GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

COCHLEAR IMPLANT PROGRAMME GUIDELINE

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SECTION 1: OVERVIEW OF SERVICE AND DEFINING OF CLINICAL ROLES

1.1. PURPOSE OF GUIDELINE

This guideline aims to standardise and optimise service delivery within the area of cochlear implants for both adult and paediatric patients and to ensure adequate flow of service for hearing impaired patients within and between adult and paediatric audiology clinics, and the cochlear implant service. The cochlear implant clinic takes place in the Speech Therapy and Audiology department in the outpatient building at Chris Hani Baragwanath Academic Hospital (CHBAH).

1.2. COCHLEAR IMPLANTS IN SOUTH AFRICA

'*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. A cochlear implant may be suitable for adults and children who have a moderate to profound sensorineural hearing loss and who derive limited benefit from conventional hearing aids. Cochlear implantation is recognised to be a safe and effective procedure. To secure standards of service and the effectiveness of adult and paediatric cochlear implantation, the South African Cochlear Implant Group (SACIG) has produced a 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.*

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. (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' (SACIG, 2017).

The CHBAH guideline below utilises the SACIG Best Practice Guidelines and Quality Standards (SACIG, 2017) and the BCIG (2018) Quality Standards Guideline to guide service delivery within the Chris Hani Baragwanath Academic Hospital Cochlear Implant Programme.

1.3. SERVICE STRUCTURE

The BCIG Guidelines for New Cochlear Implant Centres (2018) recommends that a programme ensure that the following are in place:

- Suitable location with a regional demand not met by existing cochlear implant centres
- Access to a multidisciplinary team (as discussed below)

- A cochlear implant coordinator/head of service, responsible for day to day management of the programme
- Appropriate audiological staff
- Appropriate rehabilitation staff trained in auditory verbal therapy
- Adequately trained ENT surgeons
- Provision of a choice of cochlear implant system, to the best of the team's ability
- The procurement process should permit consideration of effectiveness, quality, reliability, long term support and cost

As per the SACIG (2017 guidelines:

- All cochlear implant team personnel should be members of the South African Cochlear Implant Group (SACIG)
- Clinical team members should attend regular training in developments within the field of cochlear implantation, and participate in national and international conferences and meetings
- The team should develop partnership services with other institutions, and provide appropriate training to assist in the development of these professionals and organisations`
- Ensure that only FDA or CE approved cochlear implants are supplied by distributors.

According to the SACIG (2017) guideline, the following quality standards should be ensured:

The CHBAH cochlear implant programme multidisciplinary team must include the appropriate professionals. The core team members include an ENT, Audiologist and a speech language therapist. The team must have skill and knowledge to work with children and adults who present with complex needs additional to their hearing loss.The professionals involved and their responsibilities are listed below:

<u>Cochlear Implant Coordinator</u>

- Leadership or management role
- Responsible for day to day management of the programme
- Ensure that appropriate services are provided for each patient along the cochlear implant patient pathway
- Registered with the Health Professions Council of South Africa (HPCSA) as an ENT surgeon, audiologist and/or speech language therapist
- A core team member
- Qualified to Masters level or equivalent knowledge and skills
- Specialist training in cochlear implantation (HPCSA 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.
- 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
- Participate in and contribute to ongoing training and research in the field
- Accountable for delivery of the multidisciplinary service
- Provide scientific and clinical leadership and managerial responsibility for service design, forward planning, finance, patient management and human resources
- Ensure that at least one team member attends annual SACIG meetings
- Ensure quality standards and national specifications are achieved
- Ensure development and maintenance of a highly specialized service

Audiologists

- Program should have a minimum of 2 audiologists
- Professional registration with the Health Professions Council of South Africa
- HPCSA Certificate of Competence in Additional Training in Cochlear Implantation
- An accredited Masters in Audiology, or have the equivalent knowledge and skills
- 6 months of guided supervision by an experienced certified cochlear implant audiologist after acquiring the Certificate of Competence, prior to independent MAPping
- Provision of the following services:
    - Candidacy assessments
    - Counselling
    - Intra-operative testing
    - Initial activation and regular MAPping
    - Troubleshooting with challenging patients
    - Adult aural rehabilitation
    - Hearing aid fitting, including verification and validation
    - Booth testing of both candidates and recipients
- Maintain an awareness of different communication and amplification options, and endeavour to provide a balanced view of the various alternatives to each patient and family, ensuring that informed choice is maintained and respected throughout the patient journey
- Have knowledge and understanding of multidisciplinary areas within cochlear implantation
- If an audiologist has not practised in cochlear implantation for over 3 years, they should re-acquire HPCSA accredited certificate of competence by completing a mentorship of 60 hours by an experienced Cochlear implant audiologist with the same certification of competence.

Speech & Language Therapist / Audiologist

- Professional registration with the Health Professions Council of South Africa
- Encourage these members to become part of the Cochlear Implant team
- Develop knowledge and skills in therapy approaches that promote listening and spoken language in children with hearing loss, ideally, with a postgraduate qualification in this area
- It is recommended that a SLT is an AG Bell Academy Certified Listening and Spoken Language Specialist (LSLS Cert AVT) or has passed foundation courses in LSLS training (LSLS SA course, Auditory Verbal UK Foundation Course or 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.
- Consult regularly with experienced therapists in the field of rehabilitation of children with hearing loss
- Adhere to SACIG Guidelines for Speech-Language Therapists working with children in the field of cochlear implants. These include the following:
    - Engage in regular communication with the MAPping audiologist,
    - Participate in team meetings and patient discussions
    - Provide ongoing, intensive therapy with the child and caregiver
    - Listening checks every session
    - Liaise regularly with caregivers, schools and other stakeholders
    - Set goals jointly with the family
    - Identify red flags and communicate these to the team
    - Participate in ongoing professional development in this field
- Maintain an awareness of different communication and amplification options, and endeavour to provide a balanced view of the various alternatives to each patient and family. Endeavour to maintain and respect informed choice throughout the patient journey

Case Management

- This role may be assigned to any member of the team. Most often, this will be the audiologist or speech language therapist working closely with the candidate
- Every cochlear implant candidate is to be assigned a case manager within a month of initial assessment
- This case management role entails:
    - Monitoring the progress of the cochlear implant candidacy assessments done
    - Following up on outstanding results and booking of necessary appointments
    - Ensuring that the patient and family understand the results and progress of the assessment process
    - Summarising the patient's progress and candidacy concerns in multidisciplinary team monthly meetings. This involves:
        - Completing and updating case management information on the electronic statistics case management form
        - Summarising progress in written form prior to meetings
        - Presenting and facilitating discussion on the patient at monthly meetings
    - Accountability for overall patient management during the candidacy assessment period
    - Ensuring that all requirements are met for candidacy
    - Ongoing counselling throughout the work-up process to ensure patient and family understanding and knowledge regarding the work-up process, surgery, rehabilitation and life long commitment involved with cochlear implantation.
    - Ensuring that all preparation is completed prior to surgery, including:
        - Vaccination against meningitis
        - Final counselling
        - Signing of informed consent
        - Signing of repair costs contract

