THE COCHLEAR IMPLANT GROUP OF INDIA (CIGI)

(Registered – 2003; Registration no – 728/2003-2004)

Clinical Practice Guidelines for Cochlear Implantation

(Second Edition – 2011)

First Edition 2004

CONTENT INDEX

(ಪ್ರಮಪತ್ರ ಕ್ರಮಾಂಕ ೧೬)

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ಕರ್ನಾಟಕ ಸಂಘಗಳ ನೋಂದಣಿ ಅಧಿನಿಯಮಂ ೧೯೬೦ (೧೯೬೦ನೆಯ ಇಸವಿ ೨೮ನೆಯ ಕ್ರಮಾಂಕದ ಕರ್ನಾಟಕ ಅಧಿನಿಯಮಂದ)

ಮೇರೆಗೆ THE COCHLEAR IMPLANT GROUP OF INDIA.

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ಎಂಬ ಸಂಘವು ಇಂದು ನೋಂದಾಯಿತವಾಯಿತೆಂದು ಈ ಮೂಲಕ ಪ್ರಮಾಣೀಕರಿಸಿರುತ್ತೇನೆ.

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27/10/03

(MEHABOOB KHAN)

ಸಂಘಗಳ ರಿಜಿಸ್ಟ್ರಾರ್, ಕರ್ನಾಟಕ ಸರ್ಕಾರ
Bangalore Urban Dist., Bangalore.
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The Seal of The Registrar of Societies Bangalore district Bangalore.

DECLARATION

This document reflects the consensus opinion of the members of the Cochlear Implant Group of India. It is not binding on any individual / individual clinic. However, it is the recommendation of the Cochlear Implant Group of India that, wherever possible, this document should act as a guideline for clinics performing Cochlear Implantation in India.

The Cochlear Implant Group of India wishes to acknowledge the contributions of the authors (members of CIGI) of the first edition and the modifications to the second edition.

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PROTOCOLS

- Referral
- Stage One Assessments
- Stage Two Assessments
- Stage Three Assessments
- Team Meetings
- Surgical Protocol
- Audiological Protocol
- Habilitation Protocol

Referral to the Cochlear Implant Clinic

1. Referrals are accepted from ENT Consultants, Audiologists, Educators and other medical doctors.
2. Adults and children of all ages can be referred for assessment. Each case will be considered on an individual basis.
3. The patient must have a severe to profound hearing loss which can not be helped adequately by hearing aids.
4. The patient must be willing and able to attend the respective Cochlear implant Clinic for several assessment appointments before the operation as well as all the necessary programming and rehabilitation sessions after the operation.
5. The referring person will be kept informed of a patient's progress. A written acknowledgement of the referral will be sent with an information pack for new referrals. Written reports will be sent at all stages of the pre-operative assessment following surgery, following initial device fitting and following post-operative reviews.

Stage One Assessments

1. The patient will be seen by the ENT Consultant at the first appointment.
2. The patient is seen in Audiology for:
i. Evaluation of hearing loss
ii. Hearing aid trial if appropriate
iii. Adequate fitting of hearing aids binaurally if possible
iv. Aided audiogram after final hearing aid fitting
v. Preliminary speech tests after 6 weeks of hearing aid use
3. If the patient is suitable for cochlear implant assessment the consultant arranges a radiological evaluation at this stage. It is recommended that both High Resolution Computerized Tomography (HRCT) of temporal bones and Magnetic Resonance Imaging (MRI) are done. In cases of meningitis, a repeat scan will be performed close to the operation.
4. In some patients it may be necessary to perform a Transtympanic Electrically evoked Auditory Brainstem Response (TT-EABR) at this stage to confirm candidacy.
5. The patient is seen by the Cochlear Implant Coordinator for counseling. Counseling at stage 1 involves:
i. History taking
ii. Explanation of cochlear implant assessments and realistic outcomes of CI for that patient
iii. Explanation of the surgical procedure
iv. Dummy implant and external devices shown
v. Explanation of how the implant works
vi. Cochlear implant information folder issued
vii. Discussion about the cost of the implant and the maintenance and recurring cost involved
6. The patient is seen by the Teacher for the hearing impaired/educator for assessment of auditory skills. Auditory training will be arranged if necessary.
7. The patient is offered the opportunity to meet an implantee of similar age and hearing loss.
8. On completion of stage one assessment the patient will be discussed at the Cochlear Implant Team Meeting and test results approved before proceeding to stage two assessments.

