

Hearing the Call for Change: Developing 'Living' Guidelines for the Cochlear Implantation Process

By Meredith Holcomb, AuD, Leo De Raeve, Ángel Ramos Macías, Margaret Jorgensen, Aiya Elise Taylor, Irene Deltetto, and Colman Taylor

ABSTRACT

There has been an increasing global burden of addressing hearing loss and understanding the importance of appropriate hearing technologies, including cochlear implants. The development of guidelines to improve the worldwide utilization of these technologies was imperative, with the aim to optimize the treatment of adults who are eligible for cochlear implants and respond to continually evolving research relating to hearing loss and cochlear implant use.

In this article, the rationale for this approach is outlined, including how the Cochlear Implant Living Guidelines framework was built and adopted as part of the guideline development process.

An independent Global Cochlear Implant Task Force was established in November 2021 to endorse a novel Cochlear Implant Living Guidelines methodology approach to the development of global guidelines. This approach built a framework into the guidelines that allows for rapid review and, if appropriate, inclusion of new evidence as it emerges to ensure that the guidelines remain relevant and current.

The Cochlear Implant Living Guidelines framework offers the advantage of incorporating new evidence into practice more quickly than the more conventional publication approach. This framework ensures that the recommendations within the Living Guidelines can be updated rapidly and regularly to incorporate new evidence as it emerges, while maintaining the rigorous research standards of the original guidelines and upholding relevance as gaps in evidence or research are filled over time.

The development of the Living Guidelines contributes to a growing body of similar guidelines for the management of various conditions. The application of a global living guidelines approach can maximize their effectiveness in disease areas in which research and practice continue to evolve rapidly. This article provides a blueprint and set of principles that may be adopted by those aiming to develop living guidelines in other contexts.

INTRODUCTION

Adult hearing loss is a major global health challenge, creating a significant burden for the global economy and affected

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individuals.¹ It is often referred to as an “invisible disability” due to the lack of visible symptoms and stigma.²

Unaddressed hearing loss leads to an estimated annual loss of USD \$1 trillion.¹ Further, communication difficulties and diminished social interaction cause a significant, but difficult to quantify, emotional burden for individuals living with inadequately treated hearing loss.²⁻⁴ Other flow-on health impacts include, but are not limited to, increased risk of falls, dementia, depression, social isolation, and loneliness.⁴⁻⁸ For example, it is estimated that unaddressed hearing loss may be responsible for over 8% of dementia cases among older adults.⁶

In this context, initiatives that increase the uptake of successful interventions to treat hearing loss can offer significant value to individuals with hearing loss, as well as to the broader health system and economy. The World Health Organization (WHO) *World Report on Hearing* identified increased availability and adoption of hearing technologies, including cochlear implants (CIs), as important to reducing inadequately treated hearing loss globally.² The report recommended that “hearing aids and CIs should be included as priority assistive products made available as part of government-led services.” The report also identified “guidelines that maximize patient safety through the rational use of required medicines, technologies and equipment,” as one of five key health system requirements for equitable access to devices and products.

In 2020, a modified Delphi consensus process was convened to begin the first step towards the development of global guidelines on best practices for cochlear implantation in adults with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss.⁹ The process drew on the expertise of a panel of 30 international specialists in the fields of otology, audiology, and hearing science. The findings provided evidence that awareness of cochlear implantation among primary and hearing health care professionals is inadequate, leading to under-identification of eligible candidates. With a lack of clearly defined and internationally consistent guidelines and care pathways, there are disparate levels of access and global systemic underuse of CIs.

The concept of Cochlear Implant Living Guidelines (Living Guidelines) is a new approach to driving evidence-based practice. Building upon the foundation of the 2020 consensus process, the approach aims to improve the standard of care for adults with hearing loss and provide guidance for the role that CIs may play in the care of these individuals. The core difference from traditional clinical guidelines is that these Living Guidelines involve development and maintenance that can continually and rapidly identify, update, and adapt to new research as it emerges, even following the date of the initial guidelines’ publication. This ensures that recommendations within the Living Guidelines are always underpinned by rigorous evidence base and remain relevant within a continually evolving field of research.