<u>Ear, Nose and Throat Surgeons</u>

- An F.C.S (ORL) or equivalent qualification
- Specialist Otologist with appropriate accreditation and training
- Extended sub-speciality training and experience in cochlear implant surgery, as per SACIG guidelines
- Comply with the recommendations of the South African Society of Otorhinolaryngology Head & Neck Surgery (S.A. SOC ORL/HNS) for the minimum number of cochlear implant operations to be carried out yearly
- New surgeons should consult the SACIG guidelines regarding mentorship requirements
- 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.
- 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.

<u>Additional Professionals</u>

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 (Audiologist who has experience/training in vestibular pathologies)
- Audiologist who has experience/training in tinnitus assessment and management
- Psychologist / Psychiatrist
- Social Worker
- Educator
- Geneticist
- Physiotherapist
- Occupational Therapist
- Deaf advocates
- Cochlear Implant advocates (BCIG, June 2009)

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.

1.4. TARGET AUDIENCE

- Professionals within the cochlear implant team
- Management at Chris Hani Academic Hospital
- Higher levels of management within provincial and national public health sectors

1.5. TARGET POPULATION

- Patients of any age, from birth to adulthood,
- Adults and children children over the age of 6 months (unless exceptional circumstances indicate the need for earlier implantation (e.g. potential of ossification in the cochlea), with a bilateral, permanent hearing loss that does not benefit sufficiently from hearing aids to provide access to speech
- Before a patient can be referred into this clinic, the following should be completed:
    - Confirmation of hearing thresholds, via behavioural and/or objective measures
    - Counselling regarding hearing loss, hearing aids and communication options
    - Hearing aid fitting, wherever possible, with verification of fitting and aided thresholds
    - Completion of cochlear implant referral form, and submission of this to the team, to place onto the waiting list, and book the patient into an initial assessment

- While patients must live within the CHBAH catchment area in order to receive hearing assessments and hearing aids at this institution, patients may live anywhere within South Africa in order to access the cochlear implant service. This is because cochlear implants are considered a central, specialised service and so are not limited to catchment areas. However, patients are required to attend appointments on a regular basis, and so patients living further away must be able to arrange transport and regular visits in order to remain within this service.
- The following patients qualify to be considered for a state-funded implant:
    - South African citizens with paperwork to prove this
    - Foreign citizens and refugees may be considered for a cochlear implant only if approved by hospital management. This approval is requested via submission of a motivation which proves the patient's legal status in the

country, employment/schooling history and all appropriate visas and documentation.

1.6. CLINIC FORMAT

The daily clinic is formatted as follows:

Morning clinics:

- Audiology

Time	***Description***
8.00am- 10:00am	Audiology slot – for initial assessment, candidacy work up, MAPping, adult aural rehabilitation, annual rechecks or other audiological management
10.00am-11:45am	Audiology slot – for initial assessment, candidacy work up, MAPping, adult aural rehabilitation, annual rechecks or other audiological management

Clinic times might change due to team analyses and need

Afternoon clinics:

- Audiology

Time	***Description***
12:30 – 14:15pm	Audiology slot – for initial assessment, candidacy work up, MAPping, adult aural rehabilitation, annual rechecks or other audiological management
14:15 – 15:45pm	Audiology slot for device troubleshooting, repairs or completion of forms

1.7. RECORD KEEPING

1.7.1 Record keeping in the hospital file and department clinic notes:

- All contact with patients is to be recorded in both the patient's hospital file and in the patient's departmental file, which is opened at the initial appointment
- The patient's name and GT number are to appear on every page of the patient's file and all notes in departmental file are to be recorded in black ink
- Counselling, test results, hearing aid and cochlear implant serial numbers and programming are to be recorded
- Relevant recording forms should be completed in duplicate for patient records
- After patient interactions, electronic statistics should be completed. This includes inputting the most recent appointment on the 'monthly patient statistics' worksheet, as well as creating or updating the patient's information on the 'case management' worksheet

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1.8. SPECIAL CONSIDERATIONS

- Standard departmental infection control procedures must be applied within this clinic.
- All toys and equipment that comes into contact with the patient's saliva should disinfected after use
- After the therapy session, ensure that the room is tidied with toys replaced in appropriate containers, patient files to be put away.
- Ensure that all cupboards and drawers remain locked, and that the room remains locked when not in use

SECTION 2: COCHLEAR IMPLANT: ASSESSMENT AND MANAGEMENT

2.1. *EQUIPMENT, ACCESS AND SPACE REQUIREMENTS*

The clinical areas, waiting area, treatment rooms and testing equipment should comply with the BCIG (2018) and the SACIG (2017) guidelines.

This includes access to the following audiological facilities:

- Pure tone Audiometry
- Sound field Audiometry
- Hearing aid testing and fitting
- Probe-tube microphone measurements
- Otoscopy
- Tympanometry
- Otoacoustic Emissions
- Evoked Response Audiometry
- Speech perception testing (including an option for use of recorded speech materials, where possible)

All audiological equipment should be calibrated annually, and a system of daily checking should be in place
Adequate equipment should be available for MAPping, hearing aid verification and validation, cochlear implant validation, and for the provision of appropriate speech therapy and/or aural rehabilitation.

The team should endeavour to ensure access to troubleshooting kits, spare parts and loaner devices (where possible) and batteries for patients

Patient confidentiality should be maintained at all times.

It is important to be mindful of the need to ensure equality of access (NICE, 2009). This includes ensuring that patients are able to communicate effectively with the team members, which may require access to interpreters, written material, sign language interpreters etc. In addition, audiological assessments may need to be adapted in accordance with patients' physical or cognitive impairments, as well as to strive for cultural and linguistic sensitivity.

In a South African context, it is specifically important that patients are not denied access to the assessment or cochlear implant services on the basis of their language of communication, literacy levels or cultural beliefs. The team should strive to adapt protocols to ensure inclusion and consideration of all of those living in South Africa.

