Delphi consensus process on unilateral cochlear implant use in adults with bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss (SNHL),

Frequently asked questions

1. What is the International Consensus Paper on Adult Cochlear Implantation?

This paper is the first international consensus publication following a Delphi consensus process on unilateral cochlear implant treatment for adults living with bilateral severe to profound SNHL. It was published recently in *JAMA Otolaryngology*.

The paper will aid the development of consistent, clear national clinical guidelines and best practice treatment and aftercare for adults so they can reach their optimal hearing outcome and quality of life.

The International Consensus Paper includes twenty consensus statements on unilateral cochlear implantation for adults with bilateral severe, profound, or moderate sloping to profound SNHL. Consensus was achieved using the Delphi consensus process. See question 5 for the full outline of the methodology.

Following publication of the International Consensus Paper, wide dissemination is expected, and it is anticipated that clinical practice guidelines will be developed or updated by relevant national professional bodies.

2. Why is the International Consensus Paper important?

This Delphi consensus process is the first in the field of unilateral adult cochlear implant treatment, it has however been widely used in other fields of medical treatment to help establish standards of care and best practice clinical standards. This Delphi process fills a gap in the field of cochlear implantation by consolidating evidence and international expertise in the area of cochlear implantation for adults with bilateral severe, profound, or moderate

sloping to profound SNHL. This consensus process focused on diagnosis, referral, treatment and aftercare for adults.

The consensus statements represent an important milestone because the knowledge and guidance they foster provides guidance to clinicians that will better define referral, treatment and aftercare pathways for patients and promote best clinical practice. It will help raise awareness among patients and their carers and provide them with reference points and questions to ask when they are not getting the information they need.

3. What is understood by standard of care?

A medical standard of care refers to a diagnostic or treatment process that a clinician should follow for a certain type of patient or condition. For the treatment of hearing loss, the standard of care should encompass treatments that best improve the individual's quality of life and health, through optimizing hearing function, social participation and engagement. For adults with severe, profound, or moderate sloping to profound sensorineural hearing loss this includes proper diagnosis, timely referral to an appropriate specialist center for assessment and advice. When indicated as the most beneficial treatment option, the patient should be advised by their specialist about access to cochlear implantation and aftercare.

4. Why do we need to improve the standard of care for adults living with SNHL?

A standard of care will help raise awareness and better define referral and treatment pathways so patients can receive information about a treatment option that may help them. In many countries, adults do not have their hearing assessed as part of regular health check-ups. Of those who receive hearing checks and are diagnosed with severe, profound, or moderate sloping to profound SNHL, few are referred to an appropriately qualified hearing specialist to examine whether an implantable hearing device is indicated as the most beneficial treatment option.

Cochlear implants (CIs) are an effective medical treatment for many adults living with severe, profound, or moderate sloping to profound SNHL. However, conservative industry estimates suggest that no more than 1 in 20 adults who could benefit from a CI have one.[1,2]

5. What is a Delphi consensus process?

A Delphi consensus process is a systematic and structured method of developing consensus among a panel of clinical experts. In the Delphi process, knowledge is gathered using questionnaires, anonymous voting and iterative feedback to develop a set of consensus statements. Statements are refined over time and consensus is validated when the panel reaches a pre-defined threshold. Due to its systematic nature, the Delphi consensus process is considered more robust in establishing medical standards of care compared to market research surveys or opinion-driven publications.

6. How was this Delphi consensus process conducted?

The Delphi consensus process was underpinned by a systematic review to identify relevant studies in the subject area. These were used to inform the development of evidence-based draft consensus statements. The draft statements then entered the Delphi voting process, which entailed three anonymous voting rounds. **Figure 1** shows the details of this Delphi consensus process.

