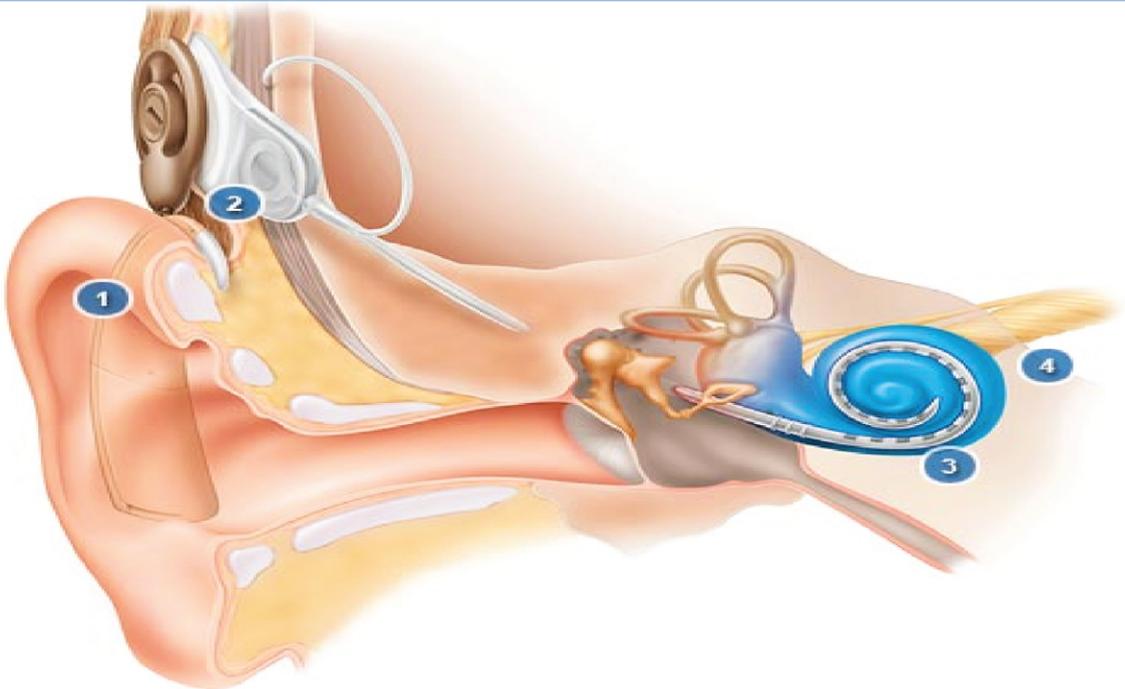




MINISTRY OF HEALTH MALAYSIA

MOH/P/PAK/181.09 (BP)



COCHLEAR IMPLANT SERVICE OPERATIONAL POLICY

SURGICAL AND EMERGENCY MEDICAL SERVICES UNIT
MEDICAL SERVICES DEVELOPMENT SECTION
MEDICAL DEVELOPMENT DIVISION

JULY 2009



MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

COCHLEAR IMPLANT SERVICE
OPERATIONAL POLICY

This policy was developed by the Medical Service Development Section of Medical Development Division and the Drafting Committee of Operational Policy of Cochlear Implant Service.

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ACKNOWLEDGEMENT

Medical Development Division would like to acknowledge the contributions of the National Cochlear Implant Team in the development of this document. Their vast experience and professionalism have facilitated the Division in developing this document.

CONTENT

FOREWORD

Director General of Health Malaysia	3
Deputy Director General of Health (Medical)	5
Chairman of National Core Committee of Cochlear Implant Service	7
List of Abbreviations	9

ARTICLES

1	Introduction	13
2	Objectives of Service	15
3	Scope of Service	16
4	Components of Service	17
5	Cochlear Implant Organisation	18
	5.1 National Core Committee	
	5.2 Satellite Committee	
6	General Statement	22
7	Pre-operative Cochlear Implant Service	26
	7.1 Initial Family Meeting	26
	7.2 Initial Medical Assessments	27
	7.3 Pediatric Assessments	28

7.4	Clinical Otorhinolaryngology Evaluation	29
7.5	Radiology Investigations	29
7.6	Audiology Assessments	30
7.7	Speech and Language Assessments	40
7.8	Immunization Recommendations for Cochlear Implant Recipients	41
7.9	Selection Criteria	43
7.10	Bilateral Cochlear Implantation	48
7.11	Recommendation for Cochlear Implant	49
7.12	Cochlear Implant Funding	50
7.13	Surgical Considerations	51
8	Intra and Immediate Post-Operative Cochlear Implant Service	52
9	Post-operative Cochlear Implant Service	57
9.1	Post-operative Care	57
9.2	Switch-on session and Subsequent Mapping Session	57
9.3	Audiology Post-operative Assessments	58
9.4	Auditory Verbal Therapy Session	59

APPENDICES	63
i Referral Guidelines for Non Satellite Hospitals	65
ii Pre-Operative Guidelines	66
iii Peri-Operative Guidelines	67
iv Post-Operative Guidelines	68
v Terms and Reference	69
vi Requirement for Professionals	74
NATIONAL CORE COMMITTEE OF COCHLEAR IMPLANT SERVICE	75
DRAFTING COMMITTEE FOR OPERATIONAL POLICY; COCHLEAR IMPLANT SERVICE	82



FOREWORD

WHO has defined Hearing Impairment as one of the major public health and social problems and estimates that there are 250 million people who are deaf or who have impaired hearing (WHO, 2005). Most of us are blessed with perfectly normal hearing at birth. With the advancement of medical technology, the disability from hearing can be reduced.

The cochlear implant is a surgically implanted electronic device that provides the sense of sound to a person who is profoundly deaf or severely hard of hearing. It is often referred to as the bionic ear. Unlike hearing aids, the implant doesn't amplify sound but works directly in stimulating any functioning auditory nerves inside the cochlea with an electric field.

Post implantation rehabilitative therapy is often critical to ensuring successful outcomes. Approximately 150,000 people worldwide have received cochlear implants with recipients split almost evenly between children and adults. There are many areas of concern which has to be addressed, like the operation, post implantation therapy and ongoing effects.

We need to ensure that properly documented operational policies are put in place in our hospitals that are acceptable, evidence based, outcome orientated, quality driven and above

all suit the needs and interests of our patients. I would like to congratulate the Medical Development Division and the otorhinolaryngology fraternity for taking the initiative to develop and publish such a comprehensive document.

Thank You.



Tan Sri Dato' Seri Dr Hj Mohd Ismail Merican

Cochlear Implant for hearing has been around for a while since the 1960s but they really began to catch on only in the 1990s .The field of cochlear implant is well established and has evolved rapidly. An implant doesn't restore normal hearing instead it can give the hearing impaired person a useful representation of sounds in the environment and help him or her to understand speech.

It is essential that efforts continue to be undertaken to ensure the good deliverance of services. The increasingly educated public continues to expect better services from our hospitals. The availability of this operational policy will provide guidance to all relevant parties on the development of a system that is more coordinated and efficient in providing care to our patients.

I would like to congratulate the Medical Development Division for initiating and coordinating this effort. I must also commend the drafting committee for their dedication in assisting the ministry to develop this document and provide better medical care to the community. I hope that the quality of our medical

services will continue to improve in tandem with the Ministry's mission to provide the country with a healthcare system that is of international standard.

Thank You.

A handwritten signature in black ink, appearing to read 'Hisham', with a long horizontal line extending to the right.

Datuk Dr Noor Hisham Abdullah

CHAIRMAN OF NATIONAL CORE COMMITTEE OF COCHLEAR IMPLANT SERVICE

Cochlear implantation specialty in children has made considerable progress in the last decade, and it is now an established clinical procedure. Together with cochlear implants for adults, it could be said to have reached the stage of being a subdiscipline in otology. It is truly an interdisciplinary team effort where surgery, audiology, speech and language therapy, pediatric, psychology, radiology, education, engineering and the biological sciences continue to make essential contributions. Like any interdisciplinary field, the best patient management and future progress will occur when there is maximal exchange of information and expertise between these disciplines.

