SOUTH AFRICAN COCHLEAR IMPLANT GROUP

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Quality Standards

Cochlear Implant Services for Adults and Children in South Africa

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1. Introduction

The South African Cochlear Implant Group (SACIG) is a professional association for those directly involved in the provision of clinical services and scientific research in the field of auditory implantation, with specific emphasis on cochlear implantation. The aims of the group are to:

- encourage the interchange of ideas and information between anyone involved, or interested in, any aspect of cochlear implants.
- provide comprehensive advice on cochlear implants and quality standards in collaboration with its members and share best practice with the services in which they work.
- provide guidelines in setting, upholding and maintaining standards of service by surgeons, audiologists, speech and language therapists or other professional services that form part of service delivery.
- These guidelines aim to protect the public and guide the professions in accordance with HPCSA requirements.

- ensure that only internationally FDA and/or CE-approved cochlear implant (CI) devices are supplied by distributors/ suppliers who will also ensure the maintenance of standards as set by SACIG.

2. Objective

This document enumerates the minimum and realistically achievable baseline standard that all clinical CI services in South Africa should provide to create and maintain the highest standards of quality care. It includes all information on the patient pathway, clinical management steps, professional composition of the CI team and the technology, facilities and infrastructure required. It also includes the related quality standards and measures. Providers of CI services should be able to demonstrate to clients or patients as well as funders that they adhere to the current SACIG Quality Standards. These guidelines are recognised within South Africa, as well as internationally, as the benchmark of good practice.

To secure standards of service and the effectiveness of adult and paediatric cochlear implantation, the South African Cochlear Implant Group has produced this set of quality standards. The standards are a realistic minimum attainable by all cochlear implant programmes in South Africa and should be considered as the current Best Practice Guidelines. These guidelines should serve as the minimum standard (Quality Standard – QS) to be utilised and implemented across all Cochlear Implant Programmes in South Africa.

This document reflects the consensus opinion of the members of the South African Cochlear Implant Group and related health professionals. It is based on international standards of best practice so that consensus and evidence-based standards are in place to provide each implant user with the best outcome possible. It is not binding on any individual / individual clinic, however, it is the recommendation of SACIG that this

document should act as a guideline for minimum standards for clinics performing cochlear implantation in South Africa.

3. Cochlear Implantation

3.1 Aim

The aim of cochlear implantation is to improve the hearing and quality of life for those with permanent functional moderate to profound hearing loss and derive limited benefit from optimally fitted conventional hearing aids, and to promote the understanding and use of spoken language.

3.2 Technology

Cochlear Implantation is a process that involves the surgical implantation of an electrode array into the cochlea to provide direct electrical stimulation of the auditory nerve endings (spiral ganglion) in the cochlea. Cochlear implantation is recognised to be a safe and effective procedure.

A CI consists of two parts, an internal part (surgically implanted) and an external part (worn either behind the ear or on the side of the head). Both parts collaborate to produce an audible signal. The internal part consists of a receiver/stimulator package and an electrode array. The external part consists of a sound processor, battery and a transmitter coil. Some sound processors combine these into a single unit. The processor powers and activates the internal part and the patient can only hear sound when it is worn. The processor is custom programmed by the audiologist to ensure that it delivers appropriate patterns of electrical stimulation to each individual electrode on the electrode array, thus bypassing the damaged hair cells and providing direct stimulation to the auditory nerve. This provides the CI user with a meaningful sound sensation.

CI systems (implants and processors) are commercially available from a small number of manufacturers worldwide. Reliability, quality, service support, cost as well as company and distributor sustainability and compliance with local and international legislatory requirements should be taken into consideration in the device selection process.

Although CI services should seek to use the most up-to-date devices, SACIG cautions against using unproven 'novel' devices. Teams should request evidence of effectiveness and reliability, and should obtain assurance of both readily available expert clinical support and long-term commitment from manufacturers and distributors.

3.3 Target patient group

Each candidate for cochlear implantation presents with a unique set of capabilities and needs. Although the factor of severely compromised hearing is common to this group, the population differs in almost every other descriptor. Age, onset, etiology, and progression of deafness, cognitive and educational level, attention, language competence, family and environment, sensory and motor skills, and personal motivation all influence the approach and considerations for assessment and long-term management and outcomes (Niparko, 2009). In addition to the above, the South African context presents us with unique challenges in assessment and management requirements, and it is imperative that collaboration exists between all role players.

The clinical responsibility of the CI team is to carefully assess all contributing variables contributing to an optimal outcome so that through improved sound awareness and speech perception a better life quality is assured. Cochlear implantation should only take place within the context of a SACIG-endorsed cochlear implant team.

Appendix B and **Appendix C** include guidelines for candidacy including guidelines for bilateral and single-sided deafness.

Cochlear implantation is considered for adults (no upper age limit) and children over the age of 6 months (unless exceptional circumstances indicate the need for earlier implantation (e.g. potential of ossification in the cochlea).

3.4 The Cochlear Implant Team

Cochlear implant team personnel should be members of the South African Cochlear Implant Group (SACIG). All clinical team members should attend regular training in developments within the field of cochlear implantation. Attendance at relevant courses, conferences and meetings at national and international levels are desirable. Regular attendance at SACIG meetings should be available for team members. All team members should have a plan for their continuing professional development.

Cochlear implant teams may develop partnership services with local services where appropriate. Such partnership services must have appropriate training and expertise.

A cochlear implant programme is made up of a multidisciplinary team consisting of the following core personnel: otologists, audiologists and specialists in rehabilitation (speech and language therapists and/or teachers of the deaf and/or auditory verbal therapists). The team must have the knowledge and skills to assess and work with children and adults with a range of complex needs, additional to their deafness.