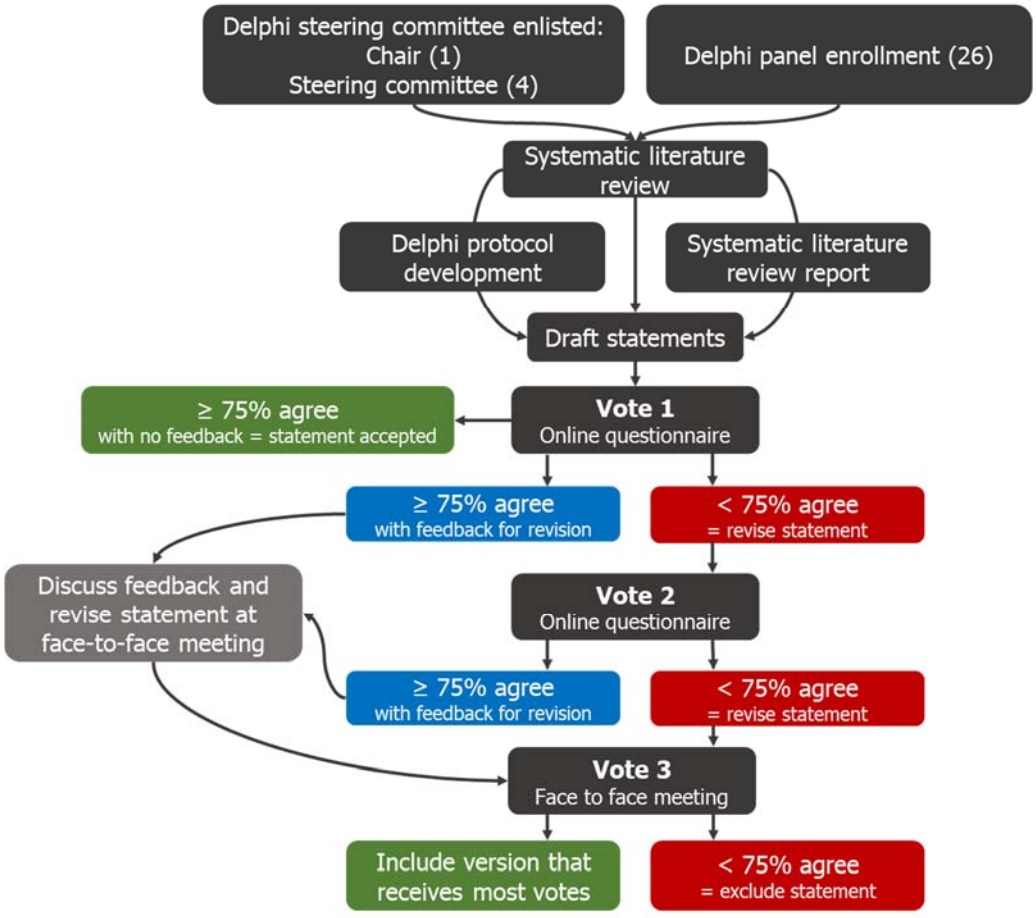

Figure 1. Delphi consensus process based on ≥ 75% agreement threshold.

Systematic literature review

A systematic literature review was conducted to identify studies relevant to at least one of six key areas: i) level of awareness of CIs; ii) best practice clinical pathway from diagnosis to surgery; iii) best practice guidelines for surgery; iv) best practice guidelines for rehabilitation; v) factors that impact CI performance and outcomes; and vi) cost implications of CIs. Studies were screened manually against pre-specified eligibility criteria, and data relevant to the six key areas of interest were extracted from the included studies. Studies were excluded for the following reasons: sample size less than 20, case studies or narrative reviews, studies published before 2005, studies of pediatric population, studies of bilateral CIs or electro-acoustic stimulation or hybrid hearing. Included studies were quality-assessed using a recognized method.[3]

The consensus statements were drafted based on the data in the included studies.

Delphi voting process

All members of the steering committee and the Delphi consensus panel, except the Chair, were able to vote in the consensus process. Voting on the draft consensus statements took place over three rounds: two rounds by questionnaire remotely, and one at the face-to-face meeting.

At each voting round, the statements were voted on anonymously using an online questionnaire. Consensus was defined *a priori* as agreement by a least 75% of respondents. During this process, all panel members had access to a report of the evidence from the systematic literature review, including the results of the quality assessment of included studies.

7. Who was involved in the Delphi consensus process?

This Delphi consensus process was guided by a non-voting Chair, **Dr Craig Buchman**, Head of Otolaryngology – Head & Neck Surgery, Washington University School of Medicine. The Chair was supported by four steering committee members who were able to vote: **Professor René Gifford**, Vanderbilt University, Nashville; **Dr David Haynes**, Vanderbilt University, Nashville; **Professor Thomas Lenarz**, Medical University of Hannover, and **Professor Gerard O'Donoghue**, University of Nottingham.

The Delphi panel comprised an additional 26 experts in the field of CI use, including audiologists and ear, nose and throat specialists from across 13 countries. See **Table 1** for details.

In addition, a Consumer and Professional Advocacy Committee (CAPAC) of international CI user and professional advocacy organizations was consulted in the development of the consensus statements but did not vote. See question 9 for more about the CAPAC.

