

# Special Report No. 3

Basic Information on Hearing

## Who gets a Cochlear Implant?

An overview of international criteria for cochlear implantation  
Germany, United Kingdom, France, Western Australia, Saudi Arabia, Republic of Korea

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## Foreword: Ingeborg Hochmair

When my husband, Erwin, and I started research into Cochlear Implants (CI) in the 1970s, we entered uncharted waters. The idea of being able to provide such a large number of hearing-impaired with implants was unthought of. Today about 320,000<sup>1</sup> people worldwide are using one or more implants. A success, but still too few. Many hearing-impaired people are even now not provided for, especially in economically disadvantaged countries. The developed countries also have a lot of catching up to do, especially concerning adults. One reason for this under-supply is that guidelines and candidacy criteria are missing: many lay people and even some experts, do not know for which degree of hearing loss an implant is an option.

That is why we are publishing this Special Report. It provides a basis for discussion for ENT doctors and patients, for audiologists, speech therapists and all interested members of the health services. Discussions are taking place in many different countries at this moment and because of this, as you read these lines, criteria are being changed in some of those countries. Just like technology, people's circumstances and attitudes are continuously developing.

We believe that every person should have the right to decide for themselves which hearing aid they wish to use. If an implant is medically and audiologically approved it should be provided if the patient so wishes.

In this spirit, I wish you informative reading and inspired discussions.

Yours  
Ingeborg Hochmair  
CEO MED-EL Medical Electronics

<sup>1</sup> National Institute on Deafness and Other Communication Disorders. WWW: <http://www.nidcd.nih.gov/health/hearing/pages/coch.aspx> (2014-12-12)

# Introduction

Everything started in the 1970s when the first deaf people were provided with a micro-electronic multi-channel Cochlear Implant (CI). Compared to single-channel implants, these could reproduce different tone pitches. The technology was ground-breaking.

However, cochlear implants were more expensive than hearing aids and the awareness of the importance of hearing was barely developed. Initially, access was limited: from the 1970s until the early 1990s the only people to receive an implant were those who had completely lost their natural hearing. Someone who could no longer hear his grandchildren, but could still hear a jack hammer, was simply given a hearing aid. Neither, at that time, were children considered appropriate candidates, nor was the person who was deaf in only one ear eligible for an implant. The bilaterally deaf received an implant in one ear only.<sup>2</sup>

People today are increasingly aware of the effects of hearing loss

Today, things are different to 40 years ago: considerably more people receive an implant now. Presumably, the main reason for this is that people today are increasingly aware of the effects of hearing loss. For example, in some countries, deaf children won't be able to attend a mainstream school and thus may later be unable to tap their full potential. Elderly people who suffer from hearing loss retreat more and more from society even though they might still have much to contribute. It is out of this awareness that, over the years, the criteria for implantation have been improved. Today, someone who can only understand 50% or less of what is spoken in a test room typically fulfils one criterion for implantation.

### New times –new challenges

So, times have changed: technology, already at the cutting edge advances every day. Good examples of this are the recent developments in sound-processing and wearer comfort.

But all is not yet rosy. Although more people worldwide receive implants than four decades ago, not every person with hearing loss is yet treated accordingly, even though they would clearly benefit from cochlear implantation.

Children are generally better off: for example, in the Flanders area of Belgium an estimated 93% of those children who are eligible have received an implant. In the United Kingdom and some other European countries it is over 90%. In the USA on the other hand, only 50% of those children who would benefit from an implant are actually using one. With adults the situation is even worse: in the USA only 5% of potential candidates are provided with an implant; in Europe and Asia it is even less.<sup>3</sup>

