Improving the standard of care for adults with hearing loss and the role of cochlear implantation: Living Guidelines

Main editor

The CI Task Force

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Disclaimer

The Living Guideline is a general guide to appropriate practice, to be followed subject to the health care practitioner's judgement and the individual's preferences. The Living Guideline is designed to provide information to assist decision-making. Recommendations and good practice statements contained herein are based on the best available evidence published up to 6th May 2022. The relevance and appropriateness of the information and recommendations in this document depend on the individual circumstances. Moreover, the recommendations and guidelines are subject to change over time.

Each of the parties involved in developing this document expressly disclaims and accepts no responsibility for any undesirable consequences arising from relying on the information or recommendations contained herein.

Sections

1. Public consultation

Info Box

Public consultation

The process for creating the Living Guidelines involves gathering input and feedback on the recommendations and good practice statements. 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. Please note you need to sign into MAGICapp to leave a comment and these comments will be public and be able to be viewed by other users. If using the submission template the feedback, identifiable information will only be visible to the administrator and will remain anonymous to the general public.

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2. Reading guide

Info Box

The guideline in MAGICapp consists of two layers: 1. recommendations and good practice statements and 2. supporting information.

1. Recommendation and good practice statements

Recommendations based on a systematic literature review are graded as either strong or weak and for or against an intervention, statements based on indirect evidence are referred to as good practice statements. The process of developing recommendations and good practice statements following the GRADE process is described in the Methodology.

2. Supporting information

Under each recommendation are several tabs which contain information that supports the recommendation. These are outlined below.

Section heading: The section heading can be expanded by clicking on the heading. This section contains information on the research question and some general information about the population or test described in the section.

Research evidence (if available): The research evidence tab contains a summary of the evidence used to make the recommendation. The evidence for the intervention versus each comparator is presented in outcomes and a summary.

- **Outcomes:** a tabular view of the overall effect estimates for each outcome assessed in the systematic review. For further information or a detailed description of the outcome, study results and certainty of the evidence click on the eyeball in the top right-hand corner of the relevant cell.
- **Summary:** Overview and brief review of the underlying evidence.

Evidence to decision: The evidence to decision tab gives a summary of the factors that the Cochlear Implant Task Force (CI Task Force) considered relevant under each GRADE domain:

- benefits and harms
- certainty of evidence
- values and preferences
- resources and other considerations

Rationale: Describes how the CI Task Force combined the factors in the evidence to decision process and/or expert opinion to develop the recommendation, overall direction and strength of the recommendation.

Practical information (if available): Provides information (if any) for healthcare professionals to implement the recommendation.

Feedback: If you are logged in as a user, you can comment here on specific recommendations. See here for guidance on how to log in.

References: Reference list for studies used to develop the recommendations.

Alternatively, you can download a PDF version of the Living Guidelines here.

3. Introduction

Hearing health is a recognised public health priority with prevalence of hearing loss rising worldwide *[7]*. Currently, there is a lack of awareness of and inconsistency in diagnosing and managing of 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.

In 2020, a modified Delphi consensus process *[5]* was convened that included a panel of 30 international specialists in the fields of otology, audiology and hearing science, representing the first step towards the development of international guidelines on best practices for cochlear implantation in adults with sensorineural hearing loss.

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 to profound or moderate sloping to profound sensorineural hearing loss, the standard of care should include accurate identification, diagnosis and timely referral to an appropriate specialist centre for assessment and counselling. When indicated as a treatment option, the patient should be advised by an appropriate healthcare professional about access to cochlear implantation and aftercare.

Clinical guidelines are integral to ensuring that healthcare decisions are based on the best available evidence. In 2021, an international group of cochlear implant users and experts in the fields of otology, audiology and hearing science were brought together to form a Task Force in partnership with the Cochlear Implant International Community of Action (CIICA). The Cochlear Implant Task Force (CI Task Force) was established to develop living practice guidelines and guidance that can be adapted and adopted in country, in order to optimise the care for adults indicated for cochlear implants. Member affiliations will extend to national and international organisations and a wide range of stakeholders implementing hearing care solutions within the community and most importantly patient representatives who represent the real-world experience of adults with severe to profound or moderate sloping to profound sensorineural hearing loss.

As the guidance and guidelines will need to be updated as new evidence is published, the aim of the CI Task Force is therefore for continuity and evolution over the long term.

Purpose
The *Cochlear Implant Living Guidelines* (Living Guidelines) provide a series of best practice recommendations to optimise the care for adults with hearing loss and indicated for cochlear implantation, using the best available evidence. The Living Guidelines should not be seen as an inflexible recipe for hearing loss or cochlear implant management; rather, they provide a guide to appropriate practice to be followed subject to clinical judgement and individual or user preferences.

Scope
The Living Guidelines cover the most critical topics for effective management of hearing loss and cochlear implants, relevant to the global context, and include 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.

The Living Guidelines do not cover:

- hearing loss and cochlear implantation in infants, children and youth, i.e. <18 years old.
- surgery and intra and post-operative care, this area is well served by existing guidelines which have been cited and referenced appropriately in each section (see Section 5.5).
- device programming, rehabilitation, patient outcome and measures in adults with hearing loss other than severe, profound or moderate sloping to profound sensorineural hearing loss.

Please refer to the available guidelines in your respective region for the management of these.

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.

Use
The primary goal of the Living Guideline is to help healthcare professionals improve the quality of the care they provide to the individual across the hearing health continuum.

Guidelines differ from clinical or care pathways (also referred to as critical pathways, care paths, integrated care pathways, case management plans, clinical care pathways or care maps). Guidelines are an overview of the current best evidence translated into clinically relevant statements. Care pathways are based on best practice guidelines but provide a local link between the guidelines and their use.

In considering the implementation of the Living Guideline at a local level, healthcare professionals are encouraged to identify the barriers, enablers and facilitators to evidence-based practice within their own environment and determine the best strategy for local needs. Where change is required, initial and ongoing education is essential and is relevant to all recommendations in the Living Guideline.

Endorsement
The Living Guideline has been endorsed by a number of organisations and associations. Refer to the document on [TBC following public consultation] that details the organisations formally endorsing the Living Guidelines.

Disclaimer
The Living Guideline is a general guide to appropriate practice, to be followed subject to the health care practitioner's judgement and the individual's preferences. The Living Guideline is designed to provide information to assist decision-making. Recommendations and good practice statements contained herein are based on the best available evidence published up to 6th May 2022. The relevance and appropriateness of the information and recommendations in this document depend on the individual circumstances. Moreover, the recommendations and guidelines are subject to change over time.

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Cochlear Implant Task Force. Improving the standard of care for adults with hearing loss and the role of cochlear implantation: Living Guidelines. Available at https://app.magicapp.org/#/guideline/j2bBrj. Accessed [insert date, month and year if applicable specific sections or chapters].

3.1 What is hearing loss?

The World Health Organization's (WHO) *World Report on Hearing* *[7]* estimates that by 2050 approximately 2.5 billion people will be living with some degree of hearing loss. After hypertension and arthritis, hearing loss is the most common chronic health problem or sensory deficit in older persons *[8][9]*. As defined by WHO, 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 of 20 dB HL or better in both ears *[7]*. Hearing loss can be mild, moderate, moderately severe, severe or profound and can affect one or both ears. Major causes of hearing loss include:

- congenital or early onset hearing loss
- chronic middle ear infections
- noise-induced hearing loss
- age-related hearing loss
- ototoxic drugs that damage the inner ear.

To standardise the way in which the severity of hearing loss is reported, WHO has adopted a grading system based on audiometric measurements. To ensure the International CI Living Guidelines are consistent with a globally recognised measure, the CI Living Guidelines will adopt the same grading system. The grades of hearing loss and related hearing experience are presented in **Table 1**.