Other novel aspects of the Living Guidelines development are (1) the creation of a framework to be able to assess and incorporate new evidence that may emerge outside of the annual literature review, (2) the establishment of a Global Cochlear Implant Task Force (CI Task Force), and (3) the adaptation of materials and a unique implementation for individual countries. (See Figure 1: Overview of the process to develop Living

Guidelines.) In doing so, this article aims to provide a blueprint and set of principles that may be adopted by those aiming to develop living guidelines in other contexts.

MATERIALS AND METHODS

Phase I: Create

CI Task Force Architecture

An independent CI Task Force was established in November 2021 to develop the Living Guidelines. The CI Task Force comprises 52 individuals across three key stakeholder groups including Ear, Nose and Throat specialists (ENTs); audiologists; and CI users. Three co-chairs were appointed to lead the CI Task Force, who similarly provide representation at the leadership level across the different stakeholder groups (an ENT, an audiologist and a CI user). In addition, an independent entity (HTANALYSTS) was engaged to support the co-chairs and assist in the coordination of the CI Task Force.

The members of the CI Task Force were selected and recommended by peers to ensure a balance of global geographical location, gender, and expertise. The members are content experts, skilled in the conduct and critical appraisal of evidence and in the implementation of evidence-based recommendations at different health system levels. The CI Task Force’s terms of reference included a description of the roles and responsibilities of the groups involved. For the full terms of reference, see **Data in Supplemental Digital Content 1**.

A key priority of the development process has been ensuring patient-centricity. This resulted in the inclusion of six CI users as part of the CI Task Force. Six CI users were included in the Task Force, which partnered with the Cochlear Implant International Community of Action to ensure a global reach and deep understanding of the experiences of CI users and their families.¹⁰ This close collaboration ensured that patient perspectives were continually incorporated into the Living Guidelines development process.

As part of the establishment of the CI Task Force, HTANALYSTS developed the framework for drafting and operationalizing the Living Guidelines approach. The framework was developed from best practices recommended and implemented by the WHO Guideline Review Committee, Australian National Health and Medical Research Council (NHMRC), and National Institute for Health and Care Excellence.¹¹⁻¹³

Develop Living Guidelines Scope

The first task of the CI Task Force was to define the scope of the Living Guidelines. To define the scope, the patient hearing journey was segmented. The clinical need was then evaluated, and the recommendations of the consensus paper were overlaid with a review of international CI guidelines to identify gaps that may be addressed by the Living Guidelines.¹⁰ The review identified that, while existing guidelines provided adequate guidance for CI surgery as well as intra- and post-operative care, underserved areas included referral and rehabilitation. Most notably, no existing guidelines detailed a process for patient-relevant assessments at key follow-up points after cochlear implantation.

The scope was structured around a patient-centred journey from hearing loss through to cochlear implantation and