2.2. REFERRAL INTO THE CLINIC

- In order to qualify for referral into this clinic, patients must present with a bilateral severe or severe to profound sensori-neural hearing loss from 2kHz – 4kHz.
- New referrals from within and outside of the hospital are accepted only on the completion of a cochlear implant referral form (see Appendix A), except if an exception is made by the team for self-referrals or patients identified by other professionals without access to the relevant information.

- Children will be given priority for initial appointments, due to the critical period of language development. Children under the age of 3 with congenital hearing loss, as well as children up to the age of 18 years with an acquired hearing loss, will be booked into the first available initial assessment slot.

- Children over the age of 3 years with congenital hearing loss will only be considered by (for) cochlear implantation in the event that they have significant spoken language skills or if there is sufficient state-funding to expand the inclusion criteria during that year (should we say that? if there is extra funding isn't it preferable to do bilateral implantation). In the event that funding is not sufficient for all of the possible candidates under the age of 4 years, the team may be required to lower the age cut-off limit accordingly (or refer to other programs which may have funding).

- Both adult and paediatric patients who have contracted meningitis within the past 6 months will also be considered priority patients, due to the risk of ossification of their cochleae. All other adults will be booked into slots, based on availability, and may be placed onto a waiting list, if there are no available slots at that time. (should there be a waiting list an information day will be scheduled to ensure that all patients referred for cochlear implant receive information timeously and are not lost to follow up),

- The clinic coordinator will ensure that patients are contacted off (use another word instead of off) the waiting list as soon as an appointment becomes available. In addition, the clinic coordinator will ensure that all patients referred into the clinic receive an appointment for an initial assessment. Should the patient miss the first appointment, he/she will be offered a second opportunity. Should the patient miss two appointments, the clinic will wait to hear from the patient before booking another assessment. (The clinician will endeavor to find out why the patient missed the first appointment and make sure that the patient and his/her significant other received proper notification of the appointment in the first place).

2.3. SELECTION CRITERIA

Cochlear implant candidacy criteria are based on international and national guidelines, which require annual review. The current candidacy guidelines are based on the SACIG (2017) Appendix B, which includes patient selection criteria and candidature for unilateral and bilateral cochlear implants, as well as the BCIG (2018) guidelines for adult and paediatric cochlear implantation. These are guided by international standards of best practice, including the NICE Guidance 166 (January 2009) and any subsequent versions. Institution- and context-specific criteria have been added, in line with the CHBAH funding constraints and selection requirements

Selection criteria for adult patients

- Severe or severe-profound bilateral sensorineural hearing loss, typically 80dB or worse at 2 and 4kHz, with a test/retest reliability margin of +/-5dBHL
- A minimum of a 3-month trial of optimised hearing aids, fitted to an appropriate prescription and optimised to meet the patient's needs
- Please note: post-meningitic patients may be fast-tracked due to the risk of ossification of the cochleae (fast tracking is determined according to when the patient had meningitis. Patients are

generally fast tracked 6-12 weeks -{not sure} post the diagnosis of meningitis. Patients who had meningitis historically (a year prior to referral) are not fast tracked).

- Limited functional benefit from hearing aids (50% or less on open-set sentence discrimination scores (with a +/- 15% test-retest reliability) at 50dB(A) without lip reading
- If the unaided audiogram or speech perception testing scores are better than the above-mentioned, they can be considered based on their functional hearing abilities
- Patients with poor functional hearing due to auditory neuropathy spectrum disorder or multisensory impairment (deaf-blind) or highly fluctuating or progressive hearing losses may be considered, even if their audiological results do not meet the above criteria (BCIG, April 2018)
- Oral/aural communication skills, with spoken language as the patient's primary language of communication
- For best results, duration of profound deafness should be less than 40% or of the patient's life, although hearing aid use and benefit should be considered when making this decision, and adults with congenital deafness can be considered, provided that they are primarily oral communicators, motivated to improve their listening skills, and realistic in their expectations of outcomes
- Motivated to be a part of the hearing world
- Skills and/or motivated to be gainfully employed
- Realistic expectations
- Functional oral language and speech intelligibility
- Commitment to the rehabilitation process
- Financial resources to attend all assessment and management appointments, and commitment to take out insurance or save money monthly to cover future battery and repair costs (should the need arise).

Contra-indications for adult patients

- Individuals who have been deaf for more than 40% of their life with no hearing aids
- Individuals wishing to be part of the Deaf community as their primary identity
- Individuals with unilateral hearing loss, or hearing losses that can be aided to within the speech banana across the speech frequencies (although unilateral severe-profound sensori-neural hearing loss is now an extended criterion for many programmes across the world and South Africa, and this may be reconsidered by the CHBAH in the future).
- Individuals who rely on sign language as their primary mode of communication
- Individuals with unrealistic expectations regarding cochlear implants
- Individuals with significant additional difficulties, such as limited cognition, that may hinder their ability to access work (these patients can still be considered if it is felt that the cochlear implant will improve the patient's quality of life, but is dependent on realistic expectations and funding constraints at the hospital at the time of patient work-up)
- Individuals with substantial ossification of the cochlea secondary to meningitis
- Individuals with significant cochlear or auditory nerve anomalies that significantly reduce the chance of a positive outcome from cochlear implant surgery

Selection criteria for paediatric patients:

- Severe-profound or moderate-severe/profound bilateral sensorineural hearing loss (i.e. thresholds at 80dBHL or worse at 2 and 4kHZ, with a test-retest reliability margin of +/- 10dB)
- A hearing aid trial of 3-6 months with optimised hearing aids, fitted to an appropriate prescription and optimised to the patient's needs
- Please note: post-meningitic patients may be fast-tracked due to the risk of ossification of the cochleae if the patient is seen within six months of the patient contracting meningitis.
- Limited functional benefit from hearing aids
- However, children with lesser degrees of hearing loss who present with poor functional hearing may be considered. This includes children with auditory neuropathy spectrum disorder, multisensory

impairment (deaf-blind), highly fluctuating or progressive losses (?children with significant motor function difficulty that may make communication with sign language difficult)

- Children who fail to develop or maintain age-appropriate speech, language and listening skills, despite daily use of optimised hearing aids, attendance at regular speech therapy to promote listening and spoken language and parental commitment to facilitate listening and spoken language

Additional selection criteria for paediatric patients:

The criteria specific to South Africa and to CHBAH programme in particular (due to limited resources and schooling options) are:

- Children with congenital or acquired hearing loss should be under the age of 3 years, unless the child has developed significant spoken language and listening skills
- Children with acquired hearing loss over the age of 3 ½ with functional oral language and speech skills and a suitable educational setting to promote further oral language development
- For children below 2 years – restricted access to speech sounds with hearing aids (i.e. aided hearing thresholds outside the speech spectrum at 2kHz and above)
- For children 2-5 years – failure to develop acceptable level of auditory, speech and language skills)
- For acquired hearing loss in children over 5 years – 50% or less open-set discrimination
- Caregivers motivated for the child to be a part of the hearing world and family commitment to the rehabilitation process
- Realistic expectations
- Financial resources to attend all assessment and management appointments, and to commit to monthly insurance payments or to save money monthly to cover future battery and repair costs (perhaps to word this differently?)