Table 1 Grades of hearing loss and related hearing experience

Grade	Hearing threshold[1] in better hearing ear in dB *	Hearing experience in a quiet environment for most adults	Hearing experience in noisy environment for most adults
Normal hearing	Less than 20 dB	No problem hearing sounds	No or minimal problem hearing sounds
Mild hearing loss	20 to < 35 dB	Does not have problems hearing conversational speech	May have difficult hearing conversational speech
Moderate hearing loss	35 to < 50 dB	May have no difficulties understanding speech in quiet	May have difficulties understanding speech in noise
Moderately-severe hearing loss	50 to < 65 dB	Difficulty hearing conversational speech, can hear raised voices without difficult	Difficulty hearing most speech and taking part in conversation
Severe hearing loss	65 to < 80 dB	Does not hear most conversational speech; may have difficulty hearing raised voices	Conversational speech cannot be heard
Profound hearing loss	80 to < 95 dB	Extreme difficulty hearing raised voices	Conversational speech cannot be heard
Complete or total hearing loss/deafness	95 dB or greater	Cannot hear speech and most environmental sounds	Cannot hear speech and most environmental sounds
Unilateral **	< 20 dB in the better ear, 35 dB or greater in the worse ear	May not have problem unless sound in near the poorer hearing ear. May have difficulty in locating sounds	May have difficult hearing speech and taking part in conversation, and in locating sounds

Source: World Health Organization (WHO) *[7]*

* The classification and grades are for epidemiological use and applicable to adults. The following points must be kept in mind while applying this classification: 1) While audiometric descriptors (e.g. category, pure-tone average) provide a useful summary of an individual's hearing thresholds, they should not be used as the sole determinant in the assessment of disability or the provision of intervention(s) including hearing aids or cochlear implants; 2) The ability to detect pure tones using earphones in a quiet environment is not, in itself, a reliable indicator of hearing disability. Audiometric descriptors alone should not be used as the measure of difficulty experienced with communication in background noise, the primary complaint of individuals with hearing loss

** Unilateral hearing loss can pose a significant challenge for an individual at any level of asymmetry. It, therefore, requires suitable attention and intervention based on the difficulty experienced by the person

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[1] 'Hearing threshold' refers to the minimum sound intensity that an ear can detect as an average of values at 500, 1000, 2000, 4000 Hz in the better ear

3.2 What is a cochlear implant?

A cochlear implant is a type of medical device that is surgically implanted into the ear to help people with severe, profound, or moderate to profound sensorineural hearing loss *[13]*. It can be inserted into one ear (unilaterally) or both ears (bilaterally) by ear, nose, and throat (ENT) specialists *[13]*. Cochlear implants have been available for adults since 1972, but in the last decade, there has been an increase in their use among adults as awareness of their effectiveness and the connection between good hearing and healthy ageing grows *[14]*. Nevertheless, cochlear implant use in adults remains underutilised.

How does a cochlear implant work?
Unlike hearing aids which amplify sound, cochlear implants stimulate the acoustic nerve directly, bypassing the ear's normal sound-conducting mechanism *[13][15]*. Cochlear implants have two parts:

1. the implant or external microphone, and
2. the speech processor (worn behind the ear).

The implant or external microphone is placed under the skin by an ENT specialist. The implant has an array of electrodes that are placed inside the cochlea by the specialist.

The speech processor converts speech and environmental sound into a digital signal and sends it across the skin to the implant. The

electrodes on the implant stimulate the cochlea's auditory (hearing) nerve fibres, and the auditory nerve carries the signal to the brain. The brain then interprets the signal as sound.

3.3 What is person and family-centred care?

Person and family-centred care is increasingly recognised as being key to ensuring good quality services and ensuring that users and families can get the best outcomes from cochlear implantation. Person-centred care is respectful and responsive to individual user preferences, needs and personal values ensuring that their needs and values guide all clinical and support decisions. Person-centred care ensures that people are equal partners in the management of their hearing and communication needs, including shared decision-making and goal setting. Family-centred care ensures health care is planned around the whole family, and all family members are recognised as care recipients and active members. Cochlear implantation provides hearing for life: person and family-centred cochlear implant services must be for life. *[152][153][154][155][156][157][158][159][160]*

As WHO concludes in the World Report on Hearing (p244), "a*dopting a people-centred approach that integrates ear and hearing care into national health systems as part of universal health coverage is the only way to confront this growing challenge* [of addressing hearing loss]". *[7][161][162]*

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Person and family-centred care for people living with hearing loss and cochlear implant users can be summarised in the quote from Delbanco: "*Nothing about me without me"* or as a cochlear implant user during the CIICA-conversation on 26 January 2023 said: "*see the person as a whole, not just this person with a hearing loss" [152].*

4. Methodology

Info Box

Methods and processes
A summary of the methodology used is provided below under 'overview of methodology'. For a comprehensive understanding of the methods and processes employed, please refer to the Technical Report Appendix A to C and Technical Report Appendix D to H (Appendix E1 and Appendix F1) or the protocol published a priori on PROSPERO (CRD: 42022325393).

Conflicts of interest
A summary of the declarations of interests can be found here.

Public consultation

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4.1 Overview of methodology

Development of questions
Questions have been extensively developed using the PICO process. PICO stands for patient/population, intervention, comparison and outcomes and is an evidence-based practice to frame and answer a clinical or health care related question. These questions will be reviewed with each iteration of the guidelines. In this 'living' phase the CI Task Force reviews the PICO questions on an annual basis. The clinical questions are listed at the start under *Clinical Guidance*.

A research protocol was then developed that described the methodology to be used to source the clinical evidence (a systematic search of the literature), select the best available evidence, critically appraise and present the evidence and determine the certainty of the evidence, using a structured assessment of the body of evidence in accordance with Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology.

Systematic review process
These evidence-based Cochlear Implant Living Guidelines were developed by following the principles proposed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group. The process involved developing a set of research questions, systematically reviewing the scientific literature for evidence related to those questions, and then developing and grading recommendations based on a structured assessment of the evidence. The methods used to apply this process are outlined here and are given in full in the accompanying technical reports *[41]* that present, in detail, the methodology used to identify the evidence base (clinical questions addressed, systematic literature search undertaken and eligibility criteria described), the characteristics of the evidence found (data extraction and risk of bias forms) and detailed results presented by outcome (evidence summary tables, forests plots).

The systematic review process was based on the description outlined in the Cochrane handbook for systematic reviews of interventions and relevant sections in the JBI Manual for Evidence Synthesis *[163]*. Covidence, a web-based platform for producing systematic reviews was used to store data that are compatible with the Cochrane data collection tools. GRADEpro GDT software was used to record decisions and derive an overall certainty of the evidence for each outcome, where evidence was available (high, moderate, low or very low). To identify the evidence base for the nine research questions outlined under *Clinical Guidance*, a systematic search of published medical literature was conducted. All potentially relevant studies were identified after applying prespecified inclusion and exclusion criteria as outlined in the research protocol. For eligible studies, the risk of bias was assessed, appropriate data was extracted into data extraction tables and results were summarised into appropriate categories according to

each question.

On an annual basis, the CI Task Force will monitor the literature for relevant, new evidence by screening all randomised controlled trials, nonrandomised studies of interventions or diagnostic accuracy studies. One member of the project team initially screens all abstracts and excludes clearly irrelevant studies. Potentially included studies are allocated to relevant topics covered by the guidelines and a second member of the project team reviews and confirms included studies prior to sending them to the relevant working group members. Any new research identified through these reviews will be incorporated into the recommendations if deemed appropriate.

Early assessment of new evidence
Early assessment and incorporation of pivotal new evidence identified by the CI Task Force or the public will be implemented between the systematic review periods. Where new evidence is identified between the annual systematic review periods, the CI Task Force will consider whether to update the guidelines prior to the next systematic review period via a prioritisation process which will consider several questions (modified from the WHO prioritisation framework) *[129]*:

- Does the evidence have the potential to change an existing Living Guideline recommendation?
- Could the evidence impact the credibility of an existing Living Guideline recommendation?
- Is there potential for an updated Living Guideline recommendation to significantly change global clinical practice?

The annual systematic review and the early assessment of new evidence will allow for any relevant evidence to be captured within a year of publication, while also providing a framework for more rapid consideration of significant evidence that may emerge between annual systematic reviews.

Brief summary of GRADE
The Living Guidelines were developed following the GRADE methodology (Grading of Recommendations, Assessment, Development and Evaluation).

GRADE 'evidence to decision' framework includes a minimum of four factors to guide the development of a recommendation and determine the strength of that recommendation:

1. The balance between desirable and undesirable consequences.
2. Confidence in the estimates of effect (quality of evidence).
3. Confidence in values and preferences and their variability (clinical and consumer preferences).
4. Resource use (cost and implementation considerations).

For full details of how GRADE is used for developing clinical recommendations, refer to the GRADE handbook, available at: http://gdt.guidelinedevelopment.org/app/handbook/handbook.html.