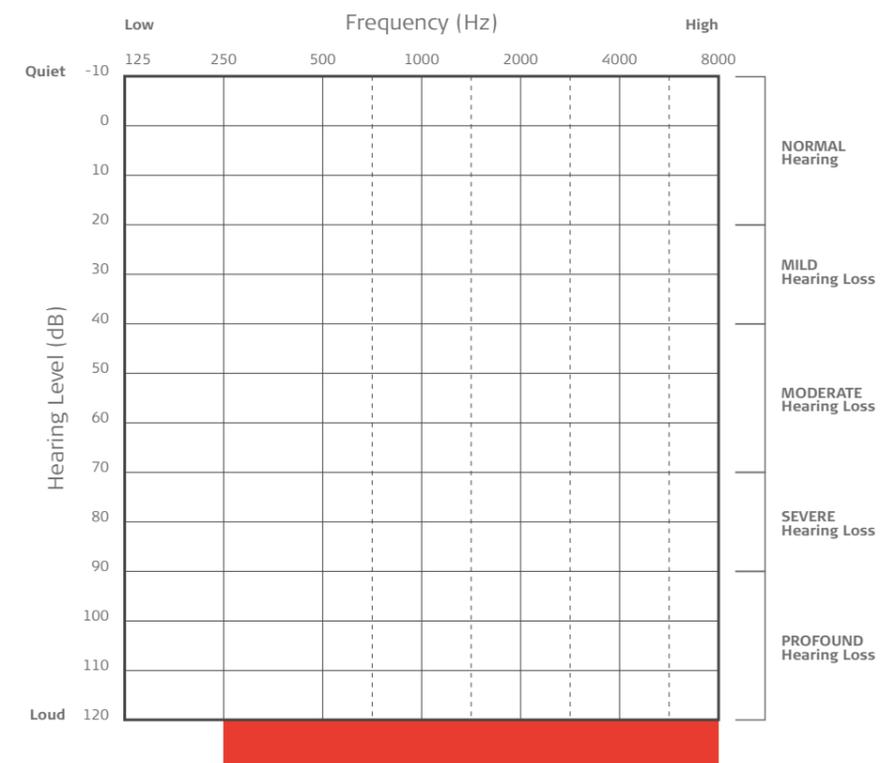
### Guidelines facilitate access

Donna L. Sorkin, from the American Cochlear Implant Alliance, says there are several reasons for this<sup>3</sup>: little awareness amongst the population as well as health-care professionals, missing or insufficient funds, and relatively strict criteria.

According to Sorkin, one single measure could put things right in most cases: clear and binding criteria as a guideline for potential implant users and experts in the area of hearing implants. These guidelines are missing in many places. Where they exist, they are not necessarily binding and in some places they do not correspond with the status quo of science and technology.

Some countries have started to establish consistent guidelines for the provision of hearing implants. This report gives an overview

The original cochlear implant candidate



<sup>2</sup> R.K. Najran: „Indications for Cochlear Implants“. IFOS Korea 2013, WCA Brisbane 2014

<sup>3</sup> D. L. Sorkin: "Access to cochlear implantation". Cochlear Implants International, Vol. 14, No. 51. W. S. Maney & Son Ltd 2013

The HEARRING Network set a good example in 2013 when it published its quality standards for hearing implants.<sup>4</sup> They include guidelines for cochlear implantation in adults, children, and adolescents, for middle-ear implants and (re)habilitation as well as for the measurement of the most important outcomes after the implantation.<sup>5, 6, 7, 8, 9</sup> The work of the HEARRING Network could serve as a model: it sets a necessary milestone and is a step forward towards a future in which more and more hearing-impaired and deaf people will be eligible for implantation.

Some countries have started to establish consistent guidelines for the provision of hearing implants. This report gives an overview of the criteria of selected countries. We chose six countries from four world regions as examples: Germany, United Kingdom, France, Western Australia, Saudi Arabia and the Republic of Korea (South Korea).

## Europe

### GERMANY

In Germany, research is very significant in informing policy decisions. Policy-makers act to take advantage of the newest developments and make sure that the German people benefit from them. Hearing-impaired and deaf people receive the best possible care as well as access to up-to-date testing procedures. The official guideline of the German Society for Ear, Nose and Throat Medicine and Head and Throat Surgery is based on the every-day life of the future implant-user.<sup>10</sup> Additionally, the guidelines consider each patient's individual needs.

