# Consumer and Professional Advocacy Committee – Summary Report

**Prepared by:**

**Value Demonstration Practice**

**Oxford PharmaGenesis**

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**Oxford PharmaGenesis Ltd**
Tubney Warren Barn, Tubney
Oxford, OX13 5QJ, UK
Tel: +44 1865 390144
Fax: +44 1865 390145
info@pharmagenesis.com
**www.pharmagenesis.com**

Registered in England and Wales
Registration number: 3488862
VAT number: GB 685 6981 65

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# Abbreviation list

| | |
|---|---|
| AAO-HNS | American Academy of Otolaryngology – Head and Neck Surgery |
| AARP | American Association of Retired Persons |
| ACIA | American Cochlear Implant Alliance |
| ANS | American Neurotology Society |
| AOS | American Otological Societies |
| ASHA | American Speech Language Hearing Association |
| ALD | Assistive listening device |
| CAPAC | Consumer and Professional Advocacy Committee |
| cm | Centimeter |
| CI | Cochlear implant |
| CNC | Consonant–nucleus–consonant |
| dB HL | Decibel hearing level |
| dB | Decibels |
| ENT | Ear, nose and throat |
| HA | Hearing aid |
| HLAA | Hearing Loss Association of America |
| HRQoL | Health-related quality of life |
| m | meter |
| NIDCD | National Institute on Deafness and Other Communication Disorders |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| PTA | Pure-tone audiometry |
| QoL | Quality of life |
| SNHL | Sensorineural hearing loss |
| SR | Systematic review |
| SSD | Single-sided deafness |
| STT | Speech-to-text |
| WHO | World Health Organization |

# 1 EXECUTIVE SUMMARY

This report summarizes the outcomes of the Delphi consensus for unilateral cochlear implant (CI) use in adults with bilateral moderate sloping to profound sensorineural hearing loss (SNHL), and more specifically the role of the Consumer and Professional Advocacy Committee (CAPAC) in support of this process.

The Delphi consensus process was composed of three voting rounds on evidence-based draft consensus statements. The first two rounds were conducted remotely, whereas the third and final round of voting was held at a face-to-face meeting in Los Angeles on 30 March 2019.

The CAPAC was formed to ensure the patients' voice was considered in the Delphi consensus process. The committee members had a non-voting role but were asked to comment on the statements at each round of voting, to provide their views on the statements from the user and their professional organization's viewpoint.

The final statements were agreed and endorsed following the final round of voting. The statements will now be used to form an international consensus paper to be published in a peer-reviewed journal. This will be the first step in the dissemination of the consensus statements. Going forward, it is hoped that the Delphi panel and CAPAC members will act as ambassadors for the cause, to raise awareness of CI use and clinical best practice. Ultimately, the intention is that the Delphi panel and the CAPAC can collectively play a part in turning the consensus statements, via the consensus paper, into practice guidelines endorsed regionally, national and internationally to improve access and best clinical practice for the use of CIs for those with hearing loss.

# 2 BACKGROUND

Hearing loss is one of the leading causes of disability worldwide, and is estimated to affect 466 million people according to the World Health Organization (WHO).[1] WHO projections suggest that, unless action is taken, there will be 630 million people living with disabling hearing loss by the year 2030; with that number expected to grow to over 900 million by 2050.[1]

Sensorineural hearing loss (SNHL) is a type of hearing loss caused by dysfunction of the cochlea in the inner ear. SNHL may be present at birth or can be acquired throughout life. It can occur gradually or be sudden in onset, and may be stable over time or progressive. It may be caused by genetics or by environmental factors, such as noise-induced SNHL.

Individuals with SNHL may be treated with hearing aids (HAs).[2] For people with mild to moderate hearing loss, HAs are an effective method of improving hearing and health-related quality of life (HRQoL).[3,4] However, they may be less effective in those with moderate to profound SNHL.

