



IMPROVING THE STANDARD OF CARE FOR ADULTS WITH HEARING LOSS AND THE ROLE OF COCHLEAR IMPLANTATION:

LIVING GUIDELINES

Hearing health is a recognised public health priority with prevalence of hearing loss rising worldwide.¹ Currently, there is a lack of awareness and inconsistency in diagnosing and managing hearing loss, especially severe to profound sensorineural hearing loss. Guidelines with clearly defined care pathways for adult cochlear implantation would enable consistent and equitable access to hearing healthcare and treatment.

An international collaboration of hearing experts, known as the CI Task Force, are leading the effort to develop Living Guidelines that will optimise care for hearing impaired adults, improve accessibility, and standardise treatment globally.

1. Wilson BS, Tucci DL, Merson MH, O'Connell J, Donoghue GM : Global hearing health care: new findings and perspectives. Lancet 2017;390(10111):2503-2515.

**TO HAVE YOUR SAY AND PROVIDE FEEDBACK
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Acknowledgements

Cochlear Implant International Community of Action (CIICA).

The Task Force would like to acknowledge the invaluable and essential work conducted by the members of the Cochlear Implant International Community of Action (CIICA). CIICA has ensured there is global advocacy for the first time, coordinating the views of cochlear implant users in this process, drawing upon their network, which includes 480+ individuals, 98 organisations from 60 countries across the globe.

For more information on CIICA and their work head to www.ciicanet.org

Reference Group

The Task Force and CIICA would like to acknowledge the work carried out by HTANALYSTS, who provided medical writing support to the Task Force for the development of the guidelines and associated manuscripts. HTANALYSTS acted in accordance with the agreed protocol and charter signed by the Task Force members.

For more information on HTANALYSTS and their work head to www.htanalysts.com.au

Funding

The CI Task Force acknowledges the financial assistance provided by Cochlear Limited.

The development of the recommendations has not been influenced by the views or interests of the funding body.

Executive summary

Hearing loss in adults is a common health condition and one of the leading causes of disability worldwide, occurring in 466 million people (6% of the total population).^{1,2} The affects of hearing loss can be wide-ranging, impacting aspects of a person's social and emotional wellbeing, communication, mental health status as well as their working life.³⁻⁶ Aside from the impact to individuals, hearing loss can place a burden on third parties such as significant others and loved ones.⁶ There is also a growing body of evidence suggesting an association between hearing loss in older adults and neurocognitive disorders, such as dementia.¹

In addition to the impact on the individual and their families, hearing loss imparts a significant economic burden. The World Health Organisation (WHO) estimates that over a trillion US dollars are lost due to hearing loss and measures such as hearing screening are a cost-effective for reducing the burden in adults.²

Given the significant impact on society, the WHO made recommendations in their 2021 World Report on Hearing to urge investment in: hearing screening and intervention; disease prevention and management; access to technology and rehabilitation; improved communication; noise reduction and greater community engagement.²

In response to this call to action, an independent international Task Force of 52 hearing experts, including those with a lived experience of hearing loss, was formed to address efforts to help reduce the global burden of hearing loss. Three key areas of focus were identified that acknowledge the need to improve access to screening of hearing loss, referral pathways to specialist evaluation and standardising aftercare for cochlear implantation.

The Task Force have developed Living Guidelines based on an extensive literature review as well as community consultations, engaging with adults with a lived experience of hearing loss, advocacy, and patient groups. This resulted in the development of evidence-based recommendations, spanning hearing loss screening, assessment, referral, specialist evaluation, rehabilitation (initial and lifelong), patient measures and outcomes. The recommendations provide key elements to support practitioners in delivering evidence-based practice. Recommendations are accompanied by good practice statements that provide context to a given recommendation, such as how a recommendation should be implemented in clinical practice, or how it is applied to a specific population or under specific circumstances. Areas such as surgery, intra and post-operative care are well served by existing guidelines. Subsequently the Task Force reviewed and included these guidelines, with appropriate citations and referenced links to original publications

Supporting evidence collected through the research and community consultations activities is presented for each recommendation, and a Technical Report provides references that informed and supported the guidelines development process. Each recommendation included in this document is preceded by a PROSPERO question.⁷

The Living Guidelines development process has been through a period of public consultation from International Cochlear Implant Day 25th February 2023 until the 31st May 2023. You are still able to provide comments and the Task Force warmly welcomes feedback from all members of the global healthcare community.

You can submit your comments using the feedback tab located under each recommendation in MAGICapp OR by downloading and using the submission template and emailing it to guidelines@htanalysts.com.au. All feedback will be considered by the Task Force, to support their evaluation of the recommendations and good practice statements included in the guidelines.

These are the first global guidelines for cochlear implantation in adults supporting the pathway for those adults with severe to profound hearing loss or moderate sloping hearing loss. The recommendations provide a framework through which evidence-based practice can be implemented. Following public consultation, the next step will be for country and regional professional hearing associations and individual practitioners to endorse and implement the guidelines; a process the Task Force and advocacy group Cochlear Implant International Community of Action (CIICA) will support through a range of activities.

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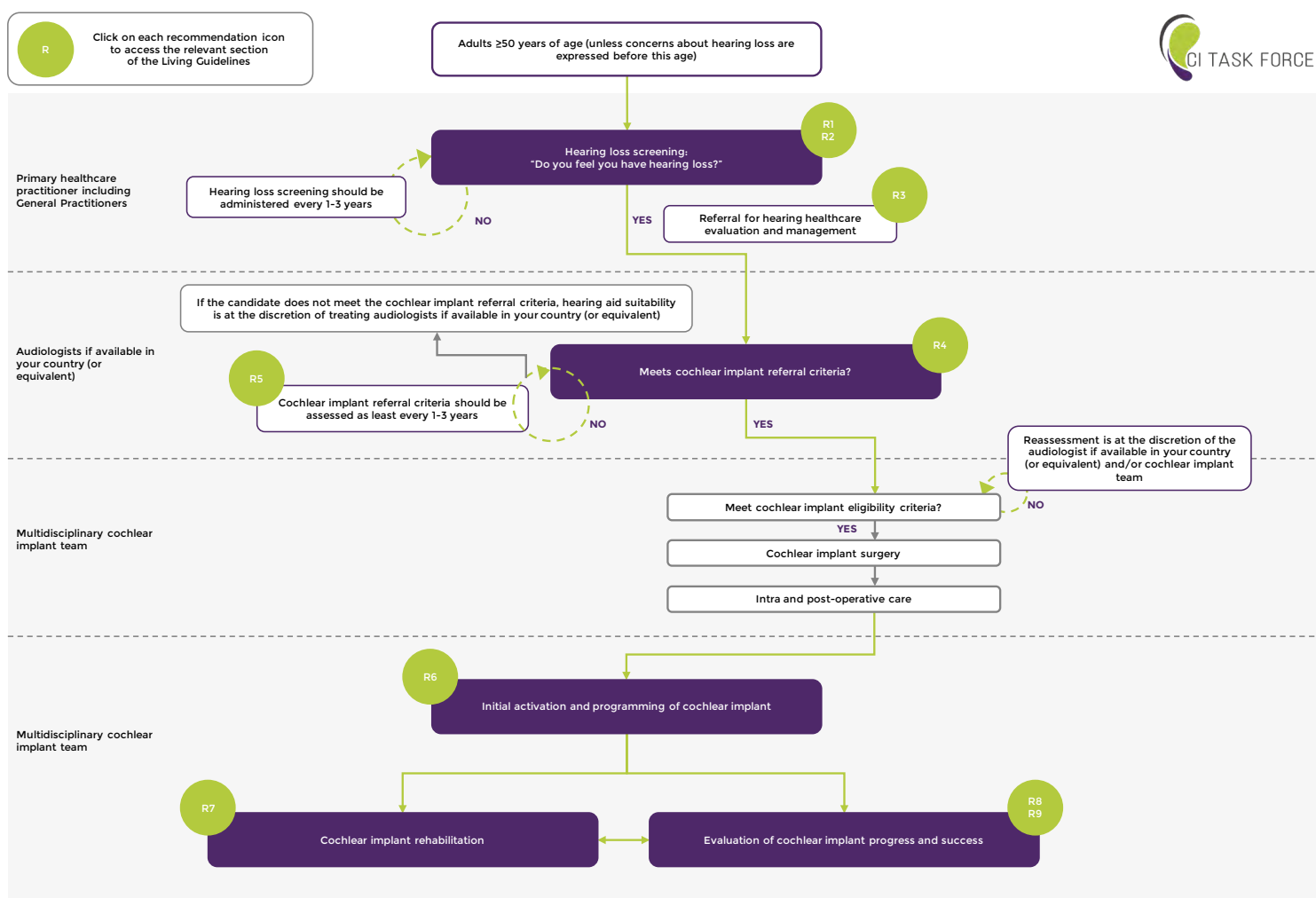
1. Dementia prevention, intervention, and care: 2020 report of the Lancet Commission, Livingston, *et al* 2020. doi.org/10.1016/S0140-6736(20)30367-6. 2. World Health Organization. World report on hearing 2021. World report on hearing (who.int). 3. Bennett RJ, Saulsman L, Eikelboom RH, Olaithe M. Coping with the social challenges and emotional distress associated with hearing loss: a qualitative investigation using Leventhal's self-regulation theory. *Int J Audiol.* 2021;1–124 Association of hearing loss with decreased employment and income among adults in the United States. *Ann Otol Rhinol Laryngol.* 2012;121:771–775. 4. Jonsson I, Hedelin B. Women's lived experiences of disabling hearing

Recommendations and good practice statements

This is a list of recommendations and good practice statements included in the guidelines. These are provided as a quick reference guide only. The recommendations should be read in the context of the accompanying good practice statements that are described in the body of this guideline.

For a full list of accompanying references and literature searches informing the guidelines, please refer to the MAGICapp site [HERE](#).

The graphic below visualises where the recommendations are mapped across the patient journey.



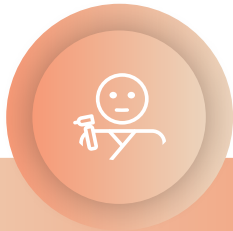
The recommendations are spaced across six key areas



HEARING LOSS SCREENING AND ASSESSMENT

PROSPERO questions.

1. Who should hearing loss screening be offered to?
2. What screening tools (questionnaires or assessments) should be used by primary healthcare professionals to screen for hearing loss?



SPECIALIST EVALUATION

PROSPERO questions.

4. In adults with any level of hearing loss, what criteria should be met by routine assessment tools (audiological and/or clinical) to determine referral for a complete cochlear implant evaluation? What is the diagnostic accuracy for each of the routine assessment tools?
5. In adults with hearing loss who may not meet the eligibility criteria for a cochlear implant, what is the optimal frequency of assessment for monitoring hearing loss and for re-assessing them to determine referral for a complete cochlear implant evaluation?



REHABILITATION

PROSPERO questions.

6. For adult cochlear Implant users with severe to profound sensorineural hearing loss (SNHL), what is the most effective number of follow-up appointments one year post cochlear implantation to achieve optimal programming/ stimulation levels?
7. For adult cochlear implant users with severe to profound SNHL what are the essential components of an appropriate clinical pathway for rehab after surgery?



REFERRAL

PROSPERO question.

3. Once adults with any level of hearing loss are identified, who and when should they be referred to for hearing healthcare evaluation/ management?



SURGERY

(No PROSPERO question). This area is well served by existing guidelines, subsequently the Task Force have reviewed and included these guidelines, with appropriate citing's and links to original material.



PATIENT OUTCOMES AND MEASURES

PROSPERO questions.