Strength of recommendations
GRADE evidence profiles were developed for each comparison and outcome, with relevance to the Australian context considered at this time. As per GRADE guidance, the body of evidence was consolidated and rated across five key domains:

- risk of bias – based on the summary assessment across studies for each outcome reported for a comparison
- inconsistency – based on heterogeneity in the observed intervention effects across studies that suggests important differences in the effect of the intervention, and whether this can be explained
- imprecision – based on the interpretation of the upper and lower confidence limits, and whether the intervention has a clinically important effect
- indirectness – based on important differences between the review questions and the characteristics of included studies that may lead to important differences in the intervention effects
- publication bias – based on the extent to which the evidence is available; such bias would be suspected when the evidence is limited to a small number of small trials

For each domain, a judgement was made about whether there were serious, very serious or no concerns, resulting in an overall grade (high, moderate, low or very low) for the certainty of evidence for each outcome, as detailed in **Table 2**. Scoring of the certainty of the evidence began as ‘high’ for randomised trials (score=4) and was downgraded by −1 for each domain with serious concerns, or −2 for very serious concerns, with observational studies being a ‘low’. Further information is detailed in the Technical Report [172].

Table 2: GRADE certainty of evidence

Level of evidence	Description
High (⨁⨁⨁⨁)	Further research is very unlikely to change the confidence in the estimate of effect
Moderate (⨁⨁⨁⊖)	Further research is likely to have an important impact in the confidence in the estimate of effect
Low (⨁⨁⊖⊖)	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low (⨁⊖⊖⊖)	Any estimate of effect is very uncertain

Formulating recommendations

The evidence-to-decisions framework provided within MAGICapp was used to inform the translation of the evidence into recommendations for use in the clinical guidance chapter. Recommendations were made after considering the following key concepts:

- Benefits and harms
- Certainty of evidence
- Values and preferences
- Resources and other considerations (e.g equity, acceptability and feasibility)

Recommendations were developed according to the processes outlined by the GRADE working group. Recommendations based on a systematic review were graded as either strong or weak and for or against an intervention. Good practice statements were developed using a consensus process and were based on indirect evidence and expert opinion from the CI Task Force. A consensus process was used to ensure that the clinical guidance was consistent with the evidence presented. The GRADE certainty of the evidence was used to inform the strength of any evidence-based recommendations that were made, with higher certainty evidence resulting in a strong recommendation for or against a particular action, and lower certainty resulting in a weak or conditional recommendation for or against a particular action as outlined in **Table 3**. The recommendations and good practice statements were reviewed by the CI Task Force between November 2022 to February 2023.

Table 3: Definition of the strength and direction of recommendations

Definition	Description
Strong recommendation for	The CI Task Force is confident that the benefits outweigh the harms for almost everyone. All or nearly all information people would likely choose this option.
Strong recommendation against	The CI Task Force is confident that the harms outweigh the benefits for almost everyone. All or nearly all people would decline the intervention.
Weak recommendation for	The benefits probably outweigh the harms, but uncertainty exists. Most informed people would not choose this intervention, however different choices may be appropriate in individual circumstances.
Weak recommendation against	The harms probably outweigh the benefits, but uncertainty exists. Most informed people would not choose this intervention, however difference choices may be appropriate in individual circumstances.
Consensus-based statements	A consensus-based statement indicates that there is either a lack of evidence or insufficient quality of evidence on which to base a recommendation but the CI Task Force believed advice should be made. Statements were developed based on consensus and expert opinion (guided by existing guidelines and any underlying or indirect evidence).
Good practice statement	A good practice statement indicates that the CI Task Force has high confidence in the indirect evidence, existing guidelines or expert opinion.

The implications of the GRADE recommendation categories (for a positive recommendation) for adults or cochlear implant users, health care practitioners and policymakers is outlined in **Table 4**.

Table 4: Implications of GRADE recommendation categories (for a positive recommendation) for adults or cochlear implant users, healthcare professionals and policymakers

	Strong recommendation	Weak recommendation
For adults or cochlear implant users	Most individuals in this situation would want the recommended course of action and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
For healthcare professionals	Most individuals should receive the recommended course of action. Adherence to this recommendation according to the Living Guidelines could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognise that different choices will be appropriate for different individuals, and that you must help each patient arrive at a management decision consistent with her or his values and preferences. Decision aids may well be useful helping individuals making decisions consistent with their values and preferences. Healthcare professionals should expect to spend more time with individuals when working towards a decision.
For policymakers	The recommendation can be adapted as policy in most situations including for the use as performance indicators.	Policy making will require substantial debates and involvement of many stakeholders. Policies are also more likely to vary between regions. Performance indicators would have to focus on the fact that adequate deliberation about the management options has taken place.

Source: GRADE Handbook (http://gdt.guidelinedevelopment.org/app/handbook/handbook.html)

For all Living Guideline recommendations, it is assumed that healthcare professionals will be appropriately qualified and skilled to carry out the intervention.

5. Clinical guidance

An overview of the elements considered within the Living Guidelines across a person's journey from hearing loss screening and assessment to cochlear implantation and rehabilitation is presented in **Figure 1.**

Figure 1 Overview of the elements considered within the Living Guidelines across a person's journey from hearing loss screening and assessment to cochlear implantation and rehabilitation

Abbreviations: CI, cochlear implant

The following research questions were used to inform the person's journey from hearing loss screening and assessment to cochlear implantation and rehabilitation:

Question 1 - Who should hearing loss screening be offered to? (Section 5.2.1)

Question 2 - What screening tools (questionnaires or assessments) should be used by primary healthcare professionals to screen for hearing loss? (Section 5.2.1)

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? (Section 5.3.1)

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 evaluation? What is the diagnostic accuracy for each of the routine assessment tools? (Section 5.4.1)

Question 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? (Section 5.4.2)

Question 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? (Section 5.6.1)

Question 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? (Section 5.6.2)

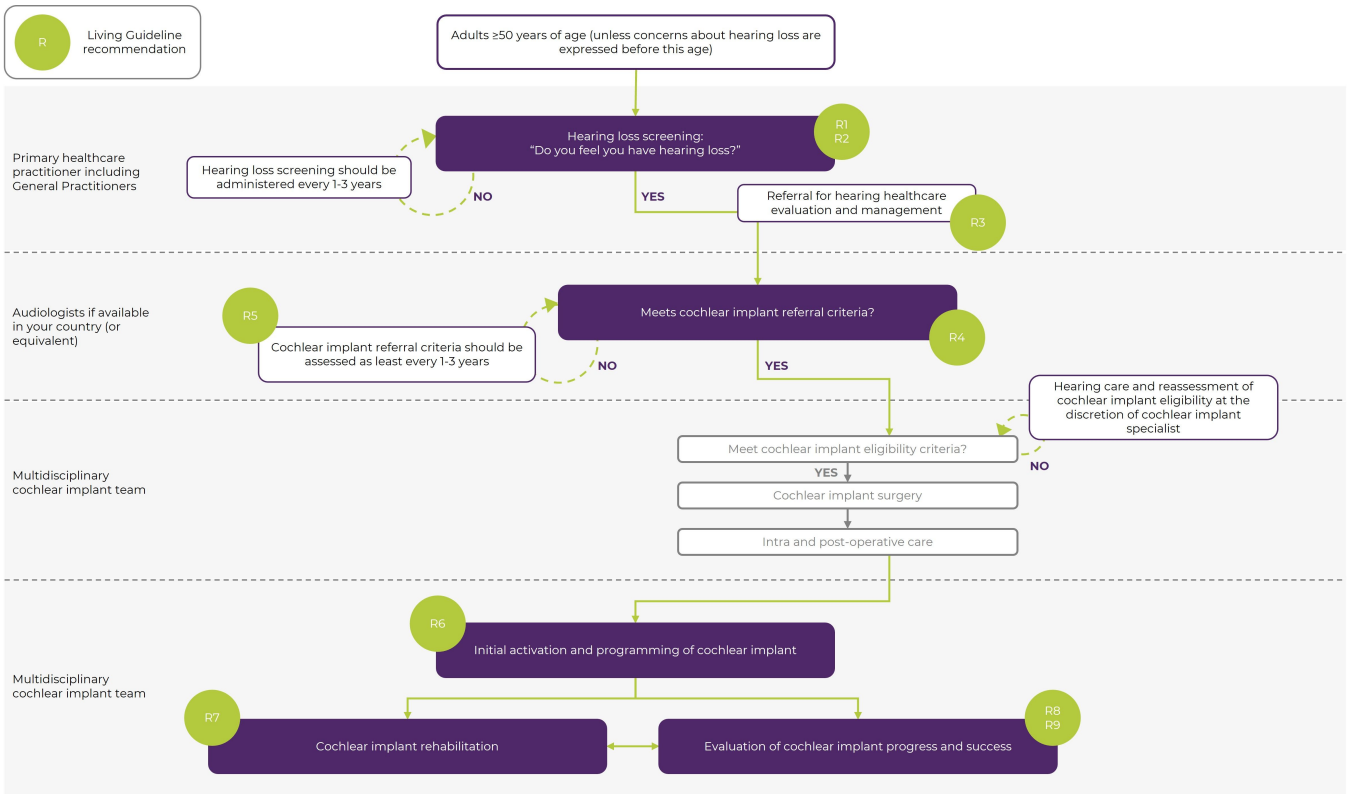
Question 8 - For adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss, which outcome measures are most meaningful to patients to assess for improvement with cochlear implants? (Section 5.7.1)

Question 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? How and when should professionals use the measurement tools and/or questionnaires? (Section 5.7.1)

5.1 Journey through the Living Guidelines

Info Box

An overview of the person's journey from hearing loss screening and assessment to cochlear implantation and rehabilitation is presented below.



