Which Quality Makes the Difference in CI Treatment?

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Key words
Cochlear implant, quality control, standardisation

Bibliography
DOI https://doi.org/10.1055/a-1019-9381
Laryngo-Rhino-Otol 2020; 99: S137–S164

ISSN 0935-8943

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ABSTRACT

Since its introduction, cochlear implantation has seen an uptake and development which could not have been anticipated. Not only have the technical possibilities seen significant change but also the range of indication. Examples include the care of very young or very old patients, bilateral implantation or the use of residual hearing for combined electric-acoustic stimulation (EAS). This development is very dynamic, offering tremendous opportunities for hearing rehabilitation of affected patients. At the same time, however, it places considerable demands on service providers to ensure the care provided is striving to be of optimal quality. In recent years, an intensive discussion has taken place with the aim of defining quality parameters to serve as the cornerstones of cochlear implant (CI) treatment. These were initially based on the description of a defined course of a cochlear implantation and thus on the partial aspects of process, structure and result quality for quality assurance. Practical implementation of these considerations then resulted among other things in the "White Paper CI Care" and the concept of a "National CI Registry" of the DGHNOKHC. In addition to a content-oriented discussion within the professional society of the DGNHNOKHC, other parties like health insurers as payers are also beginning to show interest in influencing the process of CI care (e. g. QuInCI initiative by Techniker Krankenkasse). The legislator is also preparing measures that will directly affect CI care ("Implant Registry Act"). This article will present the current state of knowledge in quality assurance of CI care and define Germany's position compared to other countries.

Contents

1 Introduction

During the last decades, the treatment of people suffering from high-grade hearing loss or deafness has experienced a revolution. Initially, it was meant to be a measure to support lip reading but meanwhile cochlear implant (CI) therapy has become the gold standard of hearing rehabilitation in severely hearing impaired people [1, 2]. The success of this method is undiscussed and it allows not only an improvement of the hearing ability of many affected patients and thus also their communication situation, but also a significantly improves their quality of life [3].

At the beginning of CI treatment, this measure was reserved to only few affected people and was offered as treatment option only in few hospitals (meanwhile often the term of cochlear implanting institution is used). Nowadays it is quasi a standard treatment with significant increase of the treated cases and the number of implanting institutions.

Over many years, the objective of CI treatment was a gradual improvement of hearing and speech understanding, the aim today is usually to achieve the best possible outcome. A multitude of action and decision options have to be considered on the way towards CI. Those are for example the choice of the electrode carrier, the choice of product-specific characteristics, the decision regarding uni- or bilateral implantation, the optional bimodal treatment (hearing aid plus cochlear implant), hearing preservation including electro-acoustic stimulation (EAS), varying fitting and rehabilitation concepts (outpatient or inpatient) as well as an enormous number of supportive technical options (e. g. wireless microphone systems or Bluetooth connectivity for smartphones etc.).

Especially with regard to other implantable hearing systems that are available today (e. g. active middle ear implants), the indication and thus the medical-audiological expertise for the assessment of patients and their hearing capacity becomes more and more important. This already challenging basic situation is completed by different rehabilitation concepts that may encompass outpatient as well as inpatient procedures for various periods. Finally, also legal requirements such as the Medical Devices Act (Medizinproduktegesetz) have to be met so that the operator of the device, generally the implanting hospital and in particular the implanting ENT surgeon, has to bear a particular responsibility.

Taking into account the detailed aspects that are relevant for the implantation process, it becomes clear that CI is not only a single measure of a surgery (implantation of the stimulator). Moreover, successful hearing rehabilitation by means of CI is based on a complex process that starting with the diagnostic and consultation phase extends over the whole period of using the implant and thus includes a life-long follow-up of this active electric inner ear prosthesis. In addition, it can be stated that it is nowadays nearly always an interdisciplinary process that involves various professional groups and experts, e. g. otolaryngologists, phoniatricians/pedaudiologists, audiologists, medico-technical assistants, radiologists, pedagogues, psychologists, hearing aid acousticians, and numerous other professional groups. Due to regional differences, the single centers established most different structures and treatment concepts in the past.

More recently, relevant initiatives for quality assurance in CI have been developed. Those are the White Paper CI Care (Weißbuch Cochlea-Implantat-Versorgung) and the initiative for establishing

a national cochlea implant registry (Nationales Cochlea-Implantat Register) of the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery (Deutsche Gesellschaft für Hals-Nasen-Ohren-Heilkunde, Kopf- und Hals-Chirurgie, DGHNOKHC) in its version of May 2018. Also legal initiatives such as the preparation of the implant registry act (Implantateregister-Gesetz) of the Federal Government and the initiatives of the cost-bearers (Qualitätsinitiative Cochlea-Implantat-Versorgung [QuInCI], quality initiative of cochlear implantation) have to be mentioned [4–6].

This manuscript will first define the term of quality in order to identify examples for quality-related parameters of CI, to classify them scientifically, and to evaluate them. Furthermore, an assessment of the current status of quality assurance regarding CI on a national and international scale will be performed.

1.1 What does quality mean?

To explain the term of quality, the difference must be made between the colloquial use of the term and its original meaning. According to a German dictionary, the term of quality has different possible meanings such as 1) the whole of the specific characteristics (of a thing, a person), 2) the (specific) characteristic (or a thing, a person), or 3) the degree of good quality [7]. Even if the last mentioned definition represents most likely the colloquial use to the term, the production-oriented perspective refers rather to the specific characteristic of a thing or a process. This understanding is mostly associated with the wish of high repetition accuracy, i. e. reproducibility.

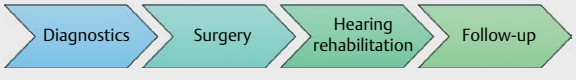
In the field of medicine, different models exist that try to transfer the concept of quality to the complex area of patient care. In many cases, these models are based on examples and ideals from the industry where the quality of a manufactured product has to be constant for the final user, such as for example the composition of pharmaceutics.

1.2 Quality models

There are a number of successive quality models for the health sector, for example the ones of Donabedian, Grönroos and Meyer/Mattmüller [8, 9]. One of the oldest and most widely spread models is the quality model according to Donabedian. This approach defines the concept of quality as the extent to which actual treatment meets the predefined criteria of good healthcare [10]. In this model, the dimensions of structural, process, and outcome quality are introduced (▶ **Fig. 1**). These terms are defined as follows:

Structural quality All structural areas that are necessary to achieve the desired objective (e. g. spatial requirements such as a sterile OR, instruments etc.).

Process quality The quality that may be influenced by improving processes (e. g. standardization of processes in order to avoid errors and mistakes).



▶ **Fig. 1** The three dimensions of quality according to Donabedian.

Quality of the outcome The defined target criterion (e. g. a certain treatment result).

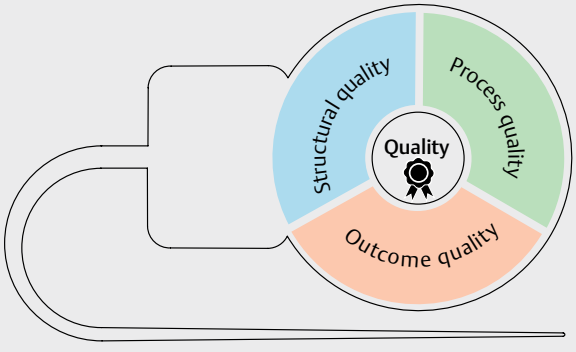
Despite the known criticism of this model (the fact that the patients'/customers' perspective is not explicitly considered with regard to the process quality etc.) [11], the model is suitable because it assesses basic dimensions, is most widely acknowledged and serves as basis that may be completed by other quality dimensions of the total quality management.

2 Cochlear Implantation in the Quality Model

Donabedian's quality model consists of the basic dimensions of process, structural, and outcome quality and in the following it will be applied to CI treatment [10]. Regarding the process, the treatment procedure of cochlear implantation regularly encompasses single steps that may be differentiated in a simplified way into the four parts of diagnostics, surgery, hearing rehabilitation, and follow-up. The objective of the single steps varies considerably and follows a chronological order. In an overall consideration, CI treatment may be seen as a total process consisting of single steps (▶ **Fig. 2**).

At the beginning of the treatment process, the indication and the suitability of the patient have to be clarified (diagnostics). After confirming the suitability, the implantation of the stimulator follows (surgery). After operative treatment, the phase of activation of the audio processor for individual fitting of the hearing impression and hearing training for optimal use of the hearing system starts (hearing rehabilitation). After the hearing rehabilitation, the phase of life-long medical, audiological, and technical aftercare follows. Hereby, the objective is pursued that the specific use of the implant and the sustainability of the achieved hearing improvement are assured (follow-up) (▶ **Fig. 2**).

Based on this generally accepted procedure, first the quality parameters will be discussed that are applied for process conduction of CI treatment (process quality). As described, they aim at the treatment phases of diagnostics, surgery, hearing rehabilitation, and follow-up. Afterwards, the structure-related quality parameters will be explained that have to the considered as precondition of performing the treatment process (structural quality). Finally, the parameters will be described that are used to assess the achieved results of CI treatment (outcome quality).



▶ **Fig. 2** The four process steps of cochlear implantation.

2.1 Process quality in CI treatment

CI treatment is a complex, life-long process with numerous process steps and involved parties that is subdivided into the four mentioned parts of diagnostics, surgery, hearing rehabilitation, and follow-up (▶ **Fig. 3**). At the beginning of the treatment process, first the suitability of a patient for CT treatment has to be determined (diagnostics). The patient undergoes several examinations that aim at confirming the indication and at assuring the feasibility of cochlear implantation. This objective is completed by an intensive consultation and information of the patient with regard to the treatment process.

2.1.1 Section of diagnostics

In the following, the contents of the part of diagnostics will be described in detail with regard to the necessary process steps. This section consists of the so-called preliminary examination and the subsequent indication of CI treatment [2] and it serves for:

1. Checking the audiological and neurootological preconditions as well as confirming the indication
2. Checking the technical/anatomical preconditions (among others fluid-filled cochlear for implantation of the electrode carrier, disposition of the hearing nerve)
3. Providing detailed information and consultation
4. Coordinating the entire treatment process

The diagnostic steps of the process will be discussed in following paragraphs (▶ **Fig. 3**):

- Audiological diagnostics
- Vestibular diagnostics
- Imaging
- Assessment of the potential of successful rehabilitation
- Medical and technical consultation
- Coordination of the treatment process

2.1.1.1 Audiological diagnostics

The verification of the audiological preconditions of cochlear implantation requires the application of subjective and objective hearing tests. Beside psychoacoustic test procedures (pure tone audiometry, speech audiometry, with and without noise), objective hearing examinations have to be performed (tympanometry, examination of otoacoustic emissions [OAE], auditory evoked potentials [AEP], if needed examination of the electric stimulation of the hearing nerve, promontory test, if needed electro-cochleography). The evaluation of the pre-existing hearing aids and a possible attempt for optimization are recommended in the phase of diagnostics. The examination by means of audiological procedures is based on several national and European standards. They concern spatial preconditions (see chapter 2.2.2) as well as the practical performance of the examinations.

In the following paragraphs, the above-mentioned relevant examination methods will be described with regard to their significance and relevance.

- **Pure tone audiometry**

The accepted standard of pure tone audiometry is defined in the DIN EN ISO 8253–1:2011–04 on “Acoustics; audiometric test methods; part 1: basic pure tone air and bone conduction threshold audiometry” [12]. In their publication entitled “Minimum reporting standards for adult cochlear implantation”, Adunka et al. suggest to regularly measure the following frequencies and to publish them in scientific publications [13]:

Air conduction: 125–250–500 – (750) * – 1000–1500–2000–4000–8000 Hz

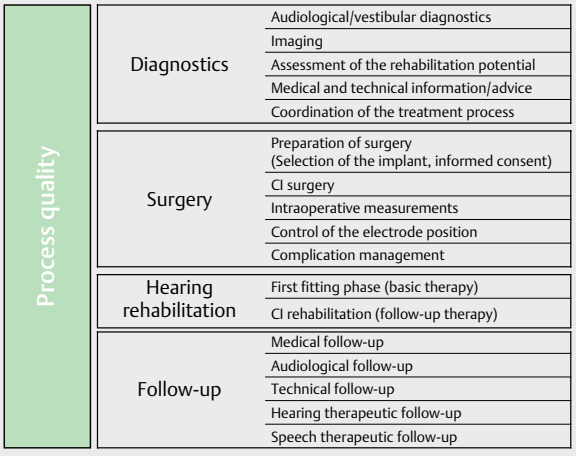
Bone conduction: 250–500 – (750) * – 1000–1500–2000–4000 Hz

Flynn et al. could show that patients with severe hearing loss or deafness have sometimes significantly different results regarding the consistency of the results between tone and speech audiometry and regarding the estimation of the hearing loss. However, pure tone audiometry is nonetheless indispensable for evaluation of the frequency-specific residual hearing, in particular in the low frequency range [14]. A reliable assessment of the residual hearing is extremely important, especially in cases of planned electro-acoustic stimulation (EAS) [15–17].