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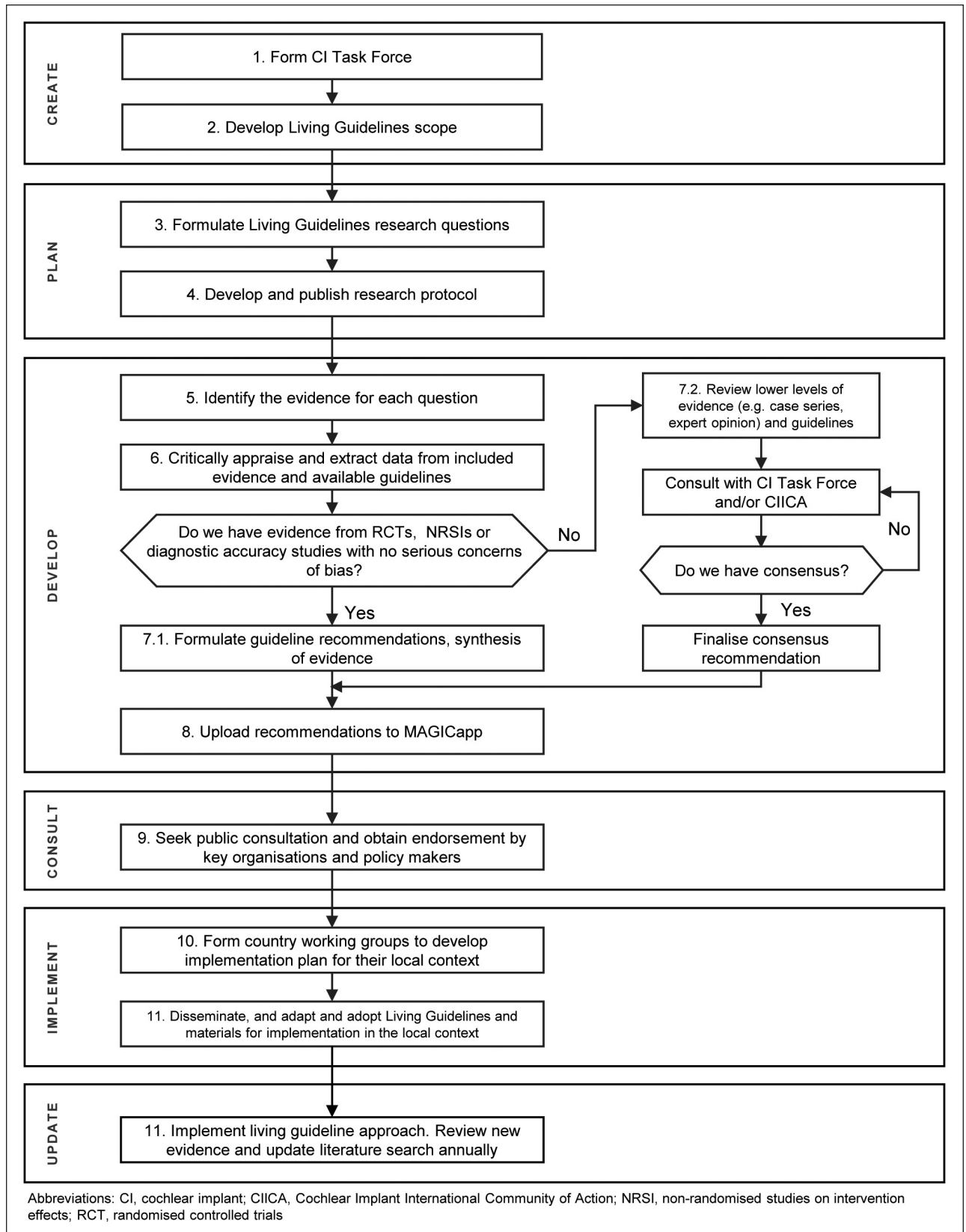


Figure 1. Overview of the process to develop Living Guidelines

rehabilitation. This resulted in key topics that included hearing health awareness (hearing loss assessment and referral) and CI awareness (regular CI screenings and assessment) in the primary health care setting, CI device programming and rehabilitation and CI outcome measurement.

Phase II: Plan

Form Living Guidelines Questions

To develop the Living Guidelines, a framework had to be built that could be applied on an ongoing basis, ensuring the guidelines can be updated consistently over time. Building the framework required translating the agreed scope into specific research questions. Forming the questions was a critical step, as this informs the type of evidence required, the search strategy, the structure of analysis and synthesis of findings, and the structure of the guideline recommendations.

Because the scope had already been structured into key topics, the CI Task Force developed an appropriate research question for each topic. Each research question was structured considering the Population, Intervention, Comparison and Outcome (PICO) format.

Considering the schedules of many members of the CI Task Force, as well as differing time zones, members of the CI Task Force were divided into three working groups, each with a diverse range of backgrounds, geographical locations, and expertise. Each group was allocated a specific topic(s) from the scope document and tasked with developing research questions for their allocated topic(s) via Microsoft Teams collaboration tools over two weeks. This process allowed for online discussion with colleagues across the world in different time zones. Following this, the broader CI Task Force reviewed and endorsed each research question via a consensus process. The consensus process required two-thirds of CI Task Force members to support the research question for it to be endorsed. For the full consensus process see **Data in Supplemental Digital Content 2**. Research questions that did not receive two-thirds support were refined in response to feedback. All attempts were made to have all members come to an agreement for all questions.

