White paper
Cochlear Implant (CI) Care

Recommendations on the structure, organization, equipment, qualification and quality assurance in the care of patients with a cochlear implant in the Federal Republic of Germany

Created by the Presidium of the DGHNO Bonn, in April 2018

Preface

The provision of highly hearing impaired or deaf patients with an electronic inner ear prosthesis (cochlear implant, CI) represents an enormous advance in the treatment of affected people. Through this measure, many affected people are given the opportunity for comprehensive hearing and speech rehabilitation or, in the case of children, language learning (habilitation). The care of patients with severe hearing loss is a complex process that requires interdisciplinary cooperation between different disciplines. In addition, a continuous further development of the therapy takes place, so that the acquisition and transfer of continuously updated knowledge is necessary. The treatment of affected people is thus a complex process involving audiological, pedagogical, technical and medical expertise within a CI-supplying institution. A CI care facility is understood to mean the implanting clinic, which is responsible for the entire care process of the patient. This care process extends from preoperative care and consultation to implantation and postoperative basic and follow-up therapy and ends with lifelong aftercare.

If the interdisciplinary care of affected patients is not observed, the following significant risks exist for them: missing or insufficient hearing and speech development of affected children, insufficient quality of results, reduction in the quality of life, loss or failure to regain socialization, loss or failure to regain the ability to work and also medical complications.

In order to counteract these risks, this white Paper aims to ensure high-quality specialist care for people with severe congenital and acquired hearing loss or deafness. The aim of CI care is to restore hearing with cochlear implants if sufficient speech comprehension and hearing cannot be achieved with hearing aids.

The present 1st version of the White Paper is based on the AWMF guideline "Supply of cochlear implants and other active ear implants" (registration number 017 - 071) and on the concept paper "Quality Initiative for the supply of Cochlear implants in Germany" (so-called "Erfurt Paper" adopted by the Presidium of the DGHNO on 23.05.2017). In addition, the contents of the White Paper, as well as those of the "CI Register" (in the appendix), were agreed with the German Society of Audiology (DGA).

The white Paper defines the necessary quality criteria (e.g. structure, result, process, qualification) of the entire CI supply process and should thus serve as a future basis for the certification of CI supply facilities and the establishment of a national CI register.

Bonn, April 2018

The Presidium of the DGHNO KHC

Content

1.

1. General aspects of CI care

Patients are eligible for CI care if they can achieve better hearing and speech understanding with CI than with hearing aids in the foreseeable future. This supply process (Fig. 1) extends over the phases of the **preoperative evaluation** and advice, the **Operation** (Implantation) up to postoperative **Basic and follow-up therapy** and ends with the lifetime guaranteed by the supplying institution **After-care**.

Due to ongoing medical and technological developments, CI care has reached a level of complexity that requires implantation in appropriately qualified centers with an interdisciplinary team of experts and appropriate equipment. Structural and process quality indicators are of particular importance.

Figure 1:
Process Description CI supply

2. Tasks of a CI-supplying institution

- Ensuring high-quality, guideline-compliant interdisciplinary care
- Ensuring the quality of structures, processes and results
- The reduction of treatment risks and undesirable treatment consequences
- Ensuring the treatment of therapy-related complications
- Ensuring individually achievable listening success
- Initiation and prescription of medically necessary Rehabilitation measures
- Ensuring the medical care of CI-treated patients
- Ensuring the audiological care of CI-treated patients
- Ensuring the pedagogical care of CI-treated patients
- Responsibility of the overall process of CI supply
- Collection and entry of the data records in the CI register

2.1. General structural requirements a CI-supplying institution

Mandatory minimum structural requirements for a CI provider
Facilities are the provision of:

1. Medical expertise and staffing,
2. Audiological expertise and staffing,
3. Technical equipment,
4. Spatial equipment,
5. Interdisciplinary cooperation structure

    a. Hearing therapy (speech therapy, linguistics, speech therapy)
    b. Phoniatrics/Paedaudiology
    c. Neurology department
    d. Neuroradiology
    e. Psychiatric ward
    f. Psychology
    g. Pediatricians

6. Ensuring the overall process responsibility of CI supply

The process responsibility is in the hands of the medical management of the CI-supplying institution.

2.2. Areas of competence and activities within the CI-supplying institution

In the following, the required areas of activity and the necessary specialist expertise within the CI-supplying institution are described:

1. Assessment of the current life situation, consultation (CI-specialized ENT doctor / pedagogue* / possibly consil. Psychologist/psychiatrist).
2. Current care, consultation (CI-specialized audiology, hearing technician).
3. Collection of medical findings (CI-specialized ENT doctor, speech therapist†).
4. Survey of the audiological findings (CI-specialized audiologist, hearing technician).
5. Collection of the neuroradiological findings (consiliary neuroradiology).
6. Assessment and assessment of rehabilitation ability (CI-specialized ENT doctor / pedagogue* / CI-specialized audiologist; if necessary, also a consultant doctor for rehabilitation medicine / psychologist / psychiatrist).
7. Explanation of the CI system technology, presentation of various devices (CI-specialized audiologist / hearing technician / CI-specialized ENT doctor).
8. Initiation of a hearing aid optimization and assessment of the result‡ (CI-specialized audiologist / hearing technician / CI-specialized ENT doctor).
9. Operative care (CI-specialized ENT doctor).
10. Intraoperative functional checks and electrophysiological tests (CI- specialized audiologist / hearing technician / CI-specialized ENT doctor).
11. Postoperative assessment of the CI electrode position (if necessary intraoperatively) (consultative neuroradiology, CI-specialized ENT doctor, CI-audiologist).
12. Basic audiological therapy (CI-specialized audiologist/hearing technician/CI-specialized ENT doctor).
13. Basic hearing therapy (hearing therapist/pedagogue*/ speech therapist / CI-specialized ENT doctor).
14. Audiological follow-up therapy (CI-specialized audiologist/hearing technician/CI-specialized ENT doctor).
15. Follow-up hearing therapy (hearing therapist/pedagogue*/ speech therapist / CI-specialized ENT doctor).
16. Follow-up care and quality assurance medical/technical (CI-specialized ENT doctor/CI-specialized audiologist/hearing technician/).