- **Speech audiometry**

The assessment of the understanding of speech is necessary in the context of hearing impairment in order to assess the patient’s capacity to communicate. To gain a better estimation of the hearing impairment especially in everyday situations, verification of the speech understanding in noise is essential. Furthermore, test procedures for examination of the speech discrimination to check the results of hearing aid provision are necessary. These examinations take place under so-called free field conditions (sound transmission via loudspeakers). To perform the speech understanding examination, the DIN EN ISO 8253–3:2012–08 entitled “Acoustics; audiometric test methods; part 3: speech audiometry” is applied [18].

There is a large variety of speech audiometric test procedures (e. g. Freiburg speech intelligibility test, Göttingen sentence test, Oldenburg sentence test, or HSM sentence test) and their



▶ **Fig. 3** Process of cochlear implantation with four process steps and secondary processes.

* In the standard cited above, the frequency of 750 Hertz is not used. However, it seems to be important in the context of residual hearing preservation so that it should also be measured.

design pursues different approaches to examine speech discrimination. The assessment of speech understanding must always be performed with consideration of the used speech intelligibility test. The discussion which test should be applied for indication finding clearly depends on the assessment of the hearing outcome after cochlear implantation (see also chapter 2.3.2). Until now, no test procedure could be established as the only method to be applied. In the following, three speech intelligibility tests will be presented that are most frequently used in German speaking countries [19, 20].

- **Freiburg speech intelligibility test**
  This test was presented at the beginning of the 1950ies by Hahlbrock and consists of two sections [21]. The first part encompasses the understanding of two or more syllable numerals and serves for assessing the hearing loss for speech and the speech understanding threshold. The second part examines the speech discrimination in the over-threshold area with monosyllabic nouns. The currently applied version of the test corresponds to the standard of DIN 45621–1:1995–08 "Speech for hearing tests – part 1: words consisting of one or more syllables" [22]. Currently, the significance of the Freiburg speech intelligibility test is discussed (see chapter 2.3.2) [23, 24].
- **Göttingen sentence test**
  The Göttingen sentence test was presented in 1997 by Kollmeier and Wesselkamp [25]. It consists of 20 test lists with 10 sentences each. These sentences have a high comparability with regard to the discrimination function, the number of words per list, the number of phonemes per list, and the frequency distribution of the phonemes per list, which is very similar to the German language. The test may be performed with and without noise.
- **Oldenburg sentence test**
  The Oldenburg sentence test was described in 1999 by Wagner et al. This test allows a standardized examination of speech understanding with and without noise, while the result does not depend from the selection of the test list. The test may be performed in the closed mode by the patients themselves and provides a high number of word lists [26–28]. Each sentence of the test consists of five words that are chosen randomly from 10 alternatives (matrix sentence test procedure).

- **Evaluation of speech audiometric procedures**
  Currently there is no general consensus with regard to the question if exclusively one certain speech test should be applied in cochlear implantation. With the background of the current study situation about the Freiburg monosyllabic test (see chapter 2.3.2), however, a combination with another speech test performed in noise seems to be reasonable [19].
- **Objective hearing testing**
  The mentioned subjective test procedures should be completed by the following objective methods:
  - **Tympanometry**
    Tympanometry allows statements about the status of the middle ear (ventilation, eardrum perforation, fluid behind the eardrum, mobility of the ossicles) and is an essential standard examination of audiological diagnostics [1, 20].
  - **Otoacoustic emissions (OAE)**
    Today the assessment of otoacoustic emissions (auditory evoked active movements of the outer hair cells of the cochlea) is a standard examination of inner ear diagnostics. If they are measured, most probably a hearing threshold of more than 35 dB HL can be expected [20]. The rapidly performed test and the high sensitivity make OAE measurements an appropriate screening examination in the context of newborn hearing screening or in cases of non-compliant patients. If perisynaptic/auditory neuropathy is suspected (objectifiable hearing loss with negative auditory evoked potentials despite evidence of OAE), the OAE method has a high relevance [29].
  - **Auditory evoked potentials (AEP)**
    In order to objectively asses a functional disorder of the hearing system, neurogenic potentials are measured at different points of the central hearing pathway. The so-called early auditory evoked potentials (EAEP) are measured by means of brainstem-evoked response audiometry (BERA), whereas the late auditory evoked potentials (LAEP) are measured by means of the so-called cortical electric response audiometry (CERA). The measurement of middle auditory evoked potentials with the auditory steady state response (ASSR) method assures a reliable frequency-specific estimation of the hearing threshold [30]. Beside the traditional click and sound impulse stimuli, increasingly chirp stimuli are applied for measurement of the EAEP that assure a stronger activation and thus better signal/noise ratio by the adaptation to the frequency-specific duration of the traveling wave in the cochlea [31].
    The significant advantage of the auditory evoked potentials is their "objectivity", i. e. measurement that is nearly independent from the cooperation of the patients. Furthermore, the examinations (BERA and ASSR) may be performed in sleeping patients or under anesthesia, which makes them important tools in the diagnostics of uncooperative patients or children. The assessment of AEP is an indispensable standard in the diagnostics of cochlear implantation [1].
  - **Promontory test**
    In cases of complete and very long duration of deafness, the promontory test may provide helpful information. The aim is to create the perception of a hearing impression (recognition of frequencies and rhythms) via the application of electric stimuli. For this purpose, an electrode is placed directly near the promontory. This may be performed after myringotomy through the eardrum or by placing a stimulation electrode on the eardrum. A positive hearing impression is considered as an indicator for the possibility of electric stimulation of the cochlear nerve via CI [32]. However, some trials show that the sensitivity and specificity of the examination are limited [33].
  - **Electrocochleography (ECochG)**
    So-called summation potentials and cochlear microphonics (CM) may be registered by means of electrocochleography

[34]. Until now, the exact origin of these potentials is unclear. However, four different locations are assumed that all contribute to these potentials. The potentials of the inner and outer hair cells as well as the dendritic potentials and the action potentials of the hearing nerve fibers [35]. Up to now, the main application field was the diagnosis of Menière's disease. However, also indications in differential diagnosis of auditory neuropathy and synaptopathy are justified. With regard to the diagnostics in the contest of CI treatment, the current research focuses on making predictive statements about the probable success of cochlear implantation by means of ECochG [35].

- **Assessment of objective hearing test procedures**
  In adults, objective hearing tests serve for verification of the findings measured in psycho-acoustic tests. In single cases, patients may be identified who have no peripheral hearing disorders, who exaggerate with their description of the hearing loss or simulate, and who are therefore not suitable for CI treatment. In children, objective hearing tests are particularly important because they are usually not able to provide reliable statements. In summary, there are many publications and instructions regarding high-quality performance of examinations [20, 29–35].
- **Checkup of hearing aids**
  A checkup and if needed the necessary optimization of hearing aids is required due to two reasons. First it is obligatory according to the act of patients' rights (§ 630e BGB) to describe treatment alternatives to patients so that they may decide for or against therapy [36]. Second, according to § 12 of the Social Security Code (SGB V), the principle of cost-effectiveness has to be observed. This means that the services have to be sufficient, appropriate, and cost-effective; they must not exceed the measure of what is really necessary. Services that are not needed or that are cost-ineffective, cannot be requested by insured people, must not be performed by the service providers, and must not be approved by the health insurances. This evidence of medical necessity is generally provided by the proof that despite best possible hearing aids, no complete compensation of the handicap in the sense of equality with healthy individuals is achieved [37]. As reference of appropriate treatment with hearing aids, the devices guideline (Hilfsmittel-Richtlinie) of the Federal Joint Committee of the health insurances (Gemeinsamer Bundesausschuss der Krankenkassen) can be mentioned. In the §§ 21 and 22, criteria for the prescription of hearing aids for one or both ears are explained [38]. The basis are tone and speech audiometry with and without noise. For further classification of the specific function of the hearing aids, an in-situ measurement and coupler measurement may be required [39].

As an orientation for speech understanding achieved with hearing aids, the so-called maximum understanding of monosyllables was applied for a long time that corresponds to the maximum percentage of the Freiburg monosyllables test. This score should theoretically be achieved in cases of best possible hearing aid provision by means of hearing aids at 65 dB. In the practice, it could be shown that this value provides at best a rough estimation for the maximum speech understanding that can be achieved with hearing aids and thus it is not at all an objective that has to be achieved necessarily [40]. On the other hand, the maximum understanding of monosyllables may support the indication of CI treatment because this value can hardly be achieved with optimal hearing aids but is regularly exceeded with CI [41].

- **Assessment of hearing aid checkup**

Together with the maximum understanding of monosyllables, the verification of the quality of hearing aids is a key point for the indication of CI treatment. Even if the assessed values must not be used uncritically and require interpretation by specialists and audiologists, they give important hints for the indication of the predictable success and also the later success of cochlear implantation.

2.1.1.2 Vestibular diagnostics

The subjective and objective audiological diagnostics are completed by vestibular diagnostics for assessment of the peripheral vestibular function. A well-known, even rare, risk of cochlear implantation is a (usually temporary) impairment of vestibular function [42–45]. The measurement of the vestibular function in the context of the diagnostic process is strongly recommended. There are numerous publications on the most common vestibular tests and the pathologies that may be diagnosed [46, 47]. In the following, important device-based tests will be described briefly. They should be completed by clinical examinations (positional tests, examination by means of Frenzel goggles) [1].

- **Caloric vestibular test**
  The caloric test is a method of testing the vestibular function that has been used since the 19th century. By means of warm and cold water or air, the outer auditory meatus is calorically stimulated in order to measure the number of resulting nystagmus per time unit. The test may be used for functional diagnosis of the horizontal semicircular canal [48].
- **Head impulse test (HIT)**
  The head impulse test verifies the vestibulo-ocular reflex by measuring of the time course of eye movements after rapid rotational acceleration of the head. Based on reference values, the system allows differentiated statements about the function of the 3 semicircular canals of each side [49].
- **Vestibular evoked myogenic potentials (VEMP)**
  Vestibular evoked myogenic potentials may be measured as reflex responses to acoustic or vibratory stimuli of cervical (cVEMP) or ocular muscles (oVEMP). The cVEMPs are relevant for the diagnostics of the saccular function and the oVEMPs for the utricular function [47].

Assessment of the vestibular diagnostics

In the context of preliminary examination before cochlear implantation, cochlear diagnostics are recommended in order to obtain basic information about the peripheral vestibular function. Sometimes, also a prognostic statement about the risk of vestibular damage associated with cochlear implantation seems to be possible [50]. Due to regularly performed vestibular diagnostics, it is possible to inform and consult in an optimized way regarding the risk of vestibular damage associated with cochlear implantation [50]. Furthermore, a vestibular test that reveals pathologic side differences may also support the decision of which side should be implanted [51].

2.1.1.3 Imaging

If a patient is suitable for CI treatment, is first determined by ENT specific examination and history taking. Hereby, particularities such as the time of occurrence of the hearing disorder, the course, speech development, early otitis, deformities of the auricle, perforations of the eardrum, or hints to middle ear diseases, e. g. cholesteatoma, must be assessed. Furthermore, the anatomical preconditions have to be clarified by means of radiologic diagnostics. Different imaging techniques reveal the cochlea, the surgical access, the auditory nerve, and anatomical particularities (e. g. the course of the facial nerve). In single cases, also an assessment of the function of the auditory nerve and the central hearing region may be necessary. As technical standard, up to now high-resolution computed tomography (hrCT) of the temporal bone is performed before cochlear implantation as well as magnet resonance imaging (MRI) of the cochlea and the auditory nerve [52].

Computed tomography is the method of choice to identify the bony anatomy and thus bony deformities or variations [53]. Indirectly, the assessment of the inner auditory meatus also allows drawing conclusions regarding the anatomy and possible anomaly of the auditory nerve. Possible CT procedures that are available are the hrCT, the flat panel CT, and cone beam tomography (CBT) [53].

- **High resolution computed tomography (hrCT)**
  Modern multidetector CT scans may provide hrCT of the temporal bone with sub-millimeter isotropic resolution in a range between 0.3 to 0.6 mm. These isotropic images can be reconstructed three-dimensionally and thus support the diagnosis of anomalies and surgery planning [53, 54].
- **Flat panel CT**
  Flat panel CT is a combination of C-arm angiography and flat radiology detectors. This combination allows calculating CT reconstructions by rotation around the patient with C arm [53, 55]. One advantage of the flat panel CT compared to conventional CT scan is the better spatial resolution that reaches the µm range [55]. A disadvantage, however, is the poorer display of soft tissue in comparison to conventional hrCT [56]. In addition, flat panel CT is currently not widely distributed.
- **Cone beam tomography (CBT)**
  CBT uses the conical course of radiation of a radiation source and combines it with flat panel detectors [57]. Compared to CT scans, this leads to relatively small and cheap devices. However, in contrast to CT scan, their clearly poorer display of soft tissue limits the application in preoperative diagnostics [52, 53].

In contrast to MRI, CT scans have the advantage of better displaying soft tissue and the absence ionizing radiation [53]. Further developments of MRI techniques with higher field intensities, stronger field gradients, and better coils led to the fact that more sequences were developed for the assessment of temporal bone structures. Even so-called T2-weighted sequences turned out to be ideal for the presentation of contrasts between neuronal structures (vestibulo-cochlear nerve and facial nerve) and CSF as well as between fluid-filled inner ear structures and their environment [58]. In addition to temporal bone presentation, some authors recommend the completion of sequences for assessment of the cerebrum because due to obliteration effects after CI treatment it can merely be assessed by means of MRI [59].

