

Quality Standards for Minimal Outcome Measurements in Adults and Children

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1. Introduction

Cochlear implantation is a multidisciplinary therapy that involves, as a key element, the surgical implantation of an electrode array into the cochlea to provide direct electrical stimulation of the auditory nerve. Cochlear implants (CIs) are designed for individuals with hearing impairment to compensate for a moderate to profound sensorineural hearing loss, if there is little or no benefit from hearing aids. CIs bypass the non-functioning part of the auditory system in order to deliver electrical signals directly to the auditory nerve. They can be used effectively by both pre-lingually and post-lingually deafened children and adults.

Studies have shown that cochlear implantation is recognized as a safe and effective procedure. However, cochlear implantation practices and outcome measures vary greatly across cochlear implant centers. Only with the use of defined measures and reporting standards, that can be compared between languages and test centers, will clinicians be able to accurately assess the value of hearing implants and determine patient performance. Therefore, the HEARRING network, in their continued commitment to the highest standards of quality and to ensure a consistently high level of service and effectiveness of cochlear implantation have established this set of quality standards on minimal outcome measurements for determining patient performance.

2. Background

2.1 Why establish minimal outcome measurements?

An important step towards international multi-center research and collaboration on cochlear implants (CI) and other implantable hearing solutions (IHS), in both a clinical and scientific setting, is a consensus on a set of minimal outcome measurements. At the moment the approach for cochlear implant patient selection and post-operative patient management varies across CI centers and across countries. Some of these variations are due to legal and reimbursement differences across countries, however, many aspects of CI and IHS patient management could be harmonized across countries.

To optimally benefit from collective experiences and to realize multi-center comparative outcome studies for IHS, standards are necessary that define a common minimal set of outcome measurements. To be useful the resultant minimal outcome measurements need to address a number of defined criteria:

- a.** Outcome measurements should answer scientific criteria of simplicity, reliability, validity and sensitivity.
- b.** The measures ought to address dimensions that are important to the patient (symptoms, disability and the patient perspective) and useful to clinicians in their clinical work.
- c.** The measures should also be sensitive to meaningful changes in the patients hearing abilities, to reflect the outcome of treatment or intervention.
- d.** A useful outcome measurement should also address one of the World Health Organization (WHO) outcome domains of impairment, activities, participation or quality of life¹.

2.2 The role of the HEARRING network

The HEARRING network, a group of leading experts in the field of hearing implants “are committed to leading the exploration of new avenues of research in hearing implant science, to advancing clinical procedures and to developing and perfecting surgical techniques” (www.hearring.com). The prime objective of the HEARRING network is to provide patients with the best possible IHS for the treatment of their individual hearing loss. To achieve this the HEARRING network has formulated this set of standards on minimal outcome measurements in the field of CI, using two adult and one children’s questionnaire.

The results of these questionnaires have been used by the HEARRING network to establish a consensus on minimal outcome measurements in cochlear implantation for adults and children.

The consensus agreement of the HEARRING network may, but does not necessarily, overlap with the questionnaire outcomes. Both shall be presented in the following set of standards.

3. Outcome Measure Collection

3.1 Database search

To begin the collection of useful outcome measurements a PubMed US National Library of Medicine (<http://www.ncbi.nlm.nih.gov/pubmed/>) database search of the last two decades was conducted focusing on outcome measures applied in clinical trials that included patients with hearing implants. Such reports, published in English, were identified using the following keywords:

- Cochlear implants
- CI
- Bone anchored hearing aid
- BAHA
- Vibrant sound bridge
- VSB
- Auditory Brainstem Implant
- ABI

3.2 Expert opinion

Experts in the field of hearing implants were also asked to provide information on potential outcome measurements.

3.3 Questionnaire

Based on the database search and expert opinions two adult and one children's questionnaire were generated.

The questionnaires were sent to members of the HEARRING network and to attendants of the Hearing Preservation Workshop, Vienna, Austria in October 2009. A total of 32 researchers gave their feedback on minimal outcome measurements: 19 otorhinolaryngology surgeons, 12 audiologists and 1 speech language pathologist. The countries of residence of these experts were Argentina, Australia, Austria, Belgium, Brazil, China, Columbia, France, Germany, Great Britain, India, Poland, Russia, Spain, Sweden, Switzerland and the United States of America.