5.2 Hearing loss screening and assessment

According to the WHO, a person is considered to have hearing if they are not able to hear as well as someone with normal hearing, meaning they have a hearing threshold of 20 dB or better in both ears *[7]*. To standardise the way in which the severity of hearing loss is reported, WHO has adopted a grading system based on audiometric measurements (see section 3.1, Table 1). 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 *[7]*. 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 *[7]*. Hearing loss has also been linked to decreased quality of life, cognitive decline and depression *[10][12]* and there is a growing body of evidence suggesting an association between hearing loss in older adults and neurocognitive disorders, such as dementia *[11]*. Additionally, hearing loss can also have an impact on the individuals close to them, such as family and friends *[139]*.

Despite being the most common sensory deficit among older adults, hearing loss is often under-recognised and poorly managed *[9]*. 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 function *[140]* and in a Danish study, just 7% of general practitioners were reported to enquire about hearing function in older patients *[141]*. In addition, adults wait for nearly 9 years before seeking help for their hearing loss *[130]*.

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.

5.2.1 Recommendation 1/2

Question 1 - Who should hearing loss screening be offered to?

Question 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?

Weak recommendation

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”, the next steps should be informed as per the *hearing loss referral recommendations* of these Living Guidelines.

Hearing loss screening should be administered at the frequency of 1–3 years *[7][19][23]*.

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 low certainty of evidence. Nonetheless, the benefits of early detection and intervention far outweigh any potential harm. 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 *[10][12][11]*. Even when considering the potential harms such as the overuse of resources or excessive referrals to hearing health care specialists, overall the benefits of referral for a full hearing assessment far outweigh any potential harms.

Certainty of the Evidence — Low

As per GRADE, the overall certainty of the evidence was low due to serious imprecision and serious inconsistency across the studies.

Values and preferences — No substantial variability expected

It is not expected that people will decline hearing loss screening using the single question, “Do you feel you have hearing loss?" or that primary health care practitioners will not use this screening tool.

Resources and other considerations — Important issues, or potential issues not investigated

Administering hearing loss screening using the single question, 'Do you feel you have hearing loss?" is not expected to disproportionately use or misuse resources in primary healthcare settings. However, a formal health economic analysis was not conducted as part of this review.

Rationale

Despite hearing loss being the most common sensory deficit in older persons, it is often under-recognised and poorly managed *[9]*. 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.

Sixty-four citations corresponding to 64 cross-sectional (cohort type diagnostic accuracy) studies were identified in the literature search (please see the Technical Report for an overview of these citations). Across the studies, there were over 30 screening tools (questionnaires or assessments) investigated.

Following a review of existing guidelines and consultation with the CI 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 *[19]*.

Three included studies, Strawbridge 2017 *[20]*, Deepthi 2012 *[21]*, and Everett 2020 *[22]* 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 *[7][19][23]*.

For more detailed information on the development of this recommendation, please see the Technical Report.

Clinical Question/ PICO

Population: Adults (over 18 years)
Intervention: Single question 'do you feel you have a hearing loss?' in primary healthcare setting
Comparator: pure-tone audiometry

Summary

What did we find?

Sixty-four citations *[20][21][22][45][46][45][46][47][48][49][50][51][52][53][54][55][56][57][58][59][60][61][62][63][64][65][66][67]* to 64 cross-sectional (cohort type diagnostic accuracy) studies were identified in the literature search (Assef 2022, Balen 2021, Barczik 2018, Bastianelli 2019, Becerril-Ramirez 2013, Boatman 2007, Bonetti 2018, Brennan-Jones 2016, Brennan-Jones 2017, Bright 2019, Canete 2020, Cardoso 2014, Chayaopas 2021, Colsman 2020, Dambha 2022, Deepthi 2012, Diao 2014, Dillon 2016, Everett 2020, Folmer 2017, Frank 2021, Fredriksson 2016, Hong 2011, Ito 2007, Jansen 2013, Jupiter 2009, Kam 2020, Kelly 2018, Koleilat 2020, Koole 2016, Li 2020, Li 2021, Livshitz 2017, Lycke 2016, Lycke 2018, McShefferty 2013, Mosites 2016, Paglialonga 2013, Paglialonga 2014, Parving 2008, Qi 2018, Ramkissoon 2011, Rodrigues 2021, Saliba 2017, Salonen 2011, Sandstrom 2020, Seluakumaran 2021, SheikhRashid 2017, Skjonsberg 2019, Strawbridge 2017, Szudek 2012, Thodi 2013, Tomioka 2013, Torres-Russotto 2009, Vaez 2014, Vaidyanath 2021, Vercammen 2018, Wang 2017, Watson 2012, Williams-Sanchez 2014, You 2020, Zanet 2021, Zhang 2019, Zimatore 2020) that assesses various hearing loss screening tools. However, only three citations *[20][21][22]* (Deepthi 2012, Everett 2020, Strawbridge 2017) used a single question that the CI Task Force considered user-friendly for any primary healthcare professional.

Study characteristics

The three included studies were carried out in primary healthcare settings in India (Deepthi 2012) and the United States (Everett 2020, Strawbridge 2017). All three studies included adults or older adults with and/or without hearing loss. Participant ages ranged from 29 to 92 years across the studies and sample sizes ranged from 125 to 175 participants (total 431 participants). These studies were found to be at some risk of bias due to a lack of information regarding the blinding of the reference standard and index test.

All included studies used pure-tone audiometry as the reference test, which is considered the gold standard.

What are the main results?

The three included studies (Deepthi 2012, Everett 2020, Strawbridge 2017) found that the use of a single question was suitable to screen for hearing loss in adults in primary healthcare settings. The three studies had sensitivities ranging from 0.31 to 0.89 and specificities ranging from 0.41 to 0.94.

Outcome Timeframe	**Study results and measurements**	**Comparator** pure-tone audiometry	**Intervention** Screening tool	**Certainty of the Evidence** (Quality of evidence)	**Plain language summary**
True positives [1]	Based on data from 431 participants in 3 studies. (Observational (non-randomized))	Effect per 1000 patients tested, by pre-test probability: 20.0% = 62 to 178; 25.5% = 79 to 227.		Low Due to serious imprecision, Due to serious inconsistency [2]	The evidence suggests that the single question - Do you feel you have hearing loss? - may correctly identify adults over 50 years with hearing loss.
False negatives [3]	Based on data from 431 participants in 3 studies. (Observational (non-randomized))	Effect per 1000 patients tested, by pre-test probability: 20.0% = 22 to 138; 25.5% = 28 to 176.		Low Due to serious inconsistency, Due to serious imprecision [4]	The evidence suggests that the single question - Do you feel you have hearing loss? - may incorrectly identify some adults over 50 years with hearing loss.
True negatives [5]	Based on data from 431 participants in 3 studies. (Observational (non-randomized))	Effect per 1000 patients tested, by pre-test probability: 20.0% = 328 to 751; 25.5% = 305 to 700.		Low Due to serious inconsistency, Due to serious imprecision [6]	The evidence suggests that the single question - Do you feel you have hearing loss? - may correctly identify most adults over 50 years without hearing loss.
False positives [7]	Based on data from 431 participants in 3 studies. (Observational (non-randomized))	Effect per 1000 patients tested, by pre-test probability: 20.0% = 49 to 472; 25.5% = 45 to 440.		Low Due to serious inconsistency, Due to serious imprecision [8]	The evidence suggests that the single question - Do you feel you have hearing loss? - may incorrectly identify some adults over 50 years without hearing loss.