2.3. Minimum staffing

The structure of the CI-supplying institution must have a comprehensive and permanent, i.e. constantly available (on weekdays during normal working hours), minimum staffing equipment for the safe provision of the necessary competence for patient consultation and treatment. This requires the provision of the following staff positions in full-time activity:

* For the care of children
† In case of limitation of the spoken language
‡If sufficient success is still to be expected from hearing aid care.

Minimum number of names

2 ENT specialists specializing in implantable hearing systems

1 "CI-specialized audiologist"

Qualification: Graduate of a technical-scientific master's degree program with additional further education in the field of audiology, e.g. medical physicist, special field of audiology or master's degree program with a focus on audiology and practical experience in the field of CI. The additional qualification of an audiologist can also be carried out on the basis of the DGA's catalog of topics "CI-Audiologist".

1 "Hearing technician"

Qualification: MA trained in the field of technical hearing aids with a technical professional qualification; e.g. FH graduate in audiology and hearing technology / hearing aid technology with practical professional experience or hearing care professional master with advanced training in the CI field.

2 Therapists of the following speech therapy occupational groups:

Language Teacher
Dipl. Sprachheilpädagoge
Speech therapist
State Recognized speech therapist
Clinical Speech Scientist
State-certified breathing, speech and voice teacher

for basic and follow-up hearing therapy (if the CI-providing institution carries out the basic and follow-up hearing therapy itself)

1 Specialist in Phoniatrics / Paedaudiology

(applies to facilities with child care)

2 Audiology Assistants or MTA-F

(with basic cochlear implant training by CI manufacturer)

1 Medical Assistant / Administration

2.4 Spatial and apparatus requirements

Minimum number	Name
1	Free-field audiometry (Sound insulation according to DIN/ISO) with class 1 clinical audiometers, impedance audiometer, loudness scaling, speech tests at rest and noise
1	Space for the adaptation and verification of technical hearing aids with hearing aid measuring box, in-situ audiometry, adaptation space with hardware and software for conventional hearing aids and implantable systems at least 3 different manufacturers
(1)	Children's audiometry facility ("Mainzer Kindertisch")*
1	Measurement booth for brainstem audiometry or acoustically evoked potentials with sufficient electromagnetic shielding such as apparatus for brainstem audiometry and otoacoustic emissions (Klick BERA, ASSR and CERA), measurement can also be carried out under anesthesia / sedation*
1	Free-field space for testing directional hearing
1	Device for performing the auditory nerve function test (promontorial test)
1	Spatial/instrumental equipment neurootological diagnostics (VEMP, KIT, caloric testing, if necessary, swivel chair testing, optokinetic tests)
1	Set-up for intraoperative implant function testing and implementation of the following intraoperative success checks (Electrically triggered stapedius reflex (ESRT), E-CAP, BERA and E-BERA)
1	Provision of special and replacement implants
1	ENT-medical examination centre
1	Room for patient consultation and discussion
1	Neuroradiological intraoperative imaging
1	Neuroradiological postoperative imaging with sufficient resolution to assess the electrode position (e.g. digital volume tomography)

* For the care of children

3. Minimum number of patients in a CI-care facility

To ensure the continuity of process quality, a minimum number of services is necessary.

Number per year	Description
>1000	Examinations in the context of routine audiometry
>100	Special audiological examinations (e.g. clarification of CI indication)

4. Quality assurance of the CI-supplying institution

Period	Description
Annual	Description and recording of the organizational, structural, diagnostic and therapeutic standardProcesses in a quality management system (incl. Manual). Inclusion of these processes in a QM certification procedure.
Annual	Carrying out the tasks in compliance with the relevant Constitutions: Medical Device Operator Regulation (MPBetreibV), Medical Devices-Safety Plan Regulation (MPSV), Medical Devices Act (MPG). Training and (Re-) certification of personnel
Continuous:	Collection of CI register records

5. Indications for CI care

The indication is made taking into account all the findings and the result of the interdisciplinary case discussion by the surgeon:

- Patients are eligible for CI restorations for whom hearing and speech comprehension will be better with cochlear implants than with hearing aids in the foreseeable future.

- The functionality of the auditory nerve and the auditory pathway must be able to be assumed on the basis of the preliminary examinations.

- If the indication is given on both sides, a bilateral CI supply should be performed.

- On average, an improvement in monosilver discrimination of ≥ 20% points must be expected by the end of the follow-up therapy for all patients treated postlingually in the CI-supplying institution.

- According to the current state of knowledge, from an audiological point of view, a CI indication thus already exists from a single-silver discrimination with optimal HG supply of ≤60% (at 65 dB).

- In postlingual (after language acquisition) deaf and hard of hearing patients, an indication can usually be assumed.

- In the case of prelingually (before language acquisition) deaf (deaf) adults, there is also an indication for implantation in selected individual cases, if a phonetically oriented language acquisition is in progress.

- In the case of prelingually deaf and perilingually deaf or partially deaf children, implantation should be carried out as early as possible (within the first years of life).

- If obliterating labyrinthitis is suspected, CI care should be performed as early as possible.

6. Process description preoperative phase

The following methods are to be provided by the CI-supplying institution and used if necessary:

6.1. Adult

General status, medical history including ENT spec. Medical history

ENT status, especially also tympanic membrane microscopy

Sound and speech audiometry (incl. Sentence test)

Freiburg tests with determination of the maximum monosilver comprehension (MeV) and detection of the discomfort threshold for speech

Sentence test in silence / background noise (e.g. OLSA, GöSa or HSM)

Hearing aid testing and optimization, testing new hearing aids if necessary
Hearing aid technology in cooperation with a hearing aid acoustician

Checking the hearing aid supply with the specified speech audiometric methods

Objective listening tests
- TEOAE / DPOAE
- Impedance audiometry
- Electrocochleography
- Klick-BERA
- Frequency-specific BERA (e.g. Chirp, SN10, ASSR, notched noise)
- CERA (useful in individual cases)

Promontorium test

Vestibular examination
- Caloric vestibular examination
- Head Impulse Test
- Position and bearing testing
- VEMPs

Neuroradiological diagnostics and diagnosis
- High-resolution rock bone CT or DVT
- High-resolution magnetic resonance imaging of the rock bone, cerebellar bridge angle and cerebrum

6.2. Additional examinations and preoperative measures

– Logopedic-phoniatric, pedagogical and psychological
Examinations of the patient's communication skills, expectations, motivation, learning ability and psychosocial situation as a criterion for the use of the cochlear

implant

- Consultation examinations regarding the clarification of risk factors (surgical ability, possibly prognostically relevant concomitant diseases)

- Control of vaccination status (HIB, pneumococcal)

- Vaccination according to the current STIKO recommendations for at-risk patients.