8. For adult cochlear implant users with severe to profound SNHL , which outcome domains are most meaningful to patients to assess for improvement with a cochlear implant?
9. For adult cochlear implant users with severe to profound SNHL, what measurement tools and/or questionnaires (e.g. speech tests, quality of life questionnaires) should be utilised to measure patient outcomes?



Hearing Screening and Assessment

According to the WHO, a person is considered to have hearing loss if they are not able to hear as well as someone with normal hearing, meaning they have a hearing threshold of >20dBHL (decibel hearing loss) in one or both ears.¹ To standardise the way in which the severity of hearing loss is reported, the WHO has adopted a grading system based on audiometric measurements. The Living Guidelines will also adopt this same grading system.

Hearing loss can range from mild to complete or total hearing loss and can affect one or both ears. Common causes include congenital hearing loss, chronic middle ear infections, noise-induced hearing loss, age-related hearing loss and ototoxic drugs that damage the inner ear.

The impact of hearing loss and delayed intervention can be substantial and far-reaching. Even a minor reduction in hearing sensitivity, as defined by the WHO in the International Classification of Functioning, Disability and Health (ICF), can be considered a potentially disabling condition.¹ The degree of disability experienced by a person with hearing loss depends not only on their hearing impairment but also on the physical, social and attitudinal environment in which they live and their access to quality healthcare services.

If a person with hearing loss does not receive proper care, they are likely to face greater limitations in their daily functioning and higher levels of disability, leading to social isolation, loneliness, frustration and a loss of independence. Hearing loss has also been linked to a decreased quality of life, cognitive decline and depression^{2,3} and there is a growing body of evidence suggesting an association between hearing loss in older adults and neurocognitive disorders, such as dementia.³ Additionally, hearing loss can also have an impact on the individuals close to them, such as family and friends.⁴

Despite being the most common sensory deficit among older adults, hearing loss is often under-recognised and poorly managed.⁷ This costs the global economy USD \$980 billion annually. In a study conducted in the United States, only 34% of primary care physicians were documented to routinely screen their older patients for hearing function⁵ and in a Danish study, just 7% of general practitioners were reported to enquire about hearing function in older patients.⁶ In addition, adults wait for nearly 9 years before seeking help for their hearing loss.⁸

Early identification is the first step in addressing hearing loss. Primary healthcare practitioners play a crucial role in detecting hearing loss in adults. As the first point of contact for many patients, they are in a unique position to identify hearing loss early on and make a referral for a full audiological assessment by a hearing healthcare specialist.

1. World Health Organization (WHO) : World report on hearing. 2. Gates GA, Cobb JL, Linn RT, Rees T., Wolf PA, D'Agostino RB : Central auditory dysfunction, cognitive dysfunction, and dementia in older people. Arch Otolaryngol Head Neck Surg 1996;122(2):161-7. 3. Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. : Hearing loss and incident dementia. Arch Neurol 2011;68(2):214-20. 4. Völter C, Götze L, Ballasch I, Harbert L, Dazert S, Thomas JP : Third-party disability in cochlear implant users. 2021; 5. Johnson CE, Danhauer JL, Koch LL, Celani KE, Lopez IP, Williams VA : Hearing and balance screening and referrals for Medicare patients: a national survey of primary care physicians. Journal of the American Academy of Audiology 2008;19(2):171-90. 6. Parving A, Christensen B, Sørensen MS : Primary physicians and the elderly hearing-impaired. Actions and attitudes. Scandinavian audiology 1996;25(4):253-8. 7. The Royal Australian College of General Practitioners (RACGP) : Diagnosis and management of hearing loss in elderly patients. Australian Journal for General Practitioners 2016;45 366-369. 8. Bennett RJ, Fletcher S, Conway N, Barr C : The role of the general practitioner in managing age-related hearing loss: perspectives of general practitioners, patients and practice staff. BMC family practice 2020;21(1):87



Hearing Screening and Assessment

PROSPERO QUESTIONS

Who should hearing loss screening be offered to?

What screening tools (questionnaires or assessments) should be used by primary healthcare professionals to screen for hearing loss?

RECOMMENDATION 1

Hearing loss screening should be offered to adults from the age of 50 years (unless concerns about hearing loss are expressed before this age) using the single question:

“Do you feel you have hearing loss?”

If a person answers “yes”, next steps should be informed as per the hearing loss recommendations of these Living Guidelines.

RECOMMENDATION 2

Hearing loss screening should be administered at the frequency of 1–3 years.^{1,2,3}



GOOD PRACTICE STATEMENT 1

Hearing loss screening can be administered by **any primary health care practitioner** including General Practitioners.



GOOD PRACTICE STATEMENT 2

Before screening for hearing loss, primary health care practitioners should explain the purpose of screening and common symptoms and signs of hearing loss. These include:⁴

- Having trouble hearing in both and/or either ear
- Having trouble hearing over the phone
- Finding it hard to follow conversations when two or more people are talking
- Needing to ask people to regularly repeat what they are saying
- Needing to turn up the television volume so loud that others complain
- Having trouble hearing because of background noise
- Thinking that others seem to mumble
- Finding different speakers difficult to hear such as children and softly spoken persons

1. World Health Organization (WHO): World report on hearing. (null) 2021; 2. Sorkin DL: Cochlear implantation in the world’s largest medical device market: utilization and awareness of cochlear implants in the United States. Cochlear implants international 2013;14 Suppl 1(Suppl 1):S4-12. 3. United States Preventative Services Task Force (USPSTF): Hearing loss in older adults: screening. 2021; 4. 1 NIH National Institute on Aging (NIA): Hearing Loss: A Common Problem for Older Adults. 2018



GOOD PRACTICE STATEMENT 3

“Do you feel you have hearing loss?”

- If a person is unable to answer the single question with “yes” or “no”, primary health care practitioners should clarify and further explain these signs and symptoms to the individual being screened.
- In addition to the single question hearing loss screener, and if resources allow, primary health care practitioners may also administer or recommend other validated hearing loss screening tools including mobile technologies designed to detect hearing.¹⁻²⁰



GOOD PRACTICE STATEMENT 4

Before screening for hearing loss, primary health care practitioners should explain the **importance of hearing health and early hearing loss interventions**, including the reduced risk of cognitive impairment, dementia, associated falls and social isolation.¹



GOOD PRACTICE STATEMENT 5

If a person is considered at a higher risk for hearing loss, hearing loss screening should be administered before the age of 50 years and/or more frequently.^{21,22,23}

Such risk factors include:

- Cardiovascular disease
- Diabetes
- Ototoxicity
- Kidney dysfunction
- Noise exposure
- Tinnitus and
- Significant family history



GOOD PRACTICE STATEMENT 6

If a person, their family and/or friends have expressed concern(s) about an individual’s hearing loss before the age of 50 years, hearing loss screening should be administered.²

Such concerns may include:

- Having trouble hearing in both and/or either ear
- Having trouble hearing over the phone
- Finding it hard to follow conversations when two or more people are talking
- Needing to ask people to regularly repeat what they are saying
- Needing to turn up the television volume so loud that others complain
- Having trouble hearing because of background noise
- Thinking that others seem to mumble
- Finding different speakers difficult to hear such as children and softly spoken persons

EVIDENCE TO DECISION

- The benefits of early detection and intervention far outweigh any potential harm. The potential harms such as the overuse of resources or excessive referrals to hearing health care specialists must be considered.
- The effects of untreated hearing loss can result in social isolation, frustration, loss of independence, depression decreased quality of life, and even cognitive decline and dementia.
- Overall, the benefits of referral for a full hearing assessment far outweigh any potential harms.

RATIONALE

- Despite hearing loss being the most common sensory deficit in older persons, it is often under-recognised and poorly managed. Primary health care practitioners must screen for hearing loss to support early intervention and refer patients toward the appropriate care pathway to optimise their audiological health and promote healthy ageing.
- 64 cross-sectional (cohort type diagnostic accuracy) studies were identified in the literature search (please see the Technical Report at [MAGICapp](#) for an overview of these citations). Across the studies, there were over 30 screening tools (questionnaires or assessments) investigated.
- A review of existing guidelines and consultation with the Task Force revealed that a single question should be used to screen for hearing loss. Other tools identified via the literature search were either too resource intensive or unable to be performed by all primary health care professionals globally. The WHO hearing guidelines also endorse the use of a single yes/no question for hearing loss screening.
- Three included studies, Strawbridge 2017²⁵, Deepthi 2012²⁶, and Everett 2020²⁷ used a version of the question “Do you feel you have hearing loss?” as the screening tool. Based on these studies and international guidelines, it is recommended that hearing loss screening should be implemented starting at age 50 and repeated once every 1-3 years.

1. Barczik J, Serpanos YC : Accuracy of Smartphone Self-Hearing Test Applications Across Frequencies and Earphone Styles in Adults. *American journal of audiology* 2018;27(4):570-580. 2. Bastianelli M., Mark AE, McAfee A., Schramm D., Lefrancois R., Bromwich M. : Adult validation of a self-administered tablet audiometer. *Journal of Otolaryngology: Head and Neck Surgery* 2019;48(1):59. 3. Brennan-Jones CG, Eikelboom RH, Swanepoel W. : Diagnosis of hearing loss using automated audiometry in an asynchronous telehealth model: A pilot accuracy study. *Journal of telemedicine and telecare* 2017;23(2) 256-262. 4. Colman A., Supp GG, Neumann J., Schneider TR : Evaluation of Accuracy and Reliability of a Mobile Screening Audiometer in Normal Hearing Adults. *Frontiers in Psychology* 2020;11 744. 5. Hong O., Ronis DL, Antonakos CL : Validity of self-rated hearing compared with audiometric measurement among construction workers. *Nursing Research* 2011;60(5) 326-332. 6. 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Referral

Primary healthcare practitioners play a crucial role in detecting hearing loss in adults, especially general practitioners who are often the first point of contact for many patients. With the opportunity to detect hearing loss early, practitioners can refer patients to the appropriate hearing health care specialists to address their hearing concerns.¹

A population-based consumer survey in the United States found that people with hearing loss are five times more likely to seek a hearing solution if their general practitioner gives a positive recommendation for hearing healthcare.²

As such, primary health care practitioners can play an instrumental role in guiding patients to make appropriate and timely choices for addressing their hearing loss.

PROSPERO QUESTION

Once adults with any level of hearing loss are identified, who and when should they be referred to for hearing healthcare evaluation/ management?

CONSENSUS BASED RECOMMENDATION 3

For an adult who presents for the first time with any level of hearing loss, or in whom hearing difficulties is suspected, the primary health care professional should:

- check for impacting factors such as impacted wax and acute infections (e.g. otitis externa, otitis media and otitis media with effusion), and
- arrange a referral to a hearing health care specialist for a full audiological assessment, and
- if sudden or rapid onset hearing loss is suspected or hearing loss is not explained by acute external or middle ear causes, additional immediate referral to an Ear, Nose and Throat specialist or an emergency department is warranted.



GOOD PRACTICE STATEMENT 1

If an adult is diagnosed with impacted wax or acute infections, please follow your local guidelines for management of these.



GOOD PRACTICE STATEMENT 2

If a full audiological assessment is required, refer to an audiologist (or equivalent) if available in your country and/or to an Ear, Nose and Throat Specialist.

1. Schneider JM, Gopinath B, McMahon CM, Britt HC, Harrison CM, Usherwood T, Leeder SR, Mitchell P : Role of general practitioners in managing age-related hearing loss. The Medical journal of Australia 2010;192(1):20-3. 2. Bennett RJ, Fletcher S, Conway N, Barr C : The role of the general practitioner in managing age-related hearing loss: perspectives of general practitioners, patients and practice staff. BMC family practice 2020;21(1):87.