The Cochlear Implant Service Operational Policy is developed to guide all involved to practice cochlear implantation to the highest professional and ethical standards. By outlining policies and procedures based on current best practices, this policy sets standards for the cochlear implant practice in the Ministry of Health hospitals. We have also taken the opportunity to introduce policies that reflect a shift towards patient centered practice with greater emphasis on patient safety and communication. I believe both health care managers and providers involved in cochlear implant service will find this document useful.

It took a great amount of time and depth of knowledge to develop this Cochlear Implant Service Operational Policy. I would like to thank all the colleagues in the Drafting Committee who have helped to develop this document and all those who have been directly or indirectly involved in the publication of this document.

Dr.(Mr.) Abd Majid bin Md Nasir

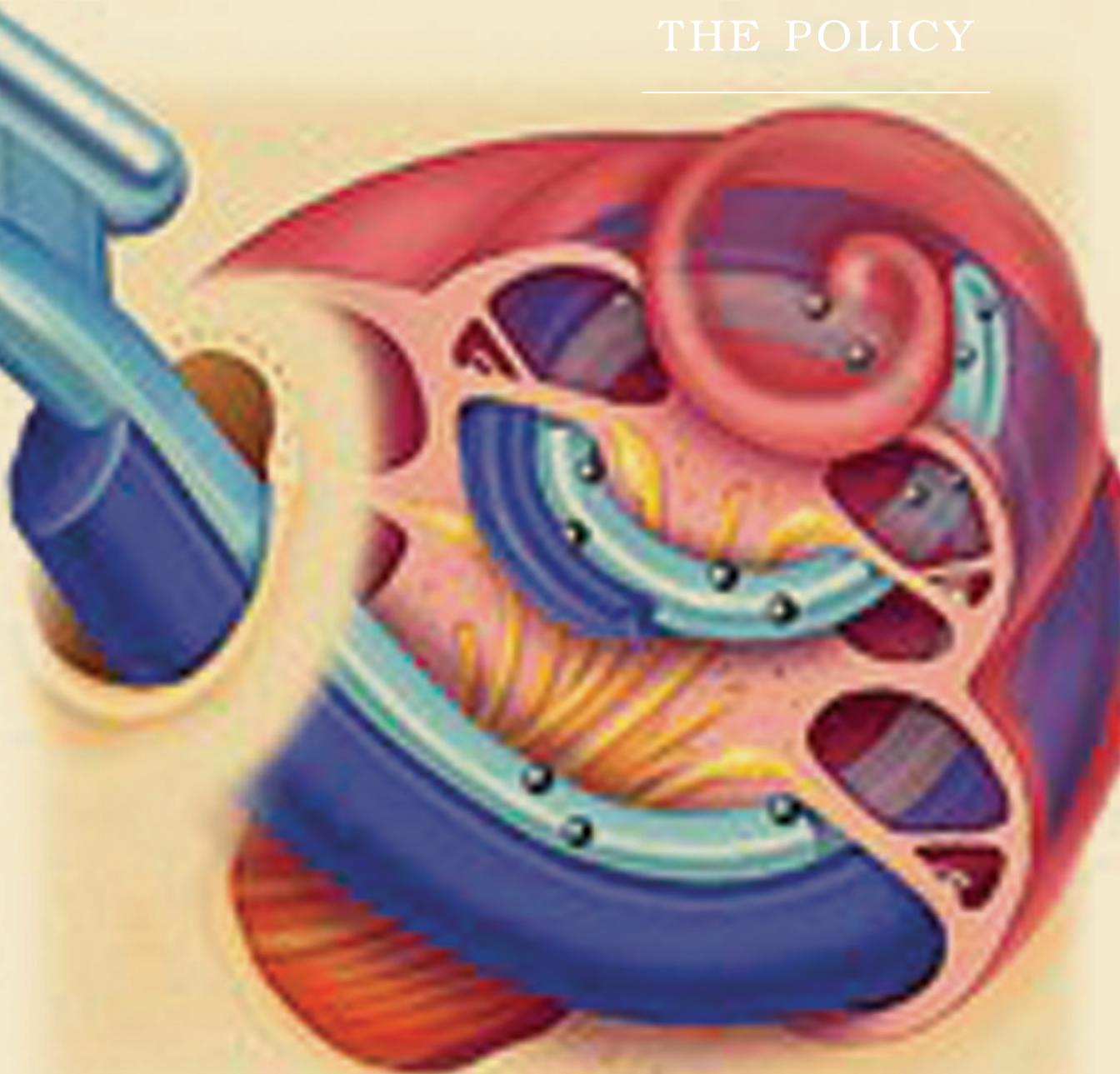


LIST OF ABBREVIATIONS

3FA	THREE FREQUENCIES AVERAGE
AAC	ALTERNATIVE AUGMENTATIVE COMMUNICATION
ABR	AUDITORY BRAINSTEM RESPONSE
APHAB	ABBREVIATED PROFILE OF HEARING AID BENEFIT
ASSR	AUDITORY STEADY STATE RESPONSE
AVT	AUDITORY VERBAL THERAPY
BOA	BEHAVIOURAL OBSERVATION AUDIOMETRY
BTE	BEHIND THE EAR
CG	COMMON GROUND
CI	COCHLEAR IMPLANT
COSI	CLIENT ORIENTED SCALE OF IMPROVEMENT
DBSPL	DECIBEL SOUND PRESSURE LEVEL
EARS	EVALUATION OF AUDITORY RESPONSES TO SPEECH
ENT	EAR, NOSE AND THROAT
GASP	GLENDOLAND AUDITORY SCREENING PROCEDURE
HIB	HAEMOPHILUS INFLUENZA
HINT	HEARING IN NOISE TEST
IQ	INTELLIGENT QUOTIENT
KKM	KEMENTERIAN KESIHATAN MALAYSIA
LIP	LISTENING PROFILE
MAIS	MEANINGFUL AUDITORY INTEGRATION SCALE
MOH	MINISTRY OF HEALTH
MRI	MAGNETIC RESONANCE IMAGING

MTP	MONOSYLLABIC-TROCHEE-POLYSYLLABIC TEST
MUSS	MEANINGFUL UNDERSTANDING OF SPEECH SCALE
NGO	NON GOVERNMENTAL ORGANISATION
NRT	NEURAL RESPONSE TELEMETRY
OAE	EVOKED OTOACOUSTIC EMISSION
ORL	OTORHINOLARYNGOLOGY
PCV 7	PNEUMOCOCCAL CONJUGATE VACCINE
PPV23	PNEUMOCOCCAL POLYSACCHARIDE VACCINE
PTA	PURE TONE AUDIOMETRY
REAR	REAL EAR AIDED RESPONSE
RECD	REAL EAR COUPLER DIFFERENCE
REIR	REAL EAR INSERTION RESPONSE
SLT	SPEECH LANGUAGE THERAPIST
UKM	UNIVERSITI KEBANGSAAN MALAYSIA
VRA	VISUAL REINFORCEMENT AUDIOMETRY

THE POLICY





1.0 INTRODUCTION

- 1.1 Cochlear Implant Service is one of the important specialty services provided by otology surgeons, audiologists, auditory verbal clinicians and speech therapists for hearing impaired patients with the support and encouragement of the Medical Development Division, Ministry of Health (MOH) since 2006.
- 1.2 Patients with severe to profound sensorineural hearing loss will have little benefits from super power hearing aids. They are able to hear environmental sounds but not for speech information. Cochlear implant devices were invented to help these children in speech development as early as possible.
- 1.3 After successful surgery is done, the implantees must undergo an intensive audiological (re)habilitation period and Auditory Verbal Therapy sessions to optimize the act of listening. It is a continuous process that also involves the patient, family, parents/ caregivers (for paediatric patients), and medical/non medical professionals.