In Germany, the following hearing implants from MED-EL are approved:

Cochlear Implants,  
Electric Acoustic Stimulation (EAS),  
Middle Ear Implants,  
Auditory Brainstem Implants and  
Bone Conduction Implants.

### The indications

According to the guidelines, cochlear implants are an option for all patients who are likely to hear and understand speech better with an implant than with a hearing aid.

Candidates for CI are children, adolescents and adults who lost their hearing after speech acquisition, as well as children who fully or partly lost their hearing before or during speech acquisition. In exceptional cases, adults who went deaf before acquiring speech are implanted if it is medically and audiologicaly indicated.

There is essentially no age limit for implantation. Children are generally implanted from six months of age, because only then is it clear whether they can hear or not. If both ears are affected, the child will be implanted on both sides. Adults also receive an implant in each ear if medically and audiologicaly indicated. For both, adults and children, bilateral implantation is possible either in two separate surgeries, allowing some time between, or at the same time (sequential or simultaneous). In case of single-sided deafness, either a cochlear implant or an EAS System (Electric Acoustic Stimulation) may be an option.

### The tests

A candidate's hearing is checked by various tests. Standard audiological procedures are pure tone and speech audiometry, testing and optimising the candidate's hearing aid (including audiometric procedures in sound field), objective measures and impedance audiometry are included. Radiological procedures such as CT and

<sup>4</sup> J. Müller, C.H. Raine: "Quality Standards for adult cochlear implantation". Cochlear Implants International. Vol. 14, 2013.

<sup>5</sup> J. Müller, C.H. Raine: "Quality Standards for adult cochlear implantation". Cochlear Implants International. Vol. 14, 2013.

<sup>6</sup> J. Martin, C.H. Raine: "Quality Standards for adult cochlear implantation in children and young adults". Cochlear Implants International. Vol. 14, 2013.

<sup>7</sup> G. Godey: "Quality Standards for middle ear implantation". Cochlear Implants International. Vol. 14, 2013.

<sup>8</sup> J. Martin: "Quality Standards for (re)habilitation". Cochlear Implants International. Vol. 14, 2013.

<sup>9</sup> A. Kleine Punte, P. Van de Heyning: "Quality Standards for minimal outcome measurements in adults and children". Cochlear Implants International. Vol. 14, 2013.

<sup>10</sup> Leitlinie der Deutschen Gesellschaft für Hals-Nasen-Ohren-Heilkunde, Kopf- und Hals-Chirurgie e. V., Bonn: "Cochlea-Implantat Versorgung und zentral-auditorische Implantate". AWMF-Register-Nr.: 017-071. 05/2012. WWW: [http://www.awmf.org/uploads/tx\\_szleitlinien/017-071L\\_S2k\\_Cochlea\\_Implant\\_Versorgung\\_2012-05\\_01.pdf](http://www.awmf.org/uploads/tx_szleitlinien/017-071L_S2k_Cochlea_Implant_Versorgung_2012-05_01.pdf) (2014-12-07)

MRI scans are done to check whether the auditory nerve and auditory pathways are working. In children, paediatric audiologists assess the child's hearing as well as their speech and language development and communication skills.