8. How were the panel members of the Delphi consensus process chosen?

Delphi consensus panel members were selected by the steering committee based on their experience of treating adults with SNHL.

9. What is the CAPAC?

The Consumer and Professional Advocacy Committee (CAPAC) includes cochlear implant users and international consumer and professional advocacy organizations. See **Table 2**. The CAPAC was formed to ensure the voice of cochlear implant users was considered in the Delphi consensus process.

10. How was the CAPAC chosen?

The CAPAC was selected by the Delphi Panel Chair, Dr Buchman because of their international leadership and experience with the relevant respected international organizations and their ability to provide a voice for cochlear implant users.

11. What was the role of the CAPAC?

The CAPAC reviewed draft consensus statements and provided suggestions on the process to the Chair of the Delphi , Dr Buchman to ensure:

- **i.** relevance and acceptability of the consensus statements to CI users and candidates, with a particular focus on the user experience, making sure that the perspectives of people with hearing loss were considered during the process
- **ii.** the process and outcomes had the input of international user organizations and leading professional organizations.

Table 1. Delphi panel members

Name	Affiliation
Dr Oliver Adunka	Ohio State University, Columbus, OH, USA
Dr Allison Biever AuD.	Rocky Mountain Ear Center, Englewood, CO, USA
Professor Robert Briggs	The University of Melbourne; Royal Victorian Eye and Ear Hospital; Royal Melbourne Hospital, Australia
Dr Matthew Carlson	Mayo Clinic School of Medicine, Rochester, MN, USA
Dr Pu Dai	Chinese PLA General Hospital, Beijing, China
Dr Colin Driscoll	Mayo Clinic School of Medicine, Rochester, MN, USA
Dr Howard Francis	Duke University School of Medicine, Durham, NC, USA
Dr Bruce Gantz	University of Iowa Health Care, Iowa City, IA, USA
Dr Richard Gurgel	University of Utah Hospitals and Clinics, Salt Lake City, UT, USA
Dr Marlan Hansen	The University of Iowa, Iowa City, IA, USA
Associate Professor Meredith Holcomb	Medical University of South Carolina, Charleston, SC, USA and University of Miami, FL, USA
Dr Eva Karltorp	Karolinska University Hospital, Stockholm, Sweden
Dr Milind Kirtane	Seth GS Medical College and KEM Hospital, Parel, Mumbai, India
Ms Jan Larky	Stanford University School of Medicine, Stanford, CA, USA
Professor Emmanual Mylanus	Radboud University Medical Center, Nijmegen, Netherlands
Dr Thomas Roland	New York University School of Medicine, New York, NY, USA
Professor Shakeel Saeed	University College Hospital; National Hospital for Neurology and Neurosurgery; Royal National Throat, Nose and Ear Hospital, London, UK
Professor Henryk Skarzynski*	Institute of Physiology and Pathology of Hearing, Warsaw, Poland

Professor Piotr Skarzynski*	Department of Teleaudiology and Screening, World Hearing Center, Institute of Physiology and Pathology of Hearing, Warsaw/Kajetany, Poland; Department of Heart Failure and Cardiac Rehabilitation, Medical University of Warsaw, Poland; 3) Institute of Sensory Organs, Kajetany, Poland
Dr Mark Syms	Arizona Hearing Center, Phoenix, AZ, USA
Associate Professor Holly Teagle	The University of Auckland, New Zealand
Professor Paul Van De Heyning	Antwerp University Hospital, University of Antwerp, Edegem, Belgium
Professor Christophe Vincent	Centre Hospitalier Régional, Universitaire de Lille, France
Professor Hao Wu	9th People's Hospital, Jiao Tong University School of Medicine, Shanghai, China
Professor Tatsuya Yamasoba	The University of Tokyo Hospital, Tokyo, Japan
Dr Terry Zwolan	University of Michigan, Ann Arbor, MI, USA

* Professors Henryk and Piotr Skarzynski worked jointly with their contribution with voting rights equivalent to one panel member.