- 1.4 This policy document is intended to guide health care providers, hospital managers and policy makers on the referral, requirements, procedures and development of cochlear implant service in the Ministry of Health hospitals.
- 1.5 The document outlines optimal achievable standards in accordance with best practice and guidelines. It can be used as the best practice standards for all related professionals in cochlear implant management.
- 1.6 The document shall be reviewed and updated every three years or when the need arises.



2.0 OBJECTIVES OF SERVICE

- 2.1 To make realistic recommendations to the potential candidates and parents of affected children on the candidature and potential for benefits to hearing, speech and language development.
- 2.2 To ensure the cochlear implant program will be carried out safely, effectively and promptly.
- 2.3 To maximize the potential for the implantees to improve speech perception and articulation, to acquire language and development of communication skills through effective coordination of the multi disciplinary team approach.
- 2.4 To promote inclusive classes for the implantees in order to gain equal education opportunities with proper support services.



3.0 SCOPE OF SERVICE

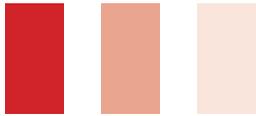
- 3.1 The National Cochlear Implant Program provides audiological, surgical and aural (re)habilitation management for hearing impaired patients requiring cochlear implants.

- 3.2 The National Cochlear Implant Program also provides financial support, counseling, parental support group, and also educational support.



4.0 COMPONENTS OF SERVICE

- 4.1 Audiology Assessment and Management
- 4.2 Pediatric Assessment
- 4.3 Clinical Otorhinolaryngology Evaluation
- 4.4 Radiology Investigation
- 4.5 Speech and Language Assessments
- 4.6 Auditory Verbal Therapy
- 4.7 Counseling Session
- 4.8 Financial Support
- 4.9 Education Support



5.0 COCHLEAR IMPLANT ORGANISATION

5.1 National Core Committee

5.1.1 The main function of the National Core Committee Of Cochlear Implant Programme is to advise the Ministry of Health in matters pertaining to selection of patient for the cochlear implant, management on manpower, training, equipment, budget and development.

5.1.2 The national committee will meet at least every 3 months to discuss the above matters.

5.1.3 The National Core Committee of Cochlear Implant consists of :

Chairman : National Advisor appointed by the MOH

Secretary : Audiologist

Elected Members : Senior Otologists / Neuro Otologists

Cochlear Implant Audiologist

Auditory Verbal Therapist

Speech Language Therapist

Pediatrician
Child Psychiatrist
Clinical Psychologist
Neuroradiologist / Radiologist
Ministry Of Education
Special Education Representative
Medical Aid Unit, MOH
Medical Social Worker

Consultants : Cochlear Implant Team UKM

5.2 Satellite Committee

- 5.2.1 The main function of the Satellite Committee is to identify suitable cochlear implant candidates, to conduct preoperative evaluation and assessment of cochlear implant patient, to perform surgery, and to conduct post implant rehabilitation and management.
- 5.2.2 The satellite committee shall received referral for suitable cochlear implant candidates from other non satellite hospitals in their respective region/zone.

5.2.3 The satellite committees are divided into zones :

North Zone

- i. Hospital Sultanah Bahiyah,
Alor Star Kedah
- ii. Hospital Ipoh, Perak

West Zone

- i. Hospital Sungai Buloh

South Zone

- i. Hospital Tuanku Ja'afar,
Seremban, Negeri Sembilan
- ii. Hospital Sultan Ismail,
Pandan, Johor Bahru, Johor

East Zone

- i. Hospital Sultanah Nur Zahirah,
Kuala Terengganu, Terengganu
- ii. Hospital Raja Perempuan Zainab II,
Kota Bharu, Kelantan
- iii. Hospital Queen Elizabeth,
Kota Kinabalu

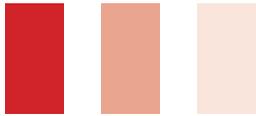
5.2.4 The satellite committee will include members from :

Otologist

Audiologist

Speech Language Therapist

Auditory Verbal Therapist/ Clinician
Neuroradiologist / Radiologist
Clinical Psychologist / Child Psychiatrist /
Pediatrician
Special Educationist
Social Worker



6.0 GENERAL STATEMENT

- 6.1 Cochlear Implant shall be considered for persons with a complete or severe to profound hearing loss and who do not attain sufficient benefits from traditional hearing aids.
- 6.2 Cochlear implantation should be considered only after an assessment by a multidisciplinary team, which should include a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).
- 6.3 When considering the assessment of adequacy of acoustic hearing aids, the multidisciplinary team should be mindful of the need to ensure equality of access. Tests should take into account a person's disabilities (such as physical impairments), or linguistic and other communication difficulties, and may need to be adapted. If it is not possible to administer tests in a language in which the person is sufficiently fluent for the tests to be appropriate, other methods of assessment should be considered.

- 6.4 The implant team must take into consideration medical, psychological, pedagogical, social, linguistic and family aspects. If old enough, the child should also be involved in the decision-making process. In all cases the final decision of whether or not to have an implant must be made by the parents.
- 6.5 The child shall have Auditory Verbal Training as a goal standard and method of communication used in the National Cochlear Implants Program.
- 6.6 The Cochlear Implant Team shall include all the necessary human and technical resources and experience on implants for assuring the following:
- Appropriate choice of the candidates, taking into account physical, neuro-physiological, psychological, audiological and family aspects;
 - High quality surgery avoiding side-effects;
 - Choice of the most appropriate device;
 - Programming by experts specialised in children;
 - Adequate and sufficient rehabilitation as well as every kind of support;
 - Close co-ordination among the professionals of the Programme;
 - Continuous follow-up of the implanted child and his/her family;
 - Technical maintenance of the device;
 - General support and advice for the child and the family.

- 6.7 Health authorities should create, and/or update, the minimum quality standards for the Cochlear Implant Programme. These quality standards must be relative to technical advances and to the required results. Health authorities must assure that the Cochlear Implant Programme follows these quality standards.
- 6.8 Cochlear Implant Programme must include the highest quality expertise and multi-professional teams. These teams must be specifically trained and sufficiently and adequately provided to meet the individual needs of each implanted child.
- 6.9 Post-implant rehabilitation and educational support are essential and they must be provided as long as needed. Special attention should be paid to the linguistic development of the child.
- 6.10 Once the decision of implantation is taken, the child should be operated without any delay.
- 6.11 Upgrades of existing components for “next generation” devices are considered medically necessary only for patients in whom response to existing components is inadequate to the point of interfering with the activities of daily living or when components are no longer functional.

- 6.12 Upgrades of an existing, functional external system to achieve aesthetic improvement, such as smaller profile components, or a switch from a body-worn, external sound processor to a behind-the-ear (BTE) model, are considered not medically necessary for all indications.



7.0 PRE-OPERATIVE COCHLEAR IMPLANT SERVICE

7.1 Initial Family Meeting

7.1.1 Target group :

Parents/ caregiver/ patient who are interested and selected for cochlear implant should attend initial family meeting with cochlear implant team in Satellite Hospitals.

7.1.2 The objectives of this meeting are to;

- a) Facilitate the exchange of information between family members and all service providers;
- b) Provide a forum for active family participation;
- c) Identify family priorities and concerns;
- d) Identify further services required by the family and the child

7.1.3 The meeting members shall discuss the following issues;

- a) Review audiological, educational and developmental progress of the child;
- b) Child's communication skills;

- c) Explanation of the cochlear implant and possible applications for the child;
- d) General overview of the surgical procedures, assessments and commitment required by the family;
- e) Funding for the cochlear implant;
- d) Contributions of the family, ENT Surgeons, Speech and Language Therapists and Audiologists in the cochlear implant candidacy evaluation process.

7.2 Initial Medical Assessments

7.2.1 The purposes of the initial medical referral to the team surgeon are;

- a) Obtaining full medical history including immunization for Haemophilus Influenza (Hib), family and social history;
- b) Patient will be assessed for relevant medical and developmental problems;
- c) Reviewing medical and audiological records. This may include obtaining medical records from the referring hospitals;

- d) If there are no apparent medical, surgical and radiological contraindications to implantation, the family is invited to join the Cochlear Implant Program for full candidacy evaluation. The patient is then referred for further investigations. All candidates are required to have a CT scan/ MRI during the evaluation period.