Develop and Publish Protocol

To finalize the framework, a systematic review protocol aligned to the research questions was developed and endorsed by the CI Task Force. This protocol was submitted to and published in PROSPERO (CRD: 42022325393).¹⁰ The published protocol outlined the process to develop the Living Guidelines.

RESULTS

Phase III: Develop Identify Evidence

The first step of developing the Living Guidelines was to carry out the systematic literature review as per the protocol. This formed the basis of a common understanding among the CI Task Force members as to the available evidence, including where gaps existed in the evidence. A separate literature search was carried out for each research question and the identified literature was screened and managed via an online platform, Covidence.

Develop Recommendations

Where evidence was available, the co-chairs developed draft recommendations with assistance from HTANALYSTS. These considered the body of evidence, the certainty of the evidence (using the Grading of Recommendations, Assessment and Evaluations (GRADE), approach and other factors relevant to potential recommendations including consideration of benefits and harms, values and preferences, resource use and acceptability.¹⁶

In circumstances where there was a lack of high certainty evidence (eg, randomised controlled trials and nonrandomised studies of intervention), global hearing health and CI guidelines were reviewed, and evidence of lower certainty (eg, case series, expert opinion) was considered to develop draft recommendations. Expert advice from the CI Task Force was also considered. These recommendations used a consensus-based approach for endorsement, requiring two-thirds of CI Task Force members to endorse it. Any evidence gaps identified were also reported within the living guidelines so as to align with research priorities.

The CI Task Force drew upon CIICA to consult with CI users when developing recommendations specific to users. Up to four meetings were held and facilitated by CIICA, involving at least 25 CI users or family or friends of users. This created an opportunity for users and related stakeholders to provide input and help co-design the draft recommendations. (See Figure 2: Overview of Phase III of the Living Guidelines.) During the guideline development process, all draft recommendations were uploaded to a digital authoring and publication platform (Making GRADE The Irresistible Choice [MAGICapp]) for feedback from the CI Task Force.¹⁵ MAGICapp provides a fully transparent forum and enables the documentation of feedback for future reference. The platform provides access to summaries of the best available evidence for specific clinical questions. Several organizations, including the WHO, have adopted MAGICapp as a tool to provide access to high quality, up-to-date evidence.

Phase IV: Consult

Public feedback was sought over 12 weeks via a mixed-method approach involving both targeted and open consultation. Targeted consultation involved key hearing stakeholders, including primary care specialists and referrers, subject matter experts, advocacy organizations, policymakers, and specialty bodies. To identify the relevant parties, the CI Task Force members were asked to pinpoint key organizations, peak bodies, and stakeholders in their country for consultation. The draft guidelines were sent directly to these organizations to review, provide feedback or endorse where appropriate.

To complement the targeted consultation, open consultation also occurred via MAGICapp, providing an opportunity for all interested parties to submit feedback. This mixed-method approach allowed for a wider range of views from target audiences, the public and CI users to be incorporated into the Living Guidelines. This process was also expected to help identify gaps in the evidence, provide advance notice of the publication of new evidence, refine recommendations to increase feasibility and acceptability, and improve language and presentation of the guidelines before final publication.