Contra-indications for paediatric patients

- Families wishing for the child to be part of the Deaf community
- Children with significant additional difficulties that make it unlikely for the child to be able to develop spoken language skills and access available educational options, unless it is felt that a cochlear implant will have a significant impact on the child's potential quality of life in the presence of realistic expectations of outcomes for multiple impaired children. This is in exceptional circumstances and is not the norm.
- Individuals with unilateral hearing loss, or hearing losses that can be aided to within the speech banana across the speech frequencies (although older children/teenagers with unilateral, sensori-neural hearing loss are now being considered for cochlear implants in many programmes across the world and South Africa, and this may be reconsidered by the CHBAH in the future).
- Individuals who rely on sign language as their primary mode of communication
- Individuals with unrealistic expectations regarding cochlear implants
- Individuals with substantial ossification of the cochlea secondary to meningitis
- Individuals with significant cochlear or auditory nerve anomalies that significantly reduce the chance of a positive outcome form cochlear implant surgery

Selection criteria for bilateral cochlear implants

A great deal of literature has examined the costs and benefits of bilateral cochlear implantation. Children using bilateral cochlear implants have achieved significantly better vocabulary and language outcomes than children with unilateral cochlear implants, with faster rates of development in these areas (Sarant, Harris, Bennet & Bant, 2014).

Based on the BCIG Position Paper (May 2007), there is evidence that patients who receive bilateral cochlear implants show the following benefits:

- Improved localisation of sound
- Improved speech understanding in quiet
- Improved speech understanding in background noise
- Stimulation of both auditory pathways
- A guarantee that the better performing ear has been implanted
- Improvements in speech, language and auditory development in children
- The assurance that, should one device fail, the patient continues to have access to listening
- Subjective reports of more natural sound
- Guarantee that the dominant ear is implanted.

The reported costs of bilateral cochlear implantation include:

- Increased surgical costs for sequential implantation (making simultaneous implantation a more suitable alternative in most cases)
- Device costs
- Clinical costs

The BCIG Position Paper (May 2009) recommends that bilateral cochlear implants be offered to:

- All profoundly deaf children in order to stimulate both auditory pathways and optimise speech, language and listening development, which will maximise academic potential
- All profoundly deaf adults who are unable to benefit from bimodal hearing
- All post-meningitis patients where failure to bilaterally implant may result in obliteration of the cochleae, preventing further auditory stimulation
- Patients with additional sensory handicap, resulting in increased reliance on binaural hearing
- Patients who experience a loss of performance in the implanted ear, but are unable to be re-implanted in the original ear

However, the NICE Guidance (2009)'s recommendation for bilateral cochlear implantation within the UK National Health System is as follows:

- Bilateral cochlear implantation for all profoundly deaf children
- Unilateral cochlear implantation for deaf adults
- Bilateral cochlear implantation can be considered in the case of additional disabilities

Important considerations for whether a patient qualifies for a bilateral cochlear implant may include:

- Unaided hearing levels must be within the criteria to qualify for a cochlear implant
- Consistent use of a hearing aid on the second side
- Presence of ossification on the second side (may contraindicate a second cochlear implant)

At present, CHBAH does not have a clear policy on which patient's quality for bilateral cochlear implants, as this is to be guided by the available funds, number of patients awaiting cochlear implants, and the discretion of the audiologists. However, it should be noted that the programme should move towards bilateral implantation of all children who qualify, as this has been shown to be best practice in facilitating speech, language and listening development.

2.4. INITIAL APPOINTMENT

2.4.1. Case history

The initial assessment should be conducted by an audiologist who has completed the additional licensing course in cochlear implants (or an equivalent qualification recognised by SACIG).

The initial case history should be conducted in a medium that is accessible to the patient or caregiver. This may require an interpreter for patients not able to converse in English or any other language spoken by the attending therapist, or the use of writing in the relaying of information for patients who are unable to hear or lip read spoken language. A patient should not be excluded from assessment for any of these reasons.

The assessment should follow the structure of the case history assessment forms, available in the cochlear implant room (or electronically). There are specific forms for adults and for children.

Information obtained should include:

- Source of referral
- Medical aid status
- Date of referral and diagnosis
- HIV/TB status
- Early history
- Medical history
- Birth history (paeds)
- Developmental history (paeds)
- Additional difficulties (possible diagnoses) - BOTH
- Otological signs and symptoms, including middle ear pathology, tinnitus, vertigo and balance difficulties
- ENT history, including referral for aetiological investigations and possible causes of the hearing loss
- Noise exposure history
- Onset of hearing loss
- When hearing loss identified (diagnosis of hearing loss)
- Hearing aid use (and duration - how long the patient has worn hearing aids and for how many hours a day)
- Previous audiological testing and results
- Previous amplification, and results
- Communication systems in place
- Schooling and employment history
- Family history of hearing loss
- Family structure and support, including emotional and financial support
- Current knowledge regarding hearing aids and cochlear implants
- Current knowledge regarding communication options, including spoken language and sign language
- Parent's expectations (PAEDS)
- Patient and family's expectations (ADULTS)
- ADL's (paeds)
- Parental level of education (paeds)
- Activity limitations and participation restrictions

For adults:

- Current speech and language skills, speech intelligibility, speech reading and benefit from hearing aids

- Highest level of education and or further studies
- Skills and drive to enter the workplace
- Expectations
- Employment history
- Activity limitations and participation restrictions

For children:

- Currently existing speech and language skills
- Play behaviour
- Schooling – current, performance, future schooling options
- Socialisation
- General development
- Parent's expectations
  Developmental history
  Birth History (listed above)

Other areas of concern

PERHAPS HAVE A COLUMN WHICH LISTS ALL INFO FOR PAEDS AND ONE THAT LIST ALL INFO FOR ADULTS - THE WAY THIS IS DONE IS DISJOINTED TO ME.

An information pamphlet has been developed to provide the patient/caregiver with an overview of the information covered in the session. This should be provided at the end of all initial assessments. The team should continuously review and update the quality and quantity of information provided, and develop a written protocol to determine which information is given at which time (BCIG, June 2009).