7.3 Pediatric Assessments

7.3.1 The purposes of medical referral to the paediatrician are;

- a) To determine whether there may be any other developmental, behavioral and medical issues which are contraindications to surgery or (re) habilitation;
- b) Paediatricians will perform medical and developmental assessments. There may be additional blood or imaging investigations required to provide information on associated disabilities or co-morbidities;
- c) Intelligent quotient (IQ) tests for suitability of the candidates;

- d) Psychologist will provide input related to the level of functioning and mental status of the child. The psychologist can also provide intervention when necessary or appropriate. For example, if family dynamics or behavioral problems present potential obstacles to success with a cochlear implant, the patient and family may be referred for counseling before and/or after cochlear implantation.

7.4 Clinical Otorhinolaryngology Evaluation

- 7.4.1 Complete systemic examination for medical and surgical problems.
- 7.4.2 Conducting a complete otorhinolaryngological examination.
- 7.4.3 Otoscopic examination to determine the status of ear canal, tympanic membrane and middle ear.

7.5 Radiological Investigations

- 7.5.1 CT Scan;
 - a) To determine the status of the cochlear that is suitable for insertion of the electrodes. Any physical impediment

to the placing of the electrode array in the cochlear or the receiver-stimulator in the mastoid bone must be evaluated and the implications explained and discussed with the family;

- b) Sedation or general anaesthesia may be used when appropriate.

7.5.2 Magnetic Resonance Imaging (MRI);

- a) To provide information regarding the integrity of the auditory nerves and other soft tissue;
- b) Sedation or general anaesthesia may be used when appropriate.

7.6 Audiology Assessments

7.6.1 The aims of audiological assessment pre operatively are to;

- a) Confirm the patient's audiological status;
- b) Ensure optimal hearing aid fitting and usage;
- c) Determine the patient's auditory sensitivity with hearing aids;
- d) Evaluate the patient's ability to make use of the auditory information perceived via his/her hearing aids;

- e) Quantify the patient's speech perception in aided condition.

7.6.2 Evaluation Of Patient's Auditory Status;

- a) Middle Ear Function – Tests
Tympanometry

- i) Tympanometry is a test to check the function of the tympanic membrane, ossicular chain, middle ear cavity and Eustachian tube function.

- b) Behavioural Tests

- i) Behavioural Observationm
Audiometry (BOA)

- ✓ This test can be performed on neonates and infants of less than 6 months of age.
- ✓ Certain noisemakers are used for this purpose such as rattles, chime bars and cymbals.
- ✓ Child's behavioural changes are closely observed to assess the child's auditory sensitivity to acoustic stimuli.

ii) Visual Reinforcement Audiometry (VRA)

- ✓ This behavioral test is used for hearing assessment in young children aged 6 to 30 months.
- ✓ The child needs to be able to sit unsupported or with minimal support and also have good head and neck control.
- ✓ The tested child will be preconditioned to respond to the stimuli, for example; flash of puppets in a darkened box as visual reinforcers.
- ✓ In the testing phase, visual reinforcements will be lighted up once a child correctly responds to a test stimulus.

iii) Play Audiometry

- ✓ This test is commonly performed in children between the age of 30 months to 7 years old.

- ✓ The child is trained to give a response only when the stimuli are presented using interesting activities such as putting in colorful pegs in the-board and etc.

- iv) Pure Tone Audiometry (PTA)
 - ✓ This is a standard method used to test older children and adults.
 - ✓ The patient is requested to press a response button whenever he/she hears a sound presented to them via a headphone.

- c) Objective Tests
 - ✓ These are computer-based tests that do not require subject's voluntarily responses.
 - ✓ Objective tests are must-do tests to establish hearing status of young babies less than 6 months of age.

- ✓ For a child less than 2 years of age, objective tests are performed to confirm the findings from behavioral measures, especially if the reliability of the behavioral test is questionable.
- ✓ These tests are also important to diagnose auditory neuropathy cases.
- ✓ The tests are:
 - i) Evoked Otoacoustic Emission (OAE)
 - ✓ The measurement from the ear canal by using a sensitive microphone within a probe assembly that records cochlear responses to acoustic stimuli.
 - ✓ It reflects the status of the peripheral auditory system extending to the cochlear outer hair cells.

ii) Auditory Brainstem Response (ABR) alone or ABR and Auditory Steady State Response (ASSR)

- ✓ The measurement that is obtained from surface electrodes that record neural activity generated in the cochlea, auditory nerve and brainstem in response to acoustic stimuli delivered via an earphone.
- ✓ It reflects the status of the peripheral auditory system, the eighth nerve and the brainstem auditory pathway.

- ✓ The ASSR can be an advantage as it allows the use of frequency specific stimulation from low to high frequencies, whereas the ABR only give information at high frequencies only.

d) Hearing Aid Assessment

i) Real Ear Measurements

➤ Real-Ear to Coupler Difference (RECD)

- ✓ The difference in decibels as a function of frequency between the outputs of a hearing aid measured in a real ear versus a 2-cc coupler.
- ✓ Useful calculation when fitting amplification on young children to avoid over amplification in their smaller ear canals.

- Real-Ear Aided Response (REAR)
 - ✓ The sound pressure level, as a function of frequency at a specified measurement point in the ear canal for the specified sound field with the hearing aid in place and turned on.

- Real-Ear Insertion Response (REIR)
 - ✓ The difference in decibels as a function of frequency between the real-ear unaided response and the real-ear aided response measurements taken at the same measurement point in the same sound field.

- Aided Sound-Field Threshold
 - ✓ This measurement is done by presenting sounds of different frequencies via a loudspeaker with the child's hearing aid being switched on.

- ✓ The test is meant to quantify the lowest sound pressure levels that could be detected by the child in the aided condition at various test frequencies ranging from 250 4000 Hz.

e) Evaluating The Functional Benefits Of The Hearing Aids

i) Outcome Assessment

- Purpose of this assessment is to document the benefits achieved through the hearing aid fitting.
- Tools to evaluate subjective and objective hearing aid benefit among older children and adult patient, e.g.;
 - ✓ Abbreviated Profile of Hearing Aid Benefit (APHAB);
 - ✓ Client-Oriented Scale of Improvement (COSI).

✓ Speech Perception Tests From The Ears Test Battery

- i) Ling sounds;

- ii) Listening Profile (LIP);
 - iii) Monosyllable Trochee Polysyllable;
 - iv) Open-set sentences.
 - v) Hearing In Noise Test
- f) Recommended Test For Suitability Of A Second Implant
- i) Assessing suitability for a second implant, two pre operative factors need to be established;
 - Unilateral performance of each ear individually with appropriately fitted hearing aid and compare its performance relative to that of a unilateral cochlear implant.
 - Binaural advantage from using two devices and the contribution of each ear to the bilateral score.
 - Recommended test sequence;
 - i) Right and left hearing aid separately in quiet;
 - ii) Bilateral hearing aid with competing noise presented to the better ear and speech from the front;
 - iii) Right and left hearing aids separately with competing noise

presented to the better ear and speech from the front;

- iv) Speech should be presented at normal conversation level of 60 dBSPL.

➤ **Structured Questionnaires For Parents**

- Meaningful Auditory Integration Scale (MAIS)
- Meaningful Understanding of Speech Scale (MUSS)

7.7 Speech And Language Assessment

7.7.1 Objective:

- a) To establish baseline levels of speech & language skills prior to implantation.
- b) To ensure that the patient is optimally aided and uses hearing aid consistently during awake hours.
- c) To provide stimulus-response training which is essential for post-operative rehabilitation (mapping/auditory training).
- d) To have a minimum trial period of 3 months of speech therapy with aided hearing for candidate suitability prior to cochlear implant.
- e) To prepare patient's final report and recommendations for discussion in final candidacy meetings.