EVIDENCE TO DECISION

Substantial net benefits of the recommended alternative

- Overall, the benefits thus outweigh the harms.
- Hearing loss can lead to social isolation, loneliness, frustration and a loss of independence and is strongly associated with decreased quality of life, cognitive decline, depression and dementia.
- The balance between benefits, harms and burdens is uncertain due to a lack of evidence identified. The potential harms include the misuse of resources or over-referral to hearing healthcare specialists. However, it is not anticipated that a referral for a full audiological assessment will cause any harm to the individual, compared to not being referred. The impacts of hearing loss and delayed intervention are far-reaching, including decreased functional ability and a loss of ability to communicate with others.

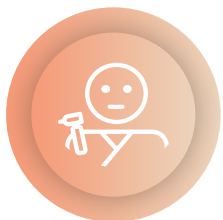
Certainty of Evidence: Very low

The systematic review did not identify any relevant evidence. As such, the recommendation is not developed with an evidence-based framework but informed through a consensus process involving a review of previous guidelines and expert opinion from the Task Force.

RATIONALE

- No studies were identified that met the inclusion criteria for research question three. This is an evidence gap for further research to be conducted.
- Following a review of existing guidelines and in consultation with the CI Task Force, a consensus-based recommendation was developed.
- The **National Institute for Health and Care Excellence (NICE) Hearing loss in adults: assessment and management guidelines**¹ were used to develop an initial draft as it was considered the most comprehensive. However, it was considered appropriate that in all scenarios, if a person presents for the first time with any level of hearing loss or is experiencing hearing difficulties then a full audiological assessment should be conducted. Without a hearing test, it is unknown if the cause of hearing loss has been addressed. If the primary healthcare professional suspects the adult has sudden or rapid onset hearing loss, then referral to an emergency department or ENT specialist for additional diagnostic assessment is recommended.

1. National Institute for Health and Care Excellence. Hearing loss in adults: assessment and management. 2018



Specialist Evaluation

Cochlear implants are suitable for many adults with severe, profound or moderate sloping to profound sensorineural hearing loss.¹ Cochlear implants can enhance speech clarity, making it easier for individuals to understand speech in noisy environments as well as when talking on the phone or listening to music through headphones.¹ In a recent study, people with cochlear implants could understand sentences eight times better than they could previously with their hearing aids.^{2,3}

Being able to understand speech better, improves a person's confidence in social situations, reducing the risk of social isolation and other hearing loss-related risk factors.⁴ Furthermore, cochlear implants have been associated with lower rates of mild cognitive disorders and a 19% decrease in the risk of long-term cognitive decline, as indicated by a systematic review of hearing restorative devices, including both cochlear implants and hearing aids.^{5,6}

Despite the potential benefits of cochlear implants, less than 10% of eligible adults will receive one in their lifetime.¹ Remarkably, in the United States of America, only 3% of all patients with moderate to profound sensorineural hearing loss are referred for a cochlear implant evaluation. This underutilisation is due, in part, to limited awareness of eligibility criteria and referral processes. Consistent criteria for identifying candidates for cochlear implants is necessary to ensure all individuals have the opportunity to be assessed and receive the best available care.^{7,8}

• PROSPERO QUESTIONS

- In adults with any level of hearing loss, what criteria should be met by routine assessment tools (audiological and/or clinical) to determine referral for a complete cochlear implant evaluation? What is the diagnostic accuracy for each of the routine assessment tools?
- In adults with hearing loss who may not meet the eligibility criteria for a cochlear implant, what is the optimal frequency of assessment for monitoring hearing loss and for re-assessing them to determine referral for a complete cochlear implant evaluation?

RECOMMENDATION 4

An adult with any level of hearing loss should be referred for cochlear implant evaluation if they meet the cochlear implant referral criteria of three frequency (500, 1000, 2000 Hz) un-aided pure tone average (PTA) in the better ear that is equal to or greater than 60 dB HL, (decibels hearing level) AND expresses difficulties with speech understanding in their everyday environment.⁷

Any adult that meets the above criterion should be referred to a cochlear implant specialist for a complete cochlear implant evaluation and preoperative assessment.

1. Carlson ML : Cochlear Implantation in Adults. The New England journal of medicine 2020;382(16):1531-1542. 2. Runge CL, Henion K, Tarima S, Beiter A, Zwolan TA : Clinical Outcomes of the Cochlear™ Nucleus® 5 Cochlear Implant System and SmartSound™ 2 Signal Processing. Journal of the American Academy of Audiology 2016;27(6):425-440. 3. Gaylor JM, Raman G, Chung M, Lee J, Rao M, Lau J, Poe DS : Cochlear implantation in adults: a systematic review and meta-analysis. JAMA otolaryngology-- head & neck surgery 2013;139(3):265-72. 4. Olusanya BO, Davis AC, Hoffman HJ : Hearing loss: rising prevalence and impact. Bulletin of the World Health Organization 2019;97(10):646-646A. 5. Gurgel RK, Duff K, Foster NL, Urano KA, deTorres A : Evaluating the Impact of Cochlear Implantation on Cognitive Function in Older Adults. The Laryngoscope 2022;132 Suppl 7(Suppl 7):S1-S15 6. Mosnier I, Vanier A, Bonnard D, Lina-Granade G, Truy E, Bordure P, Godey B, Marx M, Les-canne E, Venail F, Poncet C, Sterkers O, Belmin J : Long-Term Cognitive Prognosis of Profoundly Deaf Older Adults After Hearing Rehabilitation Using Cochlear Implants. Journal of the American Geriatrics Society 2018;66(8):1553-1556. 7. Sorkin DL : Access to cochlear implantation. 2013; 8. Bierbaum M, McMahon CM, Hughes S, Boisvert I, Lau AYS, Braithwaite J, Rapport F : Barriers and Facilitators to Cochlear Implant Uptake in Australia and the United Kingdom. Ear and hearing 2020;41(2):374-385 9. Zwolan TA, Schwartz-Leyzac KC, Pleasant T : Development of a 60/60 Guideline for Referring Adults for a Traditional Cochlear Implant Candidacy Evaluation. Otolology & neurotology : official publication of the American Otological Society, American Neurotology Society 2020;41(7):895-900



GOOD PRACTICE STATEMENT 3

- For a person that has unilateral severe, profound or moderate sloping to profound sensorineural hearing loss but does not meet the cochlear implant referral criteria above, the hearing healthcare specialists could use four frequency (500, 1000, 2000, and 4000 Hz) unaided PTA in the worse ear for referral.¹
- Until further evidence is available, hearing healthcare specialists should use their own discretion for when to refer a person with asymmetrical sensorineural hearing loss or unilateral severe, profound or moderate sloping to profound sensorineural hearing loss for cochlear.



GOOD PRACTICE STATEMENT 4

Prior to conducting the assessment to refer for a cochlear implant assessment, the hearing health specialist should ensure that those adults who have hearing aids have them correctly fitted. If the person has a hearing aid, and:

- The hearing aid is fitted correctly and worn consistently, continue to assess for referral to a complete cochlear implant evaluation.
- The hearing aid is incorrectly fitted or functioning sub-optimally, the hearing healthcare specialist should first re-fit the hearing aid, then assess for referral for a complete cochlear implant evaluation and preoperative assessment.



GOOD PRACTICE STATEMENT 5

If the cochlear implant team deems the adult is not eligible for a cochlear implant despite meeting the cochlear implant referral criteria, their hearing care should be at the discretion of the referring audiologist if available in your country (or equivalent). This may include medical or other audiological treatment alternative(s). Future reassessment of cochlear implant eligibility is at the discretion of the audiologist if available in your country (or equivalent) and/or the cochlear implant team.

EVIDENCE TO DECISION

Benefits and harms: Substantial net benefits of the recommended alternative

The criteria to determine referral for a complete cochlear implant evaluation lacks a standard of care globally, and therefore, the comparison of benefits and harms of the recommendation with alternatives is not possible. Despite this, the high certainty of evidence suggests that the benefits of being referred for a complete cochlear implant evaluation and preoperative assessment are likely to outweigh any associated harms. However, it is important to note that due to global variability on speech perception assessments, the recommendation only incorporates the PTA measure of the Zwolan 2020 guidelines.² Following consultation with the CI Task Force, it was revealed that PTA is the key criterion in determining cochlear implant candidacy globally.

1. FDA : Premarket Approval (PMA). 2023. 2. Zwolan TA, Schwartz-Leyzac KC, Pleasant T : Development of a 60/60 Guideline for Referring Adults for a Traditional Cochlear Implant Candidacy Evaluation. *Otology & neurotology* : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology 2020;41(7):895-900

CERTAINTY OF EVIDENCE

Moderate

As per GRADE, the overall certainty of the evidence was high due to no serious risk of bias, imprecision, inconsistency, or indirectness. However, the certainty of evidence was downgraded as the recommendation only took into account the PTA criteria of the Zwolan 2020 guidelines. This was due to the global variability in speech perception assessments, and consultation with the CI Task Force revealed that the PTA measure is a critical factor in determining cochlear implant candidacy on a global scale.

RATIONALE

Seven studies that assess the diagnostic accuracy of assessment tools for cochlear implant candidacy in adults with any level of hearing loss were identified in the systematic literature review. The assessment tools used across the included studies, except the 60/60 referral guideline evaluated by Lee 2022¹ and Zwolan 2020² were considered to be too complex and resource intensive for any hearing health care specialist to carry out. These five studies were also considered to be of low certainty of evidence due to the small sample size and/or a large range of sensitivity and specificity values.

Lee 2022¹ and Zwolan 2020² are retrospective studies of data from adults who underwent a cochlear implant candidacy evaluation in a population whose dominant language is English. The studies observed a sensitivity range between 62-96% and a specificity range between 66-75% when using a better ear PTA equal to or greater than 60 dB HL, and a better ear unaided monosyllabic word score less than or equal to 60% correct. However, the unaided monosyllabic word score does not yield the same accuracy in non-dominant English speakers and thus cannot be implemented internationally. Further consultation with the CI Task Force revealed that the PTA is the primary factor in determining a referral for a complete cochlear implant evaluation. Additionally, the specification of a word recognition criteria for each dominant language could be confounding due to global variability and therefore was not considered for the recommendation. Therefore, functional hearing ability and speech understanding in the adult's daily environment was deemed to be more appropriate for inclusion in a global guideline.

Until further evidence is available, the recommendation is based on Lee 2022 [ref], Zwolan 2020 [2], and expert opinion. The recommendation proposes self-reported difficulty hearing in everyday environments in conjunction with a better ear PTA greater or equal to 60 dB HL to ensure that a person who may be eligible for a cochlear implant is appropriately referred for a full cochlear implant evaluation. For further information on the development of the recommendation, please see the [technical report](#).

Practical Information

If required, you may need to follow your national guidelines for additional assessment criteria. Assessment tools measuring speech perception and/or word recognition in the adult's dominant language may be required for more complex cases.

For further information on prescribing and fitting hearing aids. The Task Force reviewed the following existing guidelines:

[Turton *et al.* 2020](#) makes recommendations around prescribing and fitting hearing aids, assistive devices and aural rehabilitation for those with severe to profound hearing loss. [The American Speech-Language-Hearing Association \(ASHA\)](#) refer to evidence maps, evidenced-based clinical practice guideline providing recommendations for the provision of aural rehabilitation to adults aged 18 years or older with hearing loss.