The guidelines do not include any specific parameters for the setting of hearing and speech tests. For adults, clinics usually use the following values: a person qualifies as a candidate from an audiological standpoint, if they only hear unaided acoustic signals from 70dB. This roughly equates to the volume of a running car engine at a distance of 10 metres. Testing frequencies are from 250Hz to 8,000Hz. Additionally, candidates must perform speech tests with hearing aids. The level of presentation is at 65dB, which can be compared to a clear conversational level. The patient is considered a candidate if he understands a maximum of 50% monosyllables spoken (monosyllabic test) and a maximum of 60% of sentences in background noise (Hearing-in-Noise Test).<sup>11</sup>

#### UNITED KINGDOM

The UK's official guideline was issued by the National Institute for Health and Clinical Excellence (NICE) for the first time in 2009 and is currently being reviewed.<sup>12</sup>

The United Kingdom is not among the leading countries when it comes to up-to-date guidelines. For example, the testing of only two frequencies (2kHz and 4kHz) does not reflect a realistic setting, since healthy natural hearing accommodates frequencies between approximately 20Hz and 20kHz. Also, technological progress and modern surgery techniques are barely factored in by the current guidelines. The decision-makers know about the weak points of the guidelines, which is why they are currently being reviewed.

In the UK, the following hearing implants from MED-EL are approved:

- Cochlear Implants,
- Electric Acoustic Stimulation (EAS),
- Middle Ear Implants,
- Auditory Brainstem Implants and
- Bone Conduction Implants.

#### The indications

Currently, unilateral cochlear implantation is recommended when a person with severe to profound hearing loss (for definition see "The tests") is unable to sufficiently hear sound when using an acoustic hearing aid.

<sup>11</sup> R.K. Najran: "Indications for Cochlear Implants". IFOS Korea 2013, WCA Brisbane 2014

<sup>12</sup> National Institute for Health and Clinical Excellence: NICE technology appraisal guidance 166, "Cochlear implants for children and adults with severe to profound deafness". Published January 2009, reviewed February 2011. WWW: <http://www.nice.org.uk/guidance/ta166/resources/guidance-cochlear-implants-for-children-and-adults-with-severe-to-profound-deafness-pdf> (2014-12-07)

NICE recommends a simultaneous bilateral implantation for

- children with severe to profound hearing loss, who do not hear adequately with an acoustic hearing aid
- adults who are blind or who have other disabilities that increase their reliance on their hearing for spatial awareness.

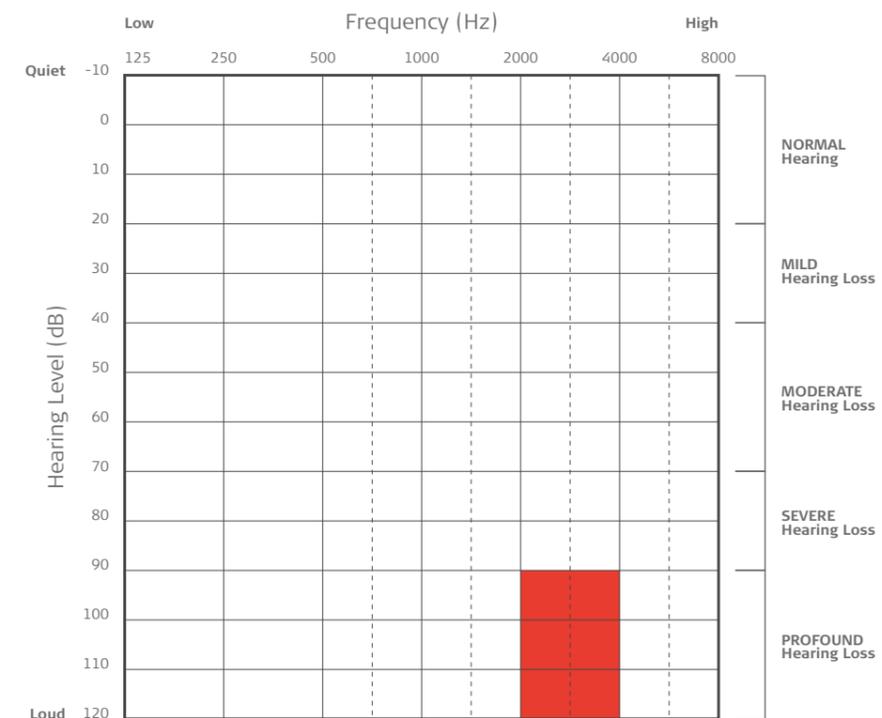
Sequential bilateral cochlear implantation is not recommended for people with severe to profound hearing loss.