Stage Two Assessments

A Clinical Psychologist will see the patient at this stage to be arranged by the Coordinator. A family member/ care giver will also be asked to attend this appointment. The clinical psychologist sends a report to the Consultant Surgeon and the Coordinator making recommendations regarding the patient's ability to cope with implantation and rehabilitation.

An evaluation of the patient's speech and communication skills is carried out by the Speech and Language Therapist. A video recording of standard conversation is made. A report is filed. If required a speech therapy programme is set up for post-implantation.

Patient is referred to a Paediatrician for evaluation. This includes vaccination protocol and fitness for undergoing the procedure.

If deemed necessary the family may be referred to a Geneticist at this stage

The patient is seen by the Cochlear Implant Coordinator for counseling. Counseling at stage 2 involves:

i. hearing with an implant;
ii risks of surgery;
iii risks following surgery;
iv switch-on, mapping and rehabilitation;
v Realistic expectations.

On completion of stage two assessments the patient will be discussed at the Cochlear Implant Team Meeting and test results approved before proceeding to stage three assessments. A date for surgery will be set if appropriate.

Stage Three Assessments

Final pre-surgical counseling is carried out by the Coordinator/Audiologist/Therapist/Surgeon.

This includes:

i] Confirmation of vaccination schedule
ii] General Anaesthesia fitness for the procedure
iii] Expectations questionnaire
iv] Risks information sheet
v] Date and time of surgery

Team Meetings

1. Team meetings are held once a month to discuss patients' progress and other business relating to the cochlear implant programme.

2. The Cochlear Implant Team includes the following professionals:
Consultant ENT Surgeon –Cochlear Implant Coordinator
Educator
Audiologist
Speech and Language Therapist
Clinical Psychologist – if necessary
(Others may be co-opted as deemed necessary)
If a team member is unavailable for a meeting, he/she should be informed in case of any problem in the progress.

3. When a patient completes any stage of the assessment programme their case is discussed at the next Cochlear Implant Team meeting. A decision will be made at team meeting whether a patient will proceed on to the next stage of the assessment programme. Decisions will also be made to carry out additional assessments/tests when necessary.

4. After stage two assessments, a decision will be made whether to proceed with surgery and a date will be set if appropriate.

SURGICAL PROTOCOL

- The Consultant ENT surgeon will perform the cochlear implant surgery.
- The Clinical Audiologist is responsible for ensuring that all relevant equipment to conduct intraoperative monitoring is available and ready for use on the day of surgery.

PRE-OPERATIVE PREPARATIONS/CHECKLISTS

- Investigations Checklist
- Re-check complete audiology assessment
- Radiology: HRCT scan/ MRI (films available in OR)
- Vaccination Protocol (Appendix 1)
- Surgical Consent form (Appendix 2)
- Anaesthesia Consent form (Appendix 3) and preoperative anaesthetic fitness
- Confirm Ear
- Confirm that implant and back up are in the theatre premises

OT INFRASTRUCTURE

- Desirable to have two levels of isolation
- Theatre to be fumigated on the previous evening
- Laminar or guided air flow in the theatre is recommended
- No infected case to be taken in the same theatre prior to CI surgery
- Minimum essential OT personnel
- Traffic in OT to be restricted with appropriate signages
- Operating high resolution microscope is recommended (Back-up microscope is desirable)
- C-Arm for intraoperative imaging is desirable
- Otologic drill with variable speed (Skeeter is desirable)
- Tympano-mastoidectomy set

- Burrs 0.8 to 7 mm
- Handpiece – Straight & Contra angle
- Powderless gloves
- Bi-polar diathermy
- Micro-suction tips (Size 16-24)
- Appropriate suture materials
- Implant specific surgical kits
- Implant specific intraoperative test equipment for electrophysiological testing
- Video camera and recording systems desirable