6.3. In-depth personal consultation and patient education

The CI-supplying institutions undertake to carry out a personal consultation and to ensure proof in the form of a consultation protocol with the following contents. If audiologically possible, a hearing aid inspection and optimization is carried out, if necessary, testing of new hearing aid technology (e.g. also systems with hearing range extension) alternatively, this can be ensured by cooperation with a hearing aid acoustician.

- Information about and testing of alternative supply options (e.g. CROS / BiCROS supply in case of unilateral deafness)

- Information on the course of a CI supply

- Information on the operating principle of CI systems

- Information about the characteristics and differences of the different available CI systems, in terms of
    - Medical indication of various electrodes
    - Various user-relevant technical audiological properties
    - Bimodal forms of care
    - Collection of individual requirements of the patient for the CI system ○ Advice on decision-making for the CI system to be used

- Operational procedure and risks of the operation

- Information on the rehabilitation process

- Prospects of success with an explicit realistic assessment of the expected increase in language comprehension

- Individual therapy planning

- Information from and contact with affected persons

6.4. Duration

The preliminary examinations should be inpatient (if necessary outpatient).

6.5. Children and adolescents

The clarification of the medical status is carried out analogously to the procedure for adults (see above). Depending on the age and ability of the child to cooperate, it may be necessary to conduct the examination under anesthesia at an appointment and, if necessary, supplement it with paracentesis and adenotomy. The decisive basis for the indication and decision-making is the completeness of the examinations.
In the presence of hearing residues potentially usable for speech comprehension, a hearing aid wearing test must be connected upstream of the CI operation. A hearing impaired-pedagogical, phoniatric-pedaudiological and logopedic assessment of hearing, hearing, speech and language status and the recording of language development and communication competence are mandatory. The associated specialists are part of the interdisciplinary team. Consultation of the institute that carries out the follow-up therapy and other funding institutions in the identification of indications.

6.6. Additional examinations and preoperative measures

- Developmental diagnostics

- Additional developmental neurological examinations,
  For example, in order to identify further disabilities, to determine partial performance disorders (additional inpatient stay in a specialized facility may be required for this purpose)

- Psychosocial diagnostics

6.7. In-depth personal advice and clarification

Conducting a hearing aid test

Information on the course of a CI supply

Information on the operating principle of CI systems

Information about the characteristics and differences of the different available CI systems, in terms of
o medical indication of various electrodes
o various, user-relevant technical audiological properties
o bimodal forms of care
o Collection of individual requirements of the patient for the CI system
o Advice on decision-making for the CI system to be used

Preoperative education

Information on the rehabilitation process

Prospects of success with an explicit realistic assessment of the expected acquisition of spoken language or gain in language understanding

Individual therapy planning

Information on postoperative imaging, in particular magnetic resonance imaging

Information from and contact with affected persons

Information on alternative communication models

These points are to be documented with the result in the consultation protocol.

7. Process description operational phase

7.1. Requirements for the surgeon and the CI-supplying institution

Many years of continuous experience in the special microsurgery of the ear and previous operational activity in a clinic specializing in CI surgery.

The implanting clinic must publish the number of CI operations and the complication statistics as part of a quality report.

7.2. Permanently available operational equipment

- Intraoperative EMG monitoring of the facial nerve
- Special surgical instruments for cochlear implantation
- Cochlear implants as well as reserve and special implants
  (at least 3 different manufacturers)
- Measuring station for intraoperative functional testing of implants from at least 3 different manufacturers and the auditory pathway
  (the measuring station must be kept up to date with the latest software and hardware)
- Possibility of intraoperative imaging
- Consultation services that must be available
  - Intensive Care
  - Neurosurgery
  - Neuroradiology
  - Pediatric Anesthesiology and Intensive Care Medicine

7.3. Fully stationary length of stay

The implantation is completely stationary. The length of stay is measured according to medical and social patient-side criteria, whereby checks for complications, especially in wound healing, are required. As a rule, a lying time of 3 days should not be undercut.

7.4. Intra- and postoperative controls

Intraoperative:

- Control of implant function by means of telemetry. The operation of the measuring station must be carried out by trained personnel employed in the CI-supplying facility (e.g. engineer / technician), who knows the procedures in the operating room exactly and can react accordingly to the specific conditions

- Intraoperative monitoring of the facial nerve by trained personnel employed in the CI-supplying institution

- Measurement of physiological responses to electrical stimulation:

- Stapedius reflexes

- neural responses (ECAP),

- E-BERA if necessary (provision required)

- Radiological control of the Electrode positionif necessary

Postoperative:

- Radiological control of the Electrode position

- Careful control of wound healing to prevent possible complications early detection.

8. Basic and follow-up therapy

In addition to the intensive preoperative diagnostics and surgery described, the postoperative basic and follow-up therapy are of decisive importance for the overall success of CI care. They are therefore an integral part of the CI supply. The specifications for the temporal structuring of the CI supply process can be found in Figure 2, among others:

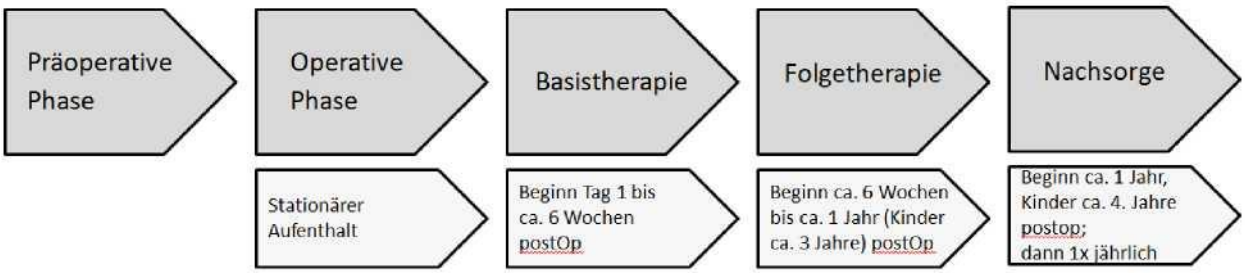


Figure 2:
Temporal structure of the CI supply process. The mentioned periods of the named process phases denote average times. These can be significantly exceeded or undercut in individual cases, depending on the individual (re)habilitation course.

