

Operational Guidelines for Sruthi Tharangam – State Cochlear Implantation project for children with Hearing Impairment

1. Introduction

Technological advancements have made it possible to identify hearing loss much early in life, ie; soon after birth. The early identification and intervention procedures initiated within six months of age would be the golden standard for the holistic development of a child with hearing loss.

One of the most dramatic developments in hearing and deafness has been the invention of cochlear implant. Over the past 35 years, the idea of restoring hearing to profoundly deaf patients by artificially stimulating the sensory system has now become a reality. Children with pre-lingual deafness do exceptionally well with cochlear implants and progress to acquire spoken language and produce intelligible speech.

In order to ensure optimum benefit hearing loss will have to be detected early and intervention should be started without loss of time. Lack of awareness at all levels about the overriding need for early detection of hearing impairment and early intervention, leads to late referral, thereby reducing the benefits of intervention.

A successful cochlear implant programme involves many steps from hearing screening to post operative rehabilitation. A coordinated multi - disciplinary approach is essential to ensure optimal outcomes. A successful cochlear implant programme cannot occur without a well resourced neonatal hearing screening programme, coordinated assessment programmes by audiology, speech pathology, educational and medical services and a dedicated audiology verbal therapy team for rehabilitation.

2. Objective

The objective of the project is to provide cochlear implant to children selected by Regional and State level technical committees for cochlear implantation and to provide financial support for auditory verbal habilitation (AVH) to operated children through empanelled hospital/ centres.

3. Name of the Project

Name of the project will be “*Sruthitharangam*”.

4. Scope of the project

The success of the project depends on several facts, like proper case selection, skill full surgery, effective auditory verbal habilitation, and motivated parents. Government will support, coordinate and follow up the project for effective implementation.

5. Mode of assistance

Government assistance fixed from time to time will be limited to supply of cochlear implant to children selected by technical committees and to give financial assistance for auditory verbal habilitation of implanted children, through empanelled hospitals. The scheme will not meet expenses for preoperative assessment, preoperative investigation, and treatment charges including operation, drugs and investigation etc. Repair and replacement charges of implants and accessories after warranty period will be met by parents. Cost of consumable which are not covered by warranty also will have to be met by parents. Parents should handle the external speech process with due care, otherwise it will be damaged. Damage to physical or accident causes are not covered warranty and any repair and replacement charges due to physical and / or mechanical damage will have to be met by parents.

6. Eligibility

Cochlear implantation is expensive and in addition to the cost of implant material there would be the expenses of surgery, post operative care, audiological mapping, trouble shooting and post implant habilitation.

There are a number of factors that determine the degree of success to expect from the operation and the device itself. Cochlear implant centres determine implant candidacy on an individual basis and take into account a person's hearing history, cause of hearing loss, amount of residual hearing, speech recognition ability, health status and family commitment to aural habilitation/ rehabilitation. It is on taking all this into account that the eligibility criteria have been laid down.

The eligibility criteria under the scheme are given below:

1. The child should be in the age group of 0-3 years. However the Screening Committee would be empowered to make exceptions beyond 3 years up to 5 years of age on a case to case basis; where the committee feel that a high possibility of success exists or if there are other compelling technical reasons warranting or making an exception.
2. The annual family income of the applicant should be below Rs. 2 Lakhs.
3. The applicant / parent should be a permanent resident of Kerala.
4. The child should be certified by a competent authority (under the scheme) regarding need for cochlear implantation surgery. There should not be any medical contradictions to surgery and or implantation.
5. The parents of the child should be prepared to undergo a mandatory training on speech therapy and post operative care.
6. Parents or Guardian of the child should give an under taking, in 100 rupees stamp paper, in the prescribed format as given in annexure 1.

7. Identification of candidates for cochlear implantation

- a). Institutions and specific doctors would be empanelled by Health & FW Department for screening / detection of children with hearing impairment. On empanelment the concerned centre would be 'competent authority' to certify the need of the child for Cochlear implantation surgery.
- b). The rates/charges for audiological test to determine extent of hearing loss will be notified by Health & FW Department with a view to ensuring uniformity.
- c). The Child Development Centre (CDC) will develop and rollout a community based programme model for early detection of hearing disability among children below the age of 3 years through the Anganwadi network. All children at risk should be referred to nearby audiological centre for screening.
- d). The costs of audiological tests for detection would have to be borne by the applicants.

- e). The parents/guardian of the child detected of hearing impairment, with a high chance of success after implantation may apply for cochlear implantation, to Kerala Social Security Mission (KSSM), in the prescribed format (Annex-2)
- f). The Health & FW Department will set up 3 Regional Screening Committees for technical screening of eligible patients. The K.S.S.M will forward applicants to the Regional Technical Committee concerned for screening.
- g). The Health and FW Department will set up three inspection committee for empanelment for private hospitals.