2.4.2. **Counselling**

This should begin at the initial assessment, but should be repeated and revised during the candidacy assessment process. The audiologist should:

- Review previous counselling regarding the patient/child's hearing loss, the implications of the hearing loss, the available amplification alternatives, and their benefits and limitations, including hearing aids and cochlear implants and other assistive devices where applicable (FM system, Tinnitus masker, etc).
- Counsel on communication options, including spoken language, sign language and total communication, including their benefits and limitations (this is for paediatric patients)
- Counsel on the mechanism of normal hearing, and how this compares to hearing via a hearing aid and with a cochlear implant
- Demonstrate the cochlear implant system, utilising pictures and the demonstration kit
- Counsel on the long-term commitment required for a cochlear implant, including costs, weekly therapy, schooling (for paeds) and limitations of cochlear implant and the importance of aural rehabilitation for both paeds and adults and how aural rehabilitation will have an impact on outcomes.
- Provide written information to support information shared in the session
- Ensure that children have been given the option to be referred to HI HOPES for home-based support If the patient/caregiver is interested in pursuing the cochlear implant assessment process, then the audiologist should counsel on the pre-operative assessment process, including the various referrals that will be made, the number of

appointments and time frames expected. The work-up process needs to be discussed with both paed and adults and MDT involvement.

- The type of work up appointments need to be discussed including ENT, Audiology, speech therapy, radiology, psychology and speech therapy. The purpose for each appointment needs to be outlined. Patients as well as caregivers need to be aware of the need for multiple ongoing appointments that are required both before and after the cochlear implant surgery.
- Discuss varying outcomes for different pathology and age groups and discuss that success is not a guarantee and certain factor may impact on the patients success namely: age of implantation, pre-implantation deafness, status of the internal structures of the cochlear, prior amplification, family's willingness to follow up on recommendations and attend regular speech therapy appointments, etc.
- Discuss the importance of hearing aid use for both paediatrics and adults. This is to be discussed in the context of the auditory cortex.
- Explain the purpose of the assessment process in assessing the patient's functional hearing abilities and to determine whether these are likely to be significantly improved through cochlear implantation
- Counsel on costs of the initial system, and hospital processes required to access funding for cochlear implants, and the uncertainty around acquiring funding
- Counsel on alternative programmes that may be able to assist the patient, and offer the patient or family the option to consult other programmes, should they so wish
- Ensure that the patient/caregivers/significant others have a clear understanding of possible benefits and limitations of cochlear implantation
- Conduct realistic expectations questionnaire to determine expectations once the patient/family has decided they would like to go ahead with a cochlear implant (this should not be done at the initial assessment, but rather closer to the time of informed consent and final counselling)
- Introduce candidates and their families to other individuals who have received a cochlear implant (this can be done via the cochlear implant support group) and provide access to a patient or family who elected to follow another route, such as sign language, to ensure true informed consent
- Involve significant others, family members, employers etc. to ensure realistic expectations and support throughout the process
- Ensure the patient is familiar with issues around cochlear implants and the views of the Deaf community
- Provide an overview (and later more detailed account) of the surgery and hospital stay, as well as post-operative follow ups
- After the candidacy assessment process and team decision regarding candidacy, the audiologist is required to meet with the patient or family to explain the team decision and determine the way forward.
- If the team decision is in favour of a cochlear implant, the patient or family should be given the opportunity to make a final decision
- If the individual is not a suitable candidate for a cochlear implant, the reasons for this are to be discussed, alternative options reviewed and psychological support offered, as required.

2.5. THE COCHLEAR IMPLANT DEVICE

According to SACIG (2017), the cochlear implant device offered must:

- Have a proven track record for safety and reliability
- Have CE and FDA approval (Battmer et al, 2010)
- Should be MRI compatible
- 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 clinical application of objective measures such as intraoperative response telemetry
- Have high quality clinical and technical support available from the manufacturer and local distributor
- Have distributors who belong to the South African Medical Device Industry Association (SAMED)

In addition, the patient should be informed of the various options and the choices available within that programme, as well as the reasons for the proposed selection of device

There are currently three cochlear Implant manufacturers currently supplying cochlear implant programmes in South Africa. These are: Med-El, Cochlear and Advanced Bionics. To date, onlyCochlear products have been used at CHBAH, as this device has been selected in multiple tenders that were opened to all 3 manufacturers. This should be explained to potential implant candidates. We are currently using both Cochlear and Med-EL devices as deemed appropriate. Cochlear devices are being used for paediatric patients as they offer accessories which assist paediatric patients within a noisy environment such as a classroom. Med-EL devices are currently being used on adult candidates.

The cochlear implant is given to the patient by the Department of Health and the sound processor is loaned to the patient. As such, the patient should be counselled on his/her responsibility to care for and maintain the device and to return the sound processor if they are no longer utilising it (BCIG, June 2009).

2.6. THE COCHLEAR IMPLANT CANDIDACY ASSESSMENT PROCESS

A case manager is to be assigned to each cochlear implant candidate who wishes to proceed with the pre-operative assessment process. It is the responsibility of the clinician who conducted the initial assessment to act as case manager until such time as another case manager may be assigned if required (at monthly team meetings)

Pre-operative assessments include the following:

2.6.1. Medical

Medical consultation with the team ENT surgeon, or an ENT identified by the team ENT surgeon, who is responsible for:

- Ensuring that the patient is medically fit to undergo the treatment, both during the assessment process and prior to admission for surgery
- Referring patients for blood tests, MRI and CT scans and ensuring that the radiological assessments are in accordance with Appendix C of the SACIG (2017) guidelines
- Referral for a vestibular assessment if indicated 9can this referral not also come from the audiologist?)
- Discussion of associated medical risks of treatment pre- and post-surgery
- Referral for vaccination to reduce the risk of pneumococcal meningitis
- Referral for genetic counselling if required
- Obtaining fully informed patient consent for (medical) treatment (scans, surgery,etc)

- In the case of HIV positive patients, refer to Appendix D of the SACIG (2017) guideline for protocols.