A distinction is made between an "audiological" and a "hearing therapeutic" part of the basic and follow-up therapy. This results in the following proportions of the care of the patient provided with a CI in the postoperative period:

1. "Basic audiological therapy"
2. "Basic hearing therapy"
3. "Audiological follow-up therapy"
4. "Follow-up hearing therapy"
5. „After-care“

The "basic audiological therapy" includes the commissioning and initial adaptation of the speech processor. The "audiological follow-up therapy" must be offered as part of a continuous care until the implant can be fully used in the manner possible in individual cases. In order to ensure a high level of quality of results in the interdisciplinary care process, the basic and follow-up audiological therapy must be located at the facility that provides CI to the patient.

In contrast to this, pedagogically / logopedically oriented hearing therapy is carried out under the responsible medical supervision as a basic and follow-up hearing therapy either at the institution providing CI care for the patient or at a cooperating institution qualified for this activity. The initiation of basic and follow-up hearing therapy and ensuring the quality of care are the responsibility of the institution providing CI to the patient.
Overall, the provision of CI is a multidisciplinary approach that must be carried out in CI-providing institutions with the appropriate expertise of basic and follow-up audiological therapy (Figure 3).

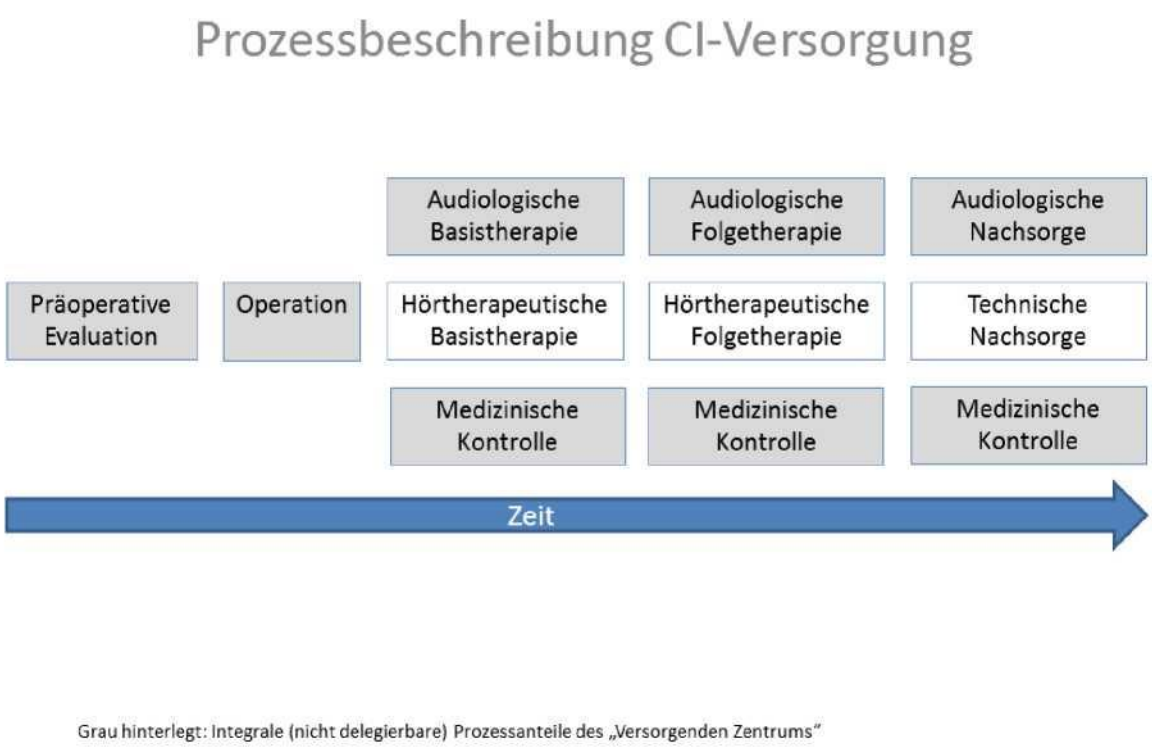


Figure 3:
Process description CI supply.

8.1. Basic therapy

Contents of medical control

- ENT medical examination
- Ear microscopy
- if necessary, radiological examination
- if necessary, laboratory examination
- Advice
- Assessment of the success of therapy

- Arrangement of diagnostic and therapeutic measures
- Ensuring the collection and documentation of the Quality assurance measures

Contents of the basic audiological therapy

- Initial setting of the speech processor
- T, C-Level, loudness balancing
- Technical and audiometric controls
- Impedances, eCAPs
- Hearing tests to assess the speech processor setting (e.g. categorical Loudness scaling, inflation curve)
- Optimization of the language processor setting
- Speech test in silence and in background noise
- Documentation and evaluation of the results
- Instruction in the handling of the CI system (care, maintenance, error detection)
- Information about any available additional devices (e.g. telephone adapter, charger, additional microphone, induction or T-coil, etc.)
- Regulation of any necessary additional devices
- Basic instruction in the handling of used accessories
- Bimodal adjustment if necessary
- For hybrid supply:
    - Adaptation of a hearing aid component in addition to the cochlear implant

Contents of the basic hearing therapy

- Psychological support (e.g. for the resolution of therapy-hindering conflicts)
- Initial listening and speech training
- Speech therapy
- Educational therapy
- Other speech therapy measures