#### The tests

Whether a patient is implanted or not is determined during a series of comprehensive and multi-disciplinary tests. They not only examine hearing ability but also a candidate's general health status as well as their cochlea and auditory nerve. In children as well as in adults, a hearing aid trial period of at least three months is part of this assessment, where possible and appropriate.

NICE defines severe to profound hearing loss as hearing only sounds from 90dB HL or louder at 2 and 4kHz without acoustic hearing aids. This equates to the loudness level of a jackhammer at a distance of ten metres. Testing is done at all frequencies.

Representative example of an unaided audiometric criterion



Decision-makers know about the weak points of the guidelines, which is why they are currently being reviewed

In France more powerful hearing aids are fitted, even though the patient would already be a candidate for a hearing implant

For an adult, an acoustic hearing aid is considered sufficient when the candidate scores 50% or more on Bamford–Kowal–Bench (BKB) sentence testing. If the score is lower, a CI is an option. The soundfield condition test is done in quiet at a sound intensity of 70dB SPL. This equates to the volume of a car engine at a distance of ten metres. In children, the tests assess whether speech, language and listening skills are appropriate for their age, developmental stage and cognitive ability.

#### FRANCE

The criteria for cochlear implantation in France are defined in a decree of the Ministry of Health from 2009.<sup>13</sup> The guideline is clearly structured and reflects modern everyday life as well as the technological progress.

Efforts are made to ensure that acoustic hearing aids are used to their maximum effect, making it difficult for users to switch to an implant later. More powerful hearing aids are fitted, even though the patient would already be a candidate for a hearing implant. Eventually, hearing aids will be ineffective. This also holds true for some other countries, such as the UK and Germany. And yet, patients would benefit if, based on objective tests, they could decide for themselves which type of hearing aid they prefer.

In France the following hearing implants from MED-EL are approved:

Cochlear Implants,  
Electric Acoustic Stimulation (EAS),  
Middle Ear Implants,  
Auditory Brainstem Implants and  
Bone Conduction Implants.

#### The indications

According to the decree, unilateral implantation in children with severe to profound hearing loss has to be performed as early as possible. The decision for the most appropriate solution, may it be a CI or an acoustic hearing aid, is made by applying comprehensive audiological and medical tests. If a child suffers from severe hearing loss, he or she will receive a CI, provided that he or she is unable to acquire speech despite using hearing aids.

A cochlear implant is not usually recommended for children born severely or profoundly deaf if

- the child is older than five years and
- has not yet developed any spoken language

Adults are unilaterally implanted if they meet the criteria. (See "The tests")

Bilateral implantation in children is recommended if a severe to profound hearing loss is caused by meningitis, trauma, or Usher syndrome. Adults are implanted bilaterally if there is a danger of ossification, or when the acoustic hearing-aid on the non-implanted ear can no longer make up for the hearing loss and the patient is thereby disadvantaged in their job or daily life, or if they lose their independence.

#### The tests

General rules for children are: a cochlear implant is an option if the child understands a maximum of 50% during a speech test. In this test, loudness is set at 60dB, which is comparable to the volume of a conversation at a distance of about one metre. The test is carried out in a sound field with optimally adjusted hearing aids and without lip-reading. If the child is not old enough to perform such a test, other age-appropriate methods have to be used, which are not specified in the act.

Adults are unilaterally implanted if they understand less than 50% of the words in a speech test. The presentation level is 60dB (loudness level of a conversation). The test is carried out in a free sound field with optimally adjusted hearing aids and without lip-reading.