The team will include a Coordinator who will have a leadership/ management role. This team member should be a clinician, with extensive experience in the field of cochlear implantation. The Coordinator must ensure the maintenance and development of a highly skilled specialized service. The Coordinator will have responsibility to ensure that the patient's needs are met throughout the entire patient pathway and that relevant Quality Standards and National Specifications are achieved.

Where new Cochlear Implant Teams are to be established, it is recommended that the guidelines in **Appendix N** *(Guidelines for Starting New Cochlear Implant Programmes)* are considered.

The document will now specify and discuss the relevant quality standards of relevant aspects in the CI service delivery process.

4. Service Structure

A cochlear implant programme is made up of a multidisciplinary team made up of the following core personnel:

4.1 Cochlear Implant Coordinator

The Coordinator is responsible for the day to day management of the programme and will ensure that appropriate services are provided for each implantee through the cochlear implant patient pathway. The coordinator should be registered with the HPCSA as an ENT surgeon, audiologist, and/or audiologist/speech-language therapist. He/she will be a core team member, qualified at least to Masters level (or equivalent knowledge and skills) in their own professional area and with further specialist training in cochlear implantation (HPCSA-accredited Certificate of Competence in Additional Training in Cochlear Implantation in the case of an audiologist) and clinical management of adults and children with severe to profound hearing loss. He/she will furthermore have extensive clinical experience (ideally a minimum of 5 years) within the field of cochlear implantation, together with knowledge and understanding of the multidisciplinary areas within the programme. He/she should participate in and contribute to ongoing training in the field. The role may also include wider research responsibilities. The coordinator will have a high degree of clinical, organisational, leadership and professional skills. The coordinator, in addition to the above, is accountable for the delivery of the multidisciplinary service. He/she will provide

scientific and clinical leadership and will have managerial responsibility for service design, forward planning, finance, patient management and human resources. The coordinator will ensure that at least one team member attends annual SACIG meetings.

4.2 Audiologists

Audiologists must hold a professional registration with the Health Professions Council of South Africa, as well as have acquired an HPCSA-accredited Certificate of Competence in Additional Training in Cochlear Implantation. S/he should hold an accredited Masters in Audiology, or have the equivalent knowledge and skills. S/he should have knowledge and understanding of the multidisciplinary areas within cochlear implantation. After having acquired the HPCSA-accredited Additional Training in Cochlear Implant MAPping and Rehabilitation, s/he may not perform MAPping independently until a period of at least 6 months of guided supervision by an experienced certified cochlear implant audiologist has been completed.

In cases where an audiologist has been out of the cochlear implant field for more than 3 years, s/he is expected to re-acquire an HPCSA-accredited Certificate of Competence by completing a mentorship period of 60h under the direct supervision of experienced CI audiologists who hold the same Certificate of Competence.

To allow continuity of care, each programme should aim to have a minimum of two audiologists.

4.3 Speech & Language Therapist

The Speech and Language Therapist (SLT) working with children must hold a professional registration with the Health Professions Council of South Africa. It is recommended that the SLT is an AG Bell Academy Certified Listening and Spoken Language Specialist (LSLS Cert AVT) or has passed one of the following foundation courses in LSLS training:

1. LSLS (South African) course;
2. Auditory Verbal UK Foundation Course;
3. MedEl Foundation Course.

Should this not be possible within the context of the cochlear implant programme, the SLT should then consult on a regular basis with a LSLS-certified AVT or therapist who has additional training in LSLS principles. SACIG *Guidelines for Speech-Language Therapists working with children with cochlear implants* (**Appendix A**) should be adhered to.

4.4 Ear, Nose & Throat Surgeons

The ENT surgeon embarking on cochlear implantation surgery must do this as part of a cochlear implant team.

If s/he is joining an established team, s/he should have an F.C.S (ORL) or equivalent qualification and a subspecialist interest in Otology. S/he should be performing middle ear and mastoid surgery on a regular basis and be well-versed in mastoid surgery and the facial recess approach to the round window.

If s/he wishes to embark upon such cochlear implant surgery where there is no established team to join, s/he should set up such an adequately-trained and skilled team (**Appendix N:** *Guidelines for Starting New Cochlear Implant Programmes*).

The otology surgeon (as described above) should have adequate training and preparation for cochlear implantation. This must include attending an introductory course for cochlear implant surgeons, which must include training in the theory of cochlear implantation, clinical decision-making in cochlear implantation and a temporal bone dissection course for cochlear implant surgeons.

Surgeons who are newly appointed to a team once appointed, will work as a member of the consultant surgical cochlear implant team, initially under the mentorship of senior surgical colleague/s. There should be at least 6 months of supervision by a senior colleague for an appropriate number of (at least 10) cochlear implant operations.

The surgeon should have experience in adults before performing the procedure on children. Where children are to be operated on, the surgeon should have extensive experience of major ear surgery in young children.

In the case of a surgeon not yet experienced in cochlear implantation setting up a new cochlear implant team, or being part of a cochlear implant team which is being newly established, the above training and mentorship should be emulated as closely as possible with the assistance of CI surgeons in established teams.

In order for a surgeon to be maintaining his / her skills in cochlear implantation, it is recommended that the surgeon be performing at least 1 (one) cochlear implant per month. Teams should endeavor to ensure that their surgeons maintain such a level of experience.

The surgeon will participate in the process of audit of cochlear implant cases and in keeping a database of such cases.

To allow continuity of care, each programme should aim to have a minimum of two experienced ear surgeons capable of performing cochlear implantation and managing any complications.

In line with the current literature on the subject, it is recommended that intraoperative facial nerve monitoring be used when:

The surgeon is not as yet very experienced

Congenital malformations are present

Revision surgery

Should any surgeon be presented with a situation where the best alternative for the patient is that s/he should perform the surgery, but the case is beyond the comfort zone and experience of the surgeon, steps should be taken to ensure adequate preoperative advice and preparation and for ready access to advice if unsuspected problems arise during surgery.