8.2. Follow-up therapy

Contents of medical control

- ENT medical examination
- Ear microscopy

- if necessary, radiological examination
- if necessary, laboratory tests
- Advice
- Assessment of therapy success n Follow-up/assurance
  diagnostic and therapeutic measures
- Ensuring the collection and documentation of quality assurance measures

Contents of the audiological follow-up therapy

- Subsequent setting of the speech processor
- T, C-Level, loudness balancing
- Technical and audiometric controls
- Impedances, eCAPs
- Hearing tests to assess the speech processor setting (e.g. categorical
  Loudness scaling, inflation curve)
- Speech test in silence and in background noise
- Documentation and evaluation of the results
- in-depth instruction in handling (care, maintenance, fault detection) and in the use of additional devices (e.g. telephone adapter, charger, additional microphone, infrared or FM system, induction or T-coil)
- Bimodal Adaptation if necessary for hybrid supply:
  - o Adaptation of a hearing aid component in addition to the cochlear implant

Contents of the hearing therapy follow-up therapy

- Educational - psychological support
  (e.g. for the resolution of therapy-hindering conflicts)
- Listening- language training at different cognitive levels
  - o Noise training
  - o Noise identification
  - o Vowel and consonant training
  - o Word training
  - o Sentence training
  - o Telephone training
  - o Dealing with media
  - o Handling of additional devices
  - o regular quality controls with standardized test material
- Specific to children:
  - o Listen to the parents' instructions in the initial
  - o Language development

- o Promotion of school education
- o Diagnostics of auditory speech development based on the known milestones of speech development and with the help of standardized, partially questionnaire-based test materials

8.3. Lifelong aftercare

CI care requires lifelong follow-up by the CI care facility. The lifelong follow-up is used for medical and technical control and advice as well as for checking hearing, speech and language performance, including documentation, with the aim of stabilizing and optimizing individual communication skills and not therapy (medical and audiological follow-up).

Contents of medical control

- ENT medical examination
- Ear microscopy
- if necessary, radiological examination
- if necessary, laboratory tests
- Advice
- Assessment of the success of therapy
- If necessary: arrangement of further diagnostic and therapeutic measures
- Ensuring the collection and documentation of the Quality assurance measures

Contents of the technical aftercare

- Control of stimulation parameters
- Objective measurements:
- Impedances, ECAP
- Hearing tests for assessing the speech processor setting (e.g. Loudness scaling, inflation curve)
- Tone audiogram according to CI register
- Language tests according to the CI register
- Technical advice and evaluation of the functionality of the CI system

If there are indications of the need for audiological follow-up during the technical follow-up, this must be carried out primarily at the CI-supplying facility.

Contents of the audiological follow-up

- T, C-Level, loudness balancing
- Technical and audiometric controls
- Impedances, eCAPs
- Hearing tests to assess the speech processor setting (e.g. loudness scaling, inflation curve)
- Optimization of the language processor setting
- Speech test in silence and in background noise

Documentation and evaluation of the results

Bimodal adjustment if necessary

for hybrid supply:

- o Adaptation of a hearing aid component in addition to the cochlear implant

9. CI Register

Quality assurance in the field of CI care is based on the assessment of implantin consideration of the applicable data protection laws. Only in this way can possible systematic implant errors be identified at an early stage or the influence of process or treatment changes on the quality of the care result be recognized. The data blocks of the "CI register" created by the DGHNO (reference to Appendix / separate document) are considered to be the basis for a uniform national data collection. At the same time, this is the basis for an independent central quality assurance under the technical direction of DGHNO.

CI Register data blocks

1-3: One-time data blocks

1 . Basic data

ID (Code) Care facility (Clinic):

Patient ID Pseudonym:

Date of Birth: DD.MM.yyyy

Date of Death: DD.MM.yyyy

Gender: W/M/ka

Native language German : y/n

2 .Preoperative audiometry (to be created for each CI implanted side)

Page: R/L

Sound Audiogram LL/KL (125/250/500/750/1000/2000/4000/8000Hz): 0-120 dB HL, not detected/ not determinable

Freiburger, Hearing loss figures (50%, 100 dB if below 50%): 0-100 dB

Freiburger Monosilver (headphone performance) (60, 65, 80, 100 dB SPL): 0-100 %

Freiburger Einsilber MeV (headphone performance min. 95 dB SPL, without HG): 0-100 %

Freiburger Monosilver(free-field performance, with HG) 65 dB SPL: 0-100 %

3 .Preoperative hearing history (to be created for each CI implant side)

Page: R/L

Hearing loss since birth: y/n

Hearing loss since childhood: y/n

Hearing loss in adolescence /adulthood: y/n

Hearing loss (CI ear) in years: 0-1, 1-5, 5-10, 10-20, >20, kA

Deafness (CI ear) in years: 0-1, 1-5, 5-10, 10-20, >20, kA

Hearing aid use in the CI ear: j/no

As of: 10.04.2018

4-9: Data blocks created several times

4.1 mplantat (to be created for each page/intervention)

Page: R/L

Date of implantation: DD.MM.YYYY

Implant Manufacturers (1: Advanced B, 2: Cochlear, 3: MedEl, 4: Oticon, 5: Others): 1-5

Implant Name: <List, Other>

Implant serial number:

Explanation: y/n

Date of declaration: DD.MM.yyyy

Reason for explanation according to classification: (C, D)

5. Operation (to be created for each page)

Page: R/L

Operation Date: DD.MM.yyyy

Reason for operation: 1: Primary Operation / 2: Revision Operation: 1-2

Electrode insertion (1: round window / 2: cochleostomy / 3: other / free text): 1-3

Insertion depth (1: partial / 2: complete): 1-2

Radiological position control electrode (1: normal / 2: not normal / 3: not done): 1-3

Radiological method: (1: conventional Rö/2: DVT/3: CT/4: miscellaneous Free text): 1-4 Revision Surgery: Y/N

Only when completing revision operation:

Classification-Dysfunction: (B1, B2, C, D): B1-D

If there is a malfunction: Selection from <Cause list with selection fields, Miscellaneous>

Implant status during revision surgery 1: Leave the device / 2: Change / 3: Explanation: 1-3