Particularities in children: Several trials show that children with inner ear hearing loss often have associated anomalies of the inner ear or the hearing nerve [60, 61]. It is the aim of imaging diagnostics by means of hrCT and MRI to preoperatively identify these anomalies [52, 62]. Currently, the regular application of hrCT in the preoperative diagnostics of children is controversially discussed because of the radiation exposure [63]. However, in the recent past, work groups (Siu et al.) could present algorithms that should reduce the frequency of hrCT in children without causing disadvantages regarding the surgical safety by ignoring anomalies [64]. Every patient first undergoes MRI. If the patient history is positive regarding ear trauma, past inflammation, or cranio-facial anomaly, an additional hrCT is recommended. If the MRI shows an anomaly, also hrCT is performed. Currently, no meta-analyses are available for evaluation of this procedure so that it must be awaited if a sufficiently safe preoperative assessment of the anatomical condition is possible.

In individual cases, more specific questions may require radiologic examinations to determine the activity of the auditory cortex. These examinations that are not part of the clinical routine include [1]:

- Positron emission computed tomography (PET-CT) [65]
- Functional magnet resonance imaging (fMRI) [66]
- Near infrared spectroscopy (NIRS) [67]

Assessment of the imaging methods

Currently, different CT procedures for assessment of bony structures of the temporal bones are applied with regard to anatomical variations and malformations. The application of MRI is current standard for the assessment of soft part structures of the temporal bones, the fluid of the cochlea, and the neural structures.

2.1.1.4 Assessement of the potential of rehabilitation

Beside a series of other factors, the success of CI treatment depends mainly on the patients' potential of rehabilitation. The patients have to be mentally and physically able to use the CI in order to benefit from treatment. In this context, also the expectations of the patients play a crucial role, so they have to be defined prior to treatment. It is undiscussed that there cannot be a general standard regarding the assessment of the potential of rehabilitation. This is especially true with the background of the treatment of patients with multiple disabilities, patients with mental disorders, patients with severe mental retardation of early childhood, or also dement patients. Even if these and other similar patient groups have to cope with a series of challenges, they must not be excluded from treatment. Often significant success is seen after CI treatment that goes far beyond the mere consideration of speech understanding (e. g. increased affection and improvement of emotional competence) [68].

The preoperative contact between patients and the people performing hearing rehabilitation (e. g. ENT specialist, CI audiologist, and pedagogues) is a possible tool to allow a first estimation of the patients' rehabilitation potential. There is no doubt that significant personal experience is the basis of such an assessment. In summary, the evaluation of the preoperative determination of the rehabilitation potential plays a relevant role that is an obligatory part of the diagnostics of CI treatment.

2.1.1.5 Medical and technical consultation

The medical and technical consultation and information of patients is essential in the preoperative phase of CI treatment. While medical consultation should emphasize the information of the patients with regard to medically relevant aspects of treatment, it encompasses more than only the description of surgical details and risks of an intervention. The explanation of the entire treatment process including the phased hearing rehabilitation, the life-long follow-up, and also the effects associated with cochlear implantation (e. g. evaluation of possible MRI examinations despite CI) as well as socio-medical aspects (e. g. consultation in the context of applying for rehab measures or for severe disability) belong to the field of medical consultation.

Furthermore, a neutral, i. e. manufacturer-independent, technical consultation of the patients is necessary. Already the enormous increase of technical devices that may be combined with CI (e. g. Bluetooth connectivity or wireless remote microphones) requires continuous learning and the necessity of competent information and advice. Even if this consultation is not bound to a specific professional group, it is often performed by CI audiologists because it requires a high technical expertise. This aspect also concerns information about available implants. In Germany, cochlear implants of four manufacturers are currently approved for implantation. Those are in alphabetical order:

- Advanced Bionics LLC, CA USA
- Cochlear Ltd., NSW Australia
- MED EL GmbH, Innsbruck, Austria
- Oticon Medical LLC, Copenhagen, Denmark

Each of these manufacturers does not only have an own implant portfolio but also offers different audio processors. Before treatment, the patients should be informed in detail about the characteristics of the single implants independently from the manufacturers. The aim must be the autonomous decision of the patients for an entire system (implant + audio processor) unless medical (e. g. obliteration of the cochlea), technical, audiological, or other relevant aspects make medical recommendation for a specific product necessary.

Legislation regulates this requirement of medical obligation to information in the Civil Code according to which the treating professional is obliged to explain all significant conditions to the patients in an understandable way at the beginning of treatment and, if needed, in the further course. Special focus must be placed on the diagnosis, the probable development of health, the therapy, and the measures that have to be taken for and after therapy [69]. Furthermore, this process of consultation and information and the final decision have to be documented.

2.1.1.6 Coordination of the treatment process

In order to assure a safe, rapid, successful, and finally also cost-effective CI treatment, the early planning and coordination of the treatment process are necessary (see also chapter 2.1.3 about hearing rehabilitation). For this purpose, the patients' individual preconditions should be taken into account in a particular way because they determine the possibilities and limitations of hearing rehabilitation. Beside the age, the individual life situation, independent living, the place of residence, comorbidities and thus the mobility, a multitude of other factors play a crucial role for planning the individual treatment concept.

It is without any doubt, that the responsibility for the organization and thus the assurance of the entire treatment process including hearing rehabilitation and follow-up has to be taken by the institutions where the patients are implanted (CI department). Even if there is the general option to delegate single steps of the process of cochlear implantation, the ultimate responsibility for performance and outcomes of the treatment steps (e. g. hearing rehabilitation and follow-up) remains with the cochlear implanting institution. Of course, this also includes long-term complications as a consequence of missing follow-up concepts. According to the Medical Device Operator Ordinance (Medizinprodukte-Betreiberverordnung), the hospital and in particular the responsible physician are considered as operators of the implant and thus they have the final responsibility for the intended use of the device [70].

In summary, the entire treatment concept including organizational implementation of hearing rehabilitation and life-long follow-up should be explained, coordinated, and documented in the context of preoperative diagnostics of CI treatment.

2.1.2 Process steps of surgery

The process steps of the operative phase encompass the time from decision making for cochlear implantation via preparation of surgery, the actual performance of implantation up to finalized wound healing (▶ **Fig. 3**). Implantation is usually understood as the CI surgery with regard to the technical performance of the treatment, i. e. the insertion of the electrode carrier into the cochlea and the insertion of the stimulator into the temporal bone. The surgery is generally performed as inpatient procedure. The objective of the following chapter is to describe the relevant aspects that are associated with the surgery. In detail, these are:

- Preparation of surgery (selection of the implant, information/consultation)
- CI surgery
- Intraoperative measurements
- Control of the electrode position
- Complication management

2.1.2.1 Preparation of surgery (selection of the implant, information/consultation)

Detailed information about all aspects of CI treatment should already be considered as part of the process step of diagnostics. It also concerns determining realistic objectives of surgery, the decision for a specific implant of a manufacturer, and the coordination of the entire cochlear implantation including hearing rehabilitation and life-long follow-up (see chapters 2.1.3. and 2.1.4.).

With regard to the specific information about the technical performance of the surgical intervention, standardized medical information sheets are available that describe the implantation of a CI in detail as well as medical and legal aspects (e. g. the German information entitled "Einsetzen eines Cochlea-Implantats" (HNO 59), Diomed Thieme Compliance Verlag). So the application of these standardized information documents seems to be reasonable.

2.1.2.2 CI surgery

The implantation of the CI is the insertion of an active electronic neurostimulator. From a surgical point of view, it is a modified surgical intervention of the temporal bone and the middle ear. This intervention, however, is completed by the surgical opening of the inner ear and the insertion of an electrode carrier into fluid-filled spaces (scala tympani) of the cochlea.

The anesthesiologic care of a patient mainly corresponds to the principles that are also applied in other surgical interventions in the area of the temporal bone. Since, however, often very young patients are treated in the context of cochlear implantation, regularly in the first year of age or even in the first few months, particular anesthesiologic experience is required [71]. This also concerns the possible necessary intensive care of multi-morbid children. Similarly, nowadays also very old patients are implanted who may also experience successful hearing rehabilitation beyond the age of 90 years. Especially this patient population frequently has numerous internal comorbidities that also require the specific experience of anesthesiologists.

- **Surgical techniques**
  The application of cochlear implants of different manufacturers sometimes varies enormously so that the specific particularities of a product and the used electrode carrier have to be looked up in the current "Surgical Manual" of the manufacturer [72–75].

As a superordinate aim of the practical performance of CI surgery, the principle of "atraumatic insertion" was established during the last years. It was first described by Lehnhardt as so-called "soft surgery" [76] and should always be applied. As an important criterion for atraumatic (preserving) surgery technique, often the degree of preservation of residual hearing is mentioned. In 2014, Santa-Maria et al. presented a meta-analysis including 24 trials that analyzed the following relevant aspects with regard to residual hearing preservation [77, 78]:

- **Access to the cochlea**
  As an access to the cochlea, generally two pathways exist, first cochleostomy (opening of the scala tympani in the basal turn of the cochlea at the promontory) and second the opening of the cochlea via the round window membrane. Critics of the round window method state that the electrode deviates from the ideal traction line because of the cochlear hook region when electrode insertion is performed in that way which might lead to injuries within the cochlea. In contrast, critics of cochleostomy state that the drilling noise may lead to damage of the hair cells and that no safe anatomic landmark is available [77]. Both methods are applied today while the round window access is often preferred in view of the current electrode design. This observation is confirmed by an article published by Schart-Moren et al. who observed the superiority of the round window method regarding the insertion trauma in a temporal bone trial [79].
- **Speed of electrode insertion**
  In the same trial, a comparison of the speed of electrode insertion into the cochlea showed a significantly higher residual hearing preservation when the electrode was inserted with lower speeds over 30 s [77]. Therefore, slow electrode insertion can be recommended.
- **Application of cortisone**
  In the context of CI surgery, glucocorticoids are applied either locally (applied in the round window niche or during cochleostomy) or systemically as intravenous bolus. Santa-Maria et al. summarized that the local intraoperative application of cortisone had a significantly positive effect on the residual hearing at 2 kHz [77]. The systemic intraoperative application of cortisone in the above-mentioned investigation has no significantly positive effect on the residual hearing preservation. Application of cortisone in the context of CI surgery may be taken into consideration.
- **Hyaluronic acid as lubricant**
  In this meta-analysis, hyaluronic acid as lubricant that ought to make electrode insertion gentler did not show a significant effect for residual hearing preservation [77].
- **Intraoperative monitoring of the facial nerve**
  The application of intraoperative monitoring of the facial nerve (EMG) is frequently observed in the context of CI surgery. Even if there is no obligation to apply this method it is meanwhile widely distributed so that nearly every CI department disposes of this option. The performance of CI surgery is certainly also possible without monitoring of the facial nerve. However, there are no reasonable arguments against using this system [80].

- **Summary of the surgical techniques**
  Meanwhile, CI surgery is standardized in many aspects, but there are numerous details that are still open and that need further scientific evidence. Santa-Maria et al. indicate that none of the analyzed trials was randomized [77]. Further, there are important differences regarding the depiction of the results that made it difficult for the authors to compare the trials. The authors require a possibly uniform standard for the description of surgery techniques and results in order to facilitate future evaluations. With the background of these statements, the establishment of a national CI registry is recommended so that therapy outcomes and treatment recommendations may be compared based on larger case numbers.

2.1.2.3 Intraoperative measurements

After implantation of the CI, measurements can already be performed during surgery with the aim to check the regular function of the implant and the correct position of the electrode carrier. In 2014, Wesarg et al. provided a detailed description of the performance and evaluation of these measurements [81]. A difference has to be made between "electronic measurements" and "audiological electrophysiological measurements". As standard for electronic measurements that are performed via manufacturer-specific computer-based cochlea implant diagnostic systems the following examinations are described [81]:

- **Coupling test**
  The coupling test confirms if the implant can be controlled by means of the coil [81].
- **Integrity test**

The integrity test is a self-check of the implant showing the technically correct function of the system [81].