3.3.1 Scope

The adult questionnaires addressed which outcome measurements they would recommend and the level of importance they would give to the each outcome

measurement. Minimal test intervals, speech materials, sound levels for speech audiometry in quiet and in noise and calibration were addressed in another questionnaire. The children's questionnaire assessed cochlear implantation practices in children.

3.4 Data analyses

The questionnaire results were inputted and analyzed using Microsoft Excel. The number of respondents that recommended each test and the relative importance of each test were calculated in absolute and percentage values.

To reach consensus the outcomes of the questionnaires were discussed during HEARRING meetings in:

- Antwerp, Belgium, February 2010
- St. Petersburg, Russia, October 2010
- Bradford, UK, October 2011

4. Minimum Outcome Measures: Consensus in Adults

The members of the HEARRING network agreed that the Minimum Outcome Measures for adults are:

4.1 Test Intervals

Adult cochlear implant users should be evaluated at the following intervals:

- Pre-operatively
- 3 months after first fitting
- 6 months after first fitting
- 12 months after first fitting
- Yearly

This is in line with current clinical practice.

4.2 Test Measures

4.2.1 Unaided Tone Audiometry

Insert ear phones are recommended for air conduction unaided tone audiometry, e.g. ER3A, ER5A.

Pure tones should be tested at 125, 250, 500, 1000, 2000, 4000 and 8000 Hz.

Bone conduction thresholds should be tested at 250, 500, 1000, 2000 and 4000 Hz.

4.2.2 Aided Tone Audiometry

Aided tone audiometry should be tested in free field at ear level. The sound source should be placed 1 meter from the listener.

Warble tones should be tested at 250, 500, 1000, 2000, 4000 and 8000 Hz.

4.2.3 Speech audiometry in quiet

Speech audiometry in quiet should be performed unaided and in the best-aided condition, pre-operatively.

Post-operatively speech audiometry in quiet should be performed with an active hearing implant.

Speech audiometry in quiet should be performed in free-field, with the speaker at ear level, 1 meter from the listener, at 0° azimuth.

When performing speech audiometry in quiet the minimally required speech testing material are monosyllables, using a fixed speech level.

For languages that do not use monosyllables, bisyllable words is the recommended speech material.

The ideal level of testing is 65 dB SPL.

Sentence testing should also be performed unaided pre-operatively and aided post-operatively.

4.2.4 Speech audiometry in noise

Speech audiometry in noise should be performed unaided and in the best-aided condition, pre-operatively.

Post-operatively speech audiometry in quiet should be performed with an active hearing implant.

Speech audiometry in noise should be performed in free-field, with the speaker at ear level, 1 meter from the listener, at 0° azimuth.

When performing speech audiometry in noise the minimally required speech testing material are Sentences, using an adaptive speech level.

Where adaptive material is not available in the test language a fixed procedure should be used.

The adaptive procedure used for speech testing in noise should be with a fixed noise level and adaptive speech level.

4.2.5 Other

A number of other tests recommended in the adult survey were discussed, which included:

- Tinnitus analysis
- Tympanometry
- Auditory Brainstem response

- Electrically evoked compound potential
- Electrical stapedial reflex threshold
- Sound localization test
- Auditory steady state response
- Electrocochleography
- Promontory stimulation

These tests do not need to be part of the minimal outcome measurements for IHS. These additional tests are better utilized in hearing research.

4.3 Questionnaires

The HEARRING network recommends that sound quality is determined using the Hearing Implant Sound Quality Index (HISQUI) Questionnaire.

4.4 Calibration of equipment

The HEARRING members recommend that centers calibrate their equipment on a yearly basis in dB SPL.

5. Minimum Outcome Measures: Consensus in Children

The members of the HEARRING network agreed that the Minimum Outcome Measures for children are:

5.1 Treatment

Children with a pre-lingual or post-lingual hearing loss should be considered for IHS in all centers.

Children with a severe to profound hearing loss (71- 95 dB HL) should most certainly be treated.

However, with the advent of electric acoustic stimulation (EAS), children with a hearing loss that is 'ski-slope' in nature should also be considered for treatment.

5.2 Implantation

In the best case scenario children should be implanted bilaterally, simultaneously.

In instances where bilateral simultaneous implantation is not possible, bilateral sequential implantation is preferred to unilateral implantation only.

5.3 Hearing Aid Trials

As most centers required children to have a hearing aid trial prior to implantation the length of time the hearing aid trial should be conducted was discussed.