SURGICAL TRAINING

- Postgraduate qualification in ENT Surgery (Otolaryngology Head & Neck Surgery) – Master of Surgery (MS-ENT) or Diplomate of the National Board (DNB-ORL) or equivalent foreign degree with minimum 5 years post PG qualification experience

- 500 ear (tympanomastoid) surgeries with additional experience of stapes surgery

- Attendance at 2 hands-on workshops on CI surgery

- Attendance as observer for 5 CI surgeries

- Participation in 5 CI surgeries as first assistant

- Mentor surgeon to be identified by the trainee cochlear implant surgeon under whose guidance the above 2 points are addressed and the mentor surgeon trains the trainee with the first few CI surgeries (around 3 or 4) until the trainee is declared independent

SURGICAL TECHNIQUE

- Operative site to be prepared
- Perioperative antibiotic and steroids to be administered intravenously
- Infiltration with local anaesthetic solution with adrenaline is recommended
- Incision depending on surgeon preference / approach
- Recommendations of the implant company to be followed as regards distance from the prospective site of the receiver stimulator package
- Standard operating procedure to be followed as recommended by the implant company
- Product handling procedures should be followed as recommended by the implant companies
- No diathermy to be used after implant package is opened
- Powderless gloves to be used when handling implant
- Fixation of the implant to the skull is recommended
- Audiologist to perform intraoperative electrophysiological testing and complete documentation along with the surgeon
- Facial nerve monitoring is recommended especially in those cases where there is an anticipated risk of injury to the facial nerve
- Intraoperative C arm x-ray to check electrode position may be performed

POSTOPERATIVE CARE

- Mastoid pressure dressing – as per surgeon's advice
- Antibiotics – one which penetrates the blood brain barrier is recommended
- Steroids – may be given in certain situations
- Diuretics – may be given in cases of profuse csf gushers
- Visits as per surgeon's recommendations
- Postoperative X-ray – Modified Stenvers view / Cochlear view for documentation

MENTOR SURGEON

- Mentor should have done more than 50 CI surgeries
- Mentor should be approved by the company
- The details of the patient should be sent to the mentor prior to the surgery including radiology
- The mentor will support the surgeon for the first few surgeries, the number being decided mutually between the mentor and the trainee

AUDIOLOGICAL PROTOCOL

CIGI recommends this audiological protocol for cochlear implantation in order to improve the quality of service and uniformity among the cochlear implant clinics in India. The test battery approach to audiological assessment is well recognized and is recommended in this protocol. CIGI strongly suggests that no single test should be used in isolation to define and describe the nature and extent of a hearing loss & to plan if cochlear implantation is required.
Following protocol is recommended for candidacy selection (children/ adult) by CIGI

Audiology Protocol: Test battery and candidacy criteria for children

- Otoscopic Inspection to rule out cerumen
- Child and family history – high risk factors
- Behavioural audiometry, including pure-tone audiometry across the frequency range for each ear and speech detection or speech recognition measures
- Tympanometry and acoustic reflex testing
- ABR (Auditory Brainstem Response) testing using air-conducted click and tone burst stimuli and bone-conducted stimuli when indicated; when a hearing loss is detected, frequency-specific ABR testing is needed to determine the degree and configuration of hearing loss in each ear; click-evoked ABR testing using both condensation and rarefaction single-polarity stimulus, if there are risk indicators for neural hearing loss (AN/AD_ Auditory Neuropathy/Auditory Dyssynchrony spectrum) to determine if cochlear microphonics are present

- ASSR (Auditory Steady State Responses) testing may be used as a supplementary tool for assessing ear and frequency specific thresholds

- Distortion product or transient evoked OAEs (otoacoustic emissions)

- Parent and clinician observations of the infant's auditory behaviour as a cross-check in conjunction with electro physiologic measures (IT MAIS)

- Sound Field Aided Response:
    a. To demonstrate if the child's response is adequate for speech-language stimulation
    b. To monitor the child's auditory progress
    c. To assess speech perception at soft (e.g. 35 dB HL) and at average
    d. conversational levels (e.g. 60 dB HL) in quiet and in the presence of noise to
    e. evaluate the effectiveness of amplification technology (Each hearing aid should be evaluated separately and then both tested together)
    f. Assessment of speech audibility using Ling 6 Sound Test at varying distances

It is not mandatory to do all the tests. The audiologist should decide the battery of tests based upon the age & co-operation of the child and should substantiate objective tests with good subjective testing and observations. The audiologist will document reliability and validity of the test results. The test finding results should be documented appropriately. Follow up of certain tests is recommended if there is any discrepancy.