1. Lee DS, Herzog JA, Walia A, Firszt JB, Zhan KY, Durakovic N, Wick CC, Buchman CA, Shew MA : External Validation of Cochlear Implant Screening Tools Demonstrates Modest Generalizability. *Otology & neurotology* : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology 2022;43(9):e1000-e1007

2. Zwolan TA, Schwartz-Leyzac KC, Pleasant T : Development of a 60/60 Guideline for Referring Adults for a Traditional Cochlear Implant Candidacy Evaluation. *Otology & neurotology* : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology 2020;41(7):895-900

CONSENSUS RECOMMENDATION 5

If an adult with any level of hearing loss does not meet the cochlear implant referral criteria upon initial assessment, cochlear implant eligibility should be assessed every 1–3 years by an audiologist if available in your country (or equivalent).^{1,2,3,4} If upon reassessment the cochlear implant referral criteria is met, they should be referred to a cochlear implant specialist for a complete cochlear implant evaluation and preoperative assessment. However, if the person has sensorineural hearing loss (50 dB – 64 dB) or the adult experiences a significant change in their hearing ability, then they should be reassessed every 6–12 months by an audiologist if available in your country (or equivalent).



GOOD PRACTICE STATEMENT 1

To raise awareness of cochlear implants as a potential treatment option in the future, hearing healthcare specialists should be proactive in discussing cochlear implants with adults who have progressive hearing loss.



GOOD PRACTICE STATEMENT 2

Hearing healthcare specialists should endeavour to convey that cochlear implantation is part of the hearing health continuum and not an end-stage treatment. Encouraging the exploration of cochlear implantation early may improve future uptake for adults with progressive hearing loss who do not currently meet the cochlear implant eligibility criteria.



GOOD PRACTICE STATEMENT 3

If the cochlear implant team deems the adult is not eligible for a cochlear implant despite meeting the cochlear implant referral criteria, their hearing care should be at the discretion of the referring audiologist if available in your country (or equivalent). This may include medical or other audiological treatment alternative(s). Future reassessment of cochlear implant eligibility is at the discretion of the audiologist if available in your country (or equivalent) and/or the cochlear implant team.

EVIDENCE TO DECISION

Benefits and harms: Substantial net benefits of the recommended alternative. The balance between benefits, harms and burdens are uncertain owing to a lack of evidence identified.

Certainty of Evidence: Low

The systematic review did not identify any relevant evidence. As such, the recommendation is not developed with an evidence-based framework but informed through a consensus process involving previous guidelines and expert opinion from the CI Task Force.

RATIONALE

No studies were identified that met the inclusion criteria for research question five. A review of the existing guidelines found no evidence or recommendations pertaining to the reassessment and monitoring of individuals who do not meet cochlear implant eligibility criteria. Following consultation with the CI Task Force, a consensus-based recommendation was developed.

The recommendation is focused on ensuring that adults with hearing loss who do not currently meet the cochlear implant candidacy criteria are not lost to follow-up in the future. Recent reports have observed that only 10% of adults who would benefit from cochlear implantation will actually receive one in their lifetime.¹ While the underutilisation of cochlear implants is the product of various factors, patient loss to follow-up likely accounts for a significant proportion of potential cochlear implant candidates going untreated.

A review of current guidelines has recommended that adults should have their hearing re-evaluated every 1–3 years in order to effectively monitor their hearing level. This reassessment is necessary to ensure accurate tracking of any changes in an adult's hearing abilities.^{2,3,4,5} The CI Task Force also revealed that those adults who have sensorineural hearing loss but do not meet the criteria should be reassessed more frequently. The recommended time frame for this indication was at least 6–12 months. Similarly, those adults who experience a significant change in their hearing ability or communication should also be reassessed within this time frame.

1. Carlson ML : Cochlear Implantation in Adults. *The New England journal of medicine* 2020;382(16):1531-1542

2. World Health Organization (WHO) : World report on hearing. (null) 2021;

3. World Health Organization (WHO) : Hearing Screening Considerations for Implementation. 2021;

4. United States Preventative Services Task Force (USPSTF) Hearing loss in older adults: screening. 2021;

5. Turton L., Souza P., Thibodeau L., Hickson L., Gifford R., Bird J., Stropahl M., Gailey L., Fulton B., Scarinci N., Ekberg K., Timmer B. : Guidelines for Best Practice in the Audiological Management of Adults with Severe and Profound Hearing Loss. *Semin Hear* 2020;41(3):141-246

ADDENDUM

Specialist Evaluation - addendum. Recommendations for a cochlear implant evaluation.

This area is well served by existing guidelines. The CI Task Force reviewed the following existing guidelines (all linked).

1. [German Weißbuch \(white paper\) guidelines \(German version\)](#)
2. [German Weißbuch \(white paper\) guidelines \(English version\)](#)
3. [AWMF Guideline S017/71 – S2k Guideline Cochlear Implantation German Society of Oto-Rhino-Laryngology, Head and Neck Surgery, 2020](#) The Association of German-speaking Audiologists, Neurotologists and Otolologists of the German Society of Otorhinolaryngology, Head and Neck Surgery made recommendations for Pre-operative diagnostics and surgery preparation in adults. For pre-diagnostics and surgery preparation in adults, the following findings should be collected: Medical history and clinical examinations including general status, medical history, including ENT-specific history, ENT status, including eardrum microscopy and sound and speech audiometry.
4. American Academy of Audiology [CLINICAL PRACTICE GUIDELINE: COCHLEAR IMPLANTS](#) [The American Academy of Audiology \(AAA\) CLINICAL PRACTICE GUIDELINE: COCHLEAR IMPLANTS](#) states that for audiological evaluation, the audiometric test battery should include a comprehensive behavioural audiological evaluation of each ear that produces key results. The specific results can be found on p28-33 of the guidelines.
5. [Turton *et al.* 2020 Guidelines for Best Practice in the Audiological Management of Adults with Severe and Profound Hearing Loss](#) For audiologist assessment people with severe and profound hearing loss should receive an individually tailored audiological assessment which should include a comprehensive audiological examination including case history, otoscopy and behavioural and physiological auditory measures. The elements of the auditory assessment and useful tools for obtaining Diagnostic Information can be found on p148. For non-auditory assessment alongside the auditory assessment, it is essential to examine factors (outside of the hearing loss) which also influence the client and the possible treatment options. These non-auditory issues may influence the need for modification in testing, additional counselling and referrals to other professionals and may change the treatment options to be offered. The assessment needs and useful tools for obtaining Diagnostic Information can be found on p149-150.
6. [FRENCH SOCIETY OF ENT \(SFORL\) GUIDELINES 2019. INDICATIONS FOR COCHLEAR IMPLANTATION IN ADULTS, European Annals of Otorhinolaryngology, Head and Neck Diseases.](#) [The FRENCH SOCIETY OF ENT \(SFORL\) GUIDELINES 2019](#) identifies questionnaires that should be used to assess cochlear implantation.



Surgery: Intra and Post Operative Care

RECOMMENDATION

This area is well served by existing guidelines.

The CI Task Force reviewed the following existing guidelines (all linked).

1. The [German Weißbuch \(white paper\) guidelines \(German version\)](#) [German Weißbuch \(white paper\) guidelines \(English version\)](#) make recommendations for adult examinations and preoperative measures. Section 6.1 Page 12
2. [The Association of German-speaking Audiologists, Neurotologists and Otolologists of the German Society of Otorhinolaryngology, Head and Neck Surgery](#) made recommendations for indications for surgery and the surgical phase. Section 6. Indications for surgery page 25. Section 8. Surgical phase page 33
3. [The American Academy of Audiology \(AAA\) CLINICAL PRACTICE GUIDELINE: COCHLEAR IMPLANTS](#) states that although the surgical procedure is not within the purview of the audiologist, there are a number of issues surrounding surgery of which the audiologist needs to be aware. Knowledge of the procedure will allow the audiologist to guide the patient through the process and understand when to refer concerns to the surgeon. The overriding issue is the communication between the surgeon and the audiologist. This communication is critical pre-operatively when the patient asks the audiologist questions regarding surgical procedure, intra-operatively during device monitoring, and post-operatively as the patient is seen for device programming. Recommendations for a Cochlear Implant Evaluation page 28



Rehabilitation

Following cochlear implant activation after surgery, the recipient should receive implant programming and rehabilitation sessions to optimise performance.¹

Cochlear implant programming is necessary for users to hear sounds through the device.² Programming focuses on device optimisation, while rehabilitation is an active learning process that helps users make sense of the sounds they perceive. The definition of rehabilitation for cochlear implant users was developed in collaboration with CIICA and based on the WHO's definition.³ It refers to a set of interventions designed to optimise hearing in cochlear implant users to ensure that the person reaches the best quality of life at a physical, functional, social, emotional and economic level. The process of learning to hear with a cochlear implant is ongoing throughout the user's lifetime and should include assistive devices, accessibility and technical assistance. However, a survey by CIICA found that users may receive a range of rehabilitation or therapy services (from 0 to 12 sessions) in the first year but no longer receive rehabilitation after that time. Good mapping, which changes with progression, was also identified as a crucial component of rehabilitation.⁴

Together, programming and rehabilitation help users achieve the best possible hearing outcomes and improve their quality of life.²

PROSPERO QUESTION

For adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss, what is the most effective number of follow-up appointments one year post cochlear implantation to achieve optimal programming/stimulation levels?

CONSENSUS RECOMMENDATION 6

Initial activation and programming of adult cochlear implant users with severe, profound, or moderate sloping to profound sensorineural hearing loss should take place within the first 28 days post-surgery based on the person's recovery and approval from the cochlear implant surgical team.⁵

Post-activation, a cochlear implant user should have between 4–6 appointments within the first twelve months of cochlear implant use.⁵

Of these, between 2–3 should be mapping appointments taking place during the first 3 months post-activation, with additional appointments in the first year being scheduled at the discretion of the cochlear implant surgical team.



GOOD PRACTICE STATEMENT 1

Device activation can take place from the day after surgery and up to four weeks thereafter.

Considerations include the influence of resource utilisation, user anxiety around device function and loss of residual hearing, and post-implant health status.

1. Buchman *et al.* Unilateral Cochlear Implants for Severe, Profound, or Moderate Sloping to Profound Bilateral Sensorineural Hearing Loss: A Systematic Review and Consensus Statements. *JAMA otolaryngology-- head & neck surgery* 2020;146(10):942-953. 2. British Cochlear Implant Group : The rehabilitation process. n.d. 3. World Health Organization (WHO) : Rehabilitation. 2021; 4. Cochlear Implant International Community of Action (CIICA) : Sharing initial data from our survey of adults with CI: thanks to you all!. n.d; 5. American Academy of Audiology : Clinical Practice Guidelines: Cochlear Implants. 2019;



GOOD PRACTICE STATEMENT 2

Additional programming and rehabilitation sessions should be scheduled if certain changes in the person's auditory responsiveness or speech production occur. These changes include, but are not limited to:

- Changes in auditory discrimination
- Increased request for repetition
- Omission of sounds
- Prolongation of vowels
- Change in vocal quality or volume
- Intermittency
- Fluctuation in hearing with device
- Balance issues
- Head trauma
- Infection or other medical concerns for the cochlear implant site
- Anxiety
- Depression
- Cognitive impairment
- Non-auditory stimulation
- Sub-optimal hearing levels/progression
- Technology updates

EVIDENCE TO DECISION

Benefits and harms: Small net benefit, or little difference between alternatives.

Certainty of Evidence: Low. The systematic review did not identify any relevant evidence. As such, the recommendation is not developed with an evidence-based framework but informed through a consensus process involving previous guidelines and expert opinion from the Task Force.

RATIONALE

No studies were identified that met the inclusion criteria. Following a review of existing guidelines and in consultation with the CI Task Force, a consensus-based recommendation was developed.