Where more than one type of cochlear implant system is offered, surgeons should ensure that they perform sufficient operations with each system to ensure an appropriately high level of experience and skill including familiarity and competence with that particular device. Surgeons must also attend training courses run by the manufacturers of each device. Surgical mentoring is advised.

QS: All professionals must be suitably qualified, registered with their professional body, and comply with Health Professional Council requirements (if applicable).
QS: Newly appointed members of the team who are less experienced must undergo an appropriate programme of training and supervision provided by relevant experienced members of a cochlear implant team.

4.5 Additional Professionals

Where the core team does not include professionals from the following services or disciplines it should have access to them as required:

- Radiologist
- Neurologist
- Paediatrician
- Vestibular Specialist
- Tinnitus Specialist

- Psychologist/Psychiatrist
- Social Worker
- Educator
- Geneticist
- Physiotherapist
- Occupational Therapist
- Cochlear Implant Advocates

Contact must be established and maintained with the referring agent and other role players in the longer-term management of patients. Contact with support services should only be made with the permission of the patient and at the discretion of the cochlear implant team.

5. Clinical and Audiological Facilities

Clinical areas should be large enough to comfortably accommodate the patient, family member(s) and clinician together with the necessary equipment. A suitable room should be available for group work including patient activities and team meetings / training. There should be a suitable waiting area near the treatment rooms, large enough and with sufficient comfortable chairs to accommodate the number of people likely to be waiting at any one time. The treatment rooms and waiting area should be sufficiently separated that noise from the waiting area does not disturb the treatment, and that privacy is maintained.

Audiological testing will be performed in soundproof booth according to SANS 10182:2006 standards. The size of the soundproof booth should also allow for free-field testing that is at least 2.2m in dimension. Examination rooms must meet current

appropriate South Africa health and safety guidelines. All rooms should comply with health and safety regulations.

5.1 Audiological Facilities

Audiological facilities should be available for:

- Pure tone Audiometry (AC + BC)
- Sound field Audiometry
- Hearing aid testing and fitting
- Probe-tube microphone measurements (HA verification)
- Tympanometry and Acoustic Reflexes
- Oto-Acoustic Emissions
- Evoked Response Audiometry
- Speech perception testing (equipment for use of recorded speech materials).

All audiological equipment should be calibrated annually, and a system of daily checking should be in place.

QS: All testing should be carried out to professionally recommended protocols and procedures.
QS: All equipment must be calibrated annually using recommended methods on equipment which in turn is traceable to nationally recognized standards: • Pure tone audiometers Air conduction SANS 10182:2006 • Pure tone audiometers: Bone conduction SANS 10182-2:2006 • Speech audiometry SANS 8253-3:1996.

6. Referral and Selection Criteria

Guidelines for referral of patients for assessment for suitability of cochlear implantation and patient selection criteria, including candidature for unilateral and bilateral cochlear implantation, should be available in writing (**Appendix B**: *Guidelines for Referral and Candidacy for Cochlear Implantation, including Guidelines for Unilateral and Bilateral implantation* and **Appendix C**: *Single-Sided Deafness: Position Statement and protocol*). Patient selection criteria should be kept under bi-annual review by SACIG. Acknowledgement of the receipt of the referral and management decision must be undertaken by the receiving Cochlear Implant Programme. Ongoing updates on selection criteria and referrals should be provided by cochlear implant teams to potential referring agents.

QS: The referral and selection criteria for cochlear implantation must be in line with SACIG guidelines and reviewed annually.

7. Care Pathway

There are five phases of patient management within the cochlear implant care pathway: pre-implant assessment, surgery, device programming, rehabilitation and equipment maintenance.

7.1 Continuity of care

The phases of patient management inter-dependent of one another; information about a patient established in one phase should be used to determine the maximally safe and effective management in another. Patient information must flow effortlessly between phases. This may not occur efficiently if professionals outside of the particular CI team are responsible for different stages of management, which may introduce risks in terms

of patient safety, clinical effectiveness and patient experience. Hence, the CI team should demonstrate that it can provide for a comprehensive, complete service across all phases of patient management.

QS: The CI team must provide for a comprehensive service across all phases of patient management: pre-implant assessment, surgery, device programming, rehabilitation & equipment maintenance. Quality measures should be in place to ensure continuity of care across patient pathways and records of such activities must be available.

7.2 Communication and information

In accordance with the Protection of Personal Information Act (POPI), patients should sign written consent regarding sharing of personal information with other team members and related professionals.

It is important that patients, their families, carers and associated professionals are given appropriate access to information both during the assessment process and post implantation as necessary. Young people should be included in discussions, directly with clinicians as appropriate, wherever appropriate and supported to participate in decision-making about their care.

Patients and parents/carers should be given information about cochlear implantation, options regarding choice of device (and where to access this device if not offered by the particular programme), the treatment process, relevant organisations

(such as national and local charities and self-help organisations), equipment and services for deaf and deafened people, including Deaf community organisations. Information should be available online for those interested in finding out about cochlear implantation, those under assessment and following implantation. Use should be made of internet-based communications including video, social media and websites. Links to information from other relevant organisations such as device manufacturers, the South African Cochlear Implant Group, third sector organisations and other relevant bodies should be provided. Whenever possible, information should be provided to patients in a language that is appropriate to their preferred method of communication, including ensuring availability of interpreting services when necessary within appointments. Verbal information should be supported by a written summary to the patient whenever indicated. Following implantation patients should be given access to information regarding Medic-Alert systems and local and national support groups.

8. Pre-Implant Assessment

The CI team should have the infrastructure to perform assessment for CI, including a full specialist team and all associated specialist equipment, materials and facilities.

Patients are assessed to establish candidacy for cochlear implantation. A wide range of tests and investigations are carried out by the multidisciplinary CI team to conclude whether individuals meet the selection criteria and are likely to benefit from cochlear implantation. The CI team and referral sources should proactively engage with each other to ensure that patients have a comprehensive, thorough and timely assessment.