The audiologist should refer the case to the nearest center if he / she does not have the facility for doing all the tests.

The audiologist should discuss the details regarding the investigations and recommend the family members the probable line of treatment. The detailed report of audiological evaluation should be provided to the parents.

The patient is seen by the Auditory Verbal Therapist/ Speech and Language Therapist & Implant Audiologist for assessment of speech, language, communication, and auditory skills. Appropriate hearing aid fitting will be done following the recommendation of the audiologists. This should be followed by Auditory training. The period of hearing aid trial before implantation will be decided on a case to case basis. However, at least two/three months of intensive auditory training with the most powerful hearing aids is mandatory for children below the age of two years & for at least six weeks for children above two years of age. However, this does not apply to cases with labyrinthitis ossificans.

When to refer to CI Clinic:

- No significant progress of speech, language and hearing skills of the child after fitting with appropriate hearing aids and adequate auditory training
- If the aided responses beyond 2 kHz are falling outside the speech spectrum
- Progressive hearing loss
- Child not progressing on speech and language skills even though appropriately fitted with hearing aids -- sealing effects

The audiologist should refer the child to the implant surgeon for ascertaining medical candidacy for cochlear implantation. Other appropriate referrals like radiology / clinical psychology/ paediatrician should be done.

The prospective implantee and his family are offered the opportunity to meet another implantee. The family should be counseled that no two cases exhibit identical results.

Audiology Protocol: Test battery & candidacy criteria for adults

The battery of tests is as follows:

a. Pure tone Audiometry
b. Aided audiogram
c. Speech Audiometry
d. Middle ear analysis
e. Otoacoustic emissions (TEOAE and / or DPOAE)
f. ABR
g. ASSR

It is not mandatory to do all the tests. The audiologist should decide the battery of tests based upon the age, co-operation and requirement. Audiological evaluations will be repeated if found necessary by the Audiologist to check the reliability of findings & for monitoring improvement in hearing status if any. The audiologist should refer the case to the nearest center if he / she does not have the facility for doing all the tests. All the reports should be well documented. The detailed report of audiological evaluation should be provided.
Fitting is done with the appropriate hearing aid. The period of hearing aid trial before implantation will be decided based upon on individual basis.

It is recommended that an electrical stimulation test (Promontory Stimulation) should be carried out for patients who had no improvement in thresholds with the hearing aid in place (aided audiogram). This is not mandatory.
When to refer to CI Clinic:

- If the aided responses beyond 2 kHz are falling outside the speech spectrum he / she can be considered for cochlear implantation
- Speech discrimination score for open set sentences and words (auditory modality only) should be less than 40% to fulfill the candidacy criteria

The patient is offered the opportunity to meet an implantee. The patient should be counseled that no two cases exhibit identical results.

Counseling

The patient is seen by the Audiologist / Cochlear Implant Surgeon / Cochlear Implant Coordinator for counseling.

Counseling involves:

- history taking
- explanation of cochlear implant assessments
- hearing with an implant
- explanation of the surgical procedure
- showing the dummy implant and external devices
- risks of surgery
- risks following surgery
- switch-on, mapping and re / habilitation
- realistic expectations (predicted benefits)
- worldwide statistics regarding the outcomes & implant

Post Operative Programming & Re / habilitation

1. It is recommended that Programming & Switch-on of the cochlear implant system should take place around 3 weeks after surgery. This is done by an audiologist.