Existing guidelines provided insight to inform the current recommendation. **The American Academy of Audiology** proposed a specific follow-up schedule of at least six appointments in the first twelve months. The recommendation proposed a prescription of appointments starting with the initial activation appointment taking place one to four weeks post-surgery. Follow-up appointments then took place at one week, one month, three months, six months, and twelve months post-activation.¹ Moreover, the **Delphi consensus guidelines** have recently highlighted evidence supporting the need for frequent programming and fitting assessments during the initial six months after cochlear implant activation, with the expectation of reducing the frequency of appointments after six months post-activation. However, due to inconsistencies in existing guidelines, an individualised approach to programming for cochlear implant users in their first year of device use was recommended taking into account their unique stimulation needs. Person-centred care in cochlear implant programming and rehabilitation has been previously recommended and is considered an important factor in achieving positive hearing health outcomes by the CI Task Force and through consultation with **CIICA**.^{2,3}

To optimise speech perception, it is recommended that users should undergo between four to six programming appointments within the first year after their initial activation session. The CI Task Force feedback provided insight on the emphasis that is required to ensure that user preference and variability was represented appropriately. Additionally, this allows the cochlear implant user to become accustomed to the device and ensures that the upper and lower stimulation levels are programmed appropriately. The CI Task Force also expressed a need to highlight circumstances where additional appointments in the first twelve months would be required. As such, a good practice statement addressing scenarios where a cochlear implant user may need additional programming appointments was developed.

1. American Academy of Audiology : Clinical Practice Guidelines: Cochlear Implants. 2019; 2. Buchman CA, *et al* . Unilateral Cochlear Implants for Severe, Profound, or Moderate Sloping to Profound Bilateral Sensorineural Hearing Loss: A Systematic Review and Consensus Statements. *JAMA otolaryngology-- head & neck surgery* 2020;146(10):942-953. 3. Aural Rehabilitation Clinical Practice Guideline Development Panel, Basura G, Cienkowski K, Hamlin L, Ray C, Rutherford C, Stamper G, Schooling T, Ambrose J : American Speech-Language-Hearing Association Clinical Practice Guideline on Aural Rehabilitation for Adults With Hearing Loss. *American journal of audiology* 2022; 1-51

PROSPERO QUESTION

For adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss, what are the essential components of an appropriate clinical pathway for rehabilitation after surgery?

CONSENSUS RECOMMENDATION 7

Cochlear implant rehabilitation for a user with severe, profound or moderate sloping to profound sensorineural hearing loss should be a multidisciplinary and person-centred approach. The essential members of the multidisciplinary cochlear implant team include:

- Ear, Nose and Throat specialist specialised in cochlear implants
- Audiologist (or equivalent)
- Speech and language therapist if available in your country (or equivalent)

The multidisciplinary cochlear implant team may involve other specialties including:

- Psychologist
- Social worker
- Neurologist
- Radiologist
- Geriatrician
- Peer support (individual and/or group)

The multidisciplinary cochlear implant team should consider initial rehabilitation (rehabilitation in the first year following cochlear implantation) and lifelong rehabilitation (ongoing rehabilitation after the first year of cochlear implantation).

The cochlear implant user, their family and/or friends should collaboratively plan their cochlear implant rehabilitation with their multidisciplinary team.



Initial Rehabilitation

The components of initial rehabilitation that should be considered include:

Ear, Nose and Throat specialist specialised in cochlear implants

- Cochlear implant follow up should take place up to three times in the first year following cochlear implantation (see recommendation 6).
- Otoscopy (using a magnifying otoscope, ear microscope or ear endoscope) and if necessary
 - a radiological examination and/ or
 - a laboratory examination

Audiologist if available in your country (or equivalent).

- Initial programming of the device to optimise access to sound and patient comfort and performance (see Recommendation 6).
- Duration of processor use per day (Holder, 2020).¹
- Check implant site related to magnet strength.
- Information and in-depth instruction in handling (care, maintenance, fault and error detection) of the cochlear implant system and in the use of available additional devices (e.g. telephone adapter, charger, additional microphone, induction or T-coil, etc.).
- Monitor aided listening performance overtime using formal free field (sound field) hearing tests and standards.
- Speech perception test in silence and in background noise.
- Counselling regarding pairing, fitting and usage of mobile media devices (e.g., smartphone TV, iPad and laptop) and other assistive listening devices.
- Training on repair strategies (i.e. basic device troubleshooting).
- In the instance of bimodal hearing, bimodal and electroacoustic adjustment should be reviewed if necessary.

Speech and language therapist if available in your country (or equivalent)

- Auditory therapy including analytic and synthetic auditory training (with phonemes, words, sentences and text) at the level of detection, discrimination, identification and comprehension in different listening conditions (in quiet, noise, with visual support e.g. lip-reading) and without visual support, using different listening devices (live voice, radio, laptop, TV, external microphone etc.).
- Training or instruction on the appropriate use and management of the sound processor and assistive listening devices.
- Training on how to improve your communication skills in daily life (at home, work, during leisure time etc.). Identify when communication has failed and why.
- Listening 1 to 1 and in (small) groups.
- Music training.
- Telephone training.

1. Holder JT, Dwyer NC, Gifford RH : Duration of Processor Use Per Day Is Significantly Correlated With Speech Recognition Abilities in Adults With Cochlear Implants. *Otology & neurotology* : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology 2020;41(2):e227-e231

Other components that could be considered on a case by case basis include:

- Counselling or psychological support.
- Peer group support.
- Social worker support for those who need extra support to live independently.

The components of lifelong rehabilitation that should be considered include:

Ear, Nose and Throat specialist specialised in cochlear implants

- Cochlear implant follow up every three years, unless otherwise indicated.

Audiologist if available in your country (or equivalent)

- Ongoing programming of the device to optimise access to sound and patient comfort and performance.
- Technical advice and evaluation of the functionality of the cochlear implant system.
- Counselling and fitting of mobile media devices and other assistive listening devices.
- Speech perception test in silence and in background noise online, if available.
- Monitor aided listening performance over time online, if available.
- Periodical adjustment and fine-tuning of processors including control of stimulation parameters.
- Training on repair strategies (i.e. basic device troubleshooting).
- In the instance of bimodal hearing, bimodal and electroacoustic adjustment should be reviewed if necessary.

Speech and language therapist if available in your country (or equivalent)

- Monitor progress on all rehabilitation topics.
- Appropriate use and management of the cochlear implant sound processor and assistive listening devices.
- Ongoing auditory therapy to train speech perception in difficult listening situations. For example, listening in group situations, from a distance, in noise and through the telephone.
- Training on how to improve communication skills in daily life (e.g. at home, work and during leisure time). Identify when communication has failed and why.

Other components of both initial and lifelong rehabilitation that could be considered on a case-by-case basis include, but are not limited to:

- Counselling or psychological support.
- Peer support (individual and/or group).
- Social worker support for those who need extra support to live independently.
- Advocacy training.



GOOD PRACTICE STATEMENT 3

Rehabilitation and expectations should be discussed with the cochlear implant user and their family prior to cochlear implantation (person-centred care).



GOOD PRACTICE STATEMENT 4

The family and/or friends of the cochlear implant user should be considered and invited to participate in rehabilitation.



GOOD PRACTICE STATEMENT 5

Cochlear implant users and relevant family and/or friends could establish specific rehabilitation goals. These goals should be reviewed to reflect the cochlear implant users progress and changing needs



GOOD PRACTICE STATEMENT 6

All cochlear implant users should be encouraged to engage in self-care using available resources. The multidisciplinary cochlear implant team should provide all users with resources available in their country for self-care and those to be used with family and/or friends. Cochlear implant manufacturer's support tools should also be offered.



GOOD PRACTICE STATEMENT 7

If available, traditional rehabilitation services in the office or remotely should be offered in conjunction with self-care.



GOOD PRACTICE STATEMENT 8

Counselling or psychological support should be considered to support the user and their family with regards to expectations, the rehabilitation procedures and their ongoing commitment to the rehabilitation program.



GOOD PRACTICE STATEMENT 9

The multidisciplinary cochlear implant team should communicate and share information (with the cochlear implant user's consent) to ensure adaption and to be able to monitor changes in the performance and success of the cochlear implant.



GOOD PRACTICE STATEMENT 10

The cochlear implant user's progress must be monitored throughout initial and lifelong rehabilitation.

EVIDENCE TO DECISION

Benefits and harms: Substantial net benefit of the recommended alternative.

The balance between benefits, harms and burdens are uncertain due to a lack of evidence identified. The potential harms include misuse of resources. However, a good rehabilitation program develops the person's ability to detect, imitate and associate meaning with the sounds of spoken language. It is thus anticipated that a comprehensive rehabilitation program for a user will outweigh any harms that may be associated with a rehabilitation program.

Certainty of evidence: Low

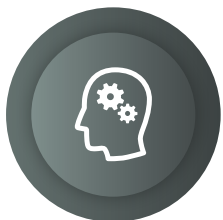
The systematic review did not identify any relevant evidence. As such, the recommendation is not developed with an evidence-based framework but informed through a consensus process involving previous guidelines and expert opinion from the Task Force.

RATIONALE

Four studies were identified that met the inclusion criteria for research question seven. However, the interventions were either very broad (i.e. did not describe the actual rehabilitation program in detail) or were investigative (e.g. amphetamine). These studies did not provide adequate or meaningful evidence to form an appropriate recommendation. A review of existing guidelines and identification of lower levels of evidence (e.g. case studies) was therefore undertaken to develop a consensus-based recommendation.

No studies considered lower level of evidence (e.g. case studies) were identified. There were also no clear and consistent guidelines on best practices for rehabilitation after cochlear implantation. Based on available guidelines - more specifically the German Weißbuch¹ as it was considered the most comprehensive - the components of rehabilitation that the multidisciplinary cochlear implant team members should consider have been proposed. Until further evidence is available, the specific programme should be tailored to the individual.

1. [German Weißbuch \(white paper\) guidelines](#)



Patient Measures and Outcomes

When evaluating the success of cochlear implantation, patient-reported outcomes should be prioritised to ensure that the treatment is providing significant benefits that are important to the individual. Speech recognition has traditionally been the primary outcome measure in the past,¹ however, other user-reported outcomes such as social wellbeing and general quality of life may be more important to cochlear implant users.

Importantly there does not appear to be a strong relationship between speech recognition ability and patient self-report.^{2,3,4} There may be two reasons for this difference:

1. The complex communication, social and emotional situations that cochlear implant users experience may not be fully represented by word or sentence recognition alone.
2. The manner in which cochlear implantation improves quality of life likely extends well beyond improvements in speech recognition.

Although what is meaningful to cochlear implant users may differ based on their personal preferences and level of hearing loss, it is important to evaluate outcomes to compare various hearing loss interventions and communicate to newly diagnosed individuals the significance of cochlear implants in a way that resonates with them.

We also acknowledge the broader impacts of cochlear implants including the potential benefits to the families and/or friends of cochlear implant users and the improvements in caregiver quality of life,⁵ however, outcome measures for such stakeholders are beyond the scope of these guidelines.

PROSPERO QUESTION

For adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss, which outcome measures are most meaningful to people to assess for improvement with a cochlear implant?