12. Table 2. CAPAC members

Name	Affiliation	Role
Ms Barbara Kelley	Executive Director, Hearing Loss Association of America (HLAA)	CAPAC co-Chair
Dr Harald Seidler	President, German Hard of Hearing Association (DSB)	CAPAC co-Chair
Dr Leo De Raeve	Technical Adviser to the Board, European Association of Cochlear Implant Users (EURO-CIU)	CAPAC member
Professor Bernard Fraysse	President, International Federation of Oto-Rhino-Laryngological Societies (IFOS)	CAPAC member

Ms Darja Pajk	Treasurer, European Federation of Hard of Hearing People (EFHOH)	CAPAC member
Ms Donna Sorkin	CEO, American Cochlear Implant Alliance (ACIA)	CAPAC member
Professor George Tavartkiladze	Secretary-General, International Society of Audiology (ISA)	CAPAC member

13. How are industry sponsors involved?

The Delphi process and medical writing support have been funded by Advanced Bionics, Cochlear Ltd, Med-El and Oticon Medical. The funding organizations did not contribute to the design, facilitation or content of the Delphi consensus process. Oxford PharmaGenesis, an independent HealthScience communications agency, which provides services to the healthcare industry, professional societies and patient groups through specialist practices, developed the protocol and searches for the systematic literature review and provided support to Dr Buchman for screening, data extraction and analysis and statement development. Oxford PharmaGenesis also coordinated and facilitated the three rounds of Delphi voting to generate and validate the consensus statements for inclusion in a final publication. Oxford PharmaGenesis facilitated communication between the Chair, steering committee, Delphi consensus panel members and the CAPAC.

No industry representatives were involved in the development of the Delphi consensus protocol or voted in the Delphi process. The consensus paper was developed independent of industry representatives.

14. What are the consensus statements?

The statements cover awareness of CIs, best practice for diagnosis, best practice for surgery, clinical effectiveness of CIs, best practice for rehabilitation after cochlear implantation, association of hearing loss with cognitive disorders, depression and loneliness/social isolation, and the cost of CIs. The full statements are as follows in **Table 3**:

Table 3: Consensus Statements 1-20
Statement 1: Awareness of cochlear implants among primary and hearing healthcare providers is inadequate, leading to under-identification of eligible candidates. Clearer referral and candidacy pathways would help increase access to cochlear implants.
Statement 2: Detection of hearing loss in adults is important; pure tone audiometry screening methods are considered the most effective. The addition of a questionnaire or interview to the screening can improve the detection of sensorineural hearing loss.
Statement 3: Preferred aided speech recognition tests for cochlear implant candidacy in adults include monosyllabic word tests and sentence tests, conducted in quiet and noise. Further standardization of speech recognition tests is needed to facilitate comparison of outcomes across studies and countries.
Statement 4: Age alone should not be a limiting factor to cochlear implant candidacy, as positive speech recognition and quality of life outcomes are experienced by older adults as well as younger adults.
Statement 5: Both curved (perimodiolar) and straight electrodes are clinically effective for cochlear implantation, with a low rate of complications.
Statement 6: When possible, hearing preservation surgery can be beneficial in individuals with substantial residual hearing.
Statement 7: Cochlear implants significantly improve speech recognition in both quiet and moderate noise in adults with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss; these gains in speech recognition are likely to remain stable over time.
Statement 8: Both word and sentence recognition tests should be used to evaluate speech recognition performance following cochlear implantation.
Statement 9: Cochlear implants significantly improve overall and hearing-specific quality of life in adults with bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss.
Statement 10: Adults who are eligible for cochlear implants should receive the implant as soon as possible to maximize post-implantation speech recognition.
Statement 11: Where appropriate, individuals should use hearing aids with their cochlear implant in order to achieve bilateral benefits and the best possible speech recognition and quality of life outcomes.
Statement 12: Many factors impact cochlear implant outcomes; further research is needed to understand the magnitude of the effects.
Statement 13: Long durations of unaided hearing loss do not rule out potential benefit of cochlear implants: individuals who receive an implant in an ear that was previously unaided

for more than 15 years have been shown to experience improvements in speech recognition.
Statement 14: Adults who have undergone cochlear implantation should receive programming sessions as needed to optimize outcomes.
Statement 15: Adults with hearing loss can be substantially affected by social isolation, loneliness, and depression; evidence suggests that treatment with cochlear implants can lead to improvement in these aspects of well-being and mental health. Longitudinal studies are needed to obtain further knowledge in this area.
Statement 16: There is an association between age-related hearing loss and cognitive/memory impairment.
Statement 17: Further research is required to confirm the nature of cognitive impairment in individuals with hearing loss, and its potential reversibility with treatment.
Statement 18: The use of cochlear implants may improve cognition in older adults with bilateral severe to profound sensorineural hearing loss.
Statement 19: Hearing loss is not a symptom of dementia; however, treatment of hearing loss may reduce the risk of dementia.
Statement 20: Unilateral cochlear implantation in adults is cost-effective when compared with no implant or no intervention at all and is associated with increased employment and income.