2. The Therapist & or Speech and Language Pathologist plan & start the postoperative rehabilitation programme with the patient. The patient will then be seen at intervals to suit individual needs. Parents should be present and participate in all assessments as well as in therapy sessions. The Therapist should also be present at audiological assessments whenever possible or send a report identifying his/her questions or concerns regarding the child's hearing and amplification.

3. A patient's map is altered as found necessary by the implant audiologist & as required by the patient. It is recommended that the programming is checked at regular intervals after Switch-on. The schedule of after 2 weeks, at 1 month, 3 months, 6 months, 9 months, at 12 months, then after 18 months, 24 months and six monthly/annually thereafter or more frequently as based on individual needs is recommended.

4. The re / habilitation programme will be charted out based upon the baseline skills of each patient.

Team Meetings & Assessments

1. Team meetings are held at regular intervals or when necessary to discuss patients' progress and other matters relating to the cochlear implant programme.
2. The Cochlear Implant Team includes the following professionals:
Consultant ENT Surgeon
Audiologist
Cochlear Implant Coordinator
Therapist / Speech and Language Therapist
Social Worker / Clinical Psychologist/Counselor
Others may be co-opted as deemed necessary.
3. If the performance of the implantee is questionable, then appropriate measures should be taken to identify the problem & find solutions, e.g. explantation followed by re-implantation with proper protocols in place with respect to each company device.

Audiological Training

- BASLP/ equivalent foreign degree with minimum 2 years experience in clinical audiology
- Three years of experience in dedicated paediatric evaluation, hearing aid fitting and counseling
- Attendance of 2 workshops dedicated to CI candidacy and mapping
- Attendance as observer at 3 different CI centres
- A mentor audiologist should be identified by the trainee audiologist under whose guidance five switch on and 10 mapping sessions will be done

Mentor Audiologist

- Mentor should have handled more than 50 CI cases independently
- Mentor should be approved by the company
- The details of the patient would be sent to the mentor prior to switch on

HABILITATION PROTOCOL

PREFACE:

The Cochlear Implant Group of India (CIGI) recognizes the importance of re/habilitation in any cochlear implant programme. The techniques used for the same are individualized and are based on the need of each cochlear implantee and his/her caretaker.

GUIDELINES:

1. CIGI recognizes that there is no minimum age for referral for implant candidates. It further subscribes to international findings that habilitation is most effective when commenced in the first year of a baby's life and that cochlear-implant surgery is most effective with children under three years of age. CIGI remains committed to lowering the age for implant surgery nation-wide.

2. It is recommended that candidates for a cochlear-implant conform to the criteria outlined by CIGI in its consensus document for Audiology.

3. Candidates for a cochlear implant should be using appropriate hearing aids for a minimum period of three months prior to implant surgery. It is recommended that candidates should attend therapy sessions at habilitation centers for at least three months prior to surgery.

4. Babies with Auditory Neuropathy, progressive hearing loss, sloping hearing loss must be carefully monitored with and without hearing aids before recommendations for amplification and/or cochlear implant surgery are made for them.

GUIDELINES FOR HABILITATION:

1. Families and their child must attend individualized therapy sessions on an on-going basis. The primary focus of such therapy must be to develop age-appropriate listening skills sequentially in implanted children, using the normal scales of development in hearing children.
2. The rehabilitation programme may include training in:
   a. Detection of sound, including localization and spatial tests.
   b. Auditory discrimination
   c. Voice quality
   c. Speech intelligibility
   d. Language comprehension and expression
   e. Social skills
   f. Lip reading
   g. Hearing tactics
3. The service offered by the re/ habilitation center must be one which is committed to parent empowerment.
4. Counseling should support the patient and the family regarding expectation, the habilitation procedures and continuing commitment to the programme.
5. The medium of instruction for habilitation preferably should be the child's primary language or one that his home environment can effectively support. If any other language is chosen for therapy this should be after discussion with the caretakers.
6. Inclusive education with reasonable accommodation will be the preferred option for all CI recipients; the centers are encouraged to work towards competence in the mainstream, rather than mere survival.