6. CI related complications

Page: R/L

Incorrect position of the electrode requiring revision: y/n

Facial palsy: HB grade I-VI

Hospitalization was required due to CI-related complications: y/n

Meningitis after CI care: y/n

Death in connection with CI care: y/n

7. CI use and rehabilitation progress

Page: R/L

Patient appeared for follow-up examination: y/n

CI Service Life (time in hours/day): 0-24, kA

Duration of use collected by (1: Patient information/2: data logging/ 3: kA): 1-3

Current rehabilitation status (1: basic therapy /2: follow-up therapy/3: follow-up care/4: unknown/5: ka): 1-5

Implant function (classification according to Consensus 2005; not specified): A, B1, B2, C, E, kA

8. Postoperative audiometry

Page: R/L

Time after CI operation in months: 0-XX (Automatic)

Sound Audiogram (unsupported) LL/KL (125/250/500/750/1000/2000/4000/8000Hz): 0-120 dB / not detected / not determinable

Acoustic component/EAS is used: y/n

Opposite side in case of residual hearing (occluded / dusted): o/v/kA

Freiburger Monosilver (with CI) 65 dB SPL: 0-100 %

Set test results (if necessary carried out with noise, only S0N0): y/n/kA

- Used speech test in noise (OLSa/GöSa/HSM): O/G/H
- OlSa threshold at rest (SRT50): 0 to +80dB /not raised
- OLSA noise threshold (SRT50): -10 to +10 dB/not detected
- GöSa threshold at rest(SRT50): 0 to +80dB /not raised
- GöSa Noise threshold (SRT50): -10 to +10 dB/not raised
- HSM at rest: 0-100%/ not charged
- HSM noise: 0-100%/ not detected
- HSM SNR: -5, 0, +5, +10 dB

9. Quality of Life (NCIQ) Elementary sound perception NCIQ1 (0-100) Speech and music perception NCIQ2 (0-100) Control of one's own voice NCIQ3 (0-100) Psychosocial consequences NCIQ4 (0-100) Activity behavior NCIQ5 (0-100)

Social contacts NCIQ6 (0-100)

NIIQ Total Score NCIQTotal (0-100)

Instructions for filling in the data blocks:

General Information:

- The data acquisition of the CI register is divided into 9 data blocks. These 9 data blocks

correspond to the identifications of the data in the diagram "Dates of data collection CI-Register" (see below).

- The data fields of data blocks 1-9 are to be filled in for both adults and children, as far as they are applicable. *A specific "children's module", based on performance data and assessments of the quality of life, will be supplemented at a later date*.
- The quality of life is recorded using the"Nijmegen Cochlear Implant Quenstionaire (NCIQ)" in German at the time points defined in the diagram "Time Points Data Collection CI Register" (see below).
- The basic therapy consisting of the audiological and hearing therapeutic part (see White Paper Cochlear Implant care) begins after implantation. The start of the basic therapy should be after 6 weeks at the latest and usually extends to several appointments.
- The follow-up therapy (see White Paper Cochlear Implant Care) begins after completion of the basic therapy (about 6 weeks to 1 year after implantation). The follow-up therapy usually includes several appointments within one year.
- At least one complete data collection (mandatory field) is carried out in the register during the "Preoperative phase" and the "Operative phase" (see also document "Dates of data collection").
- At least the complete results of an examination during the basic therapy (B1) and two follow-up therapy appointments (F1 + F2) (minimum interval of 3 – 6 months between F1 and F2) are collected in the register (mandatory fields). In data block 8 ("Postoperative Audiology"), one of the mentioned sentence tests in the interfering sound must be carried out on the specified minimum dates.
- Follow-up appointments are referred to as follow-up examinations after completion of the follow-up therapy (see White Paper Cochlear Implant Care). As an orientation, the beginning of follow-up can be assumed at about one year for adults and about four years for children after CI-OP.
- Follow-up is carried out annually (N1, N2, N3....NX)
- The time of data collection is always recorded in each data block of the register. An explicit date indication in the description was therefore omitted.
- For each page to be supplied, the data blocks 1-3 are created once. The data blocks 4-9 are created on a recurring basis during corresponding visit appointments.

- As part of the recording of implant use / function, data blocks 4, 5 and 7 contain information on malfunctions based on the "European Consensus Statement on Cochlear Implant Failures and Explanations. Otology and Neurotology 26:1097-1099“2005".

The following categories are provided here:

A:	Impl. Device;	Clinical Benefit;	in Specification:	a functioning device
B1:	Impl. Device	Clinical Benefit;	out Specification:	characteristic decrement
B2:	Impl. Device	no clinical benefit;	in Specification	Performance decrement
C:	Impl. Device	no clinical benefit;	out of Specification	Device failure

C:	Expl. Device	out of Specification	Device failure
C:	Expl. Device	in Specification	Clinical benefit (new device): Device failure
D:	Expl. Device	in Specification	No Clinical benefit (new device): Medical Reason
D:	Expl. Device	in Specification	Medical problem: Medical Reason
E:	Loss of Follow up		Device lost to follow up

Special notes:

1. **Data block: "Basic data"**

- "ID of the care facility (clinic)":
  One-time assignment of a code of a clinic / care facility by the registration center after registration for participation in the register
- "Patient ID pseudonym":
  Definition of a "unique patient ID" according to the system to be defined to avoid multiple entries of a patient

2. Data block: "Preoperative audiometry (to be created for each CI implanted side)"

- "Sound Audiogram LL/KL":
  Underlined frequencies are mandatory fields. For hybrid/EAS supply, also testing at 750 Hz.
- "Freiburger, hearing loss for numbers":
  Recording of the speech level for 50% comprehension (if no 50% is reached, "100 dB" is documented.
- "Freiburger Einsilber MeV (headphone performance)":
  "MeV" - maximum monosilver understanding: at least 95 dB SPL playback level, otherwise increase level until discomfort threshold/ audiometer limit is reached.

3. Data field: Preoperative hearing history

- "Hearing aid wearing test in the CI ear":

  The indication should refer to the current status at the time of the preoperative examination.