The HEARRING network recommends that the duration of a hearing aid trial should not be a defined period.

The duration of the hearing aid trial is determined by the need to ensure accurate diagnosis and to establish that there is limited further development of the child's auditory skills.

5.4 Test Intervals

Pediatric cochlear implant users should be evaluated at the following intervals:

- Pre-operatively
- 3 months after first fitting
- 6 months after first fitting
- 12 months after first fitting

- Yearly

5.4 Test Measures

5.4.1 Unaided Tone Audiometry

Insert ear phones are recommended for air conduction unaided tone audiometry, e.g. ER3A, ER5A, when possible.

Under circumstances where air conduction unaided tone audiometry is not possible, audiometry should be conducted using warble tones, through loud speakers.

Pure tones should be tested at 125, 250, 500, 1000, 2000, 4000 and 8000 Hz.

For bone conduction pure tones should be tested at 250, 500, 1000, 2000 and 4000 Hz.

Depending on the developmental abilities and age of the child the amount of frequencies tested can be limited.

5.4.2 Aided Tone Audiometry

Aided tone audiometry should be tested in free field at ear level. The sound source should be placed 1 meter from the listener.

Warble tones should be tested at 250, 500, 1000, 2000, 4000 and 8000 Hz.

Depending on the developmental abilities and age of the child the amount of frequencies tested can be limited.

5.4.3 Pre-operative tests

Pre-operatively the minimum test requirements for children are:

- Behavioral Thresholds
- Pediatric Speech Tests
- Otoacoustic Emissions
- Auditory Brainstem Responses
- Auditory Steady State Responses
- Mode of Communication.

These tests should always be performed where possible; based on the child's developmental abilities and age.

To aid the differential diagnosis of hearing loss a battery of these tests should ideally be used for accurate assessment.

5.4.4 Post-operative tests

Post-operatively, the measures considered the minimal requirement depend upon the age and developmental abilities of the child.

5.4.5 Speech audiometry in quiet

It is often difficult to perform speech audiometry in quiet with the co-operation of children. Thus, the HEARRING group recommends that testing should be performed, where possible, based on the child's developmental abilities and age.

Under circumstances where speech audiometry in quiet can be performed procedures in accordance with the adult standards (4.2.3) should be adhered to.

Speech material used should be adjusted to the child's age and developmental abilities.

5.4.6 Speech audiometry in noise

It is often difficult to perform speech audiometry in noise with the co-operation of children. Thus, the HEARRING group recommends that testing should be performed, where possible, based on the child's developmental abilities and age.

Under circumstances where speech audiometry in noise can be performed procedures in accordance with the adult standards (4.2.4) should be adhered to.

Speech material used should be adjusted to the child's age and developmental abilities

5.5 Questionnaires

In the pediatric cochlear implant population the most important auditory questionnaires recognized by the HEARRING network are:

- Categories of Auditory Performance
- Speech Intelligibility Rating
- The Auditory Skills Checklist
- LittleEARS Auditory Questionnaire*

These questionnaires yield consistent data that is language dependent and suited towards use in a registry.

Registries are a source of inexpensive data collection that: broaden the results of a clinical trial; create a set of heterogeneous data; aid in the determination of the effectiveness of a device; and allow for greater post-market surveillance, which is required by the EU and other regulatory authorities. Moreover, the use of the aforementioned questionnaires provides an overview of auditory perception skills as well as speech intelligibility over time and for all ages*. Thus, these questionnaires are of considerable importance to all HEARRING centers.

*The LittleEARS auditory questionnaire's value is predominantly for very young children.

5.6 *Language Development Assessment*

The members of the HEARRING network recommend that language tests should cover:

- Receptive vocabulary
- Receptive grammar
- Expressive vocabulary
- Expressive grammar

A standard test in the child's language should be used; for example the Reynell Developmental Language Scales, which has been adapted into several languages.

Results of the tests should be presented as a t-value; a value used to compare the children with a hearing loss' outcome to a normalized group of hearing children. If T-values are not available for the specific test used, the members of the HEARRING network recommend using percentage values instead.

6. Conclusion

In conclusion the information presented herein establishes a basic set of minimal outcome measurements that can be used for monitoring and standardizing clinical practice. In addition, the minimal outcome measurements can be used as a guideline for data collection and the establishment of a registry.