CONSENSUS RECOMMENDATION 8

Two outcomes were identified as most meaningful when evaluating improvement post-implantation in adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss. As such, audiologists if available in your country (or equivalent) should evaluate:

- Hearing-specific quality of life (including social-emotional functioning and wellbeing)
- Speech perception (particularly in noise)

1. McRackan TR, Bauschard M., Hatch JL, Franko-Tobin E., Droghini HR, Velozo CA, Nguyen SA, Dubno JR : Meta-analysis of Cochlear Implantation Outcomes Evaluated With General Health-related Patient-reported Outcome Measures. *Otol Neurotol* 2018;39(1):29-36. 2. Damen GWJA, Beynon AJ, Krabbe PFM, Mulder JJS, Mylanus EAM : Cochlear implantation and quality of life in postlingually deaf adults: long-term follow-up. *Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery* 2007;136(4):597-604. 3. Kumar RS, Mawman D, Sankaran D, Melling C, O'Connell M, Driscoll M, Freeman SM, Lloyd SKW : Cochlear implantation in early deafened, late implanted adults: Do they benefit?. *Cochlear implants international* 2016;17 Suppl 1 22-5. 4. Luxford WM, : Minimum speech test battery for post-lingually deafened adult cochlear implant patients. *Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery* 2001;124(2):125-6. 5. Aylward A, Gordon SA, Murphy-Meyers M, Allen CM, Patel NS, Gurgel RK : Caregiver Quality of Life After Cochlear Implantation in Older Adults. *Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otolology and Neurotology* 2022;43(2):e191-e19.

EVIDENCE TO DECISION

Benefits and harms: Substantial net benefits of the recommended alternative.

The balance between benefits, harms, and burdens are uncertain due to a lack of evidence identified. The recommendation was however formulated based on user experience via CIICA. The benefit of evaluating the outcomes identified thus outweighs the harms of not evaluating the outcomes identified.

Certainty of the Evidence: Moderate

The systematic review did not identify any relevant evidence. As such, the recommendation is not developed with an evidence-based framework but informed through a consensus process involving previous guidelines and expert opinion from CIICA, the CI Task Force, and the co-chairs.

As the recommendation was developed predominately with feedback from a consensus process, it is very likely that the recommendation will not change if evidence becomes available.

RATIONALE

No studies were identified that met the inclusion criteria for research question eight. What is meaningful to cochlear implant users may differ based on their personal preferences and level of hearing loss. However, it is important to evaluate outcomes to compare various hearing loss interventions and communicate to newly diagnosed individuals the significance of cochlear implants in a way that resonates with them.

Cochlear implant users via CIICA were consulted and a consensus-based recommendation was developed. For cochlear implant users, the most important outcome was quality of life including emotional functioning/ wellbeing.

PROSPERO QUESTION

For adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss, what measurement tools and/or questionnaires (e.g. speech tests, quality of life questionnaires) should be utilised to measure patient outcomes?

- How and when should professionals use the measurement tools and/or questionnaires?

CONSENSUS RECOMMENDATION 9

Two measurement tools should be used to evaluate the outcomes most meaningful when evaluating improvement post-implantation in adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss.

As such, audiologists if available in your country (or equivalent) should use:

- The Nijmegen Cochlear Implant Questionnaire (NCIQ) ¹ or the Cochlear Implant-Quality of Life (CIQOL) (global version at a minimum) to evaluate hearing-specific quality of life in adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss. If the NCIQ or CIQOL are not validated in the cochlear implant user's dominant language, another validated QoL measure may be used. (please see Appendix 1 in the Technical Report for the full questionnaire).
- Validated speech perception instrument in the dominant language of the adult cochlear implant user by using words and/or sentences in quiet and noise.

The NCIQ or CIQOL and speech perception tests should be administered before cochlear implantation to establish an individual's baseline and then again at least once 6–12 months after the cochlear implant is activated to measure personal progress.



GOOD PRACTICE STATEMENT 1

If resources allow, the NCIQ or CIQOL and speech perception tests could be administered 3, 6, and 12 months after cochlear implantation ² and re-evaluated annually after implantation. ³



GOOD PRACTICE STATEMENT 2

If a cochlear implant user expresses concern about their experience with their cochlear implant, the NCIQ and speech perception test could be re-administered.



GOOD PRACTICE STATEMENT 3

Before administering the NCIQ or CIQOL and speech perception tests, the purpose of these evaluations should be explained to the cochlear implant user and/or their family and friends.



GOOD PRACTICE STATEMENT 4

Speech perception tests should be in the cochlear implant user's dominant language.

1. Hinderink JB, Krabbe PF, Van Den Broek P : Development and application of a health-related quality-of-life instrument for adults with cochlear implants: the Nijmegen cochlear implant questionnaire. *Otolaryngology--head and neck surgery : official journal of American Academy of Otolaryngology-Head and Neck Surgery* 2000;123(6):756-65 2 Herr C, Brusckhe S, Baumann U, Stöver T : Weißbuch Cochlea Implantat-Versorgung –basierte Qualitätssicherung am Beispiel der „Audiologischen Basistherapie. *Laryngo-Rhino-Otologie* 2019;98(S 02):11117. 3 Plath M., Marienfeld T., Sand M., van de Weyer PS, Praetorius M., Plinkert PK, Baumann I., Zaoui K. : Prospective study on health-related quality of life in patients before and after cochlear implantation. *Eur Arch Otorhinolaryngol* 2022;279(1):115-125



GOOD PRACTICE STATEMENT 5

Hearing health care specialists should prioritise using the data gathered to inform rehabilitation efforts, including monitoring device functioning and programming.



GOOD PRACTICE STATEMENT 6

If there is a decline in a cochlear implant user's outcomes, appropriate care and support should be prioritised. This may include revision of cochlear implant programming, monitoring device functioning, and rehabilitation efforts.



GOOD PRACTICE STATEMENT 7

The NCIQ or CIQOL and speech perception tests should be administered more frequently if there is a marked decrease in an individual's score.

EVIDENCE TO DECISION

Benefits and harms: Substantial net benefits of the recommended alternative.

The balance between benefits, harms, and burdens is uncertain due to a lack of evidence identified. The recommendation was formulated based on user experience via consultation with CIICA. Therefore it is expected that the benefit of evaluating the outcomes identified outweighs the harms of not evaluating the outcomes identified.

Certainty of the Evidence Low

The recommendation was developed through a consensus process involving a review of previously published guidelines and expert opinion from CIICA, the CI Task Force and co-chairs. A systematic review of the literature was used to validate and support the consensus recommendation.

As the recommendation was developed predominantly with feedback from a consensus process, it is likely that the recommendation will not change if evidence becomes available.

RATIONALE

Review of global guidelines and recommendations provides limited insight into which specific measurement tools and/or questionnaires should be used to measure outcomes that are meaningful to cochlear implant users. Research also highlights the mismatch between general quality of life questionnaires and the cochlear implant experience.

Nevertheless, **the German Weißbuch guidelines**¹ outline a protocol for quality assurance in the field of cochlear implant care where the 60-item Nijmegen Cochlear Implant Questionnaire (NCIQ) is used to assess cochlear implant user outcomes.

The NCIQ was developed as a disease-specific measurement tool to assess both speech and quality of life for cochlear implant users. It has three domains (physical, social, and psychological) and six subdomains, including:

- Basic sound perception
- Self-esteem
- Advanced sound perception
- Activity
- Speech production
- Social interactions

Its use has been validated cross-culturally and the tool is available in English, Chinese, Spanish, Italian, Portuguese, and Turkish. Its routine use in existing clinical practice as per the German Weißbuch guidelines was further supported by the number of RCTs identified in the literature that also reference the NCIQ. 13 out of 45 of the identified studies, approximately 29%, used the NCIQ to assess cochlear implant user outcomes. Its use was equal to the Health Utilities Index (HUI), another assessment tool that measures global quality of life outcomes. However, the literature definitively recommends that disease-specific tools should be used in the context of cochlear implant users, to capture the experience of cochlear implant users sensitively and accurately.

The NCIQ was also featured in a systematic review of outcome domains and instruments which sought to inform the evidence base for those seeking to restore bilateral and binaural hearing in adults with unilateral severe, profound or moderate sloping to profound sensorineural hearing loss. Its cross-cultural validation and translation into various languages including English, Chinese, Spanish, Italian, Portuguese, and Turkish is also highly useful in the creation of these guidelines and their global implementation. Similarly, the Cochlear Implant-Quality of Life (CIQOL) questionnaire was suggested for its completeness and patient-centred creation. Its use was particularly endorsed by CI Task Force members from the Canadian/American region.

PRACTICAL INFO

Please follow the links below to find the NCIQ in its available languages:

[English](#)

Chinese

[Spanish](#)

Italian

[Portuguese](#)

Turkish

[German](#)

Please follow the link below and follow the prompts to find the CIQOL Global in its available languages (English, German, French, Hebrew, Arabic, Mandarin):

Please note, updates are currently being made to the link below. All versions and languages of the CIQOL Global should be available by the end of February 2023.

[CIQOL Global](#)

Background

Cochlear implants are an effective medical treatment for many adults living with severe, profound, or moderate sloping to profound sensorineural hearing loss (SNHL). However, it is estimated that no more than 1 in 20 adults who could benefit from a cochlear implant have one.^{1,2} One of the main barriers to cochlear implantation is inadequate awareness of cochlear implants among primary and hearing healthcare providers, leading to under-identification of eligible candidates.^{1,2}

The standard of care for adults with hearing loss should include treatments that best improve the individual's quality of life through optimising hearing function, social participation, and engagement. For adults with severe, profound, or moderate sloping to profound SNHL, the standard of care includes an accurate diagnosis and timely referral to an appropriate specialist centre for assessment and counselling. When it is indicated as a potential treatment option, the patient should be advised by an appropriate healthcare professional about access to cochlear implantation and aftercare.

Developing a consistent approach to optimising the care for hearing impaired adults who may not receive adequate benefit from hearing aids is an important objective. In addition, the initiative will help raise awareness and better define referral and treatment pathways, so patients can receive information about a treatment option that may help them, at the right time. In many countries, adults do not have their hearing assessed as part of regular health check-ups. Of those who receive hearing checks and are diagnosed with severe, profound, or moderate sloping to profound SNHL, few are referred to an appropriately qualified hearing specialist to examine whether an implantable hearing device is indicated as the most beneficial treatment option.³

1. Buchman *et al.* Unilateral Cochlear Implants for Severe, Profound, or Moderate Sloping to Profound Bilateral Sensorineural Hearing Loss A Systematic Review and Consensus Statements. 2. Sorkin, D. L. (2013). Cochlear implantation in the world's largest medical device market: utilization and awareness of cochlear implants in the United States. *Cochlear implants international*, 14(sup1), S12-S4. 3. Van de Heyning, P., Gavilán, J., Godey, B., Hagen, R., Hagr, A., Kameswaran, M., & Staecker, H. (2022). Worldwide variation in cochlear implant candidacy. *Journal of International Advanced Otology*, 18(3), 196-202.

Key Questions about the Living Guidelines for Cochlear Implantation in adults

WHAT IS THE LIVING GUIDELINES PROJECT ABOUT?

There is currently no global guidance or set of guidelines that are applicable for adult cochlear implantation. Building on the publication; Buchman *et al.* 2020 Unilateral Cochlear Implants for Severe, Profound, or Moderate Sloping to Profound Bilateral Sensorineural Hearing Loss A Systematic Review and Consensus Statements, a global Task Force has been formed to create a set of global guidance and guidelines to optimise the standard of care for adults eligible for cochlear implantation using an evidence-based, real-time repository under an appropriate governance structure. The project goal is to create living practice guidelines that can be adapted and adopted locally, to optimise the care for adults eligible for cochlear implantation.

WHY ARE THE GUIDELINES LIVING?

The concept of Living Guidelines means that they are adapted over time as more evidence becomes available. Living Guidelines are developed in the same way as traditional guidelines, but this approach is more flexible and overcomes the issue of the guidance becoming out of date over time. The guidelines and good practice statement will be reviewed on an annual basis and updated accordingly.