2.6.2. Audiological

Each patient must receive a full audiological assessment, as outlined by Appendix E of the SACIG (2017) guideline. This must include:

Audiological testing:

- Otoscopic examination
- Immittance testing
- Unaided behavioural hearing thresholds, where possible and objective diagnostic testing where appropriate
- Objective hearing threshold assessment, including acoustic reflex testing, otoacoustic emission and auditory brainstem response testing, as required
- Unaided, ear-specific speech perception testing, where possible

Hearing aid fitting and evaluation

- Re-evaluate the patient's current hearing aids, including adjusting programming, verification (using the proper equipment) and validation of fitting. Validation should include ear-specific testing of both aided sound field thresholds and speech perception testing (using pre-recorded speech material, where possible)
- Where patients have not already been fitted with hearing aids, loaner hearing aids should be fitted, utilising the above protocol
- Ear mould impressions should be taken, as required, to ensure optimal hearing aid fittings
- Patients with new hearing aids or a change of settings may require auditory rehabilitation to determine their benefit from hearing aids and several weeks to adjust to the amplification, prior to aided testing - patients with a profound sensori-neural hearing loss are fitted with silicone earmoulds.
- All paediatric patients require a period of several months to trial optimised hearing aids (with the exception of patients who have had meningitis, who may be fast-tracked due to the risk of ossification). This is generally a 6-month period, but may be considered by the team on a case-by-case basis dependent on the child's hearing thresholds and age
- Where sufficient loaner hearing aids are not available to issue to all adult candidates, an in-house trial may be offered to adult patients, particularly where their hearing thresholds are in the severe-profound range.

2.6.3. Communication

2.6.3.1. Adults (evaluation by the audiologist who conducted the initial assessment)

- Assess the patient's communication abilities and communication repair strategies
- This may (should) include an observation and subjective description or formal evaluation (participation tool).
- This assessment should provide an overview of the following:
    - Receptive language skills
    - Listening skills
    - Speech reading skills
    - Functional communication skills in conversation
    - Expressive language skills
    - Speech intelligibility and voice quality
    - Current communication situations, and areas of difficulty for the patient

2.6.3.2. Children (evaluation by a speech therapist within the cochlear implant team)

A complete assessment of the child's speech, language, listening and overall development should be conducted by a speech therapist within the cochlear implant team. For further detail, see Section 4 below.

2.6.4. Quality of life measures

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

2.6.5. Psychological assessment

All cochlear implant candidates at CHBAH require a psychological assessment as part of the pre-operative assessment. The assessment will examine the patient's mental health, learning ability, personality, motivation, adaptation, realistic expectations about cochlear implantation. In the case of paediatric patients the psychologist will assess family structure and functioning, attachment between the child and primary caregiver.

2.6.6. Occupational therapy assessment

All paediatric cochlear implant candidates at CHBAH are to undergo an occupational therapy assessment to assess visual and perceptual skills, fine and gross motor skills, learning ability and overall developmental abilities.

Adult cochlear implant candidates would benefit from an occupational therapy assessment to examine vocational abilities and return to work. At this stage, patients are referred for this assessment on a case-by-case basis, as needed. Teenagers should routinely see the occupational therapist to determine appropriate school placement and the need for specialised schooling.

2.6.7. Finances

There is no minimum salary or socioeconomic level as a prerequisite for a cochlear implant. However, the patient needs to have a stable source of income within the family in order to support the following requirements:

- Transport costs for regular appointments
    - For adults:
        - A minimum of 6 - 10 appointments during candidacy assessment and aural rehabilitation.
        - A minimum of 5 weekly appointments post-switch on
        - A minimum of monthly appointments for a period of 6 months
        - An annual follow up for life
    - For children:
        - A minimum of 7 appointments during candidacy assessment
        - Weekly appointments for both MAPping and speech therapy for a minimum of one year, ongoing until child's language is age-appropriate or child is able to access these services at a local institution (hospital, clinic or school)
        - An annual follow up for life
- Batteries
    - Children under 6 years and patients receiving a disability or pension grant do not have to pay for disposable cochlear implant batteries

- Patients over 6 years will need to pay for disposable and/or rechargeable batteries as required

- Repairs or lost items
  - The implant and processor have a warranty from the company, so that faulty parts will be repaired for a specified period of time. This time-period is determined by the specific component and by the specific company.
  - Should an item be lost, stolen or damaged beyond repair in a fire, we will endeavor to access loaner or redundant stock but the onus is generally on the patient to get a new device. Devices or parts that are out of warranty are subject to limited repairs/spare parts within the repair policy. This may include one repair within a 5 year period and access to spare parts according to department stock and ordering and as needed within the stipulated guidelines.
  - Funding is never a guarantee and patients as well as caregivers need to be informed of this and the following strong recommendations should be made for every patient:
    - The patient is required to insure their device OR (Insurance of the device)
    - The patient is required (encouraged) to put a defined amount of money into a savings account every month, in order to ensure that money is available in the event of an unexpected repair or replacement cost. This may be considered in the event that the patient is unable to qualify for insurance with the insurance company.

It is essential that all patients are counselled extensively on the likely costs for both cochlear implant components and contralateral hearing aid, and that the patient or caregiver signs the repairs contract prior to surgery.

2.7. TEAM DECISION

Once the cochlear implant candidacy assessment process is completed, the following should take place:

- The case manager should examine the results of all assessments and red flags, and summarise this into a patient profile form
- The patient will be discussed in the next monthly team meeting, at which all team members will provide input and a team decision will be made
- Where additional assessments or contact is required, this will be arranged
- Where the decision is against a cochlear implant, the audiologist will arrange a feedback session with the necessary professionals (generally a psychologist) to explain this to the patient
- Where the decision is in favour of a cochlear implant, the team must agree on which ear is to be implanted (in consultation with the patient/caregivers), and the audiologist is to arrange a date to feedback details to the patient
- At this point, the necessary steps can be taken to arrange surgery if hospital funding is available and the patient qualifies for it (SA citizenship, falls within the age criteria, etc). If funding is not available funding for the cochlear implant must be arranged, via motivation to hospital management and/or the patient's medical aid, where applicable.