1. Screening tool correctly predicts the positive hearing loss cases
2. **Risk of Bias: no serious.** No serious risk of bias. Certainty of evidence not downgraded.. **Inconsistency: serious.** There is serious inconsistency. Three studies included a wide range across sensitivity and specificity. Certainty of evidence downgraded.. **Indirectness: no serious.** There is no serious indirectness. All studies included people over the age of 60 years. The results may not be generalisable to people under the age of 60 years. Certainty of evidence not downgraded.. **Imprecision: serious.** There is serious imprecision. Three studies included a variety of sensitivity and specificity results. Certainty of evidence downgraded.. **Publication bias: no serious.** Possibility of publication bias was not excluded, but it was not sufficient to downgrade the certainty of evidence...
3. Screening tool results indicates that a person does not have hearing loss when the person actually does have hearing loss
4. **Risk of Bias: no serious.** No serious risk of bias. Certainty of evidence not downgraded.. **Inconsistency: serious.** There is serious inconsistency. Three studies included a wide range across sensitivity and specificity. Certainty of evidence downgraded. , due to [reason]. **Indirectness: no serious.** There is no serious indirectness. All studies included people over the age of 60 years. The results may not be generalisable to people under the age of 60 years. Certainty of evidence not downgraded.. **Imprecision: serious.** There is serious imprecision. Three studies included a variety of sensitivity and specificity results. Certainty of evidence downgraded. , due to [reason]. **Publication bias: no serious.** Possibility of publication bias was not excluded, but it was not sufficient to downgrade the certainty of evidence. .
5. Screening tool correctly predicts the negative hearing loss cases
6. **Risk of Bias: no serious.** No serious risk of bias. Certainty of evidence not downgraded.. **Inconsistency: serious.** There is serious inconsistency. Three studies included a wide range across sensitivity and specificity. Certainty of evidence downgraded. . **Indirectness: no serious.** There is no serious indirectness. All studies included people over the

age of 60 years. The results may not be generalisable to people under the age of 60 years. Certainty of evidence not downgraded.. **Imprecision: serious.** There is serious imprecision. Three studies included a variety of sensitivity and specificity results. Certainty of evidence downgraded. . **Publication bias: no serious.** Possibility of publication bias was not excluded, but it was not sufficient to downgrade the certainty of evidence. .
7. Screening tool incorrectly predicts that a person does have hearing loss, when the person actually does not have hearing loss
8. **Risk of Bias: no serious.** No serious risk of bias. Certainty of evidence not downgraded.. **Inconsistency: serious.** There is serious inconsistency. Three studies included a wide range across sensitivity and specificity. Certainty of evidence downgraded. . **Indirectness: no serious.** There is no serious indirectness. All studies included people over the age of 60 years. The results may not be generalisable to people under the age of 60 years. Certainty of evidence not downgraded.. **Imprecision: serious.** There is serious imprecision. Three studies included a variety of sensitivity and specificity results. Certainty of evidence downgraded. . **Publication bias: no serious.** Possibility of publication bias was not excluded, but it was not sufficient to downgrade the certainty of evidence. .

Attached Images

References

20. Strawbridge WJ, Wallhagen MI : Simple Tests Compare Well with a Hand-held Audiometer for Hearing Loss Screening in Primary Care. Journal of the American Geriatrics Society 2017;65(10):2282-2284 Pubmed Journal

21. Deepthi R, Kasthuri A : Validation of the use of self-reported hearing loss and the Hearing Handicap Inventory for elderly among rural Indian elderly population. Archives of gerontology and geriatrics 2012;55(3):762-7 Pubmed Journal

22. Everett A, Wong A, Piper R, Cone B, Marrone N : Sensitivity and Specificity of Pure-Tone and Subjective Hearing Screenings Using Spanish-Language Questions. American journal of audiology 2020;29(1):35-49 Pubmed Journal

Good practice statement

- Hearing loss screening can be administered by any primary healthcare practitioner including General Practitioners.
- Before screening for hearing loss, primary healthcare practitioners should explain the purpose of screening and common symptoms and signs of hearing loss. These include *[108]*:
    - 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.

    If a person is unable to answer the single question with “yes” or “no”, primary healthcare practitioners should clarify and further explain these signs and symptoms to the individual being screened.
- Before screening for hearing loss, primary healthcare practitioners should explain the importance of hearing health and early hearing loss interventions including the avoided risk of cognitive impairment and dementia *[107]*.
- 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 *[7][19][23]*. Such risk factors include:
    - cardiovascular disease,
    - diabetes,
    - ototoxicity,
    - kidney dysfunction,
    - noise exposure,
    - tinnitus, and
    - significant family history.
- 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. Such concerns may include *[108]*:
    - 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.
- In addition to the single question hearing loss screener, and if resources allow, primary healthcare practitioners may also administer or recommend other validated hearing loss screening tools including mobile technologies designed to detect hearing loss *[47][48][53][59][65][69][70][71][73][74][75][76][77][85][86][88][89][91][92][106]*.

5.3 Referral to hearing healthcare specialist

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 adults. With the opportunity to detect hearing loss early, practitioners can refer adults to the appropriate hearing healthcare specialists to address their hearing concerns *[142]*. 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 *[130]*. As such, primary healthcare professionals can play an instrumental role in guiding patients to make appropriate and timely choices for addressing their hearing loss.

5.3.1 Recommendation 3

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?

Consensus recommendation

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

- arrange a referral to a hearing healthcare specialist for a full audiological assessment, and
- check for impacting factors such as impacted wax and acute infections (e.g. otitis externa, otitis media and otitis media with effusion), 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 ENT specialist or an emergency department is warranted.

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 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. 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 *[10][12][11]*. Overall, the benefits thus outweigh the harms.

Certainty of the 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.

Values and preferences

No substantial variability expected

There is no reason to suspect that adults with any level of hearing loss would not accept a referral for a full audiological assessment. Some adults may choose not to have a full audiological assessment because of the potential financial burden, personal preferences and/or access issues.

Resources and other considerations

Important issues, or potential issues not investigated

For the primary healthcare practitioner to exclude certain conditions and refer an adult for a full audiological examination is not expected to disproportionately use or misuse resources in primary healthcare settings. However, a formal health economic analysis was not conducted as a part of this review.

It is acknowledged that some countries may not have audiologist assessments or ENT specialist assessments reimbursed and some patients may incur out-of-pocket costs if referred.

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 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* were used to develop an initial draft as it was considered the most comprehensive *[124]*. 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.

For more detailed information on the development of this recommendation, please see the Technical Report.

Clinical Question/ PICO

Population: Adults with any level of hearing loss
Intervention: Referral to health professional for further audiometric testing
Comparator: not specified

Summary

No studies were identified that met the inclusion criteria for research question three. This is an evidence gap for further research to be conducted.

Good practice statement

- If an adult is diagnosed with impacted wax or acute infections, please follow your local guidelines for the management of these.
- If a full audiological assessment is required, refer to an audiologist if available in your country (or equivalent) and/or to an ENT specialist.

5.4 Hearing healthcare specialist evaluation

Cochlear implants are suitable for many adults with severe to profound sensorineural hearing loss *[24]*. 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 *[24]*. In a recent study, people with cochlear implants could understand sentences eight times better than they could previously with their hearing aids *[144][143]*.

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 *[25]*. Furthermore, cochlear implants have been associated with lower rates of mild cognition cognitive disorders *[110][111]* 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 *[112]*.

Despite the potential benefits of cochlear implants, less than 10% of eligible adults will receive one in their lifetime *[24]*. 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 *[6]*. This underutilisation is due, in part, to limited awareness of eligibility criteria and referral processes *[6][17]*. 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.

5.4.1 Recommendation 4

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 evaluation?

- What is the diagnostic accuracy for each of the routine assessment tools?

Strong recommendation

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) unaided pure-tone average (PTA) in the better ear that is equal to or greater than 60 dB HL (decibels hearing level) *[26]*, AND expresses difficulties with speech understanding in their everyday environment.

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

Practical Info

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 CI Task Force reviewed the following existing guidelines:

- Turton et al. 2020 makes recommendations for prescribing and fitting hearing aids.
- 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.