15. Why are the consensus process and statements important?

This consensus process is among the first of its kind to consolidate evidence and expertise in the area of cochlear implantation for adults with bilateral severe, profound, or moderate sloping to profound SNHL. Until now there has been no international agreement on the appropriate diagnosis, referral, treatment and aftercare for adults living with severe, profound, or moderate sloping to profound SNHL. The consensus statements represent an important milestone because the knowledge and recommendations they provide in each of these areas act as the first steps towards establishing best clinical practice in the area of CIs for adults with severe, profound, or moderate sloping to profound SNHL.

16. How are the statements expected to change clinical practice?

The consensus statements aim to foster consistency in treatment patterns for adults with severe, profound, or moderate sloping to profound SNHL at all levels of care. Continued dissemination and promotion of their recommendations among clinical experts, professional

societies and advocacy organisations will improve awareness of cochlear implants. Such awareness is vital for beginning to make changes to clinical practice. In time, it is expected that new, consistent treatment patterns and recommendations will lead to greater awareness of CIs and the establishment of clinical practice guidelines for adults with severe, profound, or moderate sloping to profound SNHL.

17. Did the Delphi consensus Chair, steering committee, Delphi panel members or CAPAC members receive payment?

The Chair, steering committee, members of the Delphi process panel and CAPAC members did not receive compensation in the form of money or other benefits for their participation. Travel expenses to attend the final voting round to conclude the consensus statements were covered for Delphi process participants.

18. Who owns the intellectual property (IP)?

All consensus outputs are the IP of the authors. No industry sponsor has or should take ownership over outputs and IP.

As the Chair, in advance of any publications, Dr Buchman has the right to make the final decision on disclosure of IP. Once information is officially published in a scientific journal or conference abstract, that information will be accessible and distributable through the normal scientific channels, for example, purchasing licenses. Once published, the journal will have the copyright for the paper and parts thereof, including the consensus statements.

19. Why didn't the consensus panel consider pediatric cochlear implantation?

Use of CIs in children is a topic that deserves special focus and may be the subject of a future consensus process.

20. What level of hearing loss was considered for the consensus process?

The systematic review included studies that described participants as having bilateral severe, profound, or moderate sloping to profound SNHL.

21. Are the statements specific to any brand of cochlear implants?

No, the systematic review and Delphi consensus process was based on collective experience with the most prevalent brands and types of CI, therefore not focused on any particular CI brand. Consequently, the results and consensus statements apply to CIs as a treatment rather than any brand.

22. How do the statements relate to the use of hearing aids?

The consensus statements indicate that unilateral CIs provide superior clinical effectiveness, in terms of speech recognition, and better quality of life compared with standard care with hearing aids for adults with bilateral severe, profound, or moderate sloping to profound SNHL. The statements also recommend, where appropriate, the use of an existing hearing aid in addition to a unilateral CI; evidence suggests that use of a CI in one ear and a hearing aid in the contralateral ear may lead to bilateral benefits compared with a single aided ear.

23. Why wasn't I involved in the Delphi consensus process?

The steering committee selection process was conducted by the chair, Dr Buchman. The panel in turn was then chosen by the steering committee (see question 7 for details), based on their experience with treating adults living with severe to profound sensorineural hearing loss. Representation was taken from the U.S., Europe and Asia Pacific.

24. Why didn't the steering committee include representatives from other regions, e.g. Africa, Middle East, or South America?

The members of the panel (see question 7, **Table 1** for details) were chosen to reflect an initial stage in the development of clinical practice guidelines, there will be subsequent efforts to focus on the rest of the world. The steering committee and panel have acknowledged there were specific confines in the development of this initial stage, the authors encourage local experts to review the findings and ultimate publication alongside their own prevalent guidelines and local best practice.

25. Why did the chair, Professor Craig Buchman, not take part in the voting?

A decision was made in alignment with the formal Delphi process to appoint a Chair that would not cast a vote throughout the process.

26. This is going to have no impact in my region.

The consensus statement process is designed to act as a steppingstone in the development of clinical practice guidelines. These efforts will vary by region and country and will be dependent on various factors associated with adoption.

The authors encourage healthcare professionals and national health bodies to review and consider these recommendations within the context of national guidelines and unmet needs for people living with severe to profound sensorineural hearing loss.