The patients' experience will be improved by ensuring effective liaison and support between these services.

The assessment process typically involves several visits to the CI center or unit. For children, the CI team rehabilitation professionals should interact closely with the child's family and local professionals as well as their rehabilitation team.

Coordinated management of the pre-implant assessment is the responsibility of the Clinical Coordinator. Fast tracking of patients through the assessment process must be available when clinically indicated.

Should a patient not be in a position to fund cochlear implantation from private funds (personal or medical aid), they should be referred timeously to a state facility should that

be available.

8.1 Audiological assessment

Assessment of hearing status, benefit from optimally fitted conventional hearing aids and functional hearing ability is undertaken by the audiologist. Each patient must receive a full audiological assessment performed to professionally accepted protocols (**Appendix F**: *Guidelines for Pre-and Post-Operative Audiological Assessment of Cochlear Implant Patients (Adults and Children) and Long-Term Management).* Audiological assessment may include (as appropriate):

- Detailed patient case history
- Otoscopic examination of both ears
- Evaluation of middle ear function using tympanometry.
- Determination of unaided air and bone conduction hearing thresholds bilaterally using pure tone audiometry or other recognised methods suitable for the patient.

Objective hearing threshold assessment, including Stapedius Reflexes, Oto-Acoustic Emissions and Auditory Evoked Response Audiometry if indicated (inclusive of click and tone burst ABR and ASSR). Note: confirmation for candidacy for implantation should only be after both objective and behavioural testing confirms the degree of hearing loss (Leigh et al, 2019)

- Unaided ear specific speech perception testing (recorded materials for older children and adults) if indicated.
- Evaluation of current hearing aids and appropriate hearing aid prescription:
    - Each patient should have their current hearing aid provision re-evaluated and provision of optimized hearing aids/settings as required (in conjunction with local services as appropriate).
    - Verification of the suitability of amplification should be undertaken. Assessment of ear specific aided benefit should include:
        - Aided sound field thresholds
        - Speech perception testing using pre-recorded speech material, and live voice where appropriate.
    - Patients fitted with new hearing aids or with a change of hearing aids settings may require access to a structured programme of auditory rehabilitation. It is recommended that trials with new hearing aids or different settings be conducted.
- Referral for vestibular assessment if consideration of bilateral implantation for adults and older children or history of vertigo / disequilibrium complaints (**Appendix F**)
- Provision of specialist advice if indicated on managing hearing loss in complex cases e.g. borderline candidates, asymmetric hearing loss, single-sided deafness, patients with additional needs and Auditory Neuropathy Spectrum Disorder (ANSD).
- Evaluation of the patient's potential ability to participate in CI programming and identification of possible strategies to overcome limitations where they are identified.

- Contribution to the clinical decision making process.
- In the event of a patient being found unsuitable for CI, the team should provide advice and make recommendations on future management e.g. hearing aids, assistive listening devices, appropriate educational placement and rehabilitation.

8.2 Medical and Radiological Assessment

All patients referred to the cochlear implant programme should have a medical consultation with the team ENT surgeon. The medical CI team will liaise with the local/wider medical team (GP, Paediatrician, Consultant Otologist, Consultant Radiologist and other appropriate Specialists) to assess and ensure physical fitness for surgery and implications of possible broader medical issues.

The referral of patients for MRI and CT scans is the responsibility of the ENT surgeon. The need for a CT scan can be balanced against the specifics of the patient and the attendant potential radiation exposure.

Refer to **Appendix D** for *Radiological Guidelines for assessment and management of Cochlear Implant candidates and users*. Protocol to be reviewed bi-annually.

The following is the responsibility of the surgeon (for each patient):

- Overseeing medical aspects of the assessment process and pre- admission process to ensure the patient is medically fit to undergo the treatment.
- Establishment of etiology (where possible)
- Referral for genetic counselling (if required)
- All adults and older children under consideration for bilateral implantation (sequential or simultaneous) and any patient with vestibular / disequilibrium -related complaints to be referred for further vestibular function investigation to assist with selection of the most appropriate ear (Stevens et al, 2017) (refer to **Appendix F**).

- Advice regarding necessity for vaccination to minimize the risk of pneumococcal meningitis, confirmation of vaccination status. Arrangements should be put in place should vaccination be required.
- Confirmation of patient and/or family expectations
- Informing of associated risks of the treatment pre- and post-surgery, including implications for MRI after implantation.
- Obtaining fully informed patient consent for the treatment
- In the case of HIV positive patients refer to **Appendix E** (*Protocols for Management of HIV in Cochlear Implant Candidates)*.

8.3 Communication/Rehabilitation Assessment

Rehabilitation in listening and language development is provided by habilitation professionals such as speech and language therapists (**Appendix A**: *SACIG Guidelines for Speech-Language Therapists working with Children with Cochlear Implants*). Pre-operative assessment will cover a full specialist evaluation of the patient's potential to benefit from cochlear implantation. This will include functional hearing abilities, communication strategies including speech and language, social support network, individual family circumstances, expectations of treatment and commitment to having cochlear implants and the rehabilitation involved.

8.3.1 ADULTS

Pre-operative assessment must include an assessment of the adult's communication and social strategies. These assessments may take the form of observation or subjective description or formal evaluation if indicated. The assessment procedure will take into account the patient's age and hearing status and will normally include a detailed case history, and an assessment of the patient's receptive and expressive skills.

The following areas should be considered:

a. Receptive skills – listening skills for speech

- Lipreading skills
- Comprehension of spoken language

b. Expressive skills

- Language skills in all communication modes
- Intelligibility, voice quality

c. Details should be collated about the environment in which each adult typically communicates and where they find most difficulty.

d. Audiological assessment (**Appendix F**).