- **Impedance telemetry**
  Depending on the manufacturer, the electrode carriers have 12–22 contact points. In the context of impedance telemetry, the electric resistance is verified for every electrode. Deviations may be explained by so-called open circuits (OC) and short circuits (SC). OC measurements may be caused by air bubbles at the electrode surface, foreign bodies, or electrode cable failures. OCs that are observed initially intraoperatively may disappear within few minutes after re-measurement. SCs may be caused for example by short circuits within the electrode carrier. Depending on the number of the affected contacts, it should be discussed to intraoperatively exchange the implant [81].
- **Field telemetry**
  In the context of field telemetry, not the resistances but the voltage of the electrodes are measured after stimulation of an electrode. This allows for example the diagnosis of a tip-fold over [81, 82].
- **For audiological electrophysiological measurements, the following examinations are intraoperative standard:**
  Activation/threshold of the electrically evoked stapedius reflex
  Hereby, the acoustic-facial reflex that physiologically leads to contraction of the stapedius muscle at volume levels as of 70 dB is used to trigger a stimulation of the auditory nerve via the CI. The reflex is assessed semiobjectively by the surgeon by means of observation through the surgery microscope, and the amperages up to which the reflex can be triggered are documented [81]. In order to certainly activate the reflex, it is recommended to avoid volatile anesthetics because they might suppress the activation of the reflex [82].
- **Measurement of the electrically evoked compound action potentials of the auditory nerve (ECAPs)**
  The potentials that are acoustically evoked in the context of electrocochleography (see chapter 2.1.1.1) can partly also be electrically activated. Compound action potentials of the auditory nerve are triggered electrically via the electrode carrier and also registered. The single cochlear implant manufacturers have different names for the procedure to measure these potentials:
  - Neural Response Imaging (NRI; Advanced Bionics company)
  - Neural Response Telemetry (NRT; Cochlear company)
  - Auditory Nerve Telemetry (ART; MedEl company)
  - Electric compound action potentials (ECAP; Oticon company; no specific terminology)
- **Real-time electrocochleography (ECochG) during electrode insertion in cases of surgeries with residual hearing preservation**
  Recently, different authors reported about positive experiences with an intraoperative real-time measurement of ECochG during electrode insertion in the context of surgeries with residual hearing preservation [83, 84]. Similar to preoperative ECochG described in chapter 2.1.1.1, the acoustic stimulus originates from a sound transducer inserted in the auditory meatus. The elicited potentials may be recorded directly via the CI electrode carrier. Currently it is assumed that these potentials change at contact of the electrode with the basal membrane. The aim of real-time measurement during insertion is to create feedback for the surgeon in order to avoid an intracochlear insertion trauma. However, this method is currently not available for routine interventions; still trials are missing that might confirm the benefit based on larger case numbers [84, 85].

Summary of intraoperative measurements
In 2008, Page et al. conducted a survey with 39 CI surgeons regarding the performance of intraoperative measurements. According to the authors, the significance of intraoperative test procedures is not yet clarified [85]. With the background of the short timely effort, the application seems to the indicated, at least in order to exclude technical defects of the implant.

2.1.2.4 Control of the position of the CI electrode

In general, for verification of the position of the electrode carrier, radiological and non-radiological methods are available.

- **Radiological methods**
  Aschendorff et al. describe the advantages of a radiological control of the position of the electrode carrier after implantation [86]. It can either be performed intraoperatively or postoperatively. Intraoperatively, often a C-arm or a mobile CBT is used [87]. Postoperatively, the following examinations that have already been described in the chapter on preoperative diagnostics (chapter 2.1.1.3) may be applied [52]:
  - CBT
  - CT scan
  - Radiology according to Stenvers

  Currently, the trend goes in direction of 3D tomographic imaging, i. e. CBT or CT. Current trials confirm good possibilities for both procedures regarding control of the position. However, the necessary radiation dose seems to be lower in CBT. Until now, randomized trials or meta-analyses are missing so that no clear recommendation for one of the procedures can be given [88]. Basically, the application of the modified conventional radiography according to Stenvers ("cochlear view") is still possible, but it does not provide all information for control of the electrode position [52].
- **Non-radiological methods**
  Currently, procedures are being developed that are intended to allow statements about the correct position of the electrode array by applying electrophysiological measurement methods. The application of the so-called SOE ("spread of excitation") measurement procedure may allow the detection of a tip fold over, however, in many institutions this procedure is not part or the clinical routine [89].

Evaluation of the control of the CI electrode position
Currently, the radiological methods still represent the standard of control of the CI electrode position after implantation. Performing this examination should be recommended as important criterion of quality control.

2.1.2.5 Complication management

One important aspect of inpatient treatment is an adequate complication management. It encompasses the assessment of beginning wound healing and the identification of typical postoperative complications that may arise particularly in the direct perioperative phase. Lenarz et al. and Cohen et al. described the following frequently occurring complications [1, 90]:

- Suture dehiscence
- Infection
- Emphysema
- Hematoma
- Seroma
- Facial edema
- Facial nerve palsy
- Eardrum perforation
- Stimulation of the facial nerve
- Pains
- Vertigo
- Tinnitus
- Impaired sense of taste

It is obvious that the cochlear implanting institution must be able to manage possible complications specifically and timely. Since these complications may also arise with a certain delay, it seems to be clear that the care for a CI recipient must be assured also after inpatient treatment. Of course, this must also be possible outside the regular working hours. Even if there are currently no comparative studies, it appears logic and is described by different authors [1, 91].

2.1.3 Hearing rehabilitation

The term of hearing rehabilitation includes two different, subsequent process phases of CI treatment. The first part which is also called basic therapy or fitting phase serves for individual fitting/setting of the audio processor. The next step is called follow-up therapy or CI rehabilitation. This phase is necessary for optimizing and achieving the best possible speech understanding with the CI. The difference must be made regarding the socio-medical term of rehabilitation that defines a process of the social legislation [92]. Hearing rehabilitation describes the entire process of (re-)establishment of the communication capacity based on hearing and speech understanding as a consequence of cochlear implantation.

Generally, fitting (basic therapy) as well as CI rehabilitation (follow-up therapy) may be performed in different places. However, it is undiscussed that experiences and results from hearing rehabilitation are obligatorily needed also with regard to competent indication making. At least the fitting (basic therapy) should be performed in the CI institution.

In order to make clear the time that the first fitting phase and CI rehabilitation (follow-up therapy) need, first the existing challenges will be focused. For CI recipients, the electric impulses generated by the implant vary significantly from the hearing impressions of healthy hearing individuals. It becomes obvious that first a habituation and learning phase have to be passed in which the auditory cortex and associated brain areas have to first "learn" to translate these new stimuli into defined sounds and finally speech. Thus the fitting process is a continuous interaction between modification of the settings, habituation to new hearing impressions, and finally again adaptation of the settings of the audio processor to the hearing impression of the patient. This process requires a high professional competence and should always be performed by an experienced CI audiologist.

2.1.3.1 Fitting (Basic therapy)

The objective of the fitting phase (basic therapy) consists of determining the individually adapted lower and upper limits of the applied stimulation currents for each electrode. The lower values are called "threshold values" (T values) and represent the stimulation current at which hearing impression is just triggered. The upper values are the "comfort values" (C or MCL values) representing the stimulation current that is not yet perceived as too loud [93]. Hoppe et al. described this process in detail in their publication entitled "Anpassen von Cochlea-Implantatsystemen" (Fitting of implant systems) so that this description can be used as good orientation for the procedure in terms of basic therapy [94].

With regard to the duration and the frequency of fitting sessions, there are no binding guidelines. However, recommendations exist that are based on scientific publications of highly reputed centers [94, 95]. Nonetheless, the description of the fitting processes of single centers is different and mostly reflects "grown structures" and a successfully "lived" standard. So there are centers where the fitting phase is performed on an outpatient basis, but also centers where it is performed inpatiently. Single institutions dispose of cooperation agreements with rehabilitation departments that are responsible for fitting. A nationwide applied standard does currently not exist. However, it can be stated that the vast majority of the large, experienced CI institutions performs at least the fitting phase within the respective institution.

A survey performed worldwide by Vaerenberg et al. showed that the majority of the centers conducts fitting about 3–4 weeks after implantation in 1–3 sessions; the sessions take 60–90 min each [96]. Some groups, however, also report about fitting already some days after surgery (early fitting) [97]. According to Hoppe et al., fitting is technically an interaction between the results of psychophysical, electrophysical, and audiometrical measurements that will be explained in the following [94].

- **Psychophysical method**
  In the context of the psychophysical method, the single stimulation currents are increased until the T and C levels of each electrode are determined. This process is very slow in order to avoid an interference of the auditory impression. The advantage of this method is that there is enough time for a habituation effect to the new hearing impression and thus an over-stimulation is surely avoided [94]. A disadvantage is that this method is very time-consuming and requires highly cooperative patients. Due to the long duration of this procedure, a shorter method was developed, the so-called streamline fitting. In the context of this approach, the electric threshold is only assessed for every second or third electrode and the C levels are then defined only a bit above. Afterwards, the C levels are increased in the live mode until the patients perceive the speech of the fitting professional as comfortable. This shorter method is generally well tolerated and accepted and in most cases it leads to results of speech understanding that are comparable to the traditional method [98].
- **Fitting based on electrophysiological measurements**

Electrophysiological measurements such as early and late acoustic potentials or stapedius reflex thresholds (in cases of electrical stimulation) may provide hints for the fitting of the CI processor. In this way, a correlation between the stapedius reflex threshold and the C values could be revealed [99, 100]. The disadvantage of this method is that the fitting requires further devices for the registration of the potentials or the stapedius reflexes. With the introduction of simplified measurements of ECAPs (see chapter 2.1.2.3) the fitting by means of objective electrophysiological parameters could be significantly simplified [81, 94].

- **Automatic result-oriented fitting**
  Current efforts are undertaken to focus more on the results of hearing performance and less on the comfort levels of the patients as basis of fitting. The "Ear Group" from Antwerpen has developed an algorithm based on artificial intelligence (AI) that calculates an automatic fitting proposal for specific phonemes by means of monosyllables understanding, the hearing threshold for wobble sounds, the loudness increase function, and the discrimination [101]. In first studies, the automatic fitting is equivalent to the original fitting. Thus the results are very promising for a future AI-based fitting of an audio processor [102].

Fitting in pediatric patients

Fitting in pediatric patients is usually much more time-consuming than in adults and further encompasses numerous social and treatment-related aspects. In addition, electrophysiological fitting methods play a crucial role, in particular the intraoperative measurement of the stapedius reflex threshold and the ECAP measurement [102]. The parameter setting of the audio processor in children is a highly responsible activity that can only be performed with vast experience because it influences decisively the entire development of hearing and speaking of a child.

Summary: Fitting phase (Basic therapy)

Comparative trials are currently not available that would allow clear instructions. However, there are numerous best-practice examples and scientific publications with a large, long-term data base for successful treatment concepts. It is evident that the fitting phase is a complex and time-consuming process that is currently based on the interaction of psychophysical and electrophysical measurements. Approaches to automate the fitting process by means of AI-based algorithms seem to be promising with the background of the increasing use of E-learning and artificial intelligence, but until now they are not comprehensively applied [102].

2.1.3.2 CI rehabilitation (follow-up therapy)

CI rehabilitation is a significant aspect of CI treatment. It includes all measures that are necessary for active improvement of speech understanding with the CI [103, 104]. As mentioned above, the socio-medical term of rehabilitation has to be distinguished, which describes a process defined in the Social Code [93].

CI rehabilitation (follow-up therapy) focuses on different aspects of optimizing speech understanding with the CI and aims at medical, audiological, hearing therapeutic, and technical parts of hearing therapy. In children, the speech therapeutic component plays a particularly important role [105].

Generally, different concepts of CI rehabilitation are currently applied. They include inpatient as well as outpatient treatment concepts [104, 106]. Currently, randomized comparative trials are not available that would confirm the advantage of one of the approaches. However, it must be mentioned that many approaches for studies are not possible, already for ethical reasons. So it could not be justified to investigate a comparison of a therapy concept that would allow the possibility of poorer speech development, especially with the background of the timely limited plasticity of the auditory system. On the other hand, a comparison of the therapy approaches that are currently applied should be ethically justifiable. However, the precondition is a standardized assessment of the treatment. Such a standard does currently not exist and will most probably only be possible with the introduction of a nationwide CI registry.

Nonetheless, there are already numerous scientific publications that investigate the effect of single CI rehabilitation concepts. Zeh et al. confirmed the positive effect of inpatient rehabilitation in a large trial [107]. On the other hand, Diller states that it is not or only to a limited extent possible for adults due to job-related or private circumstances to spend 3–5 weeks as inpatient in an institution so that this gap has to be closed by means of outpatient rehabilitation [104]. A direct comparison of both concepts, however, is not possible because the approaches clearly vary with regard to the contents and the frequency as well as the duration.

Both concepts of rehabilitation have in common that they pursue a multi-dimensional and interdisciplinary approach and encompass a multitude of single therapeutic measures [104, 105, 107]. So there are audiological services such as fitting controls and fine tuning of the speech processors, audiometric controls, explanations and recommendations for the use of CI accessories, and digital wireless remote microphones and other aspects concerning the CI. These audiological services are associated with hearing therapeutic services that contain among others exercises for sound perception and discrimination, exercises for rhythmic-prosodic speech structure, exercises for vowel and consonant differentiation as well as word understanding [104, 105, 107]. These measures are accompanied with supportive therapy such as for example physiotherapy. The mentioned measures may be applied in single or group therapies [104, 105, 107].

The formal term of rehabilitation has to be distinguished from the general term of CI rehabilitation (follow-up therapy). According to § 8 of the rehabilitation guidelines issued by the Federal Joint Committee, a need for rehabilitation is present when – due to physical, psychological, or mental damage

- Not only temporary impairments of the activity that are relevant for everyday situations are present that probably threaten the patients social life
- Impairments to participate in daily life already exist
- The multi-dimensional and interdisciplinary approach of medical rehabilitation is required in addition to the curative treatment [93]

At least two of these aspects are regularly observed in CI recipients so that also a formal necessity of rehabilitation exists.

Regarding the terminology, a difference should be made between patients who lost their hearing ability after previously hearing and in whom this capacity should be restored (rehabilitation in the proper sense of the word) and patients who have never heard (e. g. children born deaf). For the latter group rather the term of "habilitation" should be used because it is a capacity that has to be newly learned. In the context of cochlear implantation, both aspects are summarized in the term of "rehabilitation" [104].

