely to take several years, it would make sense to seize the opportunity to evaluate the benefits of a quality management system and certification by an RCT, since there are currently no relevant studies available worldwide (see 4.8). IQTIG could be commissioned to design and conduct the study.

8.5 External quality assurance

In order to be able to make valid statements on the quality of care, cross-sectoral follow-up and PRO are necessary in addition to process-related quality indicators. Both are currently being developed or are being implemented initially. An evaluation of the quality of health care organizations above the process level, i.e., with respect to the implementation of a quality management system, also appears to be reasonable (discussed in detail in 5.12).

8.6 Discussion – complex challenges

There are many challenges to high-quality care:

Economic primacy, disincentives and underfunding, especially of the maximum care providers and university hospitals, lead to under-, over- and mis-supply of care for patients and to such a considerable burden on the employees that their training and health can be affected and that there is a shortage of personnel. The infrastructure of hospitals is outdated, especially with regard to digitalization. Significant adjustments to the system of funding operating and investment costs are urgently needed.

Under the primacy of distributive justice and patient well-being, cross-sectoral adjustment of outpatient and inpatient care structures should be implemented with the participation of the relevant parties of the joint self-governance system in order to use the scarce resources optimally for the benefit of all. First of all, emergency care should be reorganized. Growing legitimate expectations of patients with regard to participation, but also unjustified expectations, pose an increased demand on communication.

Rapid scientific and technological progress is challenging proven concepts of evidence gathering. The medical and scientific community will have to find answers to questions raised by big data, personalization and individualization of medicine.

The implementation of internal quality management within the institutions has understandably suffered from the introduction of the DRG system and, although legally obligatory, has not been implemented across the board to date. The necessary resources should be refinanced as part of the operating costs. In external quality assurance; further efforts are needed to develop valid outcome-related quality measurements.

9 Outlook – and First a Retrospect

One idea of quality management is that people find the greatest inner satisfaction in their work if they manage to do it self-directed and as well as possible; and everyone has a fine sense of whether this is given or not. This is especially true for our profession, because we do our work for the benefit of sick, suffering fellow human beings. Compassion towards the human being is the essence of the fundamental medical motivation

9.1 Looking back

An interesting perspective emerges when looking back at a 20-year-old position paper on quality assurance by the BÄK and KBV: This called for measures including cross-sectoral cooperation with a uniform approach to quality, the validation of quality indicators and the evaluation of quality assurance measures, the primacy of counselling over regulatory quality assurance procedures and patient surveys in the sense of PRO. All of these points are still relevant today, but few of them have been implemented. The most important demand is quoted from a resolution of the 96th German Medical Assembly in 1993 (!):

> *"Quality assurance requires appropriate personnel and organizational structures. These are associated with costs. For the additional financial expenditure incurred by the participants in quality assurance measures, additional necessary financial means must be provided" [208].*

As is well known, this requirement has also not been met. Instead, and aggravatingly, the introduction of DRGs led to an economization, with the described consequences for evidence-based, patient-oriented medicine. The KTQ project initiated by the joint self-governance exceeded its peak in 2009 and has been in decline since then. Two thirds of all hospitals do not have a proven quality management system.

9.2 Politics and quality

Expert analyses of current undesirable developments and concepts for a quality-oriented further development of the health care system are available in excellent quality and clarity and are largely in agreement. It is now up to the political protagonists of federal and state politics and the joint self-governance to lay down the direction in which the health care system will move in the future:

- Continuing on the path of economic primacy with disincentives, underfunding of top-level medicine, centralization (or rationing) of hospital services á la Bertelsmann Foundation, shortage of personnel, a quality management system that only meets minimum requirements and must therefore be enforced by external quality assurance with tighter controls and sanctions, flanked by dirigistic interventions in the autonomy of service providers.
- Or to a quality-oriented, patient- and employee-focused medicine, by containing the economic primacy in the health care system, correcting disincentives and implementing adequate, cross-sectoral capacity planning for appropriate medical care of the population. This could also free up the resources that are needed for the overdue funding of the institution's internal quality management.

9.3 Developments in quality management

The general willingness of physicians to become active beyond the obligatory external quality assurance is reflected in their strong participation in numerous voluntary quality initiatives and in IQM. Through the latter, collegial counselling by the medical peer review of the BÄK is also becoming more widespread.

The foreseeable development is to increasingly include outcome quality and PRO in external quality assurance which will provide a strong incentive for service providers to optimize their own performance by means of a comprehensive quality management system. It remains to be seen whether this will be applied exclusively internally, or whether certification or accreditation will increase again, or whether the quality assurance operated by the G-BA will be expanded to accreditation, as suggested by the AWMF. It is desirable that the concept of excellence and a reinvigorated quality culture would thus become more predominant.

ENT medicine is currently only subject to external quality assurance in the area of SHI-accredited physicians – in the future, the hospital sector is expected to be included.

9.4 Technology

Information technology (IT) will not only offer great opportunities to reduce treatment errors, but also, in combination with advances in biotechnology, to achieve a much higher level of quality by personalizing prevention and therapy (see 8.3). The digitization of hospitals that is necessary for this purpose must be decisively advanced.

One interesting application is the AI-supported, automated error analysis of endoscopic surgical videos. IT also offers new and elegant possibilities for process optimization for quality management, e.g. by simulating processes, supported by motion tracking of patients to capture the current status [209].

Controversial, strenuous political decisions on how to handle the highly sensitive health data will be necessary to ensure the interests of the entire population in the developments outlined above, but to prevent abuse with the potential for social dystopia. One example is reports of algorithms or AI that can predict the likely occurrence of a patient's death within a year, in order to direct patients to palliation in a timely manner and save "misdirected" expenditure [210, 211].

9.5 Physicians and employees

Despite all the limitations and challenges described above, the sense of responsibility and the high level of motivation of the physicians and all professional groups working with us ensures that the patients entrusted to us receive very good care overall. However, this often means that our own stress limit is exceeded with the consequences described above for health, quality of work and staffing levels. If the medical and nursing professions do not quickly become more attractive again by improving working conditions, grave effects on the quality of care can be expected.

The physicians' voice must become audible in the political background noise in order to contribute with our expertise to the necessary and overdue turnaround in health care politics.

Conflict of Interest

The authors declare that they have no conflict of interest.

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