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 *[26]*. Following consultation with the CI Task Force, it was revealed that PTA is the key criterion in determining cochlear implant candidacy globally.

Certainty of the 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 *[26]*. This was due to the global variability in speech perception assessments, and consultation with the Task Force revealed that the PTA measure is a critical factor in determining cochlear implant candidacy on a global scale.

Values and preferences

No substantial variability expected

There is no reason to suspect that adults with any level of hearing loss would reject routine assessments to determine referral for a complete cochlear implant evaluation. However, there may be some individuals who choose not to have an assessment due to financial constraints, personal preference, or access difficulties.

Resources and other considerations

Important issues, or potential issues not investigated

The use of routine assessments to determine a referral for a complete cochlear implant evaluation is not expected to

disproportionately use or misuse resources in an audiological or clinical setting. However, a formal health economic analysis was not conducted as a part of this review.

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 *[26][27][28][29][30][31][113]*. The assessment tools used across the included studies *[27][28][29][30][31]*, except the 60/60 referral guideline evaluated by Lee 2022 and Zwolan 2020 *[26][113]* were considered to be too complex and resource intensive for any hearing health care specialist to carry out. These five studies *[27][28][29][30][31]* 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 2022 and Zwolan 2020 *[26][113]* 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 *[113]*, Zwolan 2020 *[26]*, 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.

Clinical Question/ PICO

Population:	Adults with any level of hearing loss or have hearing aids
Intervention:	60/60 referral guideline
Comparator:	Pre-operative best-aided word score, AzBio sentence recognition in quiet and noise

Summary

What did we find?

Five citations (106, 108-111), corresponding to six cross-sectional (cohort type accuracy) studies (Hunter 2021, Ngombu 2021, Reddy 2022, Shim 2014, Zwolan 2020), were identified in the literature search. There were no ongoing studies and no studies awaiting classification. Two additional studies (107, 112) corresponding to two cross-sectional (cohort type accuracy) studies (Choi 2016, Lee 2022) were identified by the CI Task Force. However, only two citations (Lee 2022, Zwolan 2020) utilised a PTA measure to evaluate the need for a referral for a full cochlear implant evaluation, which the CI Task Force considered to be the most suitable evaluation method for global implementation.

Study characteristics

The two included studies (Lee 2022, Zwolan 2020) were both retrospective reviews of registry data from adults who had undergone cochlear implant candidacy evaluation (CICE) for referral to a complete CI evaluation. Participants' ages ranged from 19 to 98 and sample sizes ranged from 248 to 415 (total 663 participants). These studies were found to be at some risk of bias due to a lack of information regarding blinding of the reference standard and index test, and the timing between the index test and reference standard.

What are the main results?

The two included studies (Lee 2022, Zwolan 2020) found that a better ear PTA of 60 dB HL or greater, and a better ear unaided monosyllabic word score of 60% correct or less are suitable criteria to refer adults with hearing loss for

a complete cochlear implant evaluation. The two studies had sensitivities ranging from 0.62 to 0.96 and specificities ranging from 0.66 to 0.75.

Outcome Timeframe	**Study results and measurements**	**Comparator** Traditional CI criteria	**Intervention** 60/60 referral guideline	**Certainty of the Evidence** (Quality of evidence)	**Plain language summary**
True positives (Zwolan 2020; Lee 2022) [1]	Based on data from 663 participants in 2 studies. (Observational (non-randomized))	Effect per 1000 patients tested, by pre-test probability: 2.3% (Estimated number of adults with any level of hearing loss who have 50 - 94 dB HL) = 14 to 22, 7.7% (Estimated number of adults with any level of hearing loss who have 65 - 94 dB HL) = 48 to 74		**High** [2]	The evidence suggests that the 60/60 referral guidelines have a high likelihood of correctly identifying adults with hearing loss who should be referred for a CI evaluation.
False negatives (Zwolan et al. 2020) [3]	Based on data from 663 participants in 2 studies. (Observational (non-randomized))	Effect per 1000 patients tested, by pre-test probability: 2.3% (Estimated number of adults with any level of hearing loss who have 50 - 94 dB HL) = 1 to 9, 7.7% (Estimated number of adults with any level of hearing loss who have 65 - 94 dB HL) = 3 to 29		**High** [4]	The evidence suggests that the 60/60 referral guidelines have a high likelihood of correctly identifying adults with hearing loss who should be referred for a CI evaluation.
True negatives (Zwolan et al. 2020) [5]	Based on data from 663 participants in 2 studies. (Observational (non-randomized))	Effect per 1000 patients tested, by pre-test probability: 2.3% (Estimated number of adults with any level of hearing loss who have 50 - 94 dB HL) = 645 to 733, 7.7% (Estimated number of adults with any level of hearing loss who have 65 - 94 dB HL) = 609 to 692		**High** [6]	The evidence suggests that the 60/60 referral guidelines have a high likelihood of correctly identifying adults with hearing loss who should be referred for a CI evaluation.
False positives (Zwolan et al. 2020) [7]	Based on data from 663 participants in 2 studies. (Observational (non-randomized))	Effect per 1000 patients tested, by pre-test probability: 2.3% (Estimated number of adults with any level of hearing loss who have 50 - 94 dB HL) = 244 to 332 7.7% (Estimated number of adults with any level of hearing loss who have 65 - 94 dB HL) = 231 to 314		**High** [8]	The evidence suggests that the 60/60 referral guidelines have a high likelihood of correctly identifying adults with hearing loss who should be referred for a CI evaluation.

1. The assessment tool correctly identifies individuals who should be referred for a full cochlear implant evaluation and ultimately receive a cochlear implant.
2. **Risk of Bias: no serious.** No serious risk of bias. Certainty of evidence not downgraded . **Inconsistency: no serious.** Single study. No heterogeneity assessed. Certainty of evidence not downgraded.. **Indirectness: no serious.** No serious indirectness. The available evidence is in English speaking people with hearing loss. The evidence may not be generalisable to people who speak other languages. Certainty of evidence not downgraded.. **Imprecision: no serious.** No serious imprecision. Certainty of evidence not downgraded.. **Publication bias: no serious.** Possibility of publication bias was not excluded, but it was not sufficient to downgrade the certainty of evidence..
3. The assessment tool results indicates that a person should not receive a referral for a complete CI evaluation, when the person is actually indicated for a cochlear implant
4. **Risk of Bias: no serious.** No serious risk of bias. Certainty of evidence not downgraded.. **Inconsistency: no serious.**

Single study. No heterogeneity assessed. Certainty of evidence not downgraded.. **Indirectness: no serious.** No serious indirectness. The available evidence is in English speaking people with hearing loss. The evidence may not be generalisable to people who speak other languages. Certainty of evidence not downgraded.. **Imprecision: no serious.** No serious imprecision. Certainty of evidence not downgraded.. **Publication bias: no serious.** Possibility of publication bias was not excluded, but it was not sufficient to downgrade the certainty of evidence..
5. The assessment tool correctly predicts individuals who should not be reffered for a full cochlear implant evaluation.
6. **Risk of Bias: no serious.** No serious risk of bias. Certainty of evidence not downgraded.. **Inconsistency: no serious.** Single study. No heterogeneity assessed. Certainty of evidence not downgraded.. **Indirectness: no serious.** No serious indirectness. The available evidence is in English speaking people with hearing loss. The evidence may not be generalisable to people who speak other languages. Certainty of evidence not downgraded.. **Imprecision: no serious.** No serious imprecision. Certainty of evidence not downgraded.. **Publication bias: no serious.** Possibility of publication bias was not excluded, but it was not sufficient to downgrade the certainty of evidence..
7. Assessment tool incorrectly predicts that a person should be referred for a full cochlear implant evaluation, when the person ultimately does not need a cochlear implant.
8. **Risk of Bias: no serious.** No serious risk of bias. Certainty of evidence not downgraded.. **Inconsistency: no serious.** Single study. No heterogeneity assessed. Certainty of evidence not downgraded.. **Indirectness: no serious.** No serious indirectness. The available evidence is in English speaking people with hearing loss. The evidence may not be generalisable to people who speak other languages. Certainty of evidence not downgraded.. **Imprecision: no serious.** No serious imprecision. Certainty of evidence not downgraded.. **Publication bias: no serious.** Possibility of publication bias was not excluded, but it was not sufficient to downgrade the certainty of evidence..