HOW DOES IT WORK?

This is a long-term project, aimed at optimising care for adults with severe to profound sensorineural hearing loss (SNHL) and aligning the recommendation dissemination with the latest methodologies. The aim is to move from traditional systematic reviews to living recommendations that can be kept up to date and be adapted and adopted in countries.

Living Guidelines use continuous evidence surveillance and rapid response pathways to incorporate new relevant evidence into systematic reviews and clinical practice guideline recommendations as soon as it becomes available. From a methodological standpoint, Living Guidelines are underpinned by the same methodologies of traditional guidelines, but this approach overcomes some key issues with traditional guidelines development process.

An integral part of this process is the formation of global stakeholder committee who will form as authors to oversee the selection of key criteria for inclusion in an online authoring and publication platform. This then allows those countries to write and publish guidelines and evidence summaries in a highly structured fashion.

The platform is a web based collaborative tool that does not require any software installation and allows publication on all devices. It facilitates computerised decision support and integration in electronic medical records

WHO'S INVOLVED?

The Task Force consists of a diverse group of 52 global hearing industry experts including academics, audiologists, Ear Nose and Throat (ENT) physicians, rehabilitation specialists and those with lived hearing loss and cochlear implant experience. Given the global reach of this document, the Task Force has geographical representation. Adults with a lived experience of hearing loss and cochlear implant users are integral to the guideline development process and have been engaged throughout. A key mechanism to do this is through the Cochlear Implant international Community of Action (CIICA), whose members have provided input into the development of evidence based and consensus-based recommendations.

DO LIVING GUIDELINES EXIST FOR OTHER HEALTHCARE SECTORS?

Yes, there are many examples of Living Guidelines endorsed and used by a wide variety of countries including UK, Australia, Japan, Denmark, the Nordics and authored by highly recognised bodies such as the World Health Organisation, The Australia Government, the Stroke Foundation, and the Diabetes consortium.

WHAT IS UNDERSTOOD BY STANDARD OF CARE?

A medical standard of care refers to a diagnostic or treatment process that a clinician should follow for a certain type of patient or condition. For the treatment of hearing loss, the standard of care should encompass treatments that best improve the individual's quality of life and health, through optimising hearing function, social participation, and engagement in line with the individual's goals.

When visiting your health care professional, there is the basic expectation that you are going to receive the most appropriate and up-to-date treatment for your illness or injury, regardless of who you see and where. You also trust that the health care professional treating you will treat you in the same way they would treat any other patient suffering from the same illness.

If a health care professional is unable to provide the necessary treatment within their facilities, or the treatment required is outside of their training and expertise, the expectation is that they will refer you to a location or specialist prepared to meet your medical needs.

HOW ARE THE GUIDELINES FORMED?

The guidelines were developed based on the GRADE research framework, an internationally recognised framework for assessing the certainty and strength of practical recommendations. Based on a systematic literature review protocol (PROSPERO), the Task Force examined the peer reviewed literature around screening, referral, and cochlear implant aftercare using the evidence to develop recommendations and good practice statement. The framework of formulation of questions was structured in a PICO format (Patient, Intervention, Comparison, Outcome) and adapted where strong guidance already existed (such as cochlear implant surgery). Where sufficient evidence around the question did not yet exist, the Task Force came to consensus about the guidance following extensive community consultation.

ONCE THE GUIDELINES ARE FINALISED, HOW CAN THEY BE USED?

The Task Force acknowledges that hearing care is diverse across the global and some services may not be available and or accessible to all. The guidelines can be adapted and adopted to meet the needs of their local region. All health care professionals should consider their local context when implementing recommendations.

HOW CAN I CONTRIBUTE?

The Task Force warmly welcomes feedback from all members of the global healthcare community. To have your say, visit the MAGICapp link [HERE](#) for the full guidelines, recommendation and technical report, create an account and provide feedback under each recommendation. Alternatively, email the Task Force directly at guidelines@htanalysts.com.au. All feedback will be considered by the Task Force, to support their evaluation of the recommendations and good practice statement included in the guidelines. A full explanation of how feedback will be used, how people's personal identifiable information will be protected, and each person's rights will be provided prior to providing informed consent to provide feedback.

Target audience

The Living Guideline is designed for use by a variety of individuals, including community members and patients, primary healthcare providers, hearing healthcare specialists such as audiologists and ear, nose and throat (ENT) specialists, as well as policy makers and decision makers involved in healthcare planning and delivery. They can also be beneficial for individuals with hearing loss or who use cochlear implants, allowing them to educate themselves on the proper care they should receive and to advocate for their needs if necessary. Healthcare professionals, administrators, and funding organisations will also find the Living Guidelines useful in their interactions with people with hearing loss or cochlear implant users.

How to read the guidelines

The recommendations are designed to provide practitioners who have the appropriate qualifications, experience, knowledge, and skills with an evidence-based framework through which they can support adults with SNHL. The guidelines are set out as recommendations and good practice statement. The recommendations outline best practice in the management of adults on the pathway to cochlear implantation. Best practice is defined using evidence where available, and otherwise where evidence is insufficient, the expert Task Force comes to consensus on a recommendation.

Good practice statements are provided for each recommendation and help conceptualise each recommendation putting them into clinical context and providing examples where appropriate. It is hoped that this best-practice guidance will improve awareness and consistency of the delivery of hearing health services.

Supporting evidence collected through the research and community consultations activities is presented for each recommendation, and a Technical Report provides references that informed and supported the guidelines development process. Each recommendation included in this document is preceded by a PROSPERO⁷ question.

Stakeholder groups

OBJECTIVES AND RESPONSIBILITIES OF THE TASK FORCE

The overall objective of the Task Force is to contribute to and support the effective development and subsequent dissemination of a set of accurate, consistent, and usable guidance and guidelines. As the guidance will need to be updated as new evidence is published or new technologies are developed, the aim is for the Task Force to continue and evolve over the long-term.

Cochlear implant users and those with hearing loss are critical to the process and included on the Task Force. In addition, representatives from the CIICA network and others were consulted, bringing user perspectives from across the globe, to ensure their voice is heard in the development of guidelines and recommendations for adults living with severe, profound, or moderate sloping to profound SNHL.

Task Force: Led by three Co-Chairs, the Task Force created a global Scientific Committee, supporting the effective development and subsequent dissemination of a set of accurate, consistent, and usable recommendations and good practice statements. The Task Force brings together cochlear implant users and subject matter experts from organisations tasked with collaboratively developing Living Guidelines, to optimise the standard of care for adults eligible for cochlear implantation via an evidence based, real time repository under their governance.

Member affiliations extended to national and international organisations and a wide range of stakeholders including society representatives, speech language therapists, general practitioners (GPs), hearing aid specialists, audiologists, ear, nose and throat (ENT)/ENT GP, payer/policy, non-government organisations (NGOs), governmental agencies, academia, organisations implementing hearing care solutions within the community and most importantly patient representatives who represent the real world experience of those with severe to profound sensorineural hearing loss (SNHL). Each member had an equal opportunity and responsibility to engage in the discussion.

The overall objective of all stakeholder groups will be to contribute to and support the effective development and subsequent dissemination of a set of accurate, consistent, and usable guidance and guidelines. As the guidance will need to be updated as new evidence is published or new technologies are developed, the aim of the Task Force is therefore for continuity and evolution over the long-term. The Task Force will lead the process and be responsible for both the design and implementation of the guidelines into practice. This will include further developing and refining the guideline scope, target audience and key questions. At a minimum, Task Force members will assist and provide input into the development of evidence based and consensus derived recommendations.

Developing guidelines

STEP 1: PROSPERO RESEARCH PROTOCOL

Three populations were studied across all review questions including, screening, referral, and CI user population.

1. The screening population includes adults aged over 18. Hearing loss challenges an individual's ability to participate in meaningful activity leading to an increased risk of social isolation, loss of autonomy, reduced employability, and neurocognitive dysfunction.
2. The referral population includes adults aged over 18 who have any degree of hearing loss and have been referred to an audiologist, hearing aid technician or other hearing professional for further evaluation. Although hearing aids suffice for many persons with hearing loss, a subset of the population with greater hearing impairment and cochlear (hair cells) damage can benefit only from cochlear implantation. Cochlear implantation is a relatively low risk procedure that directly stimulates the auditory nerve, bypassing the injured cochlear hair cells. It is the only intervention that may lead to improvements in speech understanding in this population, thereby improving quality of life measures, and chances for healthy ageing for people living with severe, profound, or moderate sloping to profound severe to profound or moderate to profound sensorineural hearing loss.
3. The CI population includes CI users aged over 18 with severe, profound, or moderate sloping to profound SNHL requiring rehabilitation and aftercare. To realise the maximum benefit from a CI, recipients require consistent follow-up, rehabilitation, and aftercare post-surgery.

PROSPERO Review question(s)

1. Who should hearing loss screening be offered to?
2. What screening tools (questionnaires or assessments) should be used by primary healthcare professionals to screen for hearing loss?
 - What is the intra-rater reliability of each screening tool?
 - What is the diagnostic accuracy of each screening tool?
3. Once adults with any level of hearing loss are identified, who and when should they be referred to for hearing healthcare evaluation/management?
4. In adults with any level of hearing loss, what criteria should be met by routine assessment tools (audiological and/or clinical) to determine referral for a complete cochlear implant evaluation?
5. In adults with hearing loss who may not meet eligibility criteria for a cochlear implant, what is the optimal frequency of assessment for monitoring hearing loss and for re-assessing them to determine referral for a complete cochlear implant evaluation?
6. For adult cochlear implant users with severe, profound, or moderate sloping to profound sensorineural hearing loss, what is the most effective number of follow-up appointments one year post cochlear implantation to achieve optimal programming/stimulation levels?
7. For adult cochlear implant users with severe, profound, or moderate sloping to profound sensorineural hearing loss, what are the essential components of an appropriate clinical pathway for rehabilitation after surgery?
8. For adult cochlear implant users with severe, profound, or moderate sloping to profound sensorineural hearing loss, which outcome domains are most meaningful to patients to assess for improvement with cochlear implants?
9. For adult cochlear implant users with severe, profound, or moderate sloping to profound sensorineural hearing loss, what measurement tools and/or questionnaires (e.g., speech tests, QoL questionnaires) should be utilised to measure patient outcomes?
 - a. How and when should professionals use the measurement tools and/or questionnaires?

Developing guidelines cont.

SCOPE

- The guidelines bring together all recommendations for the effective management of hearing loss and adult cochlear implant users with severe to profound or moderate sloping to profound sensorineural hearing loss, relevant to the global context, and includes aspects of best practice across the continuum of care including assessment and diagnosis of hearing loss, referral pathways, cochlear implant assessment, cochlear implant rehabilitation after surgery and measuring cochlear implant outcomes.
- No guidance is given on hearing loss and cochlear implantation in infants, children, and youth, i.e., <18 years old, cochlear implant eligibility criteria, surgical aspects of cochlear implantation or cochlear implantation in adults with hearing loss other than severe to profound or moderate sloping to profound sensorineural hearing loss. Please refer to the available guidelines in your respective region for guidance on these.
- As the guidelines are living, the Task Force seeks to expand the scope of the guidelines to cochlear implantation in adults with hearing loss other than severe to profound or moderate sloping to profound sensorineural hearing loss in the future.