<sup>13</sup> Act about Cochlear Implants and Auditory Brainstem Implants by the French Ministry of Health and Sport. 2nd March 2009. WWW: <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000020348207> (2014-12-06)

The authorities consider the latest technological developments and are interested in regularly adapting the criteria

## Asia-Pacific region

### WESTERN AUSTRALIA

There are no uniform guidelines for the whole of Australia. Nevertheless, with the "Clinical Guidelines for Paediatric Cochlear Implantation" and the "Clinical Guidelines for Adult Cochlear Implantation", the state of Western Australia has drawn up its own guidelines.<sup>14, 15</sup> The authorities consider the latest technological developments and are interested in regularly adapting the criteria. The guidelines apply to children and adults with bilateral, moderately-severe to profound hearing loss.

In Western Australia the following hearing implants from MED-EL are approved:  
Cochlear Implants,  
Electric Acoustic Stimulation (EAS),  
Middle Ear Implants and  
Bone Conduction Implants.

### The indications

The specifications in the official guidelines incorporate the latest scientific achievements and are defined accurately. For example, they cite the adequate audiological tests and speech tests as well as medical assessments such as CT and MRI scans.

For the Western Australian authorities, an optimally adjusted acoustic hearing aid is always the preferred option. A CI is only considered once the patient can no longer hear sufficiently with hearing aids. For children, as well as for adults, bilateral implantation is regarded as the optimal solution, as long as it is justified from a medical and audiological point of view. Unilateral cochlear implantation for adults is not considered a standard procedure at the moment. For children born with a profound hearing loss, the first year of life is indicated as the best time for an implantation.

### The tests

The guidelines contain clear criteria for adults:

- Moderately-severe to profound bilateral sensorineural hearing loss, assessed without acoustic hearing aids
- Little or no useful benefit from hearing aids
- Testing with the use of hearing aids:
  - in a quiet setting, understanding less than 65% of sentences in the poorer ear and less than 85% in the better ear. Testing is carried out in open set, which means that the content is unknown and unlimited.
  - understanding less than 45% of phonemes in the poorer ear and less than 65% in the better ear. Testing is carried out in open set.

- No radiological or medical contraindications
- Appropriate expectations and commitment from the patient and the family
- The patient must be motivated

For children the following criteria apply:

- Unaided thresholds should be in the moderate to severe range in the low frequencies and severe to profound in the high frequencies.
- Aided thresholds should be outside the speech spectrum.
- Appropriate tests for older children, or those with good speech and language are:
  - Bamford-Kowal-Bench (BKB) or City University of New York (CUNY) sentences
  - North Western University - Children's Perception of Speech (Nu-Chips)
  - Arthur Boothroyd (AB) word lists and
  - Central Institute for Deaf (CID) everyday sentences for very young children.

If children reach results of at most 70% in the better ear and 40% in the poorer ear, they will be considered for a CI.

For borderline cases, an aided speech-in-noise test is used: if speech perception drops significantly under these conditions, the patient may be considered for an implant.

<sup>14</sup> Department of Health, Western Australia. Clinical Guidelines for Paediatric Cochlear Implantation. Perth: Health Networks Branch, Department of Health, Western Australia; 2011. WWW: [http://www.healthnetworks.health.wa.gov.au/docs/2011\\_CI\\_Guideline.pdf](http://www.healthnetworks.health.wa.gov.au/docs/2011_CI_Guideline.pdf) (2014-12-06)

<sup>15</sup> Department of Health, Western Australia. Clinical Guidelines for Adult Cochlear Implantation. Perth: Health Networks Branch, Department of Health, Western Australia; 2011. WWW: [http://www.healthnetworks.health.wa.gov.au/docs/1301\\_CG\\_AdultCochlearImplantation.pdf](http://www.healthnetworks.health.wa.gov.au/docs/1301_CG_AdultCochlearImplantation.pdf) (2014-12-06)

In Saudi Arabia there is the political will to care adequately for people with a hearing loss. This applies especially to children