27. I don't agree with the methodology.

This has been a thorough and systematic literature review of evidence associated with cochlear implants, and the findings were reached after consideration of over 7,000 individual pieces of literature. The Delphi process is a well-recognized progression method for the consideration of evidence, synthesized to achieve consensus.

28. These recommendations are too expensive or too impractical to adopt in most countries / my country.

These recommendations were reached after a systematic literature review and represent the consensus of 30 experts in hearing loss care. While clinical practice needs to reflect what is practical on a local level, the statements outline what the authors considered as international best practice.

29. How does the consensus paper differ from clinical practice guidelines?

It is important to differentiate between a consensus paper and clinical practice guidelines.

A consensus statement reflects the opinions synthesized from an organized group of experts into a written document. They reflect the expert views of a panel of individuals who are well

versed on the topic of interest, while carefully examining and discussing the scientific data available. Consensus Statements are not intended as legal documents or a primary source of detailed technical information.

Clinical practice guidelines are one way of increasing implementation of evidence into practice. They can serve as a guide to best practices, a framework for clinical decision making, and a benchmark for evaluating performance. Clinical practice guidelines often offer guidance on how a healthcare provider should act within a specific healthcare system, such as a country, state, or local healthcare authority.

30. Why wasn't bi-lateral implantation recommended?

The authors of the ICP considered unilateral implantation to be the starting point for the first Delphi process in this field. As bilateral implantation was not considered in this Delphi process, the International Consensus Paper makes no recommendations on the topic, therefore does not detract from respected medical opinions in relation to bilateral implantation.

Availability and reimbursement for bilateral implantation is supported in many countries because of the optimal hearing outcomes this provides in many cases of severe to profound bilateral deafness.

Current standards are varied around the world, this is why as the first step, the authors of this Consensus Paper looked to establish what could be the 'minimum standards applied'.

One of the major issues to overcome is that referrals remain low and many people who could benefit from life changing technology are missing out on the opportunity to hear. This is true even in countries with developed reimbursement systems, including those that provide support for bilateral implantation.

The most important action moving forward is to address the gaps in local systems and focus on the biggest areas of unmet need. Some countries may be ahead in reimbursement, but behind in awareness and referral pathways, while in others, it could be the opposite.

The International Consensus Paper does not detract from a widely a respected view that bilateral implants provide many severe to profoundly bilaterally deaf patients with demonstrably better hearing outcomes. Rather, the ICP provides the starting point for a minimum standard of care, which could help many adults access their first cochlear implant.

31. Is the publication relevant to all countries?

The consensus statement process is designed to act as a stepping-stone in the development of consistent, best practice clinical practice guidelines. These efforts will vary by region and country.

The authors encourage healthcare professionals and national health bodies to review and consider these Consensus statements within the context of national guidelines and unmet needs for cochlear implant treatment for people living with severe to profound sensorineural hearing loss.

32. Is this going to affect the pricing of manufacturers' products?

The panel concluded that 'unilateral cochlear implantation in adults is cost-effective when compared with no implant or no intervention at all and is associated with increased employment and income'.

This process has made no recommendations with regards to pricing of cochlear implants. The panel did not review any specific manufacturers or products.

33. This isn't new.

The consensus process was among the first of its kind to consolidate evidence and expertise in the area of cochlear implantation for bilateral severe to profound SNHL.

Whilst clinical practice guidelines and consensus statements are not new, the scope for this research project is the largest of its kind for cochlear implants, with 31 (two non-voting) members in the steering committee and 7 consumer and professional advocacy groups representing the process.

34. According to the World Health Organization (WHO), the greatest need for improvements in hearing loss care are for children in developing countries. Why has the panel focused on adults?

We believe it is important that all people living with hearing loss can access appropriate solutions for hearing loss.

In many countries, access to hearing screening for newborns and children is established within health systems and when the treatment is indicated, cochlear implants have become the Standard of Care (SoC) for babies and young children with bilateral severe to profound SNHL.

However, for adults, cochlear implantation rates remain very low, even in developed countries where access is available.

35. Who is to blame for the lack of awareness of cochlear implants among primary and hearing health providers?

There are a number of reasons why awareness is low. What is important is that moving forward, primary healthcare professionals, hearing health professionals, and CI professionals work together to understand the appropriate criteria for diagnosis, referral and treatment of adults living with severe to profound hearing loss.

References

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3. Eubank BH *et al*. *BMC Med Res Methodol* 2016;16:56.