Particularities of the rehabilitation of pediatric patients

Deaf or severely hearing impaired children who receive a CI, pass the process of rehabilitation in a very vulnerable phase of hearing and language acquisition [107]. Illig et al. investigated 2,017 children who had received CI treatment between 1986 and 2000 with regard to the professional and socio-economic status. They could confirm that these children had a significantly poorer socio-economic status in comparison to the normally hearing population [108]. They could also show that the motivation of parents regarding the speech development of their children played a particular role. This means that the rehabilitation should be extended to the parents in order to provide them with practical support for the "daily hearing life" [106]. The authors also mention that these differences will probably decrease in future generations because CI treatment is performed in much earlier ages of the children and the implanted devices have experienced technical development [109]. Based on the example of pediatric patients, the study indicates the enormous significance of hearing and speech promotion and thus rehabilitation in the context of CI treatment.

2.1.4 Aftercare

The phase of follow-up therapy (CI rehabilitation) is followed by the phase of aftercare, for which the cochlear implanting institution as provider of the implant is responsible. Even if there are no defined legal requirements regarding the intervals and contents of follow-up examinations, it is obvious that the time of aftercare must refer to the duration of the use of the implant. In other words, as long as a patient wears the implant, follow-up has to be performed. Follow-up has to be understood as routine control that evaluates the regular technical function of the implant and the achieved hearing status of the patient. It should also include socio-medical aspects of hearing impairment. An important objective in the context of follow-up is the indication of further necessary treatment measures.

It seems to be widely distributed to perform follow-up once per year and to focus on the following aspects [1]:

2.1.4.1 Medical follow-up

Hereby, the assessment of the ENT-specific medical status should exclude late complications such as infections, skin necrosis, or defects of the auditory meatus or eardrum.

2.1.4.2 Audiological follow-up

In order to assure the long-term success and the regular function of the implant, regular hearing tests should be performed. The question of which hearing test should be applied is associated with the indication and the expected result of cochlear implantation (see chapters 2.1.1.1 and 2.3.2).

2.1.4.3 Hearing therapeutic follow-up

To secure the long-term success of CI treatment, the success of the conducted hearing therapeutic rehabilitation measures should be assured. For this purpose, an evaluation performed by the respective rehabilitation institutions is useful. If needed, further rehabilitation measures should be started.

2.1.4.4 Speech therapeutic follow-up

To secure the long-term success of CI treatment, the success of the conducted speech therapeutic rehabilitation measures should be assured. For this purpose, an evaluation performed by the respective rehabilitation institutions is useful. If needed, further rehabilitation measures should be started. This mainly concerns adults and children after cochlear implantation who lost their hearing capacity before language acquisition with focus on successful speech acquisition.

2.1.4.5 Technical follow-up

Beside the medical as well as hearing and speech therapeutic follow-up, the technical care plays a major role. Regular consultations should take into consideration the patient's current life situation in order to assess the necessity for further technical support with regard to the compensation of disadvantages in daily life (job, school, social environment) and if needed to prescribe the appropriate devices (e. g. wireless remote microphone, directional microphone etc.).

The second objective of technical follow-up is the assessment of the specification-based function of the CI and/or the identification of functional deficits. Generally, every technical device may have a functional defect. In the context of cochlear implants, these defects are classified into hard failures, i. e. objectifiable failures, and soft failures that cannot be objectified [109]. In order to detect those failures, technical as well as audiometric measurements are performed. However, especially soft failures are often difficult to distinguish. In a trial, Ulanovski et al. could show that 46 % of the revision surgeries in children had been performed due to soft failures [110], which shows the importance of regular follow-up examinations.

Particularities or telemedical follow-up

Currently, various efforts are undertaken to perform at least some parts of follow-up in a decentral way via so-called remote care procedures (telemedical methods). In 2018, Cullington et al. published their results of a randomized controlled trial about remote care in Great Britain, and they could show that remote care is a good alternative for usually performed follow-up examinations [111]. However, the authors mention that only volunteers, i. e. especially motivated participants, were included in this trial. A final evaluation of this approach has to be awaited.

Assessment of follow-up

Follow-up in CI treatment encompasses different aspects of long-term assurance of hearing rehabilitation. It includes medical, audiological, hearing therapeutic, speech therapeutic, and technical

follow-up, which should be performed life-long, i. e. for the duration of the use of the CI. The organizational responsibility has to be taken by the CI hospital.

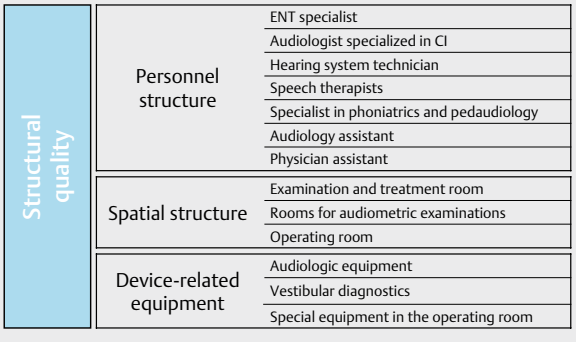
2.2 Structural quality on the example of Cochlear implants

Structural quality describes all structural requirements that have to be fulfilled in order to provide the requested medical treatment and care with the previously defined process quality. Generally different levels of structural assessment may be distinguished. The structural quality of cochlear implantation under epidemiological aspects focuses on the number of available centers per inhabitants, the number and the access to rehabilitation institutions, the regulation of payment guarantees, or the number of the planned implantations in the country (e. g. requirements planning). The structural quality, however, also has to be assess on the level of the single cochlear implanting institutions. The following description will therefore emphasize the local requirements of structural quality. The focus will be placed on relevant structural characteristics of personnel, spatial, and technical equipment (▶ **Fig. 4**).

Quality assessment may assume that the "regular services" of a hospital meet the usual medical standards of a hospitals with regard to the treatment of patients. These aspects are generally covered via separate measures such as for example ISO certification of a hospital. So the objective of assessing the structural quality of cochlear implantation is primarily oriented towards the capacity of an institution to provide additional, i. e. specific, services of the (entire) cochlear implantation process.

Historically, the structure of most CI departments developed "evolutionarily". When CI treatment was introduced in Germany in the mid-1980ies, the method was at its beginnings with regard of the achievable goals of hearing improvement. Further, only individual experience of single physicians, audiologists, or pedagogues who were involved in the process was available for the necessary accompanying treatment measures. In the course of the decades, this experience of single institutions was distributed into many hospitals without establishing a binding standard. The structures of most CI centers developed from practical experiences of some individuals. Therefore, only very few scientific publications exists that deal with clinical structures of the comparison of structures of different hospitals regarding the process of CI treatment [112]. Single articles (e. g. Slade et al.), however, confirm the reasonable application of quality-oriented assessment, e. g. by means of the "Kaizen method" in order to positively control structures, processes, and results of cochlear implantation [113]. In the following paragraphs, the structural quality of cochlear implantation of one single institution will be described, focusing on:

- Personnel structure
- Spatial structure
- Device-related structure



▶ **Fig. 4** Necessary additional structures of a cochlear implanting institution beside the structures that are usually available for healthcare.

2.2.1 Personnel structure

The personnel structure encompasses two aspects. First, it is the number of staff members and second, their qualification. Currently, neither the number nor the qualification of the staff members are legally prescribed for the process of cochlear implantation.

Scientific studies on CI treatment that refer specifically to the quality of CI in dependence of the activities of certain professional groups do not exist. Nonetheless, the long-term experience of large cochlear implanting institutions represent a best-practice standard and an expert opinion that leads to recommendations of staff resources based on reality.

General considerations may first be directed on the question of a possible definition of "minimum equipment" of an institution. Even if there are again no scientific analyses, it is obvious that the professional groups involved in the CI treatment process should at least be double staffed in an institution. This is already necessary in daily routine to assure continuous care for CI recipients, also in cases of holiday or sickness of the service providers (e. g. immediate possibility to exchange an implant in cases of defect).

With regard to the composition of the personnel structure, the provision of a complex interdisciplinary service is in the foreground. It is undiscussed that the use of an interdisciplinary team with complementary core competences is essential. The key areas of this team encompass at least the medical, audiological, technical, and pedagogical expertise of the protagonists. Even if different professional titles or formal qualifications can be imagined, the minimum qualification should be achieved. Without any doubt, there is much space for controversial discussions. The DGHNOKHC chose a constructive approach with establishing the White Paper CI Care in Germany (version of 2018) where the professionals and qualifications of an interdisciplinary team involved in the CI process are defined [4]. These teams include:

- ENT specialist (specialized in implantable hearing systems)
- Audiologists specialized in CI
- Hearing system technician
- Speech therapists
- Specialist doctor for phoniatrics and pedaudiology
- Audiology assistant
- Physician assistant

2.2.1.1 ENT specialist (Specialized in implantable hearing systems)

CI surgery is a microsurgical intervention, the key step of which is the atraumatic insertion of the electrode carrier into the cochlea [1, 76]. At first sight, this surgery does not differ much from other

middle ear or temporal bone interventions. However, the use of different implant systems (manufacturers) with numerous possible electrode systems is an enormous challenge for surgical expertise. This is especially true with the background of surgical treatment of very young children and patients with inner ear deformities.

In surgical disciplines in general, but without any doubt also in CI surgery, there is a learning curve that every surgeon passes [114, 115]. It refers to learning, maintaining, and also actualizing the individual surgical skills. It is common practice that only surgeons experienced in ear and microsurgical interventions perform CI surgery even if this is not legally required. A specific specialization, e. g. "implantable hearing systems", similar to the specialization of "plastic surgery" with own contents, minimum surgery catalogue, and separate exam, does not exist up to now.

The question of qualification and specialization is inseparably associated with the discussion of "minimum quantities" for defined interventions. This definition of quantities implies that the frequency of performing an intervention increases education, training as well as actualization of knowledge and skills. A minimum quantity is currently not determined for cochlear implantation, neither for the institution nor for the individual surgeon. In other medical disciplines, however, controversially discussed definitions took place in the past. At the time of introduction of minimum quantities by the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) in 2004, a total of 7 medical interventions fell under this rule. Those were:

- Liver transplantation (including living donation of liver portion)
- Kidney transplantation (including living donation)
- Surgery of esophageal carcinomas and other complex interventions of the esophagus
- Surgery of pancreas cancer and other complex interventions of the pancreas
- Stem cell transplantation
- Total endoprosthesis of the knee joint
- Treatment of premature children and newborns with a birth weight of less than 1,250 g

Supporters of the minimum quantity regulation for cochlear implantation state that due to the fact that there are numerous implants available (currently four manufacturers with more than 12 electrodes in their portfolio) a certain quantity of surgeries per years would be necessary to achieve sufficient training. Only in this way it would be possible to keep all parties contributing to the process on the same level of technical and scientific knowledge. Opponents, however, state that there was no evidence for the field of cochlear implantation that would justify the necessity of minimum quantities. Both positions are generally understandable so that the final clarification of this issue must be expected.

In other medical disciplines, investigations have already been performed. Nimpstch and Mansky (2017) analyzed 25 different interventions in Germany based on DRG data from 2009 to 2014 [116]. The results show that in 20 of 25 interventions that reach from emergency interventions such as cardiac catheterization in cases of acute myocardial infarction up to elective interventions such as surgeries of inguinal hernias a correlation exists between the number of surgeries and the mortality. This was mostly true for more complex interventions [117]. This trial as well as others led the German Society of General and Visceral Surgery (Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie) to requiring significantly higher minimum quantities for the certifications under its responsibility [117].

In summary, it seems to be inevitable to objectify the quality-related discussion and to establish an improved data situation. This might be successful with the introduction of the national CI registry planned by the DGHNOKHC in order to create scientific evidence that may then possibly justify a clear position regarding the question of qualification and minimum quantities of an institution or an individual CI surgeon. The answer to this question should be given under specific direction of the society that is responsible for the CI treatment process – which is the DGHNOKHC.

2.2.1.2 Audiologists specialized in CI

According to the European guideline 90/385EWG and the medical products act, active implants such as cochlear implants belong to the highest risk group (III) of medical devices [118–120]. Among other aspects, this is due to the fact that CI stimulate parts of the central nervous system via the cochlear nerve. In contrast to that, conventional hearing aids belong to a significantly lower risk level (IIa). Furthermore, the fitting process of CI is completely different from the one of hearing aids due to the functionality. While hearing aids provide an amplification of acoustic signals oriented to the hearing threshold, the fitting of CI as electronic neuro-prosthesis requires highly specialized knowledge and experience. This goes far beyond the initial setting of the CI audio processor. For example strategies for problem solution and re-settings have to be elaborated in order to control undesired side effects (e. g. stimulation of the facial nerve). The appropriate combination of residual hearing and electrostimulation, the interdisciplinary treatment of CI recipients, the science-based audiological care, and many other complex aspects of audiological CI treatment are also essential. Based on the mentioned reasons, a scientifically and technically trained person should be responsible for audiological care as one of the protagonists of an interdisciplinary team.

