Quality Standards for Cochlear Implantation in South Africa

South African Cochlear Implant Group

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Contents

1. INTRODUCTION

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 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.

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.

2. SERVICE STRUCTURE

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. Attendance at relevant courses, conferences and meetings at national and international levels is 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 made up of the following core personnel:

a. 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 co-ordinator

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 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. S/he 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 co-ordinator will have a high degree of clinical, organisational, leadership and professional skills. The co-ordinator, 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.

b. Audiologists

Audiologists must hold a professional registration with the Health Professions Council of South Africa, as well as have acquired an HPCSA 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. After having acquired the Certificate of Competence, 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.

c. Speech & Language Therapist / Audiologist

The Speech and Language Therapist / Audiologist must hold a professional registration with the Health Professions Council of South Africa. It is encouraged that on becoming a member of the Cochlear Implant team, the Speech and Language Therapist / Audiologist consult on a regular basis with experienced Speech and Language Therapists /Audiologists working in the field of rehabilitation of children with hearing loss. SACIG Guidelines for Speech-Language Therapists (Appendix A) working with children in the field of cochlear implants should be adhered to.

d. Ear, Nose and Throat Surgeons

The ENT surgeon will have an F.C.S (ORL) or equivalent qualification and will be a Specialist Otologist with appropriate accreditation and training. He/she will have experience in cochlear implant surgery, and will 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.

Newly appointed surgeons will have extended sub-speciality training at an advanced level in otology and cochlear implant surgery in appropriate

specialist centres in South Africa or overseas. This will have included attending a temporal bone dissection course for cochlear implant surgeons. Physicians should be well versed in mastoid surgery and the facial recess approach to the round window and have experience in adults before performing the procedure on children

Once appointed, the surgeon will work as a member of the consultant surgical cochlear implant team, initially under the mentorship of senior surgical colleague/s, with at least six months of supervision by a senior colleague for an appropriate number of cochlear implant operations. The senior surgeon will determine the competency level of the less experienced ENT surgeon. The surgeon will participate in the process of audit of cochlear implant cases and in keeping a database of such cases.

While the above represent recommended minimum requirements, the reality of the South African situation is such that geographical and demographical factors often make this unattainable. However as training programs improve and cochlear implantation becomes more commonly performed the opportunities for surgeons to qualify themselves to meet these standards will be more readily accessible.

Until then, where a surgeon still not meeting these standards finds him/herself in a situation where the best alternative for the patient is that s/he should perform the surgery, steps should be taken to ensure adequate preparation for possible complications 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 familiarity and competence. 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. **QS: All team personnel must maintain a programme of continued professional development to ensure ongoing competency.**

e. 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.

3. CLINICAL AND AUDIOLOGICAL FACILITIES

a. Clinical areas should be large enough to comfortably accommodate the patient, family member(s) and clinician together with the necessary equipment.
b. A suitable room should be available for group work including patient activities and team meetings / training.
c. 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.
d. 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.
e. 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.
f. Examination rooms must meet current appropriate South Africa health and safety guidelines.
g. All rooms should comply with health and safety regulations.

<u>Audiological facilities</u> should be available for:

- Pure tone Audiometry
- Sound field Audiometry
- Hearing aid testing and fitting
- Probe-tube microphone measurements
- Tympanometry
- Otoacoustic Emissions
- Evoked Response Audiometry
- Speech perception testing (including option 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 recognised standards:
Pure tone audiometers Air conduction SANS 10154-1:2004,
Pure tone audiometers: Bone conduction SANS 10154-2:2004,
Speech audiometry SANS 8253-3:1996.

4. REFERRAL AND SELECTION CRITERIA

a. 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).
b. Patient selection criteria should be kept under annual review by SACIG.
c. Acknowledgement of the receipt of the referral and management decision must be undertaken by the receiving Cochlear Implant Programme.
d. 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.

5. THE PRE-OPERATIVE ASSESSMENT PROCESS

a. The purpose of the assessment process is to assess the patient's functional hearing abilities and to determine whether these are likely to be significantly improved through cochlear implantation.
b. Co-ordinated management of the pre-implant assessment process by the Cochlear Implant Programme Clinical Coordinator is essential.
c. Locally agreed patient pathway details should be available on request.
d. Fast tracking of patients through the assessment process must be available when clinically indicated (e.g. in the case of meningitis).
e. Pre-operative assessments should include the following:

MEDICAL:

i) All patients referred to the cochlear implant programme should have a medical consultation with the team ENT surgeon.
ii) The referral of patients for MRI, CT is the responsibility of the ENT surgeon. Refer to Appendix C for Radiological Guidelines for assessment and management of Cochlear Implant candidates and users. (Appendix C). Protocol to be reviewed annually.

iii) Appropriate referral for balance /vestibular assessment should be made if indicated.

iv) It is the responsibility of the surgeon, for each patient:

1. To undertake a medical consultation during the assessment process, and pre-admission, to ensure the patient is medically fit to undergo the treatment.
2. To discuss associated risks of the treatment pre- and post-surgery.
3. To refer for vaccination to minimize the risk of pneumococcal meningitis.
4. To refer for genetic counselling if required
5. To obtain fully informed patient consent for the treatment.
6. In the case of HIV positive patients refer to Appendix D for protocols.