STEP 2: EVIDENCE TO GUIDELINE DEVELOPMENT PROCESS

- To assist in the development of the Living Guidelines, a global Task Force which included expert Ear, Nose and Throat (ENT) specialists, audiologists and equivalent, other hearing specialists and cochlear implant users was formed. The Task Force assisted in informing evidence-based recommendations, providing expert opinion, and achieving consensus on recommendations where required.
- The guideline was developed using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) processes and Evidence to Decision framework. A full systematic literature review was conducted for each clinical question to identify the highest quality evidence to support recommendation creation. Where required, the Task Force and/or the Cochlear Implant International Community Action (CIICA) group were consulted for external literature identification and expert feedback to address specific questions. Additional details are described in the methodology section of these Living Guidelines.
- Cochlear Implant Living Guidelines is any document developed by the Cochlear Implant Task Force containing recommendations for clinical practice, or public health practice or health policy. A recommendation informs the intended end-user what he or she can or should do in specific situations to achieve the best possible health outcomes, individually and/or collectively. It guides the choice among different interventions or measures to ensure a positive impact on health and implications for the use of resources. These may be evidence-based or consensus-based statements. Where evidence is unavailable, consensus-based statements reflect the consensus of the Task Force that the benefits of adhering to the intervention or course of action are large and unequivocal, and are based on expert opinion, current guidelines or on indirect and lower levels of evidence.
- For some recommendations, good practice statement are provided. These statements also reflect the consensus of the Task Force and provide additional contextual support to each recommendation where a systematic literature was not carried out.

DIVERSITY IN GLOBAL HEARING CARE

- The Task Force acknowledges that hearing care is diverse across the global and some services may not be available and or accessible to all. All health care professionals should consider their local context when implementing recommendations.

UPDATING EVIDENCE-BASED GUIDANCE

- The first edition of these Cochlear Implant Living Guidelines was released 25th February 2023 for public consultation.
- Readers should note the dates of individual recommendations. Revisions to this guidance will be communicated via the Task Force. From this point forward, these guidelines represent the latest and definitive reference for all guidance on improving the standard of care for adults with hearing loss and the role of cochlear implantation in adults with severe to profound or moderate sloping to profound sensorineural hearing loss.

DISSEMINATION AND IMPLEMENTATION

- These Living Guidelines are available on the MAGICapp online platform, linked to the Adult Hearing Website. When recommendations are updated, they will be labelled as such and will always display the date of the most recent update. Each time there is an update, an updated PDF version of the Living Guidelines will be downloadable on the Adult Hearing website to facilitate access where the Internet is not reliably available.
- Tools and practical resources will be disseminated in parallel to the implementation of these Living Guidelines to enhance uptake and facilitate successful implementation.

EVIDENCE GAPS

The following comments have been included on the MAGICapp portal in reference to each of the PROSPERO research questions

RESEARCH QUESTION 1+2

1. **Who should hearing loss screening be offered to?**
2. **What screening tools (questionnaires or assessments) should be used by primary healthcare**

There was a lack of available evidence on who should be referred for a full audiological evaluation. The intention of the literature search strategy was for the diagnostic accuracy studies to provide evidence on what populations the screening tool was most sensitive and/or specific in. However, it was identified that in specific populations for example, those with diabetes may be more at risk of hearing loss. Thus, in future versions, the Task Force will consider if a separate literature search strategy is undertaken for research question 1 that identifies all risk factors for hearing loss.

RESEARCH QUESTION 3

3. **Once adults with any level of hearing loss are identified, who and when should they be referred to for hearing healthcare evaluation/management?**

No randomised control trial (RCT) or non-randomised studies of intervention (NRSI) evidence was identified.

RESEARCH QUESTION 4

In adults with any level of hearing loss, what criteria should be met by routine assessment tools (audiological and/or clinical) to determine referral for a complete cochlear implant (CI) evaluation?

The evidence presented from the literature search identified eight assessment criteria for referral to cochlear implant evaluation. However, the co-chairs decided upon one specific criteria – a >60 dB HL PTA and <60% correct in a monosyllabic word recognition score (WRS) test – due to its ease of use and relatively low resource utilisation.

This criterion was chosen as it is easily measurable, meaning it is less resource intensive than the other criteria, and can be quickly implemented in clinical settings. It was noted, however, that this test is only validated for English, making it a less viable option for global implementation. Thus, it was suggested to use a functional hearing assessment of the adult's everyday environment as an alternative. The assessment entails the patient completing tasks that are pertinent to their daily life, such as following conversations, understanding basic instructions, and being able to communicate with others.

For adults with unilateral sensorineural hearing loss, an additional good practice statement was developed that acknowledges they may be eligible for cochlear implant candidacy, though updated evidence evaluating assessment criteria in this population is needed to amend the recommendation.

RESEARCH QUESTION 5

In adults with hearing loss who may not meet eligibility criteria for a CI, what is the optimal frequency of assessment for monitoring hearing loss and for re-assessing them to determine referral for a complete CI evaluation?

No RCT or NRSI evidence was identified.

RESEARCH QUESTION 6

For adult CI users with severe, profound, or moderate sloping to profound sensorineural hearing loss, what is the most effective number of follow-up appointments one year post CI implantation to achieve optimal programming/stimulation levels?

No RCT or NRSI evidence was identified.

RESEARCH QUESTION 7

For adult CI users with severe, profound, or moderate sloping to profound sensorineural hearing loss, what are the essential components of an appropriate clinical pathway for rehabilitation after surgery?

Four studies were identified that met the inclusion criteria for research question seven. However, the interventions were either very broad (i.e., did not describe the actual rehabilitation program in detail) or were investigative (e.g., amphetamine). These studies did not provide adequate or meaningful evidence to form an appropriate recommendation.

Further RCT and NRSI evidence is required to have a strong recommendation. Further understanding is required on what are the essential components of an appropriate clinical pathway for rehabilitation after surgery for all adult cochlear implant users with severe, profound, or moderate sloping to profound sensorineural hearing loss.

RESEARCH QUESTION 8

For adult CI users with severe, profound, or moderate sloping to profound sensorineural hearing loss, which outcome domains are most meaningful to patients to assess for improvement with CIs?

There was a lack of evidence outlining which specific outcome measures were most meaningful to assess improvement in adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss. Further research is required to inform this research question.

RESEARCH QUESTION 9

For adult CI users with severe, profound, or moderate sloping to profound sensorineural hearing loss, what measurement tools and/or questionnaires (e.g., speech tests, QoL (quality of life) questionnaires) should be utilised to measure patient outcomes?

There was a lack of evidence specifying which measurement tools and/or questionnaires should be utilised to measure patient outcomes. Nevertheless, 13 of the 45 RCTs and NRSIs identified assessed pre- and post-improvement with cochlear implants using the NCIQ. Consensus and a non-systematic review also supported the use of the CI-QoL Global, however, no RCTs nor NRSIs were identified using the questionnaire likely due to its recent publication. As such, further research is required to inform this research question.

Glossary & Abbreviations

Audiologist if available in your country (or equivalent)	Audiologist if available in your country (or equivalent) refers to a person having undergone a recognized degree or diploma course in audiology. Some Audiologists (or equivalent) have specialist expertise in cochlear implants ⁷ . In some countries, an ENT specialist undertakes the role of an audiologist.
Bimodal or bimodal hearing	Refers to the instance where an individual has a cochlear implant in one ear and hearing aid in the other ear.
Cochlear implant	A cochlear implant is a surgically implanted electronic device that provides the sensation of sound for people with severe and profound hearing loss.
Cochlear implant rehabilitation	A set of interventions designed to optimise hearing in cochlear implant users to ensure that the person reaches the best quality of life at a physical, functional, social, emotional and economic level.
Cochlear implant specialist	A healthcare professional in your country that provides specialist care in the assessment, provision and/or care of cochlear implants
Ear, nose and throat (ENT) specialist (or otolaryngologist)	A medical doctor who has received training in the management of diseases of the ear, nose and throat, through a recognised degree or diploma course.
Hearing loss	A person has hearing loss if they are not able to hear as well as someone with normal hearing, meaning they have a hearing threshold worse than 20dBHL in one or both ears ⁸
Hearing healthcare specialist	Any healthcare professional in your country that provides specialist care in diagnosing and addressing hearing loss through hearing technology
Hearing specific quality of life	Quality of life subjectively measures a person's perception of their position in life. Disease-specific quality of life assesses the special states and concerns of different diseases or conditions. These measures are typically more specific and sensitive to the changes that are important to the people living with the disease or condition.
Person-centred care	The provision of care that is respectful of and responsive to individual preferences, needs, and values and ensuring that the person's values guide all clinical decisions. Person-centred care also means involving the person's family where appropriate
Primary healthcare professional	A healthcare professional that provides care to enhance a person's overall health and wellbeing
Pure-tone average (PTA)	The average of hearing sensitivity at 500, 1000, and 2000 Hz.
Rehabilitation	A set of interventions designed to optimise functioning and reduce disability in individuals with health conditions in interaction with their environment [153]
Speech and language therapist if available in your country (or equivalent)	A person having a recognised diploma or degree in speech and language therapy. In some countries, speech therapy is part of a hearing specialist's training.

Abbreviations & Acronyms

CI	Cochlear implant
CICE	Cochlear implant candidacy evaluation
CIICA	Cochlear Implant International Community of Action
CIQOL	Cochlear Implant Quality of Life
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HUI	Health Utilities Index
NCIQ	Nijmegen Cochlear Implant Questionnaire
PTA	Pure-tone average
SNHL	Sensorineural hearing loss. A type of hearing loss caused by damage to the cochlea and/or the hearing nerve
SUN	Speech Understanding in Noise
WHO	World Health Organization
WRS	Word recognition score

Recommendation and good practice statement references

PROSPERO QUESTION 1&2

1. Who should hearing loss screening be offered to?
2. What screening tools (questionnaires or assessments) should be used by primary healthcare professionals to screen for hearing loss?

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PROSPERO QUESTION 3

Once adults with any level of hearing loss are identified, who and when should they be referred to for HEARING HEALTHCARE EVALUATION/MANAGEMENT?

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NO REFERENCES IDENTIFIED.

Reference/guidelines used to inform recommendations and good practice statement

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PROSPERO QUESTION 4

In adults with any level of hearing loss, what criteria should be met by routine assessment tools (audiological and/or clinical) to determine referral for a complete cochlear implant (CI) evaluation?

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PROSPERO QUESTION 5

In adults with hearing loss who may not meet eligibility criteria for a CI, what is the optimal frequency of assessment for monitoring hearing loss and for re-assessing them to determine referral for a complete CI evaluation?

REFERENCES CONSIDERED

NO STUDIES IDENTIFIED

Reference/guidelines used to inform recommendations and good practice statement

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PROSPERO QUESTION 6

For adult CI users with severe, profound, or moderate sloping to profound sensorineural hearing loss, what is the most effective number of follow-up appointments one year post CI implantation to achieve optimal programming/stimulation levels?

REFERENCES CONSIDERED

NO STUDIES IDENTIFIED

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PROSPERO QUESTION 7

For adult CI users with severe, profound, or moderate sloping to profound sensorineural hearing loss, what are the essential components of an appropriate clinical pathway for rehabilitation after surgery?

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PROSPERO QUESTION 8

For adult CI users with severe, profound, or moderate sloping to profound sensorineural hearing loss, which outcome domains are most meaningful to patients to assess for improvement with CI?

REFERENCES CONSIDERED

NO STUDIES IDENTIFIED

CIICA consultations were used to inform recommendations and good practice statement.

PROSPERO QUESTION 9

For adult CI users with severe, profound, or moderate sloping to profound sensorineural hearing loss, what measurement tools and/or/ questionnaires (e.g. speech tests, QoL (quality of life) questionnaires) should be utilised to measure patient outcomes?

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