Attached Images

Good practice statement

- For a person who does not meet the cochlear implant referral criteria above and has unilateral severe to profound and moderate sloping to profound sensorineural hearing loss, hearing healthcare specialists could use a poorer ear PTA of greater than or equal to 80 dB HL at four frequencies (500, 1000, 2000, and 4000 Hz) for referral *[151]*.
- 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 to profound and moderate sloping to profound sensorineural hearing loss for cochlear implant evaluation.
- Prior to conducting the assessment to refer for a complete cochlear implant evaluation and preoperative assessment, the hearing healthcare 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, continue to assess for referral for a complete cochlear implant evaluation and preoperative assessment.
  - 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.
- If the adult is not eligible for a cochlear implant after being referred for a complete cochlear implant evaluation and preoperative assessment, their hearing care and reassessment should be at the discretion of the cochlear implant team they were referred to.

5.4.2 Recommendation 5

Question 5- In adults with hearing loss who may not meet the criteria for a cochlear implant referral, 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?

Consensus recommendation

If an adult with any level of hearing loss does not meet the cochlear implant referral criteria upon initial assessment, cochlear implant referral criteria should be assessed at least every 1–3 years *[7][19][23][126]*. 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 re-assessed at least every 6–12 months.

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 the 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.

Values and preferences

No substantial variability expected

There is no plausible reason to suspect that adults with any level of hearing loss who do not meet cochlear implant candidacy criteria would not accept the monitoring and reassessment of their hearing as recommended. Some adults may not adhere or choose not to be reassessed due to potential financial burden, personal decision not to have a cochlear implant, and/or access issues.

Resources and other considerations

Important issues, or potential issues not investigated

The resource implications are uncertain. In some countries, there may be costs associated with the implementation of a reassessment for cochlear implant eligibility. However, a formal health economic analysis was not conducted as a part of this review.

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 *[24]*. 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 *[7][19][23][126]*. 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.

For further information on the development of the recommendation, please see the Technical Report.

Clinical Question/ PICO

Population: Adults with any level of hearing loss or have hearing aids
Intervention: Assessment tools to determine referral for a CI evaluation
Comparator: Not specified

Summary

No studies were identified that met the inclusion criteria for research question five. This is an evidence gap for further research to be conducted.

Good practice statement

- 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.
- 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.

5.5 CI specialist evaluation, surgery and intra and post-operative care

Info Box

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

CI evaluation

1. AWMF Guideline S017/71 - S2k Guideline Cochlear Implantation German Society of Oto-Rhino-Laryngology, Heand and Neck Surgery, 2020
2. American Academy of Audiology CLINICAL PRACTICE GUIDELINE: COCHLEAR IMPLANTS
3. Turton et al. 2020 Guidelines for Best Practice in the Audiological Management of Adults with Severe and Profound Hearing Loss
4. FRENCH SOCIETY OF ENT (SFORL) GUIDELINES 2019. INDICATIONS FOR COCHLEAR IMPLANTATION IN ADULTS, European Annals of Otorhinolaryngology. Head and Neck Diseases.

CI surgery and intra and post-operative care

1. German Weißbuch (white paper) guidelines
2. AWMF Guideline S017/71 - S2k Guideline Cochlear Implantation German Society of Oto-Rhino-Laryngology, Heand and Neck Surgery, 2020
3. American Academy of Audiology CLINICAL PRACTICE GUIDELINE: COCHLEAR IMPLANTS

Practical Info

CI evaluation

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.

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. These can be found in Table 1, p4.

American Academy of Audiology (AAA) 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.

The Association of German-speaking Audiologists, Neurootologists and Otologists of the German Society of Otorhinolaryngology, Head and Neck Surgery

The German Society of Oto-Rhino-Laryngology, Head and Neck Surgery under the guidance of the Working Group of German-speaking Audiologists, Neurootologists and Otologists (ADANO) 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.
- Sound and speech audiometry

For more information see p15-20 of the guidelines.

CI surgery and intra and post-operative care

American Academy of Audiology (AAA) CLINICAL PRACTICE GUIDELINE: COCHLEAR IMPLANTS

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.

For more information on this section, please see p42-29.

The Association of German-speaking Audiologists, Neurootologists and Otologists of the German Society of Otorhinolaryngology, Head and Neck Surgery

The German Society of Oto-Rhino-Laryngology, Head and Neck Surgery under the guidance of the Working Group of German-speaking Audiologists, Neurootologists and Otologists (ADANO) made recommendations.

- Section 6. Indications for surgery p3
- Section 8. Surgical phase p3

German Weißbuch (white paper) guidelines

The German Weißbuch (white paper) guidelines make recommendations for adult examinations and preoperative measures. For more information see p12-19 of the guidelines.

5.6 Device programming and rehabilitation

Following cochlear implant activation after surgery, the recipient should receive implant programming and rehabilitation sessions to optimise performance *[5]*.

Cochlear implant programming is necessary for users to hear sounds through the device *[147]*. 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 *[150]*. 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 typically receive 12 or more rehabilitation or therapy services in the first year but no longer receive rehabilitation after that time *[149]*. Good mapping, which changes with progression, was also identified as a crucial component of rehabilitation *[148]*.

Together, programming and rehabilitation help users achieve the best possible hearing outcomes and improve their quality of life *[147]*.

5.6.1 Recommendation 6

Question 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?

Consensus recommendation

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 *[32]*.

Post-activation, a cochlear implant user should have between 4–6 appointments within the first twelve months of cochlear implant use *[32]*. 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.

Evidence To Decision

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

The balance between benefits, harms and burdens are uncertain owing to a lack of evidence identified.

Certainty of the 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.

Values and preferences — No substantial variability expected

There is no plausible reason to suspect that cochlear implant users would not accept the recommendations of optimal

programming frequency. However, some adult users may choose not to undergo reassessment due to financial constraints, personal decisions or issues related to access.

Resources and other considerations

Important issues, or potential issues not investigated

The resource implications are uncertain. In some countries, there may be costs associated with programming appointments and follow-up schedules. However, a formal health economic analysis was not conducted as a part of this review.

Rationale

No studies were identified that met the inclusion criteria for research question six. Following a review of existing guidelines and in consultation with the 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 *[32]*. Additionally, recent the Delphi consensus guidelines found evidence suggesting frequent programming and fitting assessments within the first six months with an expectation to reduce appointment frequency six months onwards. 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 *[5]*. Patient-centered 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 *[5][114]*.

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.

For further information on the development of the recommendation, please see the Technical Report.

Clinical Question/ PICO

Population: Adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss

Intervention: Cochlear implant programming

Comparator: Not specified

Summary

No studies were identified that met the inclusion criteria for research question six. This is an evidence gap for further research to be conducted.

Good practice statement

- 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.
- Additional programming 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

5.6.2 Recommendation 7

Question 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?

Consensus recommendation

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

- ENT specialist specialised in cochlear implants
- Audiologist if available in your country (or equivalent)
- Speech therapist

The multidisciplinary cochlear implant team may involve other specialties including:

- Psychologist
- Social worker
- Neurologist
- Radiologist
- Geriatrician
- Peer group support

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:

ENT 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).
- 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.).
- Bimodal and electroacoustic adjustment, if necessary.
- 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).

Speech therapist (or audiologist, if not available)

- 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.

Lifelong rehabilitation

The components of lifelong rehabilitation that should be considered include:

ENT specialist specialised in cochlear implants

- Cochlear implant follow up every 3 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).

Speech therapist (or audiologist, if not available)

- 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

Other components of both initial and lifelong rehabilitation 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.

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 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 the 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.

Values and preferences

No substantial variability expected

There is no plausible reason to suspect that the cochlear implant user would not accept the rehabilitation program recommended and tailored to them by their multidisciplinary cochlear implant care team. The cochlear implant user and family preference should also be considered when providing cognitive rehabilitation. Some adults may not have access to or choose not to undertake some rehabilitation components because of individual circumstances, financial burden, and/or access issues.

Self-rehabilitation via online resources should always be encouraged.

Resources and other considerations

Important issues, or potential issues not investigated

The resource implications are uncertain. In some countries, there may be costs associated with the implementation of all or some of the components of the cochlear implant user's rehabilitation program. However, a formal health economic analysis was not conducted as a part of this review.

Some adults may also not have access to traditional rehabilitation services either in the office or remotely.

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 Weißbuch and German Society of Oto-Rhino-Laryngology recommendations as it was considered the most comprehensive *[121][119]* - 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.