AUDIOLOGICAL

Each patient must receive a full audiological assessment performed to professionally accepted protocols (Appendix E).

i) The audiological assessment must include:

1. Otoscopic examination of the ears.
2. Determination of bilateral middle ear function using tympanometric techniques.
3. Determination of unaided hearing thresholds bilaterally using pure tone audiometry or other recognised methods suitable for the patient.
4. Objective hearing threshold assessment, including Stapedius reflexes, Otoacoustic Emissions and Auditory Evoked Response Audiometry if indicated.
5. Unaided ear specific speech perception testing (recorded) if indicated.

ii) Hearing Aid Evaluation

Each patient should have their current hearing aid provision re-evaluated and where appropriate have new hearing aids fitted or settings revised. Verification of the suitability of amplification should be undertaken. Assessment of ear specific aided benefit should include:

1. Aided soundfield thresholds
2. Speech perception testing using pre-recorded speech material, and live voice where appropriate.

iii) Patients fitted with new hearing aids or with a change of hearing aid 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.

COMMUNICATION

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
    1. Lipreading skills
    2. Comprehension of spoken language

b. Expressive skills
    1. Language skills in all communication modes
    2. Intelligibility, voice quality

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

CHILDREN:

Pre-operative assessment for children (Appendix F).

QUALITY OF LIFE MEASURES

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

HEARING ABILITY MEASURE

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

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.

6. PRE-OPERATIVE INFORMATION AND COUNSELLING

a. Whenever possible, information should be given to patients / significant others / parents in a language that is appropriate to their preferred language.
b. Interpreters should be offered if required.
c. 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.
d. Verbal information should be supported by a written summary to the patient /parents whenever indicated.
e. Throughout the assessment period patients / significant others / parents should have a clear understanding of the main benefits and limitations of implantation. They should demonstrate that they have realistic expectations of cochlear implantation, e.g. by using a measurement tool such as an expectations questionnaire.
f. 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.
g. 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.
h. 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.
i. Waiting times for surgery and information about the hospital stay and post-operative follow-up should be outlined at the end of assessment.
j. Patients should be given information about available cochlear implantation organisations (SACIG), and self help / advocacy groups.
k. 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.
l. 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.

m. 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

7. THE COCHLEAR IMPLANT DEVICE

a. 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:

i) Advanced Bionics
ii) Cochlear Ltd.
iii) Med-El Ltd.

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

Advanced Bionics – HASS catherine@phonak.co.za
Cochlear – Southern ENT cochlear@mweb.co.za;
Med-EL Ltd. – Cassandra.brown@medel.com

b. The following recommendations are made with regard to devices to be available in South Africa:

i) FDA and/or CE mark approved
ii) MRI compatible
iii) Clinical application of objective measures should be available
iv) Clinically proven hearing performance outcomes in children and in adults

v) Safety and reliability data proven by the European Consensus report (Battmer et al., 2010)
vi) Have high quality clinical and technical support available from the manufacturer and local distributor.

c. Distributors of the cochlear implant systems should belong to South African Medical Device Industry Association (SAMED) (Appendix G).

d. 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.

e. It is recommended that patients insure their speech processors.

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.

8. SURGERY AND IN-PATIENT CARE

a. The ENT Cochlear Implant surgeon is responsible for the overall medical care of the patient.
b. The surgical team is responsible for briefing the patient about the surgical procedure and potential complications and for obtaining the patient's informed consent.
c. 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.
d. Information regarding the outcome of surgery must be documented and should be made available to the audiological team immediately after the operation.

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.

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

a. Sound processors should be fitted and programmed once the patient's wound has healed satisfactorily and the payment process has been completed.
b. 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 Additional Training in Cochlear Implants). A less experienced audiologist may only perform programming under direct supervision for a period of six months. The clinic coordinator is responsible for determining the competency level of the less experienced audiologist.
c. Before the initial programming relevant team members must:
   i) check the external cochlear implant components
   ii) explain the programming procedures to the patient
d. The completed registration form should be returned to the local distributor on the day of fitting.
e. Each device should be programmed according to the manufacturer's recommended programming procedures.
f. A comprehensive explanation on the use of the speech processor must be given.
g. Patients should be encouraged to contact the implant programme if they have any queries or concerns.
h. Printed materials on the handling, operating and care of the sound processor should be issued to the patient / parents as appropriate.
i. 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.
j. 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.

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.

10. POST-OPERATIVE REHABILITATION

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

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

11. 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 as required.
b. Adequate spares (e.g. cables / coils) 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 E).
f. Follow-up assessments by the audiologist include equipment check, programming of the sound processor, free-field thresholds, speech perception tests and questionnaires.

g. Recipients and their families should be provided with a document on safety guidelines for cochlear implant users (Appendix H).

QS: Spares or loaner sound processors should be available on the same day or within one working day.

QS: Standardised 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.

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.

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.

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.

13. 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.

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

14. MANAGEMENT OF IMPLANTEES FROM OTHER COUNTRIES. (Appendix I).

15. DEVICE FAILURE

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

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.

16. AUDIT AND SERVICE MONITORING

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 J 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 submitted to the Minister of Health (national and provincial), SASLHA, SAAA, and the ENT Society, Board of Healthcare Funders, Medical Aid Schemes and the national and provincial Department of Education.

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 J (Annual Report Template)

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

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