8.3.2 CHILDREN

These assessments may take the form of observation, subjective description or evaluation using formal test procedures. The assessment procedure will consider the patient's age, hearing status and any other medical and/or cognitive issues (**Appendix F** and **Appendix G**: *Guidelines for Speech, Language and Communication Assessment of Children Cochlear Implant Candidates*).

8.4 Other Pre-implant Assessments

8.4.1 Quality of Life Measurements

Pre-operative assessment should include a minimum of one measure of quality of life self assessment scale.

8.4.2 Hearing Ability Measure

Pre-operative assessment should include a minimum of one measure of hearing ability self-assessment scale.

8.4.3 Psychological Status

Not all patients require a psychological assessment. However, a referral to a qualified psychologist or psychiatrist should be instigated when there are concerns regarding the candidate's mental health, learning ability, personality and motivation, adaptation to their deafness, or unrealistic expectations about cochlear implantation which cannot be addressed through counselling by the cochlear implant team.

QS: Each patient must receive a full ENT, radiological and audiological assessment performed to the professionally accepted protocols.
QS: Decisions regarding cochlear implant candidacy are made by the cochlear implant team members.
QS: The ENT surgeon is responsible for ensuring that the patient has been informed of the risks of pneumococcal meningitis and has referred the patient for vaccination.

9. Pre-Operative Implant Information & Counselling

- Whenever possible, information should be given to patients/significant others/parents in a language that is appropriate to their preferred language.
- Interpreters should be offered if required.
- Teams should examine, continuously monitor, review and update the quality and quantity of the information they provide and have a written protocol to determine which information is given at which time.
- Verbal information should be supported by a written summary to the patient/ parents whenever indicated.
- Throughout the assessment period patients/significant others/parents should have a clear understanding of the main benefits and limitations of implantation based

on their specific profile of factors. They should demonstrate that they have realistic expectations of cochlear implantation, e.g. by using a measurement tool such as an expectations questionnaire.

- It is recommended that candidates, and where possible a family member / friend, meet adults who have experience of using a cochlear implant. Matching candidates and users in terms of age and duration of deafness and cochlear implant device may be beneficial. The same recommendation is made for parents of children assessed for candidacy.
- Patients, parents, relatives and friends should be encouraged to become involved in all aspects of pre- and post-implant management. This should always be done with the permission of the patient and at the discretion of the cochlear implant team.
- Issues surrounding cochlear implantation, including the views of the Deaf community, should be discussed and the patient should have an opportunity to meet people who have decided against implantation, if they wish.
- Waiting times for surgery and information about the hospital stay and post-operative follow-up should be outlined at the end of assessment.
- Patients should be given information about available cochlear implantation organisations (SACIG), and self-help / advocacy groups.
- The patient should be offered contact between the team and their employers and / or colleagues. Contact should only be made with the permission of the patient and at the discretion of the cochlear implant team.
- There should be a timetabled final discussion at the end of assessment between the patient and key team members at which agreement is reached about whether or not to proceed.
- If the outcome of the assessment is that cochlear implantation is not recommended

for a patient, reasons for this decision should be discussed with the patient and family. Recommendations for future management should be discussed together with the opportunity for re-referral in the future. These issues must be covered in a written report to the referring agent.

QS: Outcomes of the assessment and recommendations and referrals for future management should be recorded in the patient's file.
QS: The patient should be given the opportunity to discuss the recommendation not to offer cochlear implantation and be aware of any further management options.
QS: If the outcome of the assessment demonstrates that the patient would not benefit from a cochlear implant, the report to the referring agent will include: • Reasons why a cochlear implant is considered to be unsuitable. • Recommendations and referral for future management

10. The Cochlear Implant Device

There are three Cochlear Implant manufacturers currently supplying CI programmes in South Africa. Further information regarding the technical specifications of these different devices is obtainable from the individual manufacturers:

- Advanced Bionics
- Cochlear Ltd.
- Med-El Ltd.

The above cochlear implant systems are supplied by the following distributors:

Advanced Bionics – H.A.S.S. Yavini.Moodley@phonak.co.za

Cochlear – Southern ENT mirisa.m@southernear.com

Med-EL Ltd. – Charles.Dippenaar@medel.com

The following recommendations are made regarding devices to be available in South Africa:

- FDA and/or CE mark approved
- MRI compatible
- Clinical application of objective measures should be available
- Clinically proven hearing performance outcomes in children and in adults
- Safety and reliability data proven as required by the ANSI/AAMI CI-86:2017.
- Have high quality, sustainable clinical and technical support available from the manufacturer and local distributor.
- Distributors of the cochlear implant systems should belong to South African Medical Device Industry Association (SAMED) (**Appendix H**: SAMED Documents) and SACIG.
- Distributors of cochlear implant systems should meet legal requirements for importation, distribution and supply of medical devices (SAHPRA).

The patient should be given information on the cochlear implant devices available in South Africa along with an explanation as to why they have been offered a particular device, or choice of devices. Written information on the device/s offered should also be made available.

It is recommended that patients insure their speech processors.

Agreements should be reached regarding arrangements for replacement of spares, lost or damaged processors between the implanting team and the patient / carers.

QS: The Cochlear implant device offered to the implantee must:
- Have a proven track record for safety and reliability
- Have CE and/or FDA approval
- Should be MRI compatible
- Clinical application of objective measures should be available
- Have high quality clinical and technical support available from the manufacturer and local distributor.
- The local distributor should meet legal requirements for importation, distribution and supply of medical devices (SAHPRA)

11. Surgery and In-patient Care

The ENT Cochlear Implant surgeon is responsible for the overall medical care of the patient.

The surgical team is responsible for briefing the patient about the surgical procedure and potential complications and for obtaining the patient's informed consent.

Surgery will be carried out using widely accepted surgical techniques and with reference to the manufacturer's surgical manuals. The recommended and accepted surgical approach for access to the cochlea is via a Mastoidectomy and posterior tympanotomy. It is recommended that minimally invasive surgery be performed on every case. Consideration should be given on each case to the need for facial nerve monitoring.