8. Empanelment of Institutions and Doctors

Health & Family Welfare Department will empanel hospitals and doctors considering their facilities for cochlear implantation surgery and rehabilitation, altogether. Hospital seeking for empanelment should apply in the prescribed application form as given in annexure 3.

a) Properly filled application with necessary documents should be submitted to Executive Director, Kerala Social Security Mission and the same will be forwarded to concerned regional inspection committee.

b) Inspection team will visit the hospital for physical verification of facilities and records. They will recommend empanelment considering all the three basic requirements for cochlear implant surgery ie, cochlear implant surgeon with adequate experiences, adequate infrastructure, instruments, equipments and facilities for implantation surgery and auditory verbal habilitation.

c) Any ENT surgeon who had performed 10 cochlear implant surgeries independently, with FDA (Food and drug administration) of USA approved implants will be considered as surgeon with adequate experiences.

d) All the requirements mentioned in the section 10,11,13 of the application form for empanelment is essential to meet the criteria for adequate infrastructure, instruments , equipments and facilities for implantation surgery and auditory verbal habilitation, except dual channel audiometry and laminar air flow. Relaxation for 1 year will be given to develop/install above the facilities/equipment from the date of this order.

e). Hospitals seeking empanelment should have either their own facilities for auditory verbal habilitation or should have tie up with centres with the manpower and facilities mentioned in the application form for empanelment.

f). Regional Inspection Committees will submit the inspection report to Kerala social Security Mission. Application recommended by Regional Inspection Committee will be forwarded to Health & FW Department for necessary orders.

g) Government Medical college, Kozhikode will be an approved centre for cochlear implantation programme as there is adequate expertise and infrastructure for cochlear implantation surgery. Other medical colleges will also be empanelled as and when they develop adequate expertise and manpower

h) Kerala Social Security Mission will prepare a format for memorandum of Understanding (MOU) with the empanelled hospitals based on this Government Order and other terms and conditions essential for smooth and successful implementation of the project. Empanelled hospitals should sign MOU with the Executive Director, KSSM.

i) Empanelment should be reviewed every two years or in the event of empanelled doctor leaving the institution. However the responsibility of auditory verbal habilitation of already operated children rest with the empanelled doctor who performed surgery. He should arrange further follow up of children either in same hospitals or another empanelled hospital.

9. State Level Technical Committee

The State Level Technical Committee will be constituted by the Health and Family Welfare Department to (a) shall finalise the selection of implants (b) develop TOR for empanelment of institutions and doctors (c) give technical advice to Govt. in the implementation of the scheme, (d) recommend standards and specifications, suppliers, rates and terms and conditions of procurement of cochlear implant devices, (e) laying down strict protocol for diagnosis and detection, intervention and rehabilitation, (f). scrutinise the applications referred by Regional Technical Committee and to decide surgery in the case of applicants who have completed 3 years at the time of application.

Executive Director, KSSM will be the convener of the committee, other members are Executive Director, NISH, two ENT professors from Government medical colleges and one ENT surgeon with implant experience from private sector. Committee is empowered to invite audiologist from Government sector for technical assistance during technical committee meeting.

10. Regional Technical Committee.

There shall be 3 Regional Technical Committee for the north, south and central regions and the constitution, location and responsibilities of the same shall be notified by the Health and Family Welfare Department. The concerned DMO shall be the convener of the regional committee. The Regional Technical Committee will be responsible for the scrutiny of application which are suitable for cochlear Implantation on the basis of the criteria of selection for cochlear implantation, preoperative assessments and investigation reports. The Regional Technical Committees are empowered to invite audiologists preferably from Government sector for Technical assistance during screening committee meeting. They are also empowered to call the child during the selection committee meeting for clinical assessment and counselling if required.

11. Criteria of selection of children

- a). Bilateral profound sensory neural hearing loss in children in the age group of 12 months to 18 months.
- b). Bilateral severe to profound sensory neural hearing loss in children in the age group of 18 months and above. Preferably before 3 years.
- c). However the Screening Committee would be empowered to make exceptions on a case to case basis; when the committee feel that a high possibility of success exists or if there are other compelling technical reasons warranting for making an exception.
- d). No or little benefit from strong power hearing aid after speech therapy for at least for 3 months.
- e). No associated cognitive impairment
- f). No medical or anatomical contra indication.
- g). Motivated parents to attend auditory verbal habilitation.

12. Preoperative assessment:

The preoperative assessment should include the following

- Audiological Evaluation
- Speech pathology assessment
- Otological Evaluation
- Intensive Speech therapy with properly fitting hearing aid, at least for three months.
- Initial family counselling.
- Anatomical evaluation

13. Preoperative investigations:

The preoperative investigation should include the following

1. BERA/ audiogram
2. ASSR
3. OAE
4. Tympanogram
5. Aided threshold BOA / audiogram
6. Speech – language test
7. HRCT of the temporal bone
8. MRI of head & inner ear.

14. Family Counselling

Candidates for cochlear implantation need to be informed of the potential risks and benefits of cochlear-implantation and the impact it may have on their life. The surgical procedure and its risks should be described along with a physical description and, preferable demonstration, of the internal and external portions of the device. The post surgical programming and rehabilitation procedures should be charted out and informed to the parents. The most important aspect here is to give a realistic expectation regarding performance outcome with the implant.