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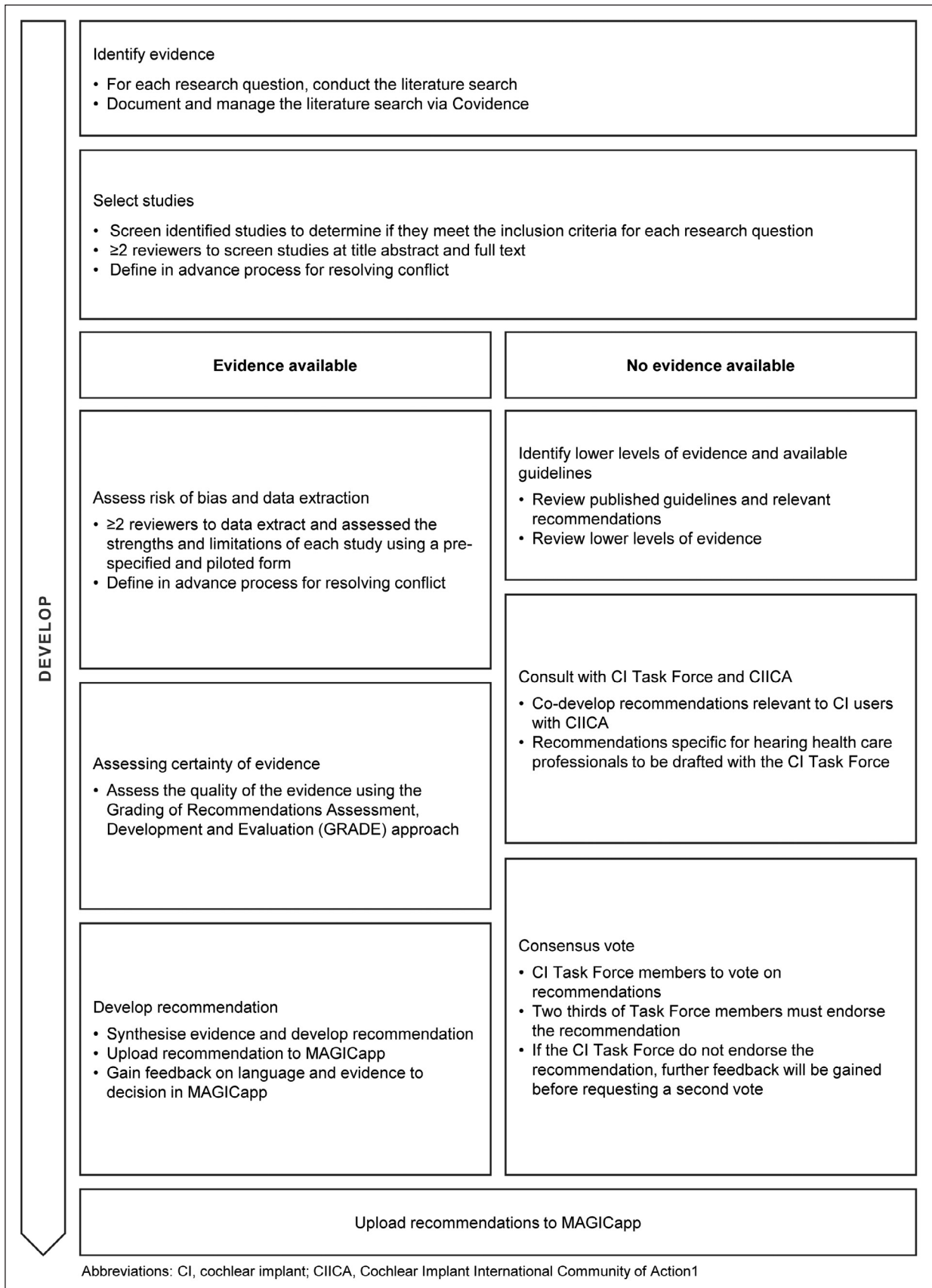


Figure 2. Overview of Phase III of the Living Guidelines

Phase V: Implement and Update

See **Table in Supplemental Digital Content 3** which presents Version 1.0 of the recommendations, published in July 2023.

See **Data in Supplemental Digital Content 4**, which presents the Good Practice Statements for each recommendation.

More detail is available on MAGICapp (CI Task Force 2023)-MAGICapp Guideline: Improving the standard of care for adults with hearing loss and the role of cochlear implantation: Living Guidelines.¹⁶

DISCUSSION

Living Guidelines Approach

The Living Guidelines approach allows for rapid review and incorporation of relevant new evidence without sacrificing the quality and thoroughness of the traditional guideline development process. This approach incorporates two processes to ensure the guidelines remain “living.” First, if a published recommendation is still relevant for clinical practice, the systematic literature reviews for that recommendation will be run annually. Any new research identified through these reviews will be incorporated into the recommendations, if deemed appropriate. Second, a process for alerting the CI Task Force via MAGICapp to early assess and incorporate pivotal new evidence will be implemented between the systematic review periods. Where this occurs, the CI Task Force will consider whether to update the guidelines before the next systematic review period via a prioritization process that will consider several questions (modified from the WHO prioritisation framework):

- Does the evidence have the potential to change an existing Living Guidelines recommendation?
- Could the evidence impact the credibility of an existing Living Guidelines recommendation?
- Is there potential for an updated Living Guidelines recommendation to significantly change global clinical practice?¹⁷

New research questions can also be nominated by stakeholders via MAGICapp for the CI Task Force to consider for future updates of the guidelines.