A new structural approach for the description of the activities and a training curriculum was recently created by the German Society of Audiology (Deutsche Gesellschaft für Audiologie; DGA) with the publication of the specialization of "CI audiologist (DGA)" [121]. The aim of this specialization is the teaching of necessary anatomical, medical, and technical-physical knowledge that is necessary for the treatment of patients who received CI. The precondition for starting this specialization is an audiological qualification, for example as bachelor in an audiological, scientific, pedagogic, or technical field or a bachelor equivalent in the sense of the "General Audiologist (EFAS)" [122].

This qualification suggested by the DGA must certainly be considered as pioneering even if it currently does not lead to a binding necessity of implementation. The contents and structure, however, will certainly influence future quality-assuring measures and thus also have an impact on the qualification of staff members. Regarding the contents, the qualification of audiologists in CI care should at least be performed with orientation to the described cur-

riculum. This qualification should thus be open to people with a medical university degree. It remains to be seen if other scientific societies develop comparable training and qualification curricula.

2.2.1.3 Hearing system technicians

Although the profession of "hearing system technician" is not yet clearly defined in a professional code or a training curriculum, the description of qualification and activity of such a person is seen in the practical implementation of audiological work with CI patients in contrast to "audiologists specialized in CI". Also the white paper of the DGHNOKHC defines a hearing system technician as a professional trained in the field of technical hearing aids with technical degree, e. g. technical college degree in audiology and hearing technology/hearing system technology with practical experience or master of acoustics with specialization in CI [4].

2.2.1.4 Speech therapists

One fundamental principle on the way to a successful CI treatment process is the implementation of the necessary hearing and speech rehabilitative measures. In this context, based on practical experience, the work of for example speech therapists and other professionals in this field is essential [104].

2.2.1.5 Specialist doctor for phoniatrics and pedaudiology

The diagnosis of pediatric peripheral hearing disorders and the consultation belong to the responsibility of specialists in ENT and phoniatrics and pediaudiology. The care and guidance of families with affected children that goes far beyond diagnostics and the mere technical aspects of cochlear implantation should regularly include specialists for phoniatrics and pedaudiology in the process of diagnosis and further treatment. This is especially true for the regular assessment of the speech level and the psychosocial development of pediatric CI recipients.

2.2.1.6 Audiology assistant

For practical performance of the necessary audiological and diagnostic measures (checkup of hearing aids, AEPs etc.) the involvement of specifically qualified professionals is recommended. Due to their specifically audiological training, these professionals qualified as "audiology assistants" or "medical technical assistants (audiology)" guarantee a high level of diagnostic quality that is the basis of sound diagnosis and later therapy success of cochlear implantation [122, 123].

2.2.1.7 Physician assistant

The continuous assurance and thus necessary organization of a lifelong follow-up after CI presents particular challenges to the structure of cochlear implanting institutions. Furthermore, the communicative skills of many CI recipients are permanently limited so that the communication with them requires significantly increased timely efforts. This circumstance makes a separate organizational structure with specifically trained physician assistants necessary.

Assessment of the personnel structure

Although there are currently no binding requirements regarding the personnel structure in terms of the quantity and qualification of the staff members, the recommendations of the DGHNOKHC (White Paper CI Care) and the DGA (CI audiologist) present important orientation for the implementation of an adequate structural quality in the context of cochlear implantation [4, 122].

2.2.2 Spatial structure of a cochlear implanting institution

The spatial structure results from the implementation of the single activities like they are described in the chapter on process quality (chapter 2.1). As it can be expected, there are currently no scientific trials that would prescribe or evaluate a minimum of rooms to depict the CI treatment process. On one hand, however, the details of the single measures make the basics of a spatial structure very clear. The complete implementation of the process structure defines certain spatial conditions. On the other hand, there are a series of constructional requirements that have to be met in particular in the context of hygiene, work safety, and acoustics [124]. As an example, the DIN EN ISO standards are mentioned for constructional preconditions in the field of audiology. Based on the above-mentioned process structure, the spatial structure of a cochlear implanting institution concern the area of diagnostics as well as therapy. Again, the DGHNOKHC established a concretely formulated minimum structure that should be adapted according to the number of treated patients. These spatial structures include mainly (following the white paper of the DGHNOKHC) [4]:

2.2.2.1 Examination and treatment room

For regular ENT specific examination and treatment, with usual technical equipment (e. g. ENT examination unit).

2.2.2.2 Rooms for audiometric and vestibular examinations

- **Test room**
  In order to perform simple audiometric basic examinations (e. g. tone audiometry, tympanometry, OAE measurement etc.). Numerous requirements exist with regard to constructional and technical particularities that have to be met (e. g. DIN ISO 8253) [12].
- **Test room for free field audiometry**
  A sound-insulated room of sufficient dimensions should be available for performing complex audiometric examinations such as verification of hearing aids in the free field (with and without noise) as well as loudness scaling. Numerous requirements exist regarding constructional and technical particularities that have to be met (e. g. DIN ISO 8253–2) [125].
- **Free field room for examination of directional hearing**
  This room should be available to allow verifying and training of directional hearing of CI recipients.
- **Room for AEP measurement**
  In order to perform high-quality measurements of auditory evoked potentials, a sufficiently electromagnetic shielding of the examination room is needed. It mostly requires specific constructions such as sound and electric insulation for the examinations (e. g. BERA, ASSR, CERA etc.). The examination of pediatric patients generally also necessitates the possibility of anesthesia/sedation in these rooms with appropriate constructional and technical equipment [126].
- **Audiometry in children**
  Quality-assured diagnostics of pediatric patients usually requires specific constructional and technical equipment. In includes

for example a so-called Mainzer Kindertisch (children's table) that often requires a separate spatial assignment.

- **Vestibular diagnostics**
  To perform neuro-otologic diagnostics (e. g. VEMP, HIT, caloric tests, rotational chair tests, optokinetic tests etc.).

2.2.2.3 Operating room

Primarily, an operating room for CI surgery does not need to meet particular requirements in comparison to other operating theaters. However, it must be taken into account that probably intraoperative measurements such as electrocochleography or E-BERA will have to be performed. Therefore, the operating room should be chosen with regard to the electromagnetic compatibility for the respective measurement procedures in order to allow these measurements if appropriate. Also the constructional and technical option of performing intraoperative radiography has to be considered (to exclude a wrong position of the CI electrode carrier). In addition, operating rooms have to meet numerous requirements that concern among others hygiene and work safety [125, 127, 128].

2.2.2.4 Other rooms

- **Consultation**
  For pre- and postoperative consultation of candidates and their relatives. Availability of information material such as models and brochures.
- **Room for fitting and verification of technical hearing aids**
  For fitting and verification of technical hearing systems (hearing aids, CI, implantable hearing aids etc.) with specifically needed technical equipment (hearing aid measurement box, in-situ audiometry, fitting space with hard- and software for conventional hearing aids and implantable systems of different manufacturers). Usually, the performance of these examination procedures requires separate spatial implementation.

2.2.3 Device-related equipment of cochlear implanting institutions

In analogy to the spatial equipment, adequate devices for the single professional groups have to be provided for examinations. The main focus in this context is placed on the possibilities of audiological and vestibular diagnostics. In Germany, medical products to determine the hearing ability (tone and speech audiometers) are subject to numerous standards and requirements (e. g. annual calibration and safety controls) [129].

Thus, the following devices and methods that are critical regarding the equipment result from the above-mentioned processes:

2.2.3.1 Audiologic equipment

- Clinical audiometer
- Free field audiometer
- Impedance audiometer
- Measurement system to assess otoacoustic emissions
- Speech audiometry (silence and noise)
- Loudness scaling measurement place
- Hearing aid measurement box
- In-situ audiometry
- System to measure AEP (including BERA, frequency-specific ASSR, and CERA)
- Device to perform extra-cochlear electric stimulation (promontory test)
- Equipment for pediatric audiometry ("Mainzer Kindertisch")

2.2.3.2 Vestibular diagnostics

- Caloric tests
- HIT
- VEMP
- Possibly rotational chair test
- Possibly optokinetic tests

2.2.3.3 Special equipment in the operating room

- Neuromonitoring EMG for the facial nerve
- Surgery microscope
- Microsurgical instruments
- Access to intraoperative radiological diagnostics (e. g. conventional X-ray or CBT)

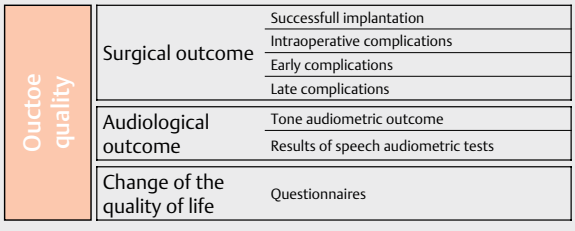
2.3 Outcome quality based on the example of cochlear implantation

In order to evaluate the outcome quality of cochlear implantation, it has to be determined first which target parameters define a "good outcome". Generally, at least three areas may be distinguished (▶ **Fig. 5**).

- Surgical outcome
- Audiological outcome
- Change of the quality of life

For the assessment of the surgical outcome, the most important objective is primarily the absence of complications. The absence of complications alone, however, is not yet an improvement of the initial situation of the affected patient in the whole process of CT treatment. Only the improvement of sound hearing and/or speech discrimination (audiological results) as well as finally the resulting improvement of the communicative skills, the participation in social life, and the quality of life represent an actually relevant result of CI treatment for the patients.

The assessment and evaluation of these results are associated with a series of challenges that are only partly solved. While relatively simple and clear outcome parameters may be defined for the mere surgical consideration (e. g. the occurrence of postoperative facial nerve palsy), it is more complex for the audiological assessment of the outcome and also of the quality of communicative skills and of life. This complexity results from the discussion which test procedure has the optimal significance for the evaluation of speech



▶ **Fig. 5** Dimensions of the quality of outcome in cochlear implantation.

discrimination of the patients. On the other hand, the question is always asked regarding the audiological basics of indication, the achieved gain in speech understanding, and the definition of a minimum target value of speech understanding. Based on this consideration and the initial value, a relative improvement for example of 30 % (in the Freiburg monosyllabic test at 65 dB) may either be a "good" but also a "bad" result, depending on the level of the original hearing. In cases of complete deafness, a gain of 30 % is a completely other outcome quality compared to an improvement of 30 % from 50 % to 80 % in the speech understanding test. The situation is even aggravated by the fact that the absolute value of the achieved percentage does not need to correlate with the patient satisfaction or even quality of life. A deaf born adult patient probably considers an outcome of 30 % understanding in the Freiburg monosyllabic test at 65 dB as significantly more positive than a patient who was short-term deaf and treated with CI and who had normal hearing capacities in both ears beforehand.

In the following paragraphs, the currently discussed parameters for assessment of the outcome quality of CI treatment will be illustrated.

2.3.1 Surgical outcome

The outcome quality of surgery focuses primarily on the question if the CI stimulator could be successfully implanted. This also includes the regular insertion of the electrode carrier. Furthermore, the absence of intervention-related complications is relevant. The definition of complication is manifold because not every side effect can be considered as complication (e. g. temporary vertigo). Complications may also occur at different times, i. e. even after discharge from the inpatient treatment (e. g. wound infections). In the literature, numerous papers can be found that undertake the effort to list relevant parameters of outcome quality. This leads to the following aspects that should be assessed in the context of cochlear implantation.

2.3.1.1 Implantation and early complications

- Was it possible to implant the CI stimulator as planned?
- Did any of the following intraoperative complications occur [130, 131]?
  - Neural damage (in particular facial nerve and chorda tympani)
  - Significant bleeding (e. g. from the sigmoid sinus)
  - CSF leak
  - Damage of the ossicular chain
  - Injury of the stapes tendon
  - Perforation of the tympanic membrane
  - Injury of the auditory canal wall
  - Problems with electrode insertion
  - Problems during anesthesia
- Did early complications occur postoperatively, i. e. complications that appeared within the first three months after implantation? Those may include [131, 132]:
  - Suture dehiscence
  - Infection
  - Emphysema
  - Hematoma
  - Seroma
  - Facial edema
  - Facial nerve palsy
  - Defect of the tympanic membrane
  - Stimulation of the facial nerve
  - Pains
  - Vertigo
  - Tinnitus
  - Disorder of the sense of taste

2.3.1.2 Late complications

- Depending on the duration of the investigation time, so-called late complications may occur. The following complications are mentioned [131, 132]:
  - Problems of the skin flap
  - Keloid
  - Otapostasis
  - Cholesteatoma
  - Arrosion of the auditory meatus
  - Electrode penetration
  - Device failure

2.3.1.3 Standardized assessment

Without any doubt, the systematic and standardized assessment of complications has a central significance for the evaluation of the surgical outcome quality. Currently, there is no standardized documentation of cochlear implantation. Proposals in this regard have already been presented in the past, for example by Adunka et al. or Santa-Maria et al. [13, 77]. They encompass the following parameters:

- Surgery side (left/right)
- Type of the electrode carrier (straight/pre-shaped)
- Length of the electrode carrier
- Insertion depth (in mm, as well as the number of contacts that remain outside the cochlea)
- Access to the cochlea (round window/cochleostomy)
- Steroid applicatiaon (systemic/intratympanic)
- Anatomic particularities
- Complications (see above)

Summary of surgical outcome

The outcome quality of the surgical aspect of CI treatment is one of the keys of structured quality assurance. The development of a consistent (national) standard of the surgical target parameters that have to be assessed is an important step towards quality assurance in cochlear implantation.