2.8. SURGERY AND IN-PATIENT CARE

- Once it is confirmed that the patient is a candidate and funding has been confirmed, the audiologist is to review the surgery and post-operative journey with the patient, and the patient is asked to sign the informed consent form

- The audiologist should review all previous counselling (listed above) with particular emphasis on the costs or maintenance of the device, realistic expectations regarding outcomes and an overview of the expected contact time of the months to follow. Emphasis on weekly speech therapy and aural rehabilitation and the importance of this is crucial for paediatric patients.
- The day prior to the surgery, the patient will be seen by the ENT surgeon for briefing, informed consent regarding the procedure and potential complications and admission. It is imperative that patients are informed of the correct time to arrive in order for ample time for admission and any other testing to be done on that day as needed
- The surgery will take place the following day
- The ENT surgeon will ensure that MRI and CT scan results are accessible prior to surgery. Scans are kept in the speech therapy and audiology room and should be organized and handed over to the ENT the day before surgery.
- The ENT surgeon and audiologist will update the patient's family on progress and result of the surgery
- The audiologist will consult the theatre checklist in the intra-operative programming laptop bag, and ensure that all list items are present prior to going to theatre
- The audiologist will familiarise him/herself with the theatre and intra-operative protocol, including keeping the implant sterile, and feeding the testing processor through a plastic sleeve to prevent contamination -this is not done for the N6. This should be guided by theatre protocols.
- The ENT surgeons have been trained in NRT testing with a remote and can conduct NRT testing independently in straight forward adult cases. The audiologist will be on call if needed to assist. The Audiologist will routinely attend in complex cases in order to conduct intra-operative testing, including impedances, stapedial reflex responses (we don't really do this) and NRT's (or equivalent). This cases including all paediatric cases, meningitic cases or cases where there has been some ossification - sentence does not make sense?.
- The audiologist will complete the device registration form on the day of surgery, make a copy for the patient's departmental file and send the original to the supplier
- The audiologist will inform the supplier on the day of surgery as to whether the surgery was successful and provide the serial number of the implant used
- The ENT Surgeon will ensure that an X-ray is done of the implant post-surgery
- The ENT surgeon will monitor the patient's recovery and manage the patient medically or surgically, as required
- The patient will be discharged within 1 to 2 days, as long as there are no complications
- The patient will be discharged home, and return for a follow up at ENT the next week
- The patient will not wear a hearing aid on the operated ear post-surgery
- Children will continue with speech therapy over the following weeks prior to switch on
- The ENT will see the patient one week after the surgery to see that the wound has healed

2.9. POST-OPERATIVE FITTING AND PROGRAMMING OF THE SOUND PROCESSOR

- The initial activation (switch on) will take place 3-4 weeks post-surgery, or at such time as the wound has healed and the BOM (bill of materials) has been delivered.
- The processor will be fitted and programmed by the audiologist (with the appropriate MAPping qualifications).
- Tasks include:
    - Checking all items in the patient kit (also known as the BOM - bill of materials) are in good working order
    - Counselling on use and care of the processor, including relevant accessories (this may be done over several sessions, depending on the pace appropriate for the specific

patient or family). The patient must however leave the initial switch on session with the basic knowledge on how to use the processor. Accessories and use of other spare parts may be discussed at follow up appointments.

- Completed the registration form to send back to the distributor
- Programme the device based on the manufacturer's recommended procedures
- Handouts regarding functioning and use of the device should be provided to the patient over the first two sessions
- Patients will be required to attend a minimum of six initial programming sessions in order to reach a stable MAP, although some patients may require additional sessions. Patients should reach an optimal MAP within one month but this may vary from patient to patient.
- Patients are to be given information regarding warranty periods for all components, as well as information regarding safety and security precautions with the device
- Patients are to be informed of the recommended guidelines on safety for cochlear implant users, guided by the BCIG guidelines (2010) (*See Appendix F)*

*2.10. **POST-OPERATIVE REHABILITATION***

This is required for all adult patients, and is generally conducted by the audiologist who conducted the initial activation of the device. This should begin at the initial activation appointment in order to assist the patient in adjusting to the new sensation

The audiologist is responsible for:

- Facilitating acclimatisation to the new device and experience of sound
- Providing reassurance to patients and family members, as needed
- Counselling the patient and significant others on the rehabilitation process
- Regular aural rehabilitation (a minimum of once a month) - this should be done at every MaPping session. A separate session can be booked on the same day for a different clinician who has received training in how to give aural rehabilitation therapy. This may be a member of the adult audiology team. This may be done on the same day as MAPping appointments, or on a separate day, based on individual patient needs. This should be available to the patient for as long as the patient wishes to access these services (BCIG, June 2009). How long should the sessions be. How long should one spend on AR? The patient should receive aural rehabilitation for a minimum of 6 months following initial activation.

According to SACIG (2017), this aural rehabilitation may include:

- Detection of sound
- Auditory training
- Voice quality
- Speech intelligibility
- Language comprehension and expression
- Social skills
- Lip reading
- Communication strategies
- Telephone training
- Music training

*2.11. **FOLLOW-UP ASSESSMENT AND LONG-TERM MANAGEMENT***

- The patient should have access to the clinic for troubleshooting, programming and rehabilitation, as required. Programming is scheduled at 1month, 3 months, 6months, 12months and 18 months post switch on. Thereafter annual follow ups are done for every cochlear implant recipient.
- The clinic has should attempt to stock spares and loaners in the event of a repair, and should endeavour to ensure that patients wait no more than one working day after reporting a fault before receiving a replacement or loaner device. Loaner devices should be issued according to the IHD team's loaner protocol.
- Patients should attend life-long follow-up appointments according to the recommended SACIG protocol (Appendix E). These include:
    - Equipment checks
    - Programming the processor
    - Free field thresholds
    - Speech perception testing
    - Questionnaires
- It is crucial that all patients are aware of the programme's policy for replacement of lost or damaged processors that is equitable for all patients (BCIG, June 2009). In line with this, the team should be transparent about the lack of long-term (rather say should be aware of the inconsistent and irregular financial support) financial support to be expected from the hospital, and ensure that patients are aware of their own responsibility to take out insurance and/or save money on a regular basis.

2.12. MANAGEMENT AND TRANSFER OF PATIENTS BETWEEN PROGRAMMES

Transfer and management of patients between cochlear implant programmes should be guided by the SACIG guidelines. It is important to note that patients from other programmes will only be accepted at CHBAH if the below criteria are met. In addition, the CHBAH cochlear implant programme will need to consider:

- Issues of costs and payment at CHBAH in comparison to the patient's current clinic
- Capacity within the CHABH cochlear implant programme to manage this (the) patient, ensuring that it is not at the expense of existing CHBAH cochlear implant recipients or other patients within the CHBAH catchment area
- Patients from other countries will not qualify for a cochlear implant from CHBAH, unless approved by hospital management based on their documentation and/or length of stay in South Africa (Perhaps we could add something about SADEC countries.) Patients from SADEC countries have been approved for cochlear implantation at CHBAH. IS THIS ABOUT NEW PATIENTS RECEIVING OR TRANSFER OF PATIENTS. THE POINT IS NOT CLEAR UNDER THE MAIN HEADING.