4. Data field: Implant

- Implant Name: <List, Other>:
  Implant type derived from manufacturer's description including design of the electrode (for different electrode variants)
- Explanation: y/n:
  Please indicate whether the above. The implant had to be removed
  different electrode variants)
- Reason for explanation according to classification (C, D):
  As part of the implant assessment, the reason for the explanation is based on the "European Consensus Statement on Cochlear Implant Failures and Explanations. Otology and Neurotology 26:1097-1099“2005". Here are technical and medical reasons to distinguish:

C:	Expl. Device out of Specification	Device failure
C:	Expl. Device in Specification Clinical benefit (new device):	Device failure
D:	Expl. Device in Specification No Clinical benefit (new device):	Medical Reason
D:	Expl. The Medical problem:	Medical Reason

5. Data field: Operation

- "Revision Operation: Y/N":
  The following fields are only filled in during revision operation.
- "Classification-Dysfunction: (B1, B2, C, D):":
  Assessment of the dysfunction based on the "European Consensus Statement on Cochlear Implant

Failures and Explanations. Otology and Neurotology 26:1097-1099.2005“. Here are technical and medical reasons to distinguish:

B1:	Impl. Device	Clinical Benefit;	out Specification:	characteristic decrement
B2:	Impl. Device	no clinical benefit;	in Specification	Performance decrement
C:	Impl. Device	no clinical benefit;	out of Specification	Device failure
C:	Expl. Device	out of Specification		Device failure
C:	Expl. Device	in Specification	Clinical benefit (new device): Device failure	
D:	Expl. Device	in Specification	No Clinical benefit (new device): Medical Reason	
D:	Expl. Device	in Specification	Medical problem:	Medical Reason

- "If there is a malfunction“:
  Here the cause of the need for revision is to be presented. A list of predefined possibilities is specified and adapted according to area code B1-D.

6. Data field: CI related complications

- "Faulty position of the electrode in need of revision: y/n":
  At a control appointment (after the operating phase), a corresponding incorrect position is determined.
- "Hospitalization was required due to CI-related complications: y/n":
  If inpatient treatment is necessary as a result of complications / side effects of CI care (e.g. dizziness, pain, infection of the implant), this must be documented.
- "Death in connection with CI care: y/n":
  Here, the death of a CI patient is to be recorded, which is in a possible connection with the direct or indirect consequences of CI care.

7. Data field: CI usage and rehabilitation progress

- "Duration of use collected by (1: Patient information/2: data logging/ 3: kA): 1-3":
  If there is no data logging, enter patient information. Necessary to record the rehabilitation success (especially CI-SSD patients)
- "Current rehabilitation status (1: basic therapy /2: follow-up therapy/3: Follow-up care/4: unknown/5: ka): 1-5“:
  Marking of the status according to the diagram "Dates of data collection CI-Register"
- Implant function (classification according to Consensus 2005; not specified): A, B1, B2, C, E, kA: see "General information"

8. Data field: Postoperative Audiometry

- "Time after CI surgery in months: 0-XX":
  Field is calculated automatically after entering the test date
- "Sound Audiogram LL/KL":
  Underlined frequencies are mandatory fields. For hybrid/EAS supply, also testing at 750 Hz.
- "Acoustic component/EAS is used: y/n":
  For patients with EAS/Hybrid system, the status of the use of the EAS/Hybrid CI processor must be

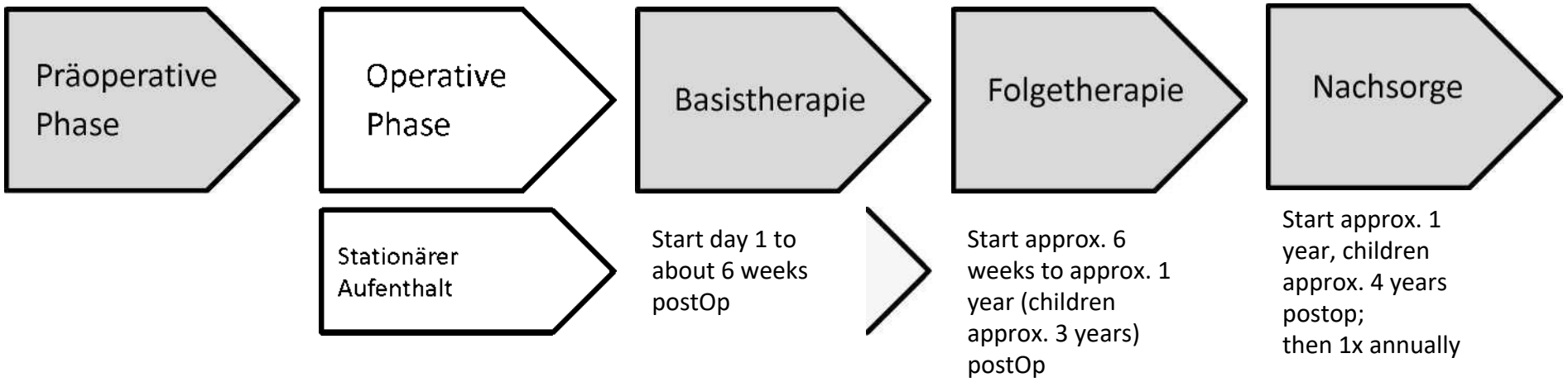
documented here.