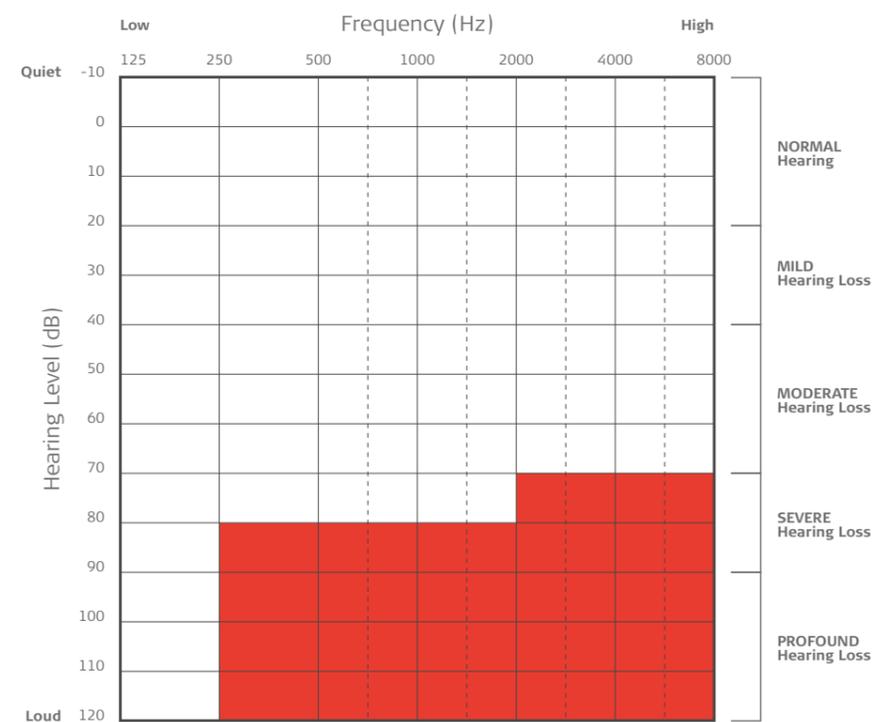
## Middle East

### KINGDOM OF SAUDI ARABIA

The Kingdom of Saudi Arabia has no official guidelines, but optimal criteria and a good degree of provision exist. To a great extent this can be attributed to the awareness within Saudi Arabian society of the importance of good hearing. There is a political will to care adequately for people with a hearing loss. This applies especially to children who are particularly important in Saudi Arabian society.

In Saudi Arabia the following hearing implants from MED-EL are approved:  
 Cochlear Implants,  
 Electric Acoustic Stimulation (EAS),  
 Middle Ear Implants,  
 Auditory Brainstem Implants (with electrode for Mi1000 Concerto) and  
 Bone Conduction Implants.