Prior to wound closure, device function and hearing responses are evaluated by electrophysiological assessment. Appropriate peri- /post-operative imaging should be carried out to determine the position of the device in accordance with policy.

The ENT surgeon will continue to check and monitor the patient's progress during the post-operative period and will be responsible for dealing with any surgical or medical problems that may arise in relation to the implant.

Information regarding the outcome of surgery must be documented and should be made available to the audiological team immediately after the operation. Communication between surgeon and audiologist is essential to confirm appropriate healing has occurred to allow for activation of the device.

All relevant registration documentation should be completed, signed and returned to the manufacturer.

QS: Prior to discharge the patient should receive information regarding care of the wound/ear and pain management post-operatively and written guidelines on what to do should medical / surgical problems arise.
QS: Advice regarding health and safety with a cochlear implant must be given to the patient, together with written SACIG and manufacturer's safety guidelines, prior to discharge from hospital. Patients should be advised to wear a Medic Alert disc and be given the relevant forms.

12. Post-Operative Fitting and Device Programming

The procedure for activating and programming the device is an ongoing scientific process requiring highly specialist skills. Unlike hearing aids which work by the amplification of sound, cochlear implants work by applying electrical signals to electrodes implanted into the cochlea. Considerable expertise and experience is required when working with infants and young children. It is crucial that this work is

carried out by an appropriately qualified, regulated and experienced audiologist. Sound processors should be fitted and programmed only by an experienced clinical audiologist who has been fully trained in the relevant protocols and procedures (HPCSA-accredited Certificate of Competence in Additional Training in Cochlear Implants). A less experienced audiologist may only perform programming under direct supervision for a period of six months (or in longer-term consultation with a more experienced Mapping audiologist and / or clinical support from the relevant company. The clinic coordinator is responsible for determining the competency level of the less experienced audiologist.

The audiology team must possess a high level of experience and expertise for each type of device that they provide. This can only be achieved by supporting a critical mass of children and adults with each particular type of CI device. It is recommended that those involved in CI programming should be seeing an adequate number of patients per week in order to maintain their skills and deliver safe, accurate and effective treatment. They should abide by the relevant professional codes of conduct, e.g. Health Professions Council of South Africa and standards for Continuing Professional Development.

The audiology team may provide programming appointments at the CI centre or in the CI recipient's local area (in the home, at a clinic, in an educational setting).

Sound processors should be fitted and programmed once the patient's wound has healed satisfactorily and the payment process has been completed.

Before the initial programming relevant team members must:

I. check the external cochlear implant component
II. explain the programming procedures to the patient

Throughout programming, each electrode on the electrode array is individually tested and activated by applying appropriate electrical stimuli. Thorough observation and monitoring of the patient is required throughout this process. Electrodes that have the potential to cause unfavorable non-auditory sensations, such as pain or muscle spasms must be de-activated. Stimulation parameters are optimized for each individual electrode to elicit sound sensations that vary in pitch and intensity (psychophysics). An appropriate processing strategy is applied to provide a meaningful sound sensation. For bilateral CI recipients, this process is carried out for each ear separately.

The parameters are programmed into the patient's sound processor(s). Different programmes can be generated for each ear for a variety of listening conditions.

Appropriate audiological, standardized speech perception and quality of life outcome measures should be completed at regular intervals to facilitate the monitoring of functional hearing (**Appendix F**).

- The completed registration form should be returned to the local distributor on the day of fitting.
- Each device should be programmed according to the manufacturer's recommended programming procedures.
- A comprehensive explanation on the use of the speech processor and accessories must be given.
- Patients should be encouraged to contact the implant programme if they have any queries or concerns.
- Printed materials on the handling, operating and care of the sound processor should be issued to the patient / parents as appropriate.

- The number of **initial** programming sessions required by each patient varies, but typically six initial sessions for older children and adults are recommended, although some patients may require additional appointments according to clinical needs. For younger children an intensive initial programming period is required.
- The patient must have open access to the cochlear implant programme (or a designated satellite clinic) for checking the whole implant system and reprogramming of the sound processor.
- Annual contact should be made with all implanted patients: this is the responsibility of the implanting programme. Comprehensive records should be maintained of patient reviews, transfers, deceased or non-users which should form part of the annual audit.

QS: The appropriate number of programming sessions should be offered to each patient according to their clinical need. Typically, this is currently six programming appointments in initial activation period for adults and more for younger children.

13. Post-Operative Rehabilitation

The re/habilitation schedule and programme should be adapted to the individual needs of each patient. For children, outcomes of cochlear implantation lie in the domains of audition, communication (including speech and language), education and quality of life. Rehabilitation professionals from the team work in partnership with the child's local professionals monitoring progress and providing appropriate rehabilitation advice and support. Recommendations for rehabilitative care by the speech-language therapist are outlined in **Appendix A** and **G**.

a) Post-operative rehabilitation should begin immediately after initial fitting to:
    i) facilitate adjustment to the new sensation of sound
    ii) counsel the patient and family / carer
    iii) outline and implement the rehabilitation programme

b) The rehabilitation programme should be tailored to each individual's needs. Counselling should support the patient and his/her family regarding expectations, the rehabilitation procedures, and continuing commitment to the rehabilitation programme.

c) The rehabilitation programme may include evaluation of and training in:
    i. Detection of sound
    ii. Auditory training
    iii. Voice quality
    iv. Speech intelligibility
    v. Language comprehension and expression
    vi. Social skills
    vii. Lip reading
    viii. Communication strategies
    ix. Telephone training
    x. Music training

d) The patient must have open access to the cochlear implant programme (or a local partner-service) for rehabilitation and counselling as required.

e) Family members should be included in the therapeutic process.

f) Online rehabilitation programmes are widely available and the implantee should be informed of these options.

g) Long-term follow up includes monitoring the need for continued rehabilitation intervention.

h) Should the managing audiologist be in a situation where complex mapping difficulties result in a situation of a poor outcome or where the patient is dissatisfied with the outcome, s/he should consult with the programme Coordinator. Should this not resolve the problem the clinical support specialist of the distributor / company should be consulted.