RECOMMENDATIONS:

1. Habilitation centers are must regularly monitor and evaluate annually the individual progress of the children attending their centers, using both informal and formal standardized assessments.
2. It is recommended that the professionals concerned should receive written reports on progress.
3. Sufficient and individualized sessions should be offered to optimize cochlear implant use.

APPENDIX 1

Vaccination Schedule

It is recommended that every cochlear implantee is vaccinated against H.Influenzae, Meningococcus and Pneumococcus. These recommendations can be viewed in detail on the CDC (Centre for Diseases Control) website: *(http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm)*

Pneumococcal Conjugate vaccine		
Age at first dose(months)	**Primary series**	**Additional dose**
2-6	3 doses, 2 months apart	1 dose at 12-15 months of age
7-11	2 doses, 2 months apart	1 dose at 12-15 months of age
12-23	2 doses, 2 months apart	Not indicated
24-59	2 doses, 2 months apart	Not indicated
60 months or older	Not indicated	Not indicated

Polysaccharide Pneumococcal vaccine		
Age at first dose	**Primary**	**Booster**
< 2 years of age	Cannot be given	At 2 years
> 2 years of age	Immediate	Every 3-4 years

Hemophilus Influenza vaccine		
Age at first dose(months)	**Primary series**	**Additional dose**
1 ½ - 3 ½	3 doses, 1 month apart	18 months
4 - 7	3 doses, 1 month apart	18 months
7 - 11	2 doses, 1 month apart	18 months
12 – 14	1 dose	1 month after
15- 59	1 dose	Not required

APPENDIX 2:

Consent Form for
COCHLEAR IMPLANTATION SURGERY

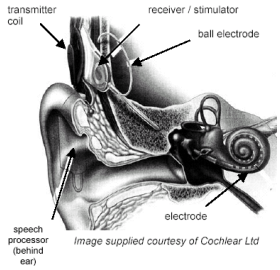
Name:	Age / Sex:	Date:
Address:		
Hospital No:	Date of Birth:	

PROPOSED TREATMENT

The doctor has explained that I/ my…….. ..… have / has (condition/diagnosis)……..…… ……..…and that a cochlear implant on the ……side/s is proposed. I have chosen to get…….model of…….company implanted on myself/ my……..

COCHLEAR IMPLANTATION

A cochlear implant is an electronic device that is implanted inside the cochlea (inner ear), which bypasses damaged or absent hair cells and provides electrical stimulation directly to the hearing nerve fibres. Under a general anaesthetic, an opening is made behind the ear and a small area of the mastoid bone hollowed out to lodge the receiver / stimulator part of the device. An array of electrodes is inserted into the cochlea (inner ear). Any bleeding is stopped and the skin wound closed over the device. The external part of the device will be programmed & fitted when the wound has healed. The programming is usually done after two or three weeks.



BENEFITS OF COCHLEAR IMPLANTATION

Cochlear implantation is designed for people with severe to profound hearing loss who derive limited benefits from hearing aids. The speech / language / hearing skills will improve following cochlear implantation. The improvement depends upon many factors which have been explained to me by the cochlear implant team, audiologist and therapist.

RISKS

These are the more common risks. There may be other unusual risks that have not been listed here. Please ask your ENT surgeon if you have any general or specific concerns.

I understand there are risks associated with any anaesthesia.

I/ my …… may have side effects from any of the drugs used. The common side effects include light-headedness, nausea, skin rash and constipation.

I understand the procedure has the following specific risks and limitations:

- The device will not cure my/my…… deafness nor will it completely restore my hearing. I am likely to need some 'listening' training to be able to benefit as much as possible.
- There may be circumstances where it may not be possible to insert the implant completely and this may sometimes affect eventual outcomes.
- The ability of the implant to improve speech perception will depend on the ability of the auditory nerve to conduct the electrical stimulus and the functional integrity of the auditory cortex. This may not be possible to detect with current investigative methods accurately and so if the auditory cortex and the nerve are defective the outcomes may be poor.
- Static electricity may damage the electronic components of the device or the program
- I/ my…….. will need to have regular follow-up for ENT consultation, programming and auditory verbal therapy and the device will need regular maintenance.