Below is an excerpt from the SACIG (2017) guideline to guide this aspect of service delivery at CHBAH:

'When a patient is transferred to another program:

a. *Contact should first be made between the referring audiologist and 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*

REFERRING AUDIOLOGIST

- *Ensure that the program to which the patient is referred has the appropriate device compatibility.*
- *Provide the following information in a written report:*

a. *Full case history:*
   - *(i) Audiological background including etiology, onset of loss, duration of loss, hearing aid fitting information, tinnitus, vertigo etc.*
   - *(ii) Medical history*
   - *(iii) Psycho-social background (previous and current)*
   - *(iv) Educational background (in case of children details on educational needs and status)*
   - *(v) Developmental history (in case of children)*
   - *(vi) Communication development (in case of children, results of last assessment)*

b. *Surgery:*
   Date of implantation, ear, type of device, type of electrode, serial number, surgical outcome and complications.

c. *Programming:*
   i) Date of initial programming, type of speech processor, serial number, (processors owned).
   ii) Copy of first and last MAP as well as programming history.
   iii) Information regarding MAP management in case of complications

d. *Audiological test results:*
   i) Pre-operative aided and unaided thresholds and speech perception results (each ear)
   ii) Most recent post-operative speech perception results
   iii) Most recent post-operative free-field thresholds

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.*

Management of patients by members of different cochlear implant programmes:

a. *For various reasons it can occur that patients who have the CI surgery with one team need to be followed-up at another program.*
b. *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:*
   - *i) The members of both teams involved should agree that the patient is a good candidate.*
   - *ii) Prior to receiving a surgery date, the patient should have met all team members who will be involved in the case.*
   - *iii) The members concerned must agree on regular communication prior to the operation. This is particularly important between therapists and audiologists during (re)habilitation.*
   - *iv) The surgery date must be suitable to both teams in terms of initial programming and (re)habilitation.' (SACIG, 2017) Perhaps we could add something about JCIC helping us with switch ons here.*

*2.13. **DEVICE FAILURE***

In the event of a suspected internal device failure, the SACIG (2017) guidelines (below) should be followed:

i) 'If a cochlear implant internal device failure is suspected, the patient should be offered an appointment promptly to check the internal and external components.
ii) The implant manufacturer should be contacted urgently via the South African distributor regarding investigation of the device failure.
iii) Following confirmation from the manufacturer that the internal device has failed, a signed report is delivered to the surgeon and Audiologist.
iv) 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
v) 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.
vi) Should the internal device not be warranted, the team should submit an order form specifying re-implant date and device choice.
vii) Re-implantation and programming should be carried out as detailed above.
viii) Further rehabilitation needs should be assessed and put into place as appropriate'

(SACIG, 2017)

2.14. AUDIT AND SERVICE MONITORING

According to SACIG (2017), all aspects of the cochlear implant service should have:

- Transparent record keeping and email tracking (GRAMMATICALLY CORRECT? - what does email tracking mean?)
- Service auditing, according to SACIG standards
- An annual report, submitted to SACIG

In addition, the CHBAH team will ensure clinical audits are done in audiology and speech therapy to ensure that clinical standards are maintained. These will take place a minimum of twice per year.

SECTION 3: HEARING AID MANAGEMENT

3.1. *GUIDING DOCUMENTS AND PRINCIPLES*

All hearing aid management should be consistent across teams within the Speech Therapy and Audiology Department at Chris Hani Baragwanath Academic Hospital.

This section of the guideline will be guided by:

- The CHBAH Paediatric Aural Rehabilitation Guideline
- The CHBAH Adult Aural Rehabilitation Guideline

With ongoing review and input based on:

- International best practice guidelines
- Evidence-based practice
- SACIG guidelines

Please refer to the Chris Hani Baragwanath Academic Hospital Paediatric Hearing Aid Fitting guideline and the Adult Audiology Hearing Aid Guidelines for hearing aid fitting and management protocols.

3.2. *OVERVIEW OF HEARING AID MANAGEMENT PROTOCOL*

The cochlear implant team audiologist is responsible for:

- Hearing assessment (where required)
- Hearing aid fitting, which involves the following 4 stages:
    - Prescription/Assessment
    - Hearing aid selection
    - Hearing aid verification (as per Paediatric Aural Rehabilitation Guideline)
    - Hearing aid Validation

  (Boothroyd, 2000; Cunningham, 2008)
- Arrange for the patient/caregiver to sign the hearing aid contract, keeping one copy in the patient's hospital file, and one in the patient's departmental records
- Provide paediatric care kit accessories, as required
- Ensure that all hearing aid features are appropriately selected, according to the attached Paediatric Aural Rehabilitation Guideline.
- Hearing aid follow ups, including
    - Earmould impressions
    - RECDs and verification
- Hearing aid repairs – these may be handled within the cochlear implant audiology appointment or patients may be seen within the Audiology Hearing Aid Repair Clinic on a Monday afternoon.
    - Troubleshooting of the hearing aid
    - Listening checks
    - Arrange for faulty hearing aids to be sent for repair (liaise with hearing aid repair coordinator)
    - Provide a loaner hearing aid, where possible, in line with the departmental loaner hearing aid guidelines and protocols
- Aural rehabilitation (see Section 2 for more detail)
- Loudness balancing across cochlear implants and for bimodal fits
- Aided soundfield testing:
    - This differs from the Paediatric Aural Rehabilitation Guideline in that:
        - ***Testing should be done with each ear independently, in order to obtain ear-specific information***

SECTION 4: ADMINISTRATION

List of Authors

- Sections 1 and 2 by Dani Schlesinger: Chief Speech Therapist and Audiologist, with sections adapted from the SACIG (2011) cochlear implant guideline
- Section 3 adapted from the Audiology section of the Paediatric Aural Rehabilitation Guideline, by Leanne Teixeira: Chief Audiologist
- Reviewed by Nwabisa Vulangengqele in 2021, with sections adapted from the SACIG (2017) cochlear implant guideline

Signed off by team

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Date first compiled: 10/01/2013

Date reviewed: 2021

Date for next review: 2023

SECTION 5: REFERENCES

SECTION 1 AND 2: COCHLEAR IMPLANT ASSESSMENT AND MANAGEMENT

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SECTION 7: APPENDICES

Appendix A: Cochlear implant referral form
Appendix B: Patient selection criteria (SACIG, 2017)
Appendix C: Radiological guidelines (SACIG, 2017)
Appendix D: HIV guidelines (SACIG, 2017)
Appendix E: Audiological guidelines (SACIG, 2017)
Appendix F: Recommended guidelines on safety for cochlear implant users (BCIG, 2018)
Appendix G: Paediatric aural rehabilitation communication assessment form (CHBAH, 2012)
Appendix H: Paediatric aural rehabilitation speech therapy form (CHBAH, 2012)