QS: Sufficient rehabilitation sessions should be offered to optimize cochlear implant use.
QS: Long-term follow up includes monitoring the need for continued rehabilitation intervention.

14. Follow-Up Assessment and Long-term Management

a) The patient must have open access to the cochlear implant programme (or local satellite clinic) for programming and rehabilitation.
b) Adequate spares (e.g. cables / coils / batteries) must be made available by the distributor within one working day.
c) Replacement or loaner sound processors should be made available on the same or within one working day.
d) Individual programmes should have a policy for replacement of lost or damaged processors that is equitable for all patients.
e) Patients should attend life-long follow-up assessments according to the recommended SACIG protocol **(Appendix F).**
f) Follow-up assessments by the audiologist include equipment check, programming of the sound processor, otoscopy and tympanometry, free-field thresholds, standardised speech perception tests and quality of life questionnaires.

g) Recipients and their families should be provided with a document on Safety Guidelines for cochlear implant users for the specific type of implant (**Appendix I**).
h) Patients will need to be seen in the CI Department urgently if they experience non-auditory sensations or a sudden change in sound sensation. They should have rapid access to an experienced CI audiologist on the team for an emergency appointment when a cochlear implant device failure is suspected.

QS: Spares or loaner sound processors should be available on the same day or within one working day.
QS: Standardized audiological and speech perception measures, as well as questionnaires should be performed on at least two occasions in the first year following surgery.
QS: Long-term management should be according to the protocol outlined in Appendix E.

15. Transfer of Patients to other Cochlear Implant Programmes

When a patient chooses to transfer, or is referred to another program:

a) Contact should first be made between the referring audiologist and the receiving audiologist.
b) The patient will have the option to return to the referring audiologist at any time.
c) The patient should only be referred by the program where the patient was implanted after the SIX MONTHS follow-up visit in the case of children, and after the THREE MONTHS follow-up visit in the case of adults.
d) If the patient chooses to move to another team for programming the audiologists of the two teams should communicate to ensure best patient care.

15.1) REFERRING AUDIOLOGIST

a. Ensure that the program to which the patient is referred has the appropriate device compatibility and available infrastructure to accept the patient.
b. Provide the following information in a written Transfer report (**Appendix M**: *Transfer of Patients*):
    i. Full case history: Audiological background including etiology, onset of loss, duration of loss, hearing aid fitting information, tinnitus, vertigo etc.; Medical history; Psycho-social background (previous and current); Educational background (in case of children details on educational needs and status); Developmental history (in case of children); Communication development (in case of children, results of last assessment)
    ii. Surgery: Date of implantation, ear, type of device, type of electrode, serial number, surgical outcome and complications.
    iii. Programming:
        a. Date of initial programming, type of speech processor, serial number, (processors owned).
        b. Copy of first and last MAP as well as programming history (can also be provided on a USB).
        c. Information regarding MAP management in case of complications
    iv. Audiological test results:
        a. Pre-operative aided and unaided thresholds and speech perception results (each ear)
        b. Most recent post-operative speech perception results
        c. Most recent post-operative free-field thresholds

15.2) RECEIVING AUDIOLOGIST

a. The receiving audiologist should send results (programming and speech perception tests) to the referring audiologist at the time of the first assessment in the new program.
b. The referring audiologist should be informed if the patient cannot be contacted or does not attend appointments.

QS: The receiving audiologist should send results (programming and speech perception tests) to the referring audiologist at the time of the first assessment in the new program.
QS: The referring audiologist should be informed if the patient cannot be contacted or does not attend appointments.

16. Management of Patients by Different Cochlear Implant Programmes

For various reasons it can occur that patients who have the CI surgery with one team need to be followed-up at another program.

The main consideration should be best patient care. It is essential that patients are counselled regarding the possible length of (re)habilitation and the need for ongoing programming. In most cases, the patient will receive the best care when managed by one team, but for those cases where this is difficult the following is recommended:

a. The members of both teams involved should agree that the patient is a good candidate.
b. Prior to receiving a surgery date, the patient should have met all team members who will be involved in the case.

c. The members concerned must agree on regular communication prior to the operation. This is particularly important between therapists and audiologists during (re)habilitation.
d. The surgery date must be suitable to both teams in terms of initial programming and (re)habilitation.

QS: If patients are managed by two programmes, patient's best care is the underlying philosophy.

17. Management of Implantees from Other Countries

(Appendix J: *Guidelines for Management of "Out of Towner" implantees***).**

18. Device Failure

Cochlear implant reliability is high overall, but device failures can arise and they should be managed proactively and without delay. Management of suspected and confirmed failures should be considered by the CI programme, patient and manufacturers as an emergency. The patient should be scheduled for surgery as soon as possible to have the malfunctioning device replaced.

Cochlear implant recipients may also require revision surgery for medical reasons (e.g. infection or device migration). In these cases, device removal and subsequent re-implantation may compel a two-stage procedure or having CI surgery in the contralateral ear.

When a device failure is suspected, implant function testing (integrity testing) should be carried out by an experienced clinical specialist from the local CI distributor or manufacturer. This should not be more than within 7 working days unless exceptional circumstances dictate otherwise. Following confirmation from the manufacturer that the internal device has failed, a signed report is delivered to the surgeon and audiologist.

Should the internal device be warranted, a free of charge replacement will be delivered to the clinic together with an explant kit once a surgery date is nominated. The device type selected for re-implantation is selected by the team, but it is encouraged that the most recent implant suitable for that recipient be selected. Should the internal device not be warranted, the team should submit an order form specifying re-implant date and device choice.