A cochlear implant (CI) is a surgically implanted neurostimulator, which is suitable for individuals with bilateral SNHL who gain limited benefit from optimal acoustic HAs. The key advantage of CIs over HAs is that, whereas the function of HAs is limited to the amplification of sound, CIs work by replacing the function of the damaged inner ear; with the benefit of enabling people with no residual hearing to hear.[5]

According to a review published in 2017 on criteria for CI candidacy around the world, 20 countries have clinical practice guidelines or protocols for the use of CIs for the management of SNHL.[6] Without standard international guidelines, individuals in countries with no guidelines may not be receiving CI technology even though it could benefit them. Furthermore, in many developing regions, access to CIs is limited due to a lack of public funding, so individuals are required to provide their own funding for treatment. Thus, there is a need for international guidelines with well-defined eligibility criteria for CIs.

There may be several other reasons contributing to under provision of CIs. These include low awareness of the benefits of CIs among the individuals with SNHL, low awareness among healthcare professionals, and a lack of specific referral pathways.[7] Under provision leads to a substantial unnecessary burden to the individual with hearing loss, leading to poor quality of life (QoL).[7]

With the objective of increasing awareness of CIs and improving best practice for their use, a steering committee of CI experts was created to conduct a Delphi consensus process with the aim of developing an evidence-based set of international consensus statements on cochlear implantation (See section 8.1 in Appendices for full details of the Delphi Chair, steering committee and panel members). A systematic review (SR) was conducted of the available evidence on topics identified by the steering committee as key to improving understanding of and access to CIs among individuals with severe, profound or moderate sloping to profound SNHL. The funding for this initiative was provided by Advanced Bionics, Cochlear Ltd, MED-EL and Oticon Medical.

This report summarizes the outcomes of the Delphi consensus process, the finalized and endorsed consensus statements on the use of unilateral CIs in adults with bilateral moderate sloping to profound SNHL, and the role the CAPAC has played in achieving these.

# 3 OBJECTIVES OF CAPAC

## 3.1 PURPOSE

The purpose of the CAPAC is to provide a bridge between the CI Delphi consensus process and the international organizations needed to help with dissemination and real-world acceptance of the final consensus statements. The CAPAC had the opportunity to review draft statements and provide suggestions and advice on the relevance of the statements in a non-voting capacity. They were also asked to give insights on dissemination and ideas to promote real-world acceptance, with a focus on the user experience. It is hoped that the involvement of the CAPAC has ensured that the perspectives of healthcare providers and users have been taken into account, increasing positive engagement of CI users and professional organizations with the Delphi consensus process and ultimately strengthening the outcomes.

A key objective of the CAPAC is in an advocacy role to promote the knowledge, dissemination, acceptance and adoption of consensus statements among consumer advocacy organizations and healthcare providers and their professional organizations. It is hoped that they will verify the importance and credibility of the paper at the international, regional and country level. Going forward, it will be important for the CAPAC to adopt roles as speakers at key user and professional conferences to facilitate dissemination of the consensus statements to as wide an audience as possible. It is hoped that the CAPAC will have an ongoing role in the field of global CI advocacy.