15. Surgery

a). The empanelled hospital will do the surgery according to the selection list prepared by Kerala Social Security Mission. Implants will be supplied to concerned hospitals by selected firms according to the supply orders issued by KSSM. After completion of surgery, the concerned hospitals should submit Delivery chalan, Operative note and a copy of implant registration form. Kerala Social Security Mission will release the payment to concerned cochlear companies after obtaining above documents and invoice from concerned companies.

b) Empanelled private hospitals will be permitted to charge an amount fixed by empowerment committee for surgery and post operative management from time to time. No other charges should be collected from parents for surgery and post operative care.

c) As and when required, empanelled private hospitals should permit two ENT surgeons and an audiologist from medical education department as observers during each implantation surgery under the scheme.

d). Empanelled government hospitals will meet cost of drugs and investigation which are not available in the hospital from HDS fund.

The choice of institutions for surgery will be done by the Kerala Social Security Mission after considering following factors.

(a). Interest of the parents.

(b). Willingness to pay the amount fixed by the Empowered committee if they are opting a private hospital.

(c). Domiciliary district of child.

(d). Availability of the facilities for cochlear implant in the Government sector.

Executive Director, KSSM will prepare centre wise priority list of selected candidates for surgery and submit it to the Secretary, Social Welfare Department for approval.

16. Rehabilitation

a). Empanelled hospitals will be responsible for mapping and two year long auditory habilitation. Empowered committee will decide charges for mapping and two year long auditory habilitation from time to time. Kerala Social Security Mission will release the amount in four instalments to private hospitals. The first instalment, (40 %) will be released

after getting copy of product registration and mapping report from concerned hospitals. Balance amount will be released in three equal instalments at six months interval after getting periodical progress and follow up reports from concerned hospitals. No amount should be collected from parents for auditory verbal habilitation.

b). No amount will be released to Government Hospitals for AVH, KSSM will provide minimum number of speech therapist on contract basis.

17. Funding

The expenses of cochlear implantation will be met from the budget provision of Government and through public mobilisation by KSSM.

18. Capacity Building

All key agencies and institutions will need to be trained in discharging their responsibilities under the scheme. DMO's, DSWO's and other stakeholders will be oriented about the scheme and its conditionality, NISH, CRC (Composite Regional Centre) and CDC will take lead role in the capacitating of key players.

19. Social mobilisation

Social mobilisation is focused on getting children to early detection and screening for optimum results and for mobilising sponsorship through the payment gateway of Kerala Social Security Mission. A range of communication media will be used for social mobilisation.

20. Implementation

The scheme will be jointly implemented by Social Welfare Department & Health and Family Welfare Department. Secretary (Social Welfare) will be the Nodal Officer and K.S.S.M will be the nodal agency.

Empowered committee with Minister (Panchayath & Social Welfare) as Chairman and Minister (Health & FW) as Co Chairman will be the supreme authority for making the policy decisions.

The Empowered committee will fix the surgery charges for private hospitals from time to time. Empowered committee will decide the charges for mapping and the two year long auditory habilitation from time to time.

State Level Monitoring Committee chaired by the Secretary, Social Welfare will monitor the implementation of the programme.

The following are the members of Empowered Committee:

- Minister (P & Social Welfare) - Chairperson
- Minister (Health & FW) - Co Chairperson
- Shri. Benny Behanan, MLA - Member
- Secretary, Revenue - Member
- Secretary, Finance - Member
- Secretary (H & FWD) - Member
- Secretary (Social Welfare) - Member
- Shri. G.Vijayaraghavan, Member,
State Planning Board - Member
- Director of Social Welfare - Member
- Director of Health Services - Member
- Director of Medical Education - Member
- Benny Joseph
Hridayathalam - Member
- Dr.P.M.Namboodiri - Member
- Dr.John Panicker
Santhwana Hospital - Member
- Dr.M.P.Manoj, ENT Hospital, Calicut - Member
- Dr.Ravi, MIMS - Member
- Dr.M.K.C.Nair - Member
- Dr.A.Sharafudeen, Al-Shifa Hospital,
Perinthalmanna - Member
- Executive Director, KSSM - Member, Convener

21. State Level Monitoring Committee

There will be a State Level Committee for (a) monitoring and review of implementation, (b) grievance redressal.

The composition of the committee will be as below:

Secretary (Social Welfare)	-	Chairman
Secretary (Health & Family Welfare)	-	Member
Secretary (Fiancne)	-	Member
Secretary (Revenue)	-	Member
DME	-	Member
DHS	-	Member
Executive Director, NISH	-	Member
Executive Director, KSSM	-	Member, Convener

22. Transparency

Hearing loss can now be detected at birth and children can develop fluent spoken language with the help of audition when intervened with appropriate intervention strategies like cochlear implantation and auditory verbal practice. This will enable the child's holistic development and successful integration into mainstream society and have better quality of life.

There will be complete transparency in the process of detection, implantation and rehabilitation of children with hearing impairment. The Kerala Social Security Mission will suo moto give the public full access to all relevant information.