For further information on the development of the recommendation, please see the Technical Report.

Clinical Question/ PICO

Population: Adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss

Intervention: Rehabilitation

Comparator: Not specified

Summary

No studies were identified that met the inclusion criteria for research question seven. This is an evidence gap for further research to be conducted.

Good practice statement

- Rehabilitation and expectations should be discussed with the cochlear implant user and their family and/or friends prior to cochlear implantation (person and family-centred care).
- The family and/or friends of the cochlear implant user should be considered and invited to participate in rehabilitation.
- 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.
- If available, traditional rehabilitation services in the office or remotely should be offered in conjunction with self-care.
- Counselling or psychological support should be considered to support the user and their family and/or friends with regards to expectations, the rehabilitation procedures and their ongoing commitment to the rehabilitation program.
- 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.
- The cochlear implant user's progress must be monitored throughout initial and lifelong rehabilitation.

5.7 Patient outcomes and measures

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 *[36]*, 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 *[42][43][44]*. 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 *[109]*, however, outcome measures for such stakeholders are beyond the scope of these guidelines.

5.7.1 Recommendation 8

Question 8 - 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

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:

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

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.

Values and preferences

No substantial variability expected

It is not expected that adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss would object to the use of cochlear implant-specific quality of life as the most meaningful measure for evaluating the effectiveness of the implant in improving their lives. However, it is acknowledged that some cochlear implant users may have different priorities in terms of the outcomes they value, depending on their stage of life and individual circumstances.

Resources and other considerations

Important issues, or potential issues not investigated

The resource implications are uncertain. In some countries, there may be costs associated with the additional time required to measure outcomes for adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss. However, a formal health economic analysis was not conducted as a part of this review.

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 the 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.

For further information on the development of the recommendation, please see the Technical Report.

Clinical Question/ PICO

Population: Adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss

Intervention: Patient relevant outcome measures post cochlear implantation

Comparator: Not specified

Summary

No studies were identified that met the inclusion criteria for research question eight and nine. This is an evidence gap for further research to be conducted.

5.7.2 Recommendation 9

Question 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?

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

Consensus recommendation

Two measurement tools should be used to evaluate the outcomes most meaningful to a person when evaluating improvement post-implantation in 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:

1. The Nijmegen Cochlear Implant Questionnaire (NCIQ) *[40]* or the Cochlear Implant-Quality of Life (CI-QoL) *[164]*(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 CI-QoL are not validated in the cochlear implant user's dominant language, another validated QoL measure may be used.
2. Validated communication measures including speech perception tests in the dominant language of the adult cochlear implant user by using words and/or sentences in quiet and noise.

The NCIQ or CI-QoL and speech perception measures 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.

Practical Info

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

- English *[40]*
- Chinese *[167]*
- Spanish *[145]*
- Italian
- Portuguese *[39]*
- Turkish
- German *[146]*

Please follow the link below and follow the prompts to find the CI-QoL 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 CI-QOL Global should be available by the end of February 2023.

- CI-QoL Global *[164]*

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 with not change if evidence becomes available.

Values and preferences

No substantial variability expected

It is not expected that adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss would object to the use of a hearing-specific quality of life questionnaire as the most useful tool to measure the effectiveness of the implant in improving their lives nor the evaluation of speech perception in quiet and in noise. Similarly, it is not expected that hearing specialists would object to the administration of such tools for adult cochlear implant users.

Resources and other considerations

Important issues, or potential issues not investigated

The resource implications are uncertain. In some countries, there may be costs associated with the additional time required to measure outcomes for adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss. However, a formal health economic analysis was not conducted as part of this review.

Rationale

Review of global guidelines and recommendations (see sections D8.1.1 to D8.1.8 of the Technical Report) 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 *[36][39]*. Nevertheless, the German Weißbuch guidelines *[34]* 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 *[37]*. It has three domains (physical, social, and psychological) and six subdomains *[37][40]*, including:

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

Its use has been validated cross-culturally and the tool is available in English, Chinese, Spanish, Italian, Portuguese, and Turkish *[37]*.

Its routine use in existing clinical practice as per the German Weißbuch guidelines *[121]* 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 *[33][36]*. 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 *[36][39]*.

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 to profound sensorineural hearing loss *[35]*. 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 *[37]*.

Similarly, the Cochlear Implant-Quality of Life (CI-QoL) 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.

HTANALYSTS communicated with the author of the CI-QoL, Dr. Theodore McRackan, who confirmed the CI-QoL was available and validated in multiple languages, including English, Hebrew, Arabic, French, German, and Mandarin *[131][132][133][134][135][136][137]*. The questionnaire is also currently in the process of cross-cultural validation into Danish, Turkish, Malay, and Afrikaans.

For further information on the development of the recommendation, please see the Technical Report.

Clinical Question/ PICO

Population: Adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss

Intervention: Patient relevant outcome measures post cochlear implantation

Comparator: Not specified

Summary

No studies were identified that met the inclusion criteria for research question eight and nine. This is an evidence gap for further research to be conducted.

Good practice statement

- If resources allow, the NCIQ or CI-QoL and speech perception measures could be administered 3, 6, and 12 months after cochlear implantation *[38]* and re-evaluated annually after implantation *[34]*.
- If a user expresses concern about their experience with their cochlear implant, the NCIQ or CI-QoL and speech perception measures could be re-administered.
- Before administering the NCIQ or CI-QoL and speech perception measures, the purpose of these evaluations should be explained to the cochlear implant user and/or their family and friends.
- Speech perception tests should be in the cochlear implant user’s dominant language.
- Audiologists if available in your country (or equivalent) should prioritise using the data gathered to inform rehabilitation efforts, including monitoring device functioning and programming.
- If there is a decrease 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.
- The NCIQ or CI-QoL and speech perception measures should be administered more frequently if there is a marked decrease in an individual's score

6. Evidence gaps

Research Question 1 and 2

Question 1 - Who should hearing loss screening be offered to?

Question 2 - What screening tools (questionnaires or assessments) should be used by primary healthcare professionals to screen for hearing loss?

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 CI 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

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?

No RCT or NRSI evidence was identified.

Research Question 4

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 evaluation? What is the diagnostic accuracy for each of the routine assessment tools?

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 criteria 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 asymmetrical or unilateral severe to profound and moderate sloping to profound sensorineural hearing loss, an additional practice point was developed that acknowledges they may be eligible for a cochlear implant candidacy, though updated evidence evaluating assessment criteria in this population is needed to amend the recommendation.

Research Question 5

Question 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?

No RCT or NRSI evidence was identified.

Research Question 6

Question 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?

No RCT or NRSI evidence was identified.

Research Question 7

Question 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?

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

Question 8 - For adult cochlear implant users with severe, profound or moderate sloping to profound sensorineural hearing loss, which outcome measures are most meaningful to patients to assess for improvement with cochlear implants?

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

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

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 NSRIs 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.

7. Glossary and abbreviations

7.1 Glossary

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.
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 of 20 dB HL or better in 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 and family-centred care	The provision of care that is respectful of and responsive to individual patient and family preferences, needs, and values and ensuring that the person‘s values guide all clinical decisions. Person and family-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 *[150]*
Speech therapist	A person having a recognised diploma or degree in speech therapy. In some countries, speech therapy is part of a hearing specialist's training.
Speech perception	The process of hearing, interpreting, and understanding sounds of language. Therefore speech perception tests assess an individual's ability to hear, interpret, and understand sounds of language.

7.2 Abbreviations and acronyms

CI	Cochlear implant
CICE	Cochlear implant candidacy evaluation
CIICA	Cochlear Implant International Community of Action
CI-QoL	Cochlear Implant Quality of Life
Db	Decibels
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HUI	Health Utilities Index

HL	Hearing level
NCIQ	Nijmegen Cochlear Implant Questionnaire
PTA	Pure-tone average
SUN	Speech Understanding in Noise
WHO	World Health Organization
WRS	Word recognition score

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Cochlear Implant International Community of Action (CIICA).

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HTANALYSTS

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8.2 Conflicts of interest

All members of the Living Guidelines Task Force were required to disclose potential conflicts of interest (COIs). It was the responsibility of each member of the Task Force to disclose any real or perceived conflicts. The summary of Task Force member COIs are summarised here.

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168. Living Guidelines Task Force Conflict of Interest.

169. Public Consultation: Submission Template.

170. Technical Report Appendix E1.

171. Technical Report F1.