- f) To liaise with associated professionals (medical teams, audiologist, educational bodies, clinical psychologist etc).

7.8 Immunization Recommendations For Cochlear Implant Recipients

- a) Cochlear implant recipients are at risk of developing bacterial meningitis. The implant itself being a foreign body may act as a nidus for infection. Other risk factors may include congenital abnormalities of the ear and cochlea, otitis media and immunodeficiency.
- b) It is therefore recommended that recipients of a cochlear implant should be vaccinated against the 2 commonest causative organisms Streptococcus Pneumonia and Haemophilus Influenza B.
- c) Below are the recommended schedules for vaccinating individuals according to age. Vaccinations should be done at least 2 weeks before surgery.
- d) Pneumococcal Vaccination Schedule

Age at first dose	Immunisation schedule
2-6 months	<ul style="list-style-type: none"> • 3 doses of pneumococcal conjugate vaccine (PCV7), 6-8 weeks apart • 1 booster dose of PCV7 at 12-15 months • 1 dose of pneumococcal polysaccharide vaccine (PPV23) at 2 years of age at least 8 weeks after the last dose of PCV
7-11 months	<ul style="list-style-type: none"> • 2 doses of PCV7 6-8 weeks apart • 1 booster dose of PCV7 at 12-15 months • 1 dose of PPV23 at 2 years of age at least 8 weeks after the last dose of PCV7
12-23 months	<ul style="list-style-type: none"> • 2 doses of PCV 7 6-8 weeks apart • 1 dose of PPV 23 at 2 years of age at least 8 weeks after the last dose of PCV 7
24-59 months Individuals ≥ 5 years old	<ul style="list-style-type: none"> • 2 doses of PCV 7 administered 8 weeks apart • 1 dose of PPV23 at least 8 weeks after the second dose of PCV7 • 1 dose of PPV23

e) Haemophilus Influenza Vaccination Schedule

Age at first dose (months)	Primary series	Age at booster dose (months)
2-6	3 doses , 2 months apart	15-18
7-11	2 doses , 2 months apart	15-18
12-14	1 dose	15-18
15-59	1 dose	

7.9 Selection Criteria

7.9.1 The respective periphery hospitals shall present a brief summary of relevant reports to the National Cochlear Implant Team. Members are required to comment on the suitability of the candidate for implantation.

7.9.2 The National Cochlear Implant Team will decide on the candidates list based on the candidacy criteria listed below. These criteria are used to determine the suitability of the referred candidates for cochlear implant.

- i) The age of the candidate;
 - For pre-lingual children, the child can be at or under 4 years old. But selection also depends on the audiological, speech assessment, surgical and pediatrics progress

reports on child's performance after hearing aid trial.

- There is no maximum age for cochlear implant consideration in crossover candidates and postlingual children and adults.

ii) Hearing Loss;

- The candidate should demonstrate;
- A severe-to profound hearing loss in both ears. The three frequencies average (3FA) at 500Hz, 1000Hz and 2000Hz for both ears must be more than 70 dBHL
- In cases of auditory neuropathy, a child with a lesser degree of hearing loss can be considered, if the child demonstrates minimal functional benefit from hearing aid (for example, total *Meaningful Auditory Integration Scale (MAIS)* score of less than 40%)
- In cases of postlingual adults, the

candidates should demonstrate minimal functional benefit from hearing aids as measured using open-set speech perception test and outcome assessment tools (eg Client Oriented Scale of Improvement (COSI)).

iii) Hearing Aid Trial;

- The candidate should wear a hearing aid consistently during waking hours (at least 6-8 hours hearing aid usage per day) on a daily basis for at least 3-6 months, except in special circumstances (i.e. meningitis) whereby shorter duration trial period could be considered.
- Aided thresholds using optimally fitted hearing aids at 2000Hz and above that fall outside the maximum speech range in the better ear.
- The candidate demonstrates minimal or no functional benefit from the hearing aid using objective measurement of speech

perception. Example of relevant information could be obtained from the following assessment;

- i) The 6 Ling Sound test;
- ii) Objective outcome measures for example using the EARS test battery, or the auditory skill placement test. For instance, showing no progress in the MAIS/ meaningful understanding of speech scale (MUSS) score over the trial period suggest that the candidate received a minimal functional benefit from the hearing aid;
- iii) Hearing in Noise Test (HINT) in quiet and noise, open set speech perception test score of less than 40%;
- iv) Outcome measures such as Client Oriented Scale of Improvement (COSI), Abbreviated Profile of Hearing Aid Benefit (APHAB).

- iv) Speech And Language Assessment;
 - The candidate does not or show only minimal improvement in terms of auditory or language skills despite consistent usage of hearing aids over the trial period.

- v) Surgical And Medical Considerations;
 - There should be no medical, surgical and radiological contraindications for cochlear implant surgery or rehabilitation.
 - Anticipated difficulties to the placement of the cochlear implant device into the appropriate position (based on CT scan or MRI imaging) must be evaluated and the implications accepted by all involved.

- vi) Family Issues;
 - Families/candidates should commit to a continuous auditory learning and assessment program offered by the team.
 - Families/candidates should be well motivated and able to attend all rehabilitation appointments necessary for optimal use of the device.

- Families/candidates need to have appropriate expectations and understand the potential and limitations of a cochlear implant.
- vii) Other Considerations;
- Educational and developmental assessments may identify potential difficulties for the audiological or rehabilitation program. The implications of these findings will be carefully discussed with the family and an appropriate plan agreed upon by all.
 - Any psychological and behavioral issues need to be addressed as well.
 - Post-lingual and crossover candidates must show commitment in continuing the auditory oral or auditory verbal method of communication.

7.10 Bilateral Cochlear Implantation

- 7.10.1 Candidates can be considered for bilateral sequential cochlear implantation when the following criteria are met;
- a) Must show binaural advantage with binaural hearing aid /bimodal fitting.

- b) Candidates/family must show interest to undergo the second implantation.
- c) Can afford costs for maintenance of head sets and accessories.
- d) Must show definite improvement in auditory skills or consistent progress in speech and language using single cochlear implant.
- e) Must have strong family commitment to continue post op audiological and speech rehabilitation.
- f) Candidate and family must have realistic expectations of second implant.
- g) Availability of adequate funding to support the second implant.
- h) Must have at least a 6 month experience with single cochlear implant except in cases of post-meningitis.
- i) Must have no medical or surgical contraindications.

7.11 Recommendation for Cochlear Implant

- 7.11.1 If the cochlear implantation is **RECOMMENDED**, then parents patients have to make the final decision. Upon decision to proceed with cochlear implantation a pre-operative consultation is arranged with

the team surgeon to discuss the following issues;

- a) Possible date for surgery;
- b) An overview of the surgical procedure;
- c) Potential surgical risks;
- d) Post-operative care;
- e) Precautions for cochlear implant users
e.g. sports, travel, infections;
- f) Available implant technology;
- g) Possible device complications.

7.11.2 Parents/patient may change their mind at any time after the meeting prior to the surgery.

7.11.3 If an implant is **NOT RECOMMENDED**, the candidate/parents will be informed verbally and in writing.

7.11.4 If an implant is not recommended or the family does not wish to proceed with a cochlear implantation, the patient will be seen by the SLT/audiologist in-charge to discuss alternative (re)habilitation plans.

7.11.5 Re-evaluation may be recommended at a later date based on case to case basis.

7.12 Cochlear Implant Funding;

7.12.1 Funding for this program will be obtained from the following sources;

- Ministry of Health.
- National Welfare Fund.
- Self funding.
- Other sources e.g. Non Governmental Organisation (NGO), insurance etc.

7.12.2 A letter to obtain financial assistance will be issued.

7.12.3 When funding is ready, the operation date will be scheduled.

7.13 Surgical Considerations;

7.13.1 The candidate will be reviewed as soon as possible after the cochlear implant candidacy meeting.

7.13.2 The surgeon will review the patient about a week prior to surgery to ensure that the patient's conditions are optimum for surgery.