2.3.2 Audiological outcome

The indication of CI treatment consists of the intended improvement of hearing and speech understanding. Accordingly, audiological procedures play a key role in the context of determining the outcome quality. As already described (see chapter 2.1.1.1 on audiological diagnostics), the evaluation of the audiological outcome quality is inseparably associated with the indication of CI treatment. This is the case because the audiological test procedures are ap-

plied for indication as well as for the assessment of the improvement after cochlear implantation. Some of the test procedures that have already been described in chapter 2.1.1.1 (tone audiometry, Freiburg speech test, Göttingen sentence test, Oldenburg sentence test) will be discussed with regard to their relevance.

2.3.2.1 Tone audiometry

In the assessment of the results of cochlear implantation, tone audiometry is highly important for the evaluation of the residual hearing preservation. As described in chapter 2.1.1.1, a preservation of the natural hearing performance is of highest functional importance for patients with residual hearing of low frequencies. Therefore, tone audiometry is essential as method for assessment of the outcome parameter of "residual hearing". According to the literature, it is recommended to regularly measure the residual hearing capacities of the following frequencies [13, 19]:

Air conduction: 125–250–500–750–1000–1500–2000–4000–8000 Hz.

Bone conduction: 250–500–750–1000–1500–2000–4000 Hz

To define the preservation of the residual hearing, often a four-part classification is applied. A complete preservation of residual hearing is defined as an average postoperative loss of less than 10 dB, a partial preservation of the residual hearing is a hearing loss between 10 and 30 dB, and a minimal preservation of residual hearing means a decline of the hearing threshold of more than 30 dB. If the hearing threshold in low frequencies is above 80 dB, it is defined as residual hearing loss [132, 133].

The measurement of the postoperative residual hearing provides a simple option to assess the outcome quality, at least for the preoperative objective of preservation of residual hearing.

2.3.2.2 Speech audiometry

Currently, the indication for CI treatment is mainly made based on the preoperative speech test results. This includes the application in noise and the verification of the performance of hearing aids ("best aided condition"). That is why the methods for assessment of the speech understanding are highly important in the consideration of the outcome quality of CI treatment. The three most widely distributed methods, i. e. Freiburg speech test, Göttingen sentence test, and Oldenburg sentence test, were already presented in chapter 2.1.1.1. In the following paragraphs, the respective particularities of the test procedures will be discussed with reference to the evaluation of the outcome quality.

- Freiburg speech test
  Even if the Freiburg speech test is a long-established test procedure, there are a series of critical aspects. Hoth summarized them as follows [134]:
- The test lists are perceptively not equivalent, i. e. they are different with regard to their difficulty and comprehensibility [135–140].
- Some of the test words are no longer used [141].
- The test lists are not equivalent or balanced in terms of phonemes.
- There is no notification stimulus.
- There is no evaluation of phoneme confusion.
- The presentation level is not balanced.
- The measurement accuracy and thus the sensibility are rather low.
- The discrimination function is very flat.
- There is no standardized background noise.

Thus, Hoth draws the conclusion that the Freiburg speech test has numerous weaknesses but the ideal test procedure that meets all requirements of the above-mentioned DIN ISO does currently not exist. One main critic is the use in background noise. For the assessment of speech understanding, a combination of the Freiburg speech test with other hearing tests, preferably in noise, should be achieved. Nonetheless, the examination of the monosyllabic understanding by means of the Freiburg test is an important element of individual CI consultation and thus also of the assessment of the outcome quality [41].

- **Göttingen sentence test**
  The everyday sentences used in the Göttingen sentence test can be applied, as mentioned above, without training lists as well as with and without background noise. The result of the Göttingen sentence test in noise is considered as speech understanding threshold with "L50 [dB SNR]" with adaptive performance. The L50 value determines the difference of the sound levels between noise and test sentence of which the test person understands 50 % of the offered words. For assessment of the results, it must be taken into account if the noise of the test signal was adaptively adjusted. Thiele et al. revealed that there are differences in the Göttingen sentence test in noise with regard to the understanding of different groups of hearing impaired individuals. It could be shown that the hearing performance in noise of patients with moderate to high-grade hearing loss cannot be predicted based on the average hearing loss [142]. Another problem of the Göttingen sentence test is its conciseness. Since there is only a limited number of lists, many patients remember the contents when the tests are regularly performed.
- **Oldenburg sentence test**
  The Oldenburg sentence test is a matrix test procedure that can be performed with and without background noise. Matrix test procedure means that randomly a combination of name, verb, numeral, adjective, and object with 10 alternatives each is available per word. In addition, the answer may be given directly by the patient because the test is conceived as closed procedure. The noise consists of all words of the lists that are spoken simultaneously. This leads to the effect of a very good speech-covering noise [26–28]. This effect simulates what hearing aids and implant recipients report: the understanding of speech, i. e. in the context of social events, is clearly limited. Therefore, the test is particularly suitable to simulate these challenging hearing situations.

Tests that may be compared with the Oldenburg sentence test are meanwhile available in 16 languages and so they are called multilingual matrix tests. According to Kießling et al., this test procedure is most suitable to establish international standards in speech audiometry [39].

Summary: Hearing test procedures for outcome quality

Beside tone audiometric assessment of the preservation of residual hearing, the application of methods of speech audiometry allows the evaluation of the improved hearing status in the postoperative course. Even if there are numerous test procedures, especially the application of the widely distributed Freiburg speech test and of a speech test in noise (Göttingen or Oldenburg sentence test) are reasonable [39].

2.3.3 Change of the quality of life

Beside the improvement of hearing and speech understanding, the assessment of the subjective quality of life before and after cochlear implantation is the second outcome parameter of cochlear implantation that is often used in the literature. A series of investigations could show that the subjective quality of life increases significantly after CI treatment [143–145]. Surprisingly, a large meta-analysis revealed that the increased quality of life does not correlate with an increased speech understanding after cochlear implantation [146]. This means that the individual change of the subjective quality of life – in comparison of the situation before and after CI treatment – might be a more important outcome parameter. Several measurement tools (questionnaires) have meanwhile been described for the assessment of the quality of life in the context of CI treatment. This will be described briefly in the following:

- **Nijmegen Cochlear Implant Questionnaire (NCIQ)**
  This questionnaire was especially developed for the assessment of the hearing and quality of life of CI recipients. It contains 60 questions that focus on the physical, mental, and social situation of the patients [146]. Due to its special focus on CI recipients and its primary conception in English, this questionnaire became one of the most important instruments in the field of assessing the outcome quality after CI treatment. A German translation is available [147].
- **Speech, Spatial and Qualities of Hearing (SSQ)**
  In 2004, Gatehouse and Noble introduced this test. It assesses 14 items on speech understanding, 17 items on spatial hearing, and 18 items on the quality of hearing [148]. This test does not contain any aspects on the general quality of life and was mainly conceived for hearing aid users. Nonetheless, this test is also applied for the evaluation of the outcome quality of cochlear implantation. A German translation was developed by Kießling et al. in 2011 [149].
- **Hearing Handicap Inventory for Adults (HHI-A-Inventar)**
  This test was introduced by Newman et al. in 1990 as adaptation of the "Hearing Handicap Inventory of the Elderly (HHIE)". It encompasses 25 items on the social and mental situation [150]. The test allows very well assessing the subjective symptom severity of hearing loss [39].

Summary: Outcome quality of cochlear implantation

The question of "Which quality makes the difference?" in CI treatment is mainly reflected in the discussion about the outcome quality, especially because it must be realized that there is no universal parameter but many single parameters that have to be included in the evaluation of the outcome.

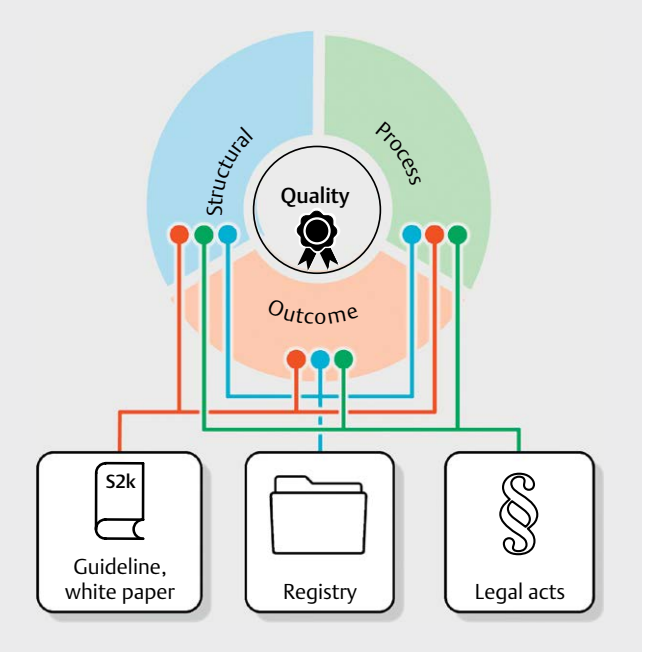
Taking a glance on other disciplines may help approaching this challenge. At the beginning of the 1990ies, the task of quality improvement was the treatment of polytraumatized patients. At that time, the German Society of Trauma Surgery (Deutsche Gesellschaft für Unfallchirurgie) established a trauma registry to solve this problem. By means of standardized data entry forms, hospitals prospectively reported data of all patients from the type of trauma up to discharge. These data allowed many single evaluations with highly significant improvement options in trauma treatment that finally led to the foundation of the trauma network of Germany. Finally, 677 hospitals were included in an association that elaborated consistent quality standards [151]. Transferring this model to CI treatment, a national registry would be the basis for quality assurance in cochlear implantation.

2.4 Instruments of quality management (process, structural, and outcome quality)

In medicine, various instruments are applied for quality management in order to control and assess processes, structures, and outcomes. These instruments are among others registries, guidelines, and/or recommendations of scientific medical societies as well as legal acts (▶ **Fig. 6**).

In 2019, Schraven and Mlynski published a detailed summary about registries, their implementation, operation, and objectives, in which they emphasized their significance for example for displaying of epidemiological correlations as well as for quality assurance and improvement [152].

Another instrument to control processes, structures, and outcomes, are guidelines of the Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der wissenschaftlichen medizinischen Fachgesellschaften, AWMF) or recommendations of the scientific societies issued in form of white papers [153]. Guidelines are generally established in consensus procedures of all contributing scientific societies and are based on the scientific know-



▶ **Fig. 6** Instruments of quality management derived from the dimensions of quality.

ledge that is available at the current time. In contrast, the recommendation of a scientific society (e. g. white paper) is mostly given by one single society.

As a third instrument, also the government may directly influence processes, structures, and outcomes of medical treatment by issuing legal acts. Examples in this context are staff-related minimum requirements in the field nursing care, legal requirements regarding waiting times for appointments fixed in the specialists' act, or also the planned implant registry act.

In the following chapter, the status of the international and national implementation of quality measures (CI registry, guideline, and legal requirements) will be discussed.

3 Quality Assurance in Cochlear Implantation: International

3.1 Methodical approach

In the following chapter, the implementation of quality assurance in other countries will be described. As mentioned in the previous chapter, different mechanisms may be applied to assure the quality of processes, structures, and outcomes of cochlear implantation. On a national level, these objectives may be included in the creation of guidelines, registries and legal requirements. For evaluating the level of implementation of quality assurance in CI treatment of a country, the assessment of these three parameters seems to be appropriate.

As expected, there are only few scientific publications focusing on this topic. Vickers et al. asked 2016 CI surgeons from 25 countries regarding financing, indication, and the existence of guidelines on CI treatment in their respective countries [154]. It could be revealed that guidelines or legal acts are applied in 70 % of the countries. It must be mentioned critically that this article describes primarily the assessment of the indication criteria and not the aspects of guidelines in the narrower sense of quality management (quality of processes, structures, and outcomes) [155].

We performed an internet-based search for information that showed publicly accessible guidelines, registries, or legal acts concerning CI treatment in other countries. Beside this search, the scientific literature and the internet presentations of national ENT societies were considered with regard to this information. Exemplary results of this research are summarized in ▶ **Table 1**.

▶ **Table 1** Presence of guidelines, registries, and legal acts for quality assurance in cochlear implantation, exemplary for the mentioned 8 countries (+ = existing; (+) = existing but not accessible; - = not existing).

Country	Guideline	Registry	Legal acts
Australia	+	(+)	+
France	(+)	-	-
Great Britain	+	+	+
Canada	+	+	+
Switzerland	+	+	-
Spain	+	-	-
Thailand	-	+	-
USA	+	-	-

3.2 Quality assurance in cochlear implantation in Switzerland and Great Britain

The above-mentioned approach identified 8 countries that dispose of publicly accessible guidelines in German or English or a registry. Great Britain and Switzerland were selected from these countries for the further detailed consideration of positive examples. In comparison to Germany, it is not assumed that the incidence of hearing disorders or the structure of the population in these two middle-European countries varies significantly. There are also similarities between Switzerland and Germany with regard to the social insurance system, although this system is organized very regionally in Switzerland. In England, however, a national healthcare system exists that is completely different from the Swiss and German systems with regard to control and definition of requirements of payment of treatments. Switzerland and Great Britain were chosen as objects of comparison because they implement two and three of the above-mentioned instruments, respectively, of quality management (guideline, registry, and legal act) but their organization and structure are different. These two countries will be considered more in detail in the following chapters.