The majority of manufacturers provide a 10-year warranty for the internal component of the cochlear implant device. The warranty replacement should be authorized by the CI manufacturer within 7 days of the tests being carried out if appropriate. Funding should be sought from patients for systems which are out of warranty.

Where re-implantation is required, the CI programme should arrange for the surgery to be scheduled as soon as practically possible.

The explanted device should be returned to the manufacturer for analysis. The manufacturer should provide the CI programme with a detailed report of the analysis within 3 months of the device being returned.

Re-implantation and programming should be carried out as detailed above. Further rehabilitation needs should be assessed and put into place as appropriate.

All device failures (for all reasons) should be recorded by the implanting programme, reported to the manufacturer and an audit maintained. This audit forms part of the

annual report submitted to SACIG. **Appendix K**: *Annual Report Template* should be utilised for reporting of device failures.

QS: If device failure is suspected the patient must be offered an appointment promptly to check the external and internal components of the implant device. If re-implantation is agreed this should be carried out as soon as medically possible and appropriate to minimise any auditory deprivation.
QS: If under warrantee the distributor should supply a replacement implant as soon as the surgery date has been arranged.

19. Audit and Service Monitoring

Clinical benefit is evaluated through performance assessments and questionnaires, with performance measures being obtained before implantation and over time thereafter. Clinical audit should be carried out systematically. CI programmes should undertake comprehensive monitoring of their service routinely and aim to provide a clinically- and cost- effective service of the highest quality.

a. All aspects of the cochlear implant service should have adequate systems of record keeping to facilitate auditing and planning. Service provision should be monitored against the targets and the standards set out in this document. The clinic coordinator is responsible for maintaining these standards.
b. An annual report should be provided to SACIG at the annual business meeting by the clinic coordinator of each cochlear implant programme. **Appendix K** can be used as a guideline for the annual report.
c. The Chairperson of SACIG will compile an Executive report of the outcomes of the year's activity of the national cochlear implantation process. This report should be available on request.

CI services should maintain adequate records of the following measures which may include, but are not limited to:

a. Safe and successful CI surgery, e.g. report on unplanned re-admissions within 30 days of surgery, explanation / re-implantation due to medical complications or device failures

b. Cochlear Implant device use

c. Specific outcome measures

d. Information about deceased and lost-to-follow up CI recipients should be provided to manufacturers to inform device cumulative survival rate data

e. Professionals working in CI services should liaise regularly with peers from other services throughout South Africa (e.g. though SACIG and its associated professional groups) to review case management and share examples of good clinical and managerial practice.

QS: Each implant programme should perform an annual audit and comply with SACIG requests for national audit data. The audit should cover: ● Clinical activity ● Staffing levels ● Patient performance outcomes ● Device failures ● Medical / Surgical complications ● Research interests and outcomes
QS: Reports to be submitted according to Appendix K (Annual Report Template)

20. Resources and Authors

The South African Cochlear Implant Group wishes to acknowledge the contributions of the authors and contributions of SACIG members in the compilation of this document.

20.1 Resources

Quality Standards: Cochlear Implant Services for Children and Adults. British Cochlear Implant Group, 1 April 2018.

The Cochlear Implant Group of India (CIGI) Clinical Practice Guidelines (2011)

International Standard: International Organisation for Standardisation (ISO) 8253-1 (1989) and ISO 8352-2 (1992).

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20.2 Authors

Appendix A: SACIG Guidelines for Speech-Language Therapists working with children with Cochlear Implants

Louise Ashton, Barbara Kellett, Jenni Bester, Dani Schlesinger, Estelle Roberts

Appendix B: Guidelines for Referral and Candidacy for Cochlear Implantation, including guidelines for unilateral and bilateral cochlear implantation

Lida Müller, Jenny Perold

Appendix C: Single-Sided Deafness: Position Statement and Protocol

Dr E Burden, Nicolize Cass, Estienne Havenga, Dr Maurice Hockman, Mirisa Meyer, Jenny Perold, Dr Kurt Schlemmer, Tamara van Zyl

Appendix D: Radiological Guidelines for Assessment and Management of Cochlear Implant Patients and Users

Professor L Janse van Rensburg, Dr Christelle Ackermann, Dr A du Plessis

Appendix E: Protocols for management of HIV in cochlear implant candidates

Dr M Hockman, Dr Kurt Schlemmer

Appendix F: Guidelines for Pre- and Post-operative Audiological Assessment of Cochlear Implant Patients (Adults and Children) and Long-Term Management

Lida Müller, Jenny Perold.

Vestibular testing: Dr Kurt Schlemmer, Dr Louis Hofmeyr

Appendix F: Guidelines for Speech, Language and Communication Assessment of Children Cochlear Implant Candidates (Pre- and Post-operative)

Louise Ashton, Estelle Roberts, Barbara Kellett, Jenni Bester, Dani Schlesinger

Appendix H: SAMED Document

Appendix I: Safety Guidelines (Advanced Bionics, Cochlear, MEDEL)

Provided by Manufacturers (See websites)

Appendix J: Guidelines for Management of “Out of Towners” Implantees

Estelle Roberts, Leone Naute, Wendy Deverson

Appendix K: Annual Report Template

Tamara van Zyl, Jenny Perold

Appendix L: Red Flags

Louise Ashton

Appendix M: Transfer of Patients

Lida Müller, Jenny Perold

Appendix N: Guidelines for Starting New Cochlear Implant Programmes

Lida Müller, Jenny Perold

This document and appendices have been drawn up by the above authors and has been circulated to cochlear implant professionals in South Africa, Distributors, Health Professions Council of South Africa, ENT Society, South African Association of Audiologists (SAAA), South African Speech Language and Hearing Association (SASLHA) and the Universities.

The document has been modified according to suggestions received.