7.13.3 Informed consent for cochlear implantation will be obtained at this time.



8.0 INTRA AND IMMEDIATE POST-OPERATIVE COCHLEAR IMPLANT SERVICE

- 8.1 All cochlear implant recipients shall have general anaesthesia service in the operating theatre.
- 8.2 The minimum standards for the safe conduct of anaesthesia in the operating theatre shall be strictly adhered to (Australia and New Zealand College of Anesthesiologists. T12000. Recommendations on Minimum Facilities for Safe Anesthesia Practice in Operating Suites).
- 8.3 Separation of children from parents or guardians prior to anaesthesia is to be discouraged.
- 8.4 While under anaesthesia, the patient may have a small amount of hair shaven from behind the ear. An incision is made behind the ear, which is later closed with sutures. Prophylactic antibiotic is given routinely in order to minimize infection risks.

- 8.5 The implant test is routinely done at the time of surgery whilst the patient is still under general anaesthesia. An audiologist will perform the implant test and NRT intra-operatively. An x-ray may be done to see the location of the implant.
- 8.6 The implant test is a quick, 2 minute test of the implant receiver / stimulator and electrodes. This test is routinely done directly after surgery, at switch-on and mapping sessions.
- 8.7 The implant test does not require sedation, and cannot be heard or felt by the patient.
- 8.8 The NRT is the recording of the auditory nerve electrical activity using the cochlear implants to both (i) stimulate the nerve, and (ii) record the nerve electrical's response.
- 8.9 The test result may provide useful objective information to assist the audiologist during the mapping session, especially at switch-on session. It is also useful in the case of children who do not show considerate behavioral responses to auditory stimulation. The NRT test is best done initially under anaesthesia, as the procedure is audible to the child, and may exceed upper loudness comfort levels.

- 8.10 Apart from the usual risks associated with any surgery and general anaesthesia, there are some specific complications that can be associated with cochlear implant surgery. Awareness of these risks is important, but the likelihood of them actually occurring is very low. The risks are:
- Facial nerve palsy.
 - Temporal nausea and balance problems (vertigo).
 - Wound infection / wound breakdown.
- 8.11 Very occasionally the tissue around the implant device may be infected. This may require removal of the device and re-implantation later.
- 8.12 The team surgeon needs to be contacted if any of these symptoms arise.

8.13 Guidelines in using the Back-up Implant

- 8.13.1 Below are possible scenarios when the Back-up Implant would be used. This document is recommended to be used as a guideline only. Thus, it may not contain all possible conditions when the back-up implant may be used.
- The stylet is stuck.

- The surgeon fails at the first attempt at pre-curved electrode array due to the possibility of damaging the lumen and opening a pathway to infection, the stylet holding the electrode array is not reloadable. In this case, the surgeon should not attempt to reload and should use the back-up. This also happens with poor scan interpretation where the insertion fails because it is too difficult and the array gets mangled.
- The implant is dropped or it comes out of the sterile field. In that case, it is better to use the sterile back up.
- If an intraoperative x-ray (Modified Stenver's view) suggests unusual electrode placement and the surgeon determines that the electrode is not in the cochlea and a pre-curved electrode array has been used (typically the stylet removed), it is recommended to use the back-up implant.
- If during surgery, impedance telemetry measures show multiple shorted or open electrodes.

- Open circuit electrodes – impedance is greater than 30 kOhms
- Short circuit electrode – impedance is lower than 700 Ohms in Common ground (CG) mode
 - * Impedance values obtained intraoperatively may be higher compared to those obtained during switch on. Need to have tissue or fluid to be in contact with electrode for valid impedance testing Skin flap should be over receiver/stimulator so that MP2 ground electrode is covered.



9.0 POST-OPERATIVE COCHLEAR IMPLANT SERVICE

9.1 Post Operative Care

- 9.1.1 The mastoid dressing shall be applied for about 2 days.
- 9.1.2 In uncomplicated cases, the patient shall be discharged after 2 days.
- 9.1.3 The wound shall be reviewed in about 2 weeks post-operatively before the device is switched on and during the switch-on session.

9.2 Switch-On Session and Subsequent Mapping Session

- 9.2.1 The implanted device shall be activated (switch on) after two to three weeks post-operation when the wound has healed.
- 9.2.2 A trained audiologist must perform the cochlear implant mapping.
- 9.2.3 For the first 3 years the mapping schedule will be as follows;
 - Weekly for 2 weeks;
 - Monthly for 3 months;
 - 3-monthly for 6 months;

- 6-monthly until 2nd year of rehab;
 - Annually or on need basis.
- 9.2.4 Electrodes that are not measured in the initial mapping session shall be measured in the second and subsequent visits.
- 9.2.5 A sound filed audiogram is obtained within the first month of switch on and regularly thereafter to determine the patients' ability to detect soft sound with the implant.
- 9.2.6 It is important to monitor the outcome of the program and carry out re-mapping procedures regularly to ensure each patient's learning potential is optimized.

9.3 Audiology Post-operative Assessment

- 9.3.1 The following are the assessment tools used;
- i) Aided sound field thresholds (using warble tones tested at 250 Hz – 4000 Hz).
 - ii) Selected EARS speech test battery which may include;
 - MTP (all age group) – syllable and word discrimination;
 - Close - set sentences (children who have acquired sufficient vocabularies);

- Open-set (Glendoland Auditory Screening Procedure) GASP sentences (children who have acquired sufficient vocabularies);
 - MAIS & MUSS questionnaires (all age group).
- iii) Paediatric Malay in Hearing in Noise Test (P-MyHINT)
- Open-set sentences tested in quiet and in noise with noise coming from the front (0° azimuth), left and right (90° azimuth to the left and right).

9.4 Auditory Verbal Therapy Session

- 9.4.1 The objectives of Auditory Verbal Therapy are;
- i) To develop optimal listening and language skills with the cochlear implant.
 - ii) To develop a team approach with other relevant professionals in order to promote optimum use of listening.
 - iii) To guide and empower parents to be the main facilitator of speech and language development.

- iv) To provide (re)habilitation in all areas of development.
 - v) To assist the child to acquire spoken language skills that is necessary to access learning in mainstream setting.
- 9.4.2 Non-formal or formal assessments may be used to gauge the child's progress in;
- Audition;
 - Speech;
 - Language;
 - Cognitive.
- 9.4.3 Any difficulties or problems relating to the patient's progress that cannot be settled by the Auditory Verbal Therapy/Clinician, Speech Language Therapist or Audiologist managing the child should be reported to the central team meetings as soon as they become evident. The Auditory Verbal Therapy/ Clinician, Speech Language Therapist or Audiologist in charge will be asked to at least submit a written report about the patient. Relevant professionals from the CI team will conduct the evaluation and make recommendations.
- 9.4.4 Methods Of Evaluation;
- Listening skills assessment based on hearing age development (3-6 month).

- Video analysis of parent's child interaction (every 3 – 6 months).
- Speech production and language sample analysis (every 6 – 12 months) .
- School & home visit (when necessary).

9.4.5 Candidates Who Do Not Show Progress

- Candidates who do not show much progress following one year of optimal (re)habilitation should be considered for Alternative Augmentative Communication (AAC) system. This should be reported to the CI Team and they should be referred for evaluation by the core team.
- Before being considered for an AAC;
- Refer the candidates for a team evaluation to state the appropriate recommendations and rationale.
- The implantees will be given a 6 months diagnostic window. The SLT will provide therapy during this period.
- At this time, the implantees may also be referred to related professionals such as a paediatrician for a developmental assessment or an occupational therapist (for a behaviour modification/cognitive development programme / pre-school readiness).

- At the end of the 6 months, the implantees will be reevaluated by a team. If appropriate, the professionals will discuss with the family on the AAC option and their recommendations.