Together, this ensures that relevant evidence is captured within a year of publication via the annual systematic literature review, while also providing a framework for more rapid consideration of significant evidence that may emerge between annual systematic reviews. This creates an iterative approach to guideline development, resulting in ongoing relevance and credibility, and reducing the need for a refreshed literature review from database inception and guideline redevelopment process several years in the future. (See Figure 3: Overview of Phase V of the Living Guidelines.)

The Living Guidelines approach offers faster availability of updated recommendations and reduced costs, while maintaining rigour and transparency. The traditional method for developing guidelines, which includes multiple recommendations, usually takes one to two years and requires significant resources.² The Living Guidelines approach is more efficient by focusing only on individual recommendations that require updates, avoiding the costs of updating reviews and convening the CI Task Force for recommendations that are unlikely to

change. The use of more frequent online meetings also reduces costs and is more convenient for CI Task Force members.

Global to Local Guideline Translation

To maximise the feasibility and acceptability of the global recommendations, country-specific working groups have been convened. These working groups include CI Task Force members and local health care professionals who review the final global recommendations and consider adapting the tools and resources available to maximize relevancy for their community.

As of the date of publication, this local adaptation process has commenced in Australia and the United States, with further working groups scheduled to commence soon.

Ensuring Guidelines Translate into Practice

Translating guidelines into practice can be challenging due to the different levels at which they must be adopted: from the government and regulatory level down to the patient and clinician level. To address these challenges, the CI Task Force undertook a study (in press) to explore the barriers and facilitators for successful implementation of the Living Guidelines and to understand what guideline implementation tools will be required to support implementation at the country level. The study found that limited awareness of CIs and hearing loss, as well as economic factors such as out-of-pocket costs and access to referral channels, could be significant barriers to the Living Guidelines translating into practice and enabling improved use of CIs globally. Both the consensus paper and CI Task Force qualitative study also highlighted that, for the living guidelines to have impact, they must reach primary health care professionals, such as general practitioners and audiologists who can influence an individual’s hearing health journey.⁹

Considering this, in addition to public consultation and endorsement of the guidelines, a new workstream has been established focusing on the implementation and dissemination of the Living Guidelines. Practical steps to support adoption in individual countries include ensuring the guidelines adhere to the best available evidence and endorsement by key professional bodies, health care professionals, and policymakers. Tools such as economic evaluations, quick reference guides, and social media campaigns may also facilitate uptake of the living guidelines and are under consideration. At the time of publication, these and other initiatives are being considered as part of the separate implementation and dissemination workstream.

CONCLUSIONS

In a constantly evolving research environment, living guidelines offer the advantage of incorporating new evidence into practice more quickly than the more conventional publication approach. For patients, it means they are receiving care that is based on the best available evidence at that moment in time. This calls for a novel approach reflected in the framework established to develop the Living Guidelines as outlined in this paper. This framework ensures that the recommendations within the Living Guidelines can be updated rapidly and regularly to incorporate new evidence as it