I / my…….may have some dizziness, dryness in my mouth and/or ringing in my ear(s) after the operation as a result of the surgery to the ear.

I/ my……. wound may become infected and I may need antibiotics for this. Rarely the skin wound may fail to heal and the device may have to be removed.

Very rarely, I may have some bleeding after the operation, which may require local treatment or occasionally a return to the operating theatre.

I may notice some numbness or stiffness around the ear, which in most cases will improve gradually with time.

I may have some loss of taste on the side of the operation, which may be temporary or permanent.

Rarely, I may have some temporary weakness of my face muscles if there is some swelling near the facial nerve, which runs close to the operation site. This usually resolves over the course of some weeks, but permanent paralysis may rarely occur.

I may have some pain in the area of the coil, which should improve over time.

Very rarely, my body may 'reject' the implant, which may be extruded.

Placement of the implant may stimulate new bone growth, which may damage surviving nerves and make replacement of my device difficult.

The implants have been in use for over 30 years without any reports of consequences from electrical stimulation. If problems should develop in future, the implant can be easily removed.

The external equipment may fail and require re-mapping.

The internal device may fail and need a second surgery to replace the damaged device. I/ my relative will need to avoid sports where there is a potential to damage the device, and must warn medical staff that I/ my relative have one, as some procedures or investigations can damage the device. Hence we should contact the implant surgeon for advice.

I understand some of the above risks are more likely if I/ my relative smoke/s become overweight, diabetic, have high blood pressure or other medical conditions.

INDIVIDUAL RISKS

I understand the following are possible significant risks and complications specific to my ……individual circumstances, that I have considered in deciding to have this operation:

……
……
…….
……
……

DECLARATION BY PATIENT/ RELATIVE

I acknowledge that the ENT surgeon & Audiologist have informed me about the procedure, alternative treatments and answered my specific queries and concerns about this matter.

I understand the need for continuous follow up care and auditory verbal therapy for adequate benefit

I acknowledge that I have discussed with the ENT surgeon regarding any significant risks and complications specific to my/ our individual circumstances that I have considered in deciding to have this operation.

I agree to any other additional procedures considered necessary in the judgment of my/our ENT surgeon during this operation.

I understand that a doctor other than the specialist ENT surgeon may perform the procedure, when necessary.

I have received a copy of this form to take home with me.

If a needle stick / sharps injury occurs to staff during any procedure I give my permission for blood to be taken and tested for HIV and other blood borne disorders. I understand that I will be advised and counseled as soon as practicable after the operation if this has been necessary.

I understand that the recordings from my surgery/ programming may be used at presentations/promotions if necessary without revealing my identity.

Signature of patient/ relative
Relationship to patient Date

DECLARATION BY DOCTOR

I declare that I have explained the nature and consequences of the operation to be performed, and discussed the risks that particularly concern the patient.

I have given the patient an opportunity to ask questions and I have answered these.

Doctor's signature
Doctor's name
Date

INTERPRETER'S DECLARATION

I confirm I have accurately interpreted the contents of this form and the related conversations between the patient and the doctor

Interpreter's
Signature
Date
Interpreter's name

APPENDIX 3:

Anaesthesia Consent Form

I _____ acknowledge that my doctor has explained to me that I / my _____will have a cochlear implantation done. My doctor has explained the cost, risks of the procedure and risks of not having the procedure and told me about the expected outcome. I also understand that anaesthesia services are needed so that my doctor can perform the operation or procedure.

It has been explained to me that all forms of anaesthesia involve some risks and no guarantees or promises can be made concerning the results of my procedure or treatment. Although rare, unexpected severe complications with anaesthesia can occur and include the remote possibility of infection, bleeding, drug reactions, brain damage or death.

I, hereby consent to the anaesthesia service and authorise that it may be administered by Dr _____ or his/her associates all of whom are credentialed to provide anaesthesia services.

I certify that I have read this form or had it read out to me, that I understand the risks and expected result of the anaesthesia services and that I had ample time to ask questions and consider my decision.

Signature of Patient / Relative

Relationship to the patient

Signature of the witness

Date and time