9.4.6 Termination of (Re)Habilitation Program;

9.3.7.1 The following may be grounds for terminations of the post-operative (re)habilitation program;

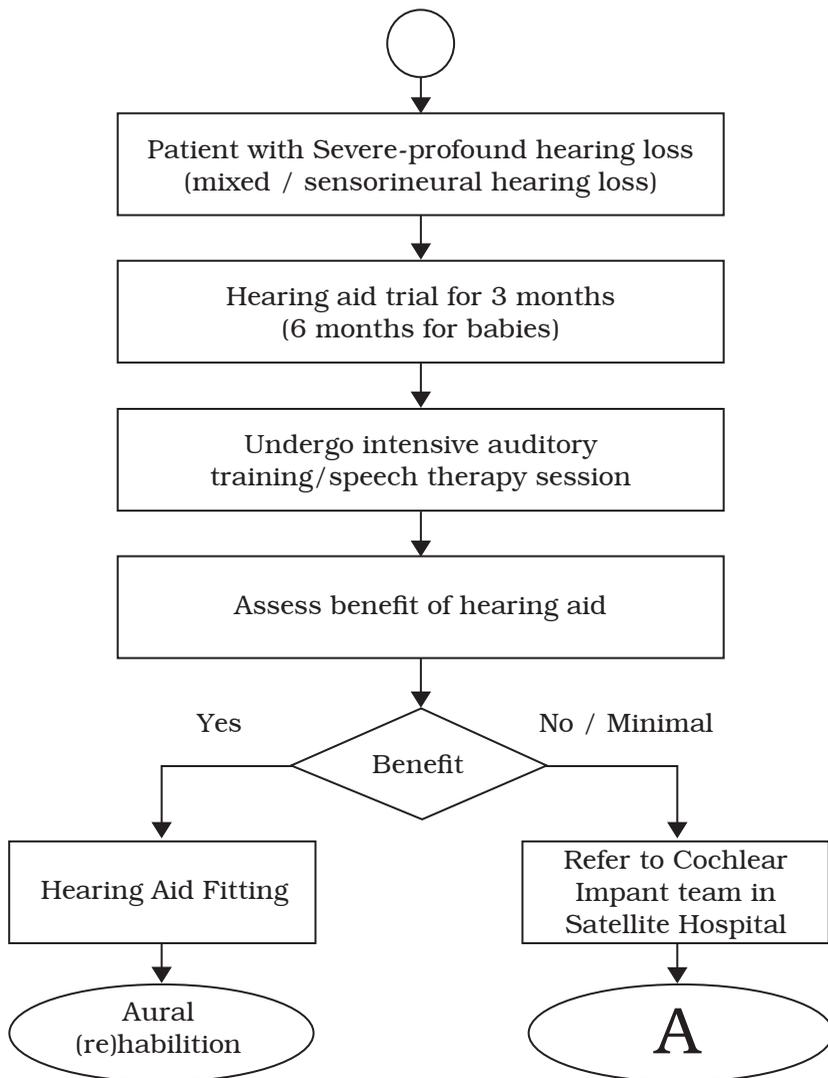
- Completed (re)habilitation successfully.
- Lack of parent commitment to attend regular post-operative (re)habilitation appointments.
- Implantee is not showing any progress and recommended for alternative augmentative communications (AAC) system.
- Any clinician who wishes to discharge an implantee from the (re)habilitation program due to the second or the third point above must first report this to the CI Team meeting and implantee will have to undergo a comprehensive evaluation.