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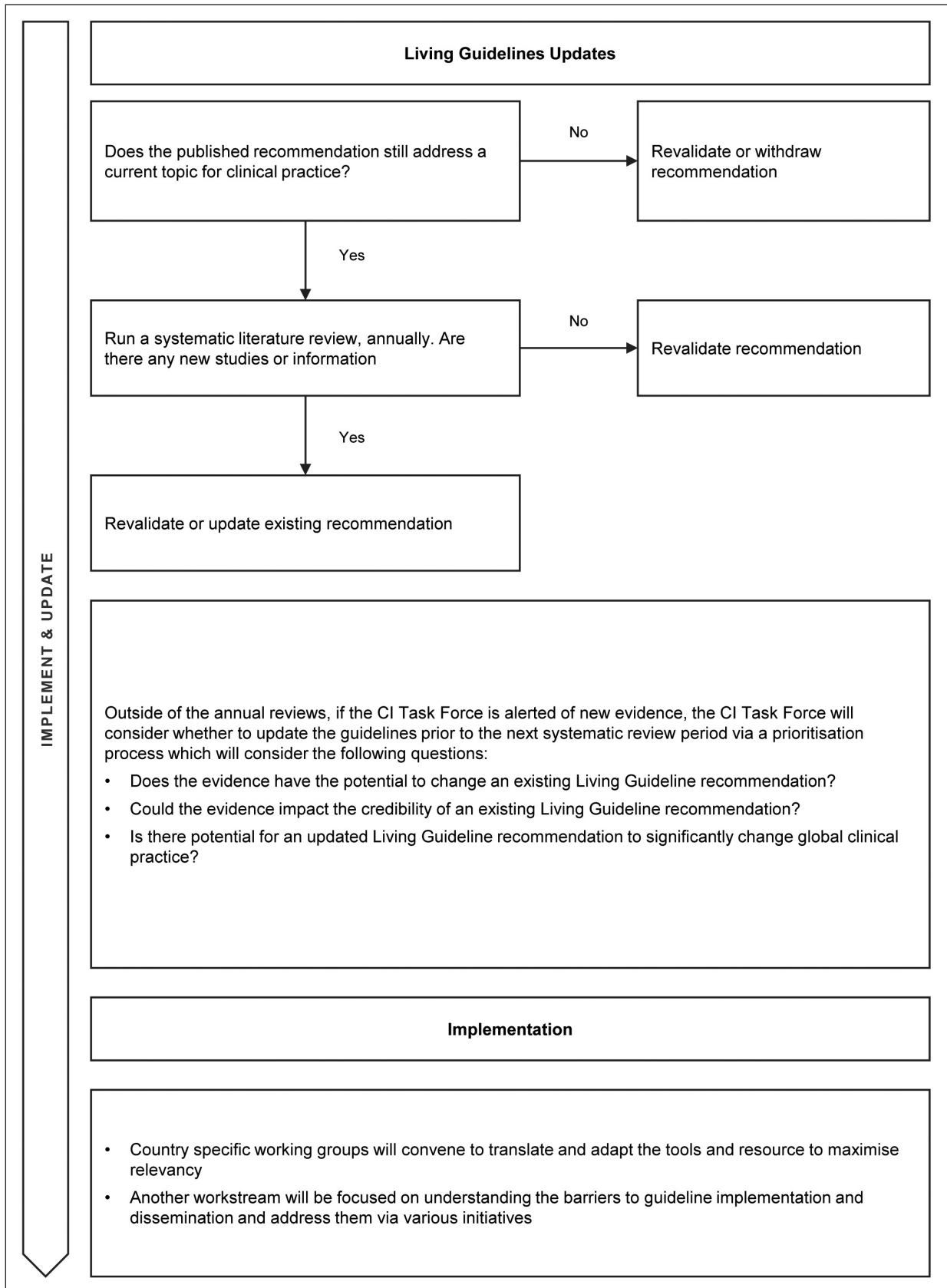


Figure 3. Overview of Phase V of the Living Guidelines

emerges either via an annual systematic literature review or more promptly where significant developments in research are noted between review periods. This ensures the rigorous research standards of the original guidelines are maintained while also upholding relevance as gaps in evidence or research are filled over time. Compared to traditional periodic guidelines, this approach is also more efficient, focusing updates on only those areas where the literature review highlights new evidence.

The Living Guidelines were also designed to maximize international acceptability and translation into clinical practice. This includes establishing a global task force, a mixed methods consultation approach, and establishing local working groups to facilitate uptake of the Living Guidelines. This approach also avoids the need for costly and time-consuming development of standalone local guidelines for each country. For low- to middle-income countries, this is also an important step in responding to the WHO's call to action to promote equitable access to hearing health services.²

The development of the Living Guidelines contributes to a growing body of Living Guidelines for the management of various conditions, with other examples including COVID-19, stroke, diabetes, and arthritis.^{2,12,18,19} This article provides a blueprint and set of principles that may be adopted by those aiming to develop Living Guidelines in other contexts. The application of a global Living Guidelines approach can maximize the effectiveness of guidelines in disease areas in which research and practice continue to evolve rapidly.


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