Representative example of an unaided audiometric criterion for an adult

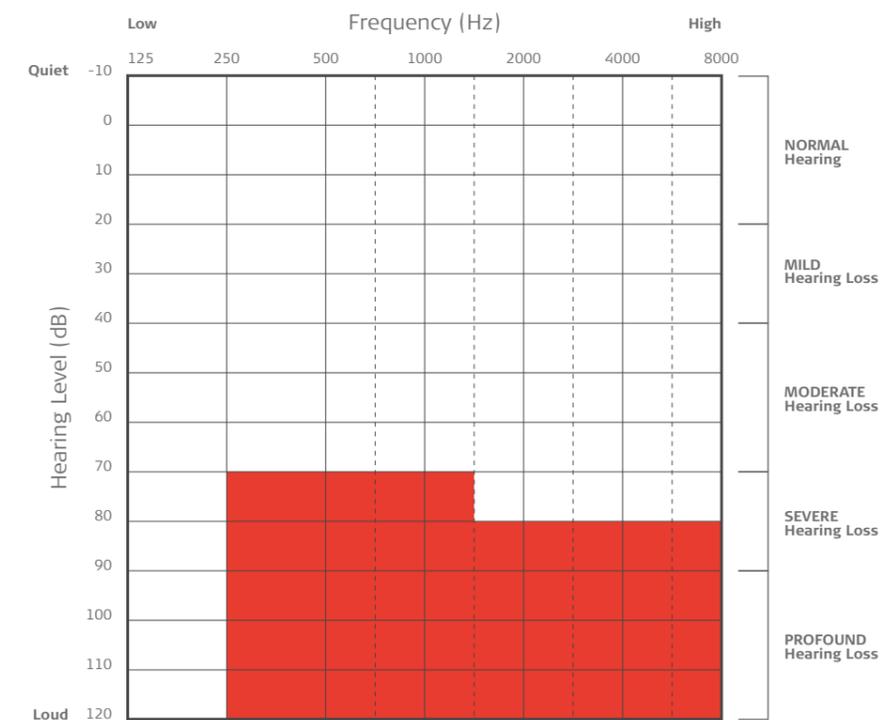


### The indications and tests

While in some countries, the speech-perception test is performed in noise, it is performed in quiet in Saudi Arabia. Patients are considered for an implant if they understand 60% or less in the monosyllabic and/or bisyllabic test. The test is done without a hearing aid at the presentation level that was previously determined from an audiogram as adequate for the individual patient (Most Comfortable Loudness Level, MCL).<sup>16</sup>

Bilateral implantations in adults and children are done simultaneously as well as sequentially. Patients with single-sided deafness receive a cochlear implant. Children are implanted as early as possible - there is no maximum age limit.<sup>16</sup>

Representative example of an unaided audiometric criterion for a paediatric



## Asia

### REPUBLIC OF KOREA

South Korea's criteria were developed about ten years ago. They are among the world's most advanced and are currently being reviewed in order to further improve the standard of quality of provision.

In the Republic of Korea the following hearing implants from MED-EL are approved: Cochlear Implants, Electric Acoustic Stimulation (EAS), Middle Ear Implants and Bone Conduction Implants.

### The indications and tests

Patients are considered for an implant if they understand at most 50% in a speech test in quiet, using a hearing aid. The test is done at the presentation level that was previously determined from an audiogram as adequate for the individual patient (Most comfortable loudness level, MCL).

In children, implantation is possible from the 12th month of age. Children under 15 years old are implanted bilaterally, either simultaneously or sequentially. Unilateral hearing loss is currently not treated with cochlear implants.<sup>17</sup>

The abovementioned countries are among the pioneers: they realise the importance of clear guidelines are in order to ensure optimal treatment for persons with hearing loss. From our point of view, Germany and Saudi Arabia may be considered the benchmark countries.

The German experts deliberately designed the guidelines to be general, in order to allow for individual treatment for each patient. Hearing implants are available for both children and adults equally, and bilateral implantation is standard at all ages. At the same time, the criteria are specific enough to make sure that the most important medical and audiological parameters are determined and that only those people receive an implant who no longer (or never did) benefit from an acoustic hearing aid.

The policy makers of Saudi Arabia have a relatively open approach to implantation: whoever needs an implant, receives one, regardless of age. If bilateral provision is necessary from an audiological point of view, the patient will receive two implants.

Primarily, policy makers' commitment is required in order to ensure that as many affected people as possible are provided with CI. To begin with, people need to be aware of the major effects that hearing loss can have; it is important to realise what part good hearing plays in our society and how people are affected when they lose their hearing. Deaf children may never learn to speak clearly enough to fully participate in regular school. Adults in working life bluff their way through meetings and increasingly avoid social contact, and elderly people retreat, in the worst case losing their physical and mental strength. It is therefore of the utmost importance to recognise the value of good hearing.

So, from our perspective, the current criteria of Germany and Saudi Arabia are optimal. They focus on the people. This must surely be a sound aim.

Policy makers' commitment is required in order to ensure that as many affected people as possible are provided with CI.

March 2015

<sup>17</sup> R.K. Najran: "Indications for Cochlear Implants". IFOS Korea 2013, WCA Brisbane 2014

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