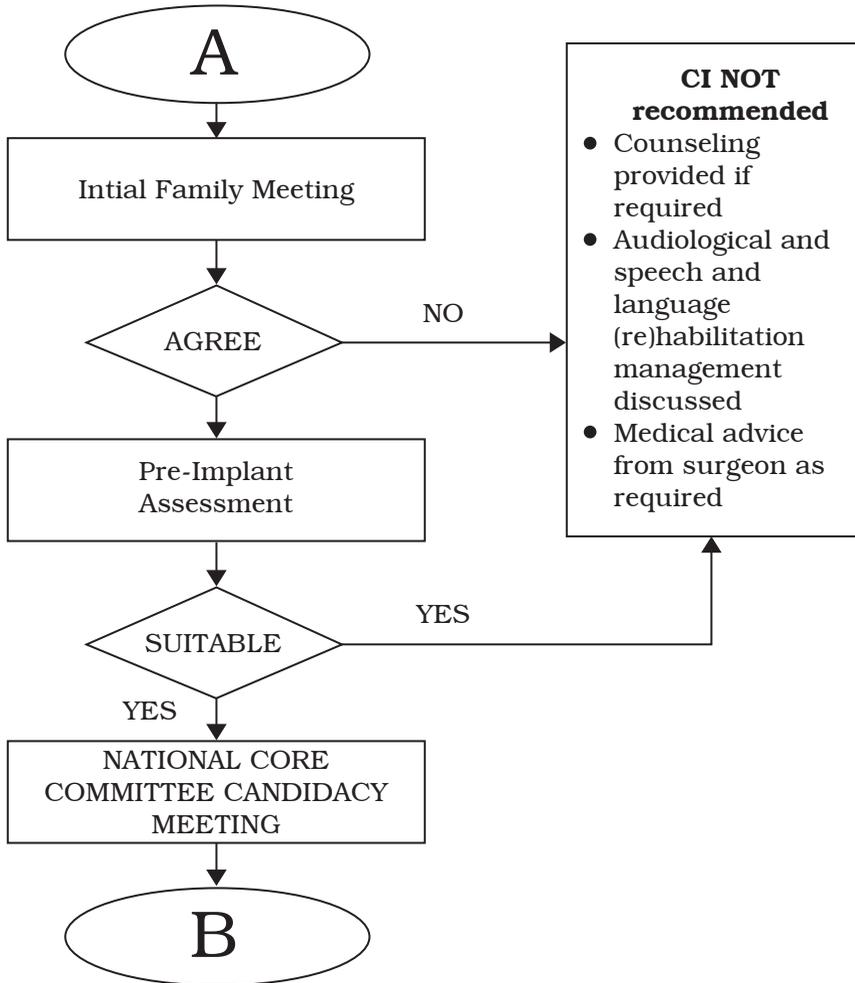
APPENDICES



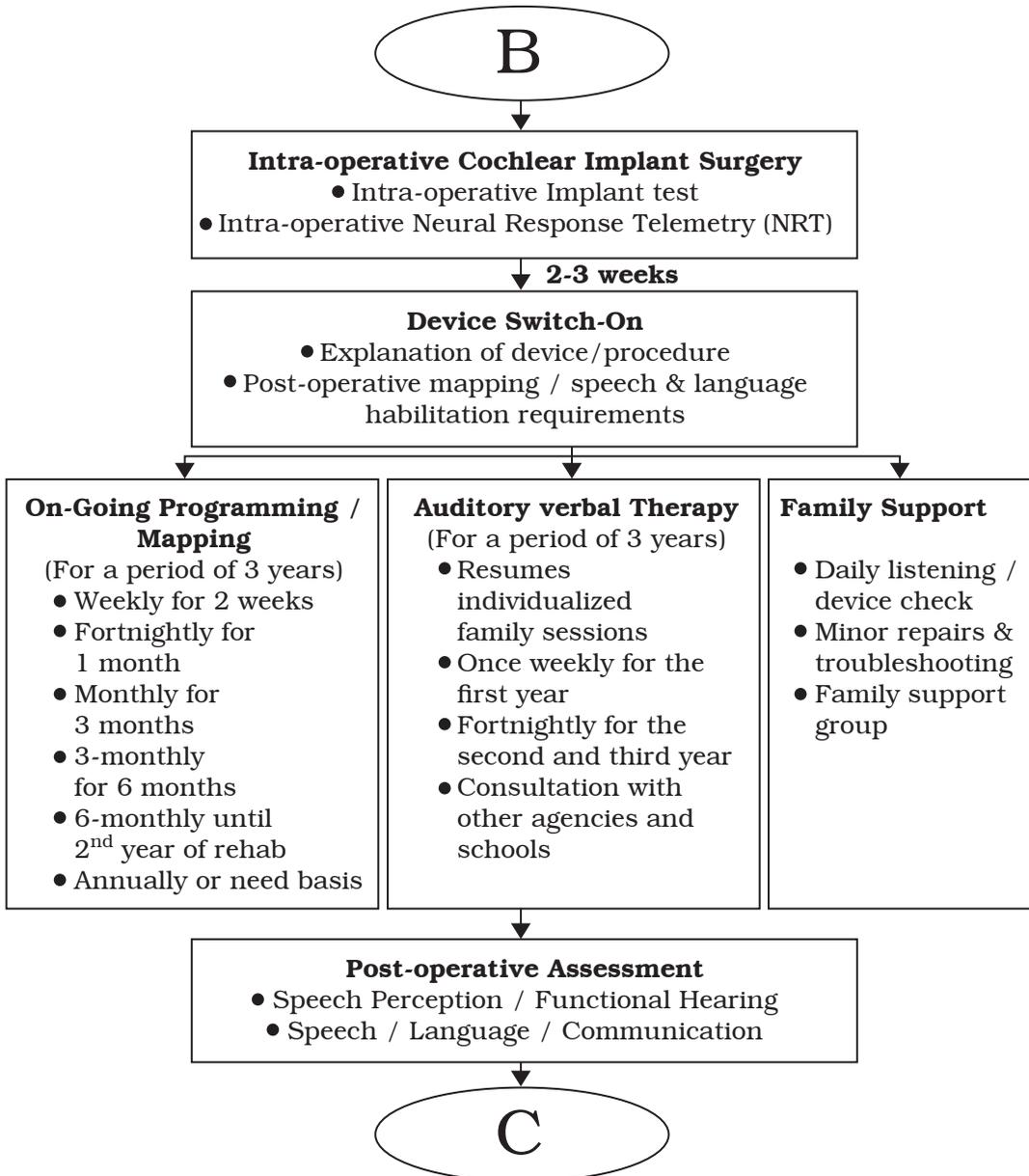
i. REFERRAL GUIDELINES FOR NON SATELLITE HOSPITALS



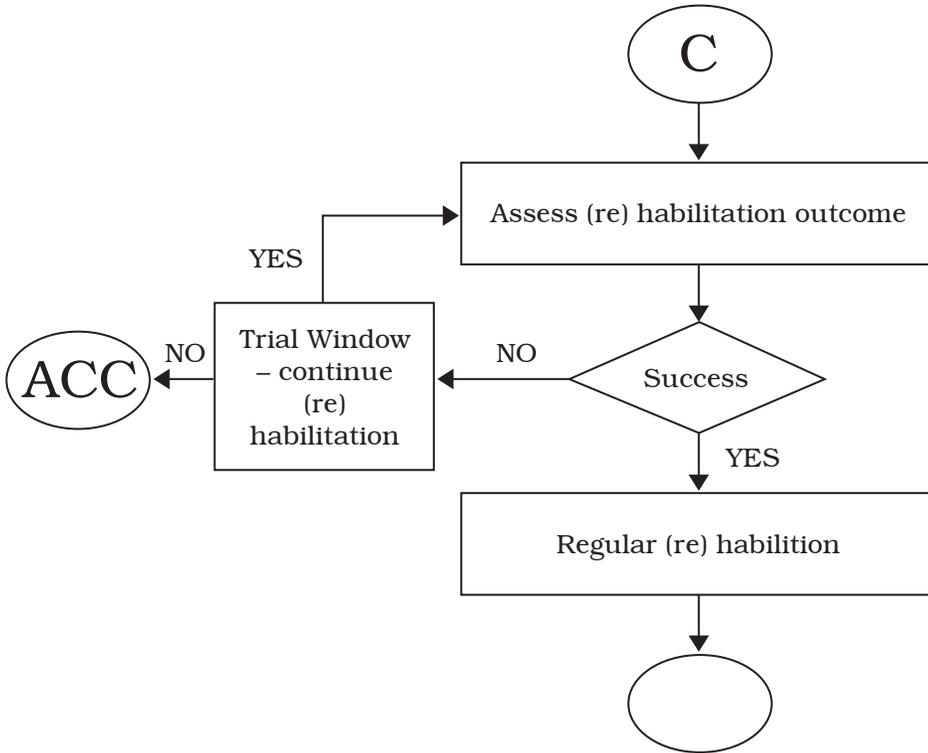
ii. PRE-OPERATIVE GUIDELINES



iii. PERI-OPERATIVE GUIDELINES



iv. POST- OPERATIVE GUIDELINES



v. TERM OF REFERENCE

- i) National Core Committee
 - a. To develop, review and update the policies, standard operating procedure and other related document of cochlear implant;
 - b. Develop clear, consistent criteria about which candidates are considered suitable for implantation;
 - c. To ensure the criteria developed are followed;
 - d. To regulate funding for implantation program among regional centers;
 - e. To ensure the involvement of experts from all relevant professions, ensuring a true multi-disciplinary approach;
 - f. To ensure safe surgical procedures performed with minimal impact and trauma;

- g. To ensure the surgical procedures performed by competence and credential implant team;
- h. To ensure all cochlear implant patients receive adequate post operative care and service;
- i. To ensure cochlear implantees receive appropriate education system and support
- j. To adequately develop facilities and equipments in regional centre for the purpose of cochlear implantation;
- k. To adequately develop human resources in regional centre for the purpose of cochlear implantation;
- l. To recognize the competency of regional centers for the purpose of cochlear implant program;
- m. To ensure an adequate training among cochlear implant team members;
- n. To establish national data base on cochlear implant program for the purpose of research and continuous quality improvement;

- o. To plan and modify with regards to effectiveness and expansion of the future programme; and
- p. To link up with other relevant programmes pertaining to cochlear implant such as universal hearing screening, preschool and early intervention programme.

ii) Satellite Committee

- a. To ensure all the policies and standard operating procedures established are followed;
- b. To select cochlear implant candidates based on the set criteria;
- c. To apply for implantation funding through National Core Team;
- d. To collect and provide data to the National Core Team;
- e. To involve experts from all relevant professions, ensuring a true multi disciplinary approach;

- f. To perform safe surgical procedures performed with minimal impact and trauma;
- g. To maintain facilities and equipments in their centre for the purpose of cochlear implantation;
- h. To ensure adequate human resources in their centre for the purpose of cochlear implantation;
- i. To ensure their cochlear implant team members are well and adequately trained;
- j. To provide parents and candidates with effective counseling and support whether or not receives an implant
- k. Give parents and candidates a realistic information about the potential outcomes for their child
- l. Ensure parents/candidates are provided with appropriate information as regards to cochlear implantation;

- m. Provide opportunities for families considering an implant for their child to meet other children, with and without an implant, and provide the opportunity to meet deaf adults;
- n. Ensure the candidates are, wherever possible, fully involved in the decision making process procedure; and
- o. To ensure all cochlear implantees receive adequate post operative care and service;
- p. To ensure cochlear implantees receive appropriate education system and support.

vi. REQUIREMENTS FOR PROFESSIONALS

a) Satellite Hospital

Recognized by the National Core Committee

b) Surgeon

Otologist/ Neuro-Otologist/ Pediatric ORL Surgeon Trained and attended hands-on cochlear implant courses Certified by the national core committee

c) Audiologist

Trained and attended hands-on cochlear implant courses Certified by the national core committee

d) Auditory Verbal Clinician

Trained and attended Auditory Verbal and cochlear implant courses Certified by the national core committee



NATIONAL CORE COMMITTEE OF COCHLEAR IMPLANT SERVICE

CHAIRMAN

Dr Abd. Majid bin Md Nasir

Head of Otorhinolaryngology Service
Ministry of Health, Malaysia

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Pn Nurul Huda bt Bani

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Audiologist

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En Amirudin b. Mohamed

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Pn Norhana bt Abu Seman @ Talib

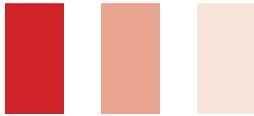
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