- "Opposite side in case of residual hearing (occluded / dusted): o/v/kA":
  Important for asymmetrical hearing /SSD patients (single sided Deafness): Identification of the method used (occlusion, obturation) to block the unaudited ear.
- "Freiburger Monosilver (with CI) 65 dB SPL: 0-100 %:
  Carrying out the test in the open field at 65 dB and S0 position speakers.
- "Set test results (if necessary carried out with noise, only S0N0): y/n/kA.": Loudspeaker arrangement S0N0 for harmonization of the test arrangements.
  Indication of record test results in noise, at least one test at rest and in noise. Attention is drawn to the implementation of a suitable number of training lists.
  Adaptive test methods (threshold at rest, threshold in background noise): Omitted if the hearing performance of the patient does not allow threshold measurements.
- "Used speech test in noise (OLSa/GöSa/HSM): O/G/H": Indication of the set test procedure used.
- "OlSa threshold at rest (SRT50): 0 to +80dB /not raised":
  Speech comprehension threshold at rest, adaptive test procedure, starting level suggestion 55 dB.
- "OlSa noise threshold (SRT50): -10 to +10 dB/not detected":
  SRT50 Results > +10 dB: entry +10 dB, adaptive test procedure.
- "GöSa threshold at rest(SRT50): 0 to +80dB /not raised":
  Speech comprehension threshold at rest, adaptive test procedure, starting level suggestion 55 dB.
- "GöSa noise threshold (SRT50): -10 to +10 dB/not raised":
  SRT50 results > +10 dB: entry +10 dB, adaptive test procedure,
- "HSM at rest: 0-100%/not charged":
  Voice level 65 dB.
- "HSM noise: 0-100%/ not detected":
  Voice level 65 dB, fixed SNR, specification of the SNR required, see next point.
- "HSM SNR: -5, 0, +5, +10, +15 dB":
  Indication of the SNR used

9. Data field

Assessment of the quality of life according to the modified "Nijmegen Cochlear Implant Quenstionaire (NCIQ)": Rapid Positive Influence of Cochlear Implantation on the Quality of Life in Adults 70 Years and Older. Olze H, et al. Audiol Neurotol. 2016 (Questionnaire see annex).

Dates of data collection CI-Register



Preoperative	OP	B1		Bx	F1	F2 Fx		N1(+x)
1	4	4	4	4	4	4	4	4
2	5	5	5	5	5	5	5	5
3	6	6	6	6	6	6	6	6
		7	7	7	7	7	7	7
9		8	8	8	8	8	8	8
			9	9	9	9	9	9

STAND. 10.04.2018

Nijmegen Questionnaire before CI implantation

Please answer the following questions by ticking each **one** Possibility of response.
Please use the field "no answer " only if you are unable to assess the requested situation, e.g. because you have never experienced it before or if none of the possible answers apply.
This questionnaire is about the subjective assessment of your quality of life as a result of your specific hearing situation.

Name: ..... Middle name: ..... Date: .....

	• ○	rare	sometimes	o	always	no answer
1. Can you hear background noise (toilet flushing, vacuum cleaner)?						
2. Is your hearing impairment a serious obstacle to contact with hearing-impaired people?						
3. Can you whisper if it is necessary?						
4. Do you feel comfortable in company despite your hearing impairment?						
5. Can you have a conversation with a person (with or without a mouth picture) in a quiet environment?						
6. Is your hearing impairment a serious problem during your work or during your studies?						
7. Can you hear the footsteps of other people in your house (e.g. in the hallway or on the stairs)?						
8. Is your hearing impairment a serious obstacle to contact with deaf people?						
9. Can you scream when it is necessary?						
10. Does it bother you that you hear badly?						
11. Can you have a conversation with two or more people (with or without a mouth picture) in a quiet environment?						
12. Is your hearing impairment a serious problem in road traffic?						
13. Can you hear your own phone or doorbell?						
14. Is your hearing impairment a serious problem if you are in a group (hobbies, sports, holidays)?						
15. Can you make yourself understood by strangers without using gestures?						
16. Does it irritate you if you can not follow a conversation?						
17. If you are in a full store, can you understand the seller?						
18. Is your hearing impairment a serious problem in your free time?						
19. Can you hear (not feel) the apartment door slamming when you are busy at home?						
20. Is your hearing impairment a serious problem when contacting the people you live with (family/ partner)?						
21. Can you adapt your voice to different situations (noisy environment/ quiet environment)?						
22. Do you avoid talking to strangers?						
23. Can you enjoy music?						
24. Is your hearing impairment a serious problem in your domestic activities?						
25. Can you hear approaching cars on the road?						
26. Are you excluded from society because of your hearing impairment?						
27. Can strangers hear from your voice that you are deaf or hard of hearing?						
28. Do you ask other people to speak louder or more clearly if they speak too quietly or indistinctly?						
29. Can you recognize certain melodies when listening to music?						
30. Is your hearing impairment a serious problem when shopping?						
31. Can you hear quiet sounds (key falling to the floor/ microwave signal)?						

	• ○	rare	sometimes	o	always	no answer
32. Do you go to places where your hearing impairment could be a serious obstacle?						
33. Can you make yourself understandable to new acquaintances without gestures?						
34. Do you feel anxious when talking to strangers?						
35. Can you recognize certain rhythms when listening to music?						
36. Is your hearing impairment a serious problem when watching TV?						
37. Can you hear (not feel) someone coming closer from behind?						
38. Is your hearing impairment a serious obstacle to contact with people from your neighborhood?						
39. How often do you mind that others hear because of your voice/speech, that you have a hearing problem?						
40. Can you understand strangers without a mouth image?						
41. Is your hearing impairment a serious problem at parties (e.g. birthday)?						
42. Can you hear people talking on the radio (not necessarily understand)?						
43. Is your hearing impairment a serious problem when you are with friends?						
44. Can you easily make contacts with other people despite your hearing impairment?						
45. Can you hear the difference between a man's voice, a woman's voice and a child's voice?						
46. Is your hearing impairment a serious problem if you are dealing with formal matters (insurance, lawyer, administration?)						
47. Can you hear when someone calls you?						
48. Is your hearing impairment a serious problem in contacts with your family members?						
49. Are there any situations in which you would feel more comfortable if you were not hearing impaired?						
50. Do you find it tiring to listen (with or without a mouth image)?						
51. Is your hearing impairment a serious problem when you travel?						
52. Can you hear voices from other rooms (e.g. children playing, baby screaming)?						
53. If you are in a group, do you feel that your hearing impairment prevents other people from taking you seriously?						
54. Does your hearing impairment limit your self-confidence?						
55. Does your hearing impairment prevent you from standing up for yourself or defending yourself against others (at work, in a relationship)?						
	No	hard	reasonably	good	very good	no answer
56. Can you make your voice sound annoying, kind or sad?						
57. Can you control the height of your voice (high, low)?						
58. Can you control the volume of your voice?						
59. Can you make your voice sound "natural" (so that it does not sound like the voice of a deaf person)?						
60. Can you have a simple telephone conversation?						