3.2.1 Switzerland

About 8.5 million people live in Switzerland with a population density of about 200 inhabitants per km². Currently, CI treatment is exclusively performed by the four University Hospitals of Basel, Bern, Geneva, and Zurich as well as one specialized Cantonal Hospital (Luzern). These hospitals are organized in the group of "Cochlea-Implantate der Schweizerischen ORL-Gesellschaft (CICH)" (cochlear implants of the Swiss ORL society) [155].

- **CI guideline, Switzerland**
  In 2018, the guideline on cochlear implantation and follow-up was published. It had been elaborated by the group of the Swiss ORL Society named CICH with contributions of the "Kommission für Audiologie und Expertenwesen der ORL-Gesellschaft" (commission for audiology and expert system of the ORL society) [156]. In its current form, it was also approved by the Swiss Federal Office for Social Insurance (Bundesamt für Sozialversicherung). The guideline encompasses around 3,600 words and is divided into 7 chapters (1. Introduction, 2. Preoperative diagnostics, 3. Indication, 4. Contraindication, 5. Surgery phase, 6. Postoperative basic and follow-up therapy, and 7. Infrastructure and staff). As it can be seen in this table of contents, important aspects of process and structural quality are contained. In the single chapters, recommendations are given that leave enough decision-making flexibility for the single centers. For example, tone and speech audiometry are recommended for preoperative diagnostics, but no specific speech understanding test is determined [157].

- **Registries in Switzerland**
  The "Schweizerische Cochlea-Implant-Register (CI-Datenbank)" (Swiss Cochlea Implant Registry [CI Database]) was already introduced 27 years ago (in 1992) and is operated by the Swiss ENT Society. Also patients were included in this registry that had been treated with CI before 1992 [157]. Currently, the registry encompasses about 3600 implantations. The operators of the registry regularly publish a publicly accessible report describing the development of the surgery numbers including re-implantations and treatments of the second side. Furthermore, the report publishes data regarding the achieved speech understanding and the subjective satisfaction [158]. Further reaching evaluations concerning the implanted devices, surgery techniques, or detailed follow-up results are not published. It is not known if the data are evaluated in the context of scientific articles.

- **Legal acts in Switzerland**
  The research revealed that no specific legal acts regarding CI treatment exist on a nationwide level in Switzerland that define quality assurance of cochlear implantation.

3.2.2 Great Britain

Great Britain has 66.5 million inhabitants. Since the 1980ies, a program on CI treatment exists. In contrast to Germany and Switzerland, one particularity is the strongly regulated national healthcare system where the government bears all expenses.

- **CI guideline, Great Britain**
  In Great Britain, the CI guideline entitled "Quality Standards Cochlear Implant Services for Children and Adults" of the British Cochlear Implant Group (BCIG) was published in its current version in 2018 [158]. The BCIG is an association of all professional of the British healthcare system who are responsible for CI treatment or for the scientific aspects [159]. The guideline encompasses about 9,500 words and is divided into 23 chapters that will not be presented here. In summary, the defined goal of the guideline is to give a description of the minimum standards. The guideline contains information about the examination and treatment process, clinical steps, composition of a CI team, information on the applied technology as well as concrete details about the necessary rooms and further infrastructure [159]. Furthermore, the guideline describes indications for quality assurance for every single step. This guideline is a good example for detailed requirements with regard to the quality of processes, structures, and outcomes of CI treatment.

- **CI registry of Great Britain**
  The British Cochlear Implant Group is the operator of the CI registry and collects data concerning the indications and implantations of each cochlear implanting institution. These data are accessible for participating institutions and are mainly suitable to compare the numbers of surgeries and the treatment type (e. g. uni- or bilateral). Data about hearing capacities, complications, or other particularities are not published. It is unclear if these data are nonetheless assessed for internal purposes of quality assurance [160].

- **Legal acts in Great Britain**
  In Great Britain, a revised version of the so-called "Technology appraisal guidance" was published in 2019 by the National Institute for Health and Care Excellence (NICE), an independent institution that develops evidence-based guidelines and recommendations for the nationwide healthcare system [161, 162]. This "Technology appraisal guidance" has legal character. Cochlear implanting institutions have to implement the instructions in order to be financed by the national healthcare system. Indications for cochlear implantation are exactly defined and also which implants are suitable for which patient group. The main objective of this technology appraisal guidance is to weigh the cost-benefit ratio of CI treatment for the British healthcare system and to give according recommendations [162].

Summary

Switzerland and Great Britain represent two examples of countries where already important steps of quality assurance in CI treatment could be implemented by means of guidelines as well as registries that are oriented mainly on the aspects of the quality of processes, structures, and outcomes.

4 Quality Assurance in CI Treatment in Germany

In the following chapter, the current status of quality assurance regarding the quality of processes, structures, and outcomes in CI treatment in Germany will be described. The focus is placed mainly on the instruments of

- CI guideline
- White Paper CI Care
- Legal requirements/implant registry act
- Treatment contracts with cost bearers

4.1 CI guideline

Currently, the AWMF guideline on CI treatment and central auditory implants (responsible scientific society: DGHNOKHC, registry number 017–071 dated May 2, 2012) is in effect [163]. This guideline is in the state of revision so that only the current guideline may be discussed. It encompasses 30 pages and was elaborated in an interdisciplinary consensus process. Taking into account the single perspectives of the quality of processes, structures, and outcomes, the elaboration contains a series of approaches to integrate these reflections in a structured framework. From the perspective of process quality, this guideline already contains a detailed description of the necessary single steps [164]. With regard to the quality of the outcome, the expected weaknesses concerning the detailed objective of CI treatment are observed (e. g. definition of target values in audiological tests). However, test procedures and methods are clearly described in order to limit the necessary approaches. Regarding the structural quality, the guideline still has gaps concerning the description of staff-related requirements and their qualification. For the upcoming revision of the CI guideine, activity approaches result in order to give specific recommendations especially regarding concrete implementation.

4.2 White Paper CI Care

In April 2018, the White Paper CI Care was created and published by the board of the DGHNOKHC [4]. The document gives recommendations regarding structure, organization, equipment, and qualification of staff members and thus to quality assurance in the treatment of patients with CI. Considering the aspects of the quality of processes, structures, and outcomes elaborated in this manuscript, this white paper gives very detailed recommendations for implementation [4]. In contrast to the current guideline, in particular the aspect of the quality of structure and process is in the focus. Regarding the process quality, the responsibility for the entire CI treatment process is attributed to the cochlear implanting institution (in general CI hospital) that is also responsible for the life-long follow-up of the patients. With regard to the structural quality, there is for the first time the concrete description of the professional groups involved in hearing rehabilitation (e. g. audiologist specialized in CI and hearing technicians) including their qualification [4]. The professional qualification of an audiologist specialized in CI should be performed guided by the catalogue of CI audiologist DGA. This description requires for the first time a qualification for audiologically qualified hearing rehabilitation including basic therapy and CI rehabilitation up to follow-up [4]. The elaboration of the white paper by the DGHNOKHC is a milestone in quality assurance of CI treatment in Germany.

4.3 CI registry

In the appendix of the White Paper CI Care of the DGHNOKHC a detailed proposal was made for the structure of a (national) CI registry. The structure provides a total of 9 data blocs that should assess the areas of basic data, preoperative audiometry, preoperative hearing history, implant data, surgery, CI-related complications, CI use, and rehabilitation progress, postoperative audiometry as well as quality of life by means of different data entry fields. The suggested 9 data blocs include all areas of the quality of processes, structures, and outcomes of CI treatment so that a proposal could be elaborated that may provide a significant contribution to quality assurance. A model might be the trauma registry of the work group of trauma surgery (Arbeitsgemeinschaft Unfallchirurgie [AUC]) [152].

Currently, the registry is in the final planning phase to clarify data protection and practical implementation and also financial aspects of realization. Nonetheless it is out of question that the introduction of a national CI registry will represent a key contribution to quality assurance of CI treatment in Germany. On an international level, the DGHNOKHC would assume an important measure to catch up with registry approaches for quality assurance that are already established in other countries.

4.4 Legal requirements/implant registry act

Legal requirements that would define obligatorily specific indications, performance, documentation, or structural requirements of CI treatment in Germany, do currently not exist in Germany. It is not known if they are planned.

In contrast to this, there is currently the initiative of the legislator to introduce an implant registry act. A draft of this act, called implant registry introduction act, is being elaborated [164]. This project pursues mainly two important objectives. First it is the establishment of a binding nationwide implant registry. The participation in this registry shall be obligatory for the responsible healthcare institutions, the affected patients as well as manufacturers of implantable medical products [165]. Second, the evaluation of new examination and treatment methods by the G-BA and their inclusion in the medical treatment shall be accelerated [165]. Hereby, pseudonymized data as well as medical data on surgery and follow-up are sent to the German Institute for Medical Documentation and Information (DIMDI). Beside joint prostheses (for hip, knee, shoulder, elbow, and ankle), breast implants, heart valves, other cardiac implants (defibrillators and pacemakers), neurostimulators, vertebral body replacement systems, disc prostheses, and stents also cochlear implants are mentioned in the current draft [165]. For these 14 defined implants, the responsible medical societies have already established 12 implant registries. Neither for neurostimulators nor for cochlear implants currently exist registries of the respective medical societies (▶ **Table 2**).

4.5 Treatment contracts with cost bearers

In 2018, under the aegis of the Techniker Krankenkasse (TKK) all service providers have been offered contracts for special treat-

▶ **Table 2** Summary of already existing and planned registries of implants mentioned in the implant registry introduction act.

	Registry	Scientific Society
Hip/knee	Endoprostheses registry of Germany	DGOOC
Shoulder/elbow	Shoulder and elbow prostheses registry of Germany	DVSE
Ankle prostheses	D.A.F. registry	D.A.F
Breast implants	Breast implant and net registry (AWOgyn)	AWOgyn
Heart valves	German heart valve registry	DGTHG/DGK
Defibrillators/pacemakers	German pacemaker and defibrillator registry	DGTHG/DGK/IQTIG
Neurostimulators	Not known	DGNC (?)
Cochlea Implantats	Planned	DGHNOKHC
Vertebral body replacement system/disc prostheses	German spine registry	DWG/Spine Society of Europe/ISPM
Stents	German carotid stent registry (GeCAS)	Foundation IHF/ALKK

ments. Beside the TKK, also the association of health insurance companies (Verband der Ersatzkassen [VDEK], consisting of Barmer, TK, DAK, HeK, and HKK) are involved in this process. The acronym chosen by the TKK of this agreement is "QuIn-CI" (Qualitätsinitiative zur Cochlea-Implant-Versorgung in Deutschland; quality initiative on CI treatment in Germany) [165]. A detailed document for control of the quality of processes, structures, and outcomes was established in the context of cochlear implantation with primary specific assistance of the CIGD (Cochlea-Implant-Gesellschaft Deutschland; cochlea implant society in Germany). The participation in this contract is voluntary and at the current time it is associated neither with a changed remuneration nor with non-remuneration of non-participating cochlear implanting institutions. The merely formal aspect of this type of contract is currently discussed so that a final evaluation is not available. Currently, the contract may be considered as voluntary measure for quality assurance of cochlear implanting institutions.

5 Outlook

Since the introduction of CI treatment about 40 years ago, this treatment has experienced a revolutionary development that can hardly be compared to other procedures in medicine. This is mainly due to the individual commitment of physicians, engineers, audiologist, pedagogues, and many other professionals, but also to highly committed patients. Over the time, these individual performances of single persons led to recommendations and regulations that are often realized in practice but that have not been translated into obligatory rules for all aspects.

Currently, an intensive discussion is conducted about the preconditions, conditions, and objectives of CI treatment. This discussion takes place on the level of the DGHNOKHC, in exchange with other scientific societies (AWMF), cost bearers as well as legislation. In terms of the contents, this discussion aims at the question of realizing quality assurance with regard to process, structural, and outcome quality.

Several detailed preliminary action was taken by the DGHNOKHC in form of the White Paper CI Care, the elaboration of a concept for a national cochlear implant registry, the current revision of the CI guideline, and the active exchange with cost bearers. There is no doubt that the specific knowledge and the expertise of the DGHNOKHC has to be made available for the process of quality assurance because only in this way a specific and constructive development of CI treatment can be conceived. In this context, the consequent orientation of CI treatment based on evidence-related criteria is without any alternative because they alone represent the fundaments of our scientific expertise.

In summary, the implementation of a national CI registry scientifically supported by the DGHNOKHC plays a crucial role. This registry is not only necessary to suffice the upcoming legal requirements but also to assess clinically relevant data and results so that evidence-based recommendations for quality-assured CI treatment may be established on this scientific basis.

Acknowledgement

The authors want to thank Dr. Sabine Kramer, Kirsten Duggan, and Prof. Dr. Uwe Baumann for their critical review of the manuscript.

Conflict of Interest

The author receives research support and lectures for the companies: MED EL Elektromedizinische Geräte Deutschland GmbH; Cochlear Germany GmbH + Co. KG; Advance Bionics GmbH

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