# 4 PROCESS

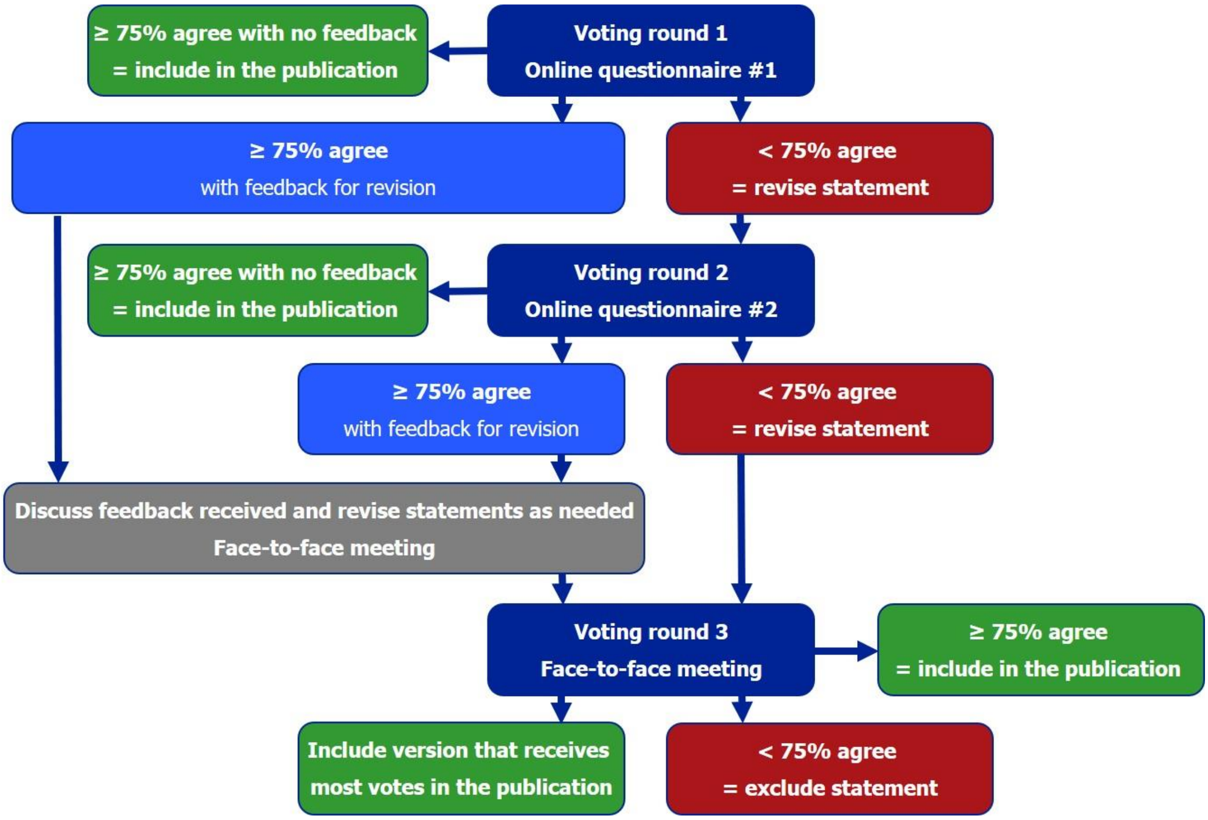
## 4.1 DELPHI PROCESS

The Delphi consensus process was used to generate and validate consensus statements based on evidence identified from the scientific literature. Over three rounds of voting, a panel of clinical experts was asked to vote on how strongly they agreed with statements on topics of hearing loss and cochlear implantation. Any feedback provided was incorporated in an anonymous manner. The results of the voting rounds were used to develop and refine the statements over the course of the process. The final set of consensus statements are those that had reached the specified threshold of agreement by the end of the final voting round.

### 4.1.1 Voting rounds

Statements were drafted, based upon the evidence identified in the SR, and were included in the Delphi consensus voting process, which consists of three distinct voting rounds. Figure 1 details the key stages of the voting process.

*Figure 1 Delphi consensus voting rounds*



At each of the three voting rounds, the following thresholds were applied for selecting statements to be included in the consensus publication and to identify which required further revision:

- Statement included in the consensus publication: ≥ **75%** of participants agree with the statement.
- Statement requires further revision: < **75%** of participants agree with the statement.

Voting rounds 1 and 2 were carried out via an online questionnaire. At voting rounds 1 and 2, statements that did not meet the inclusion threshold were revised based upon the feedback received and reviewed by the steering committee. Once reviewed, the revised statements were included in the next round of voting.

Following voting round 3, which took place at the face-to-face meeting, any statement that did not meet the inclusion threshold was not included in the final set of consensus statements. Feedback received on the statements that reached the inclusion threshold at either voting rounds 1 or 2 was also discussed. Several statements that reached the inclusion threshold at the earlier voting rounds also received suggestions for improvement to the wording. In accordance with the protocol, these statements were revised based upon the feedback received and the panel members voted for whether they preferred the original or revised wording.

## 4.2 CAPAC PROCESS

The CAPAC is composed of seven CI users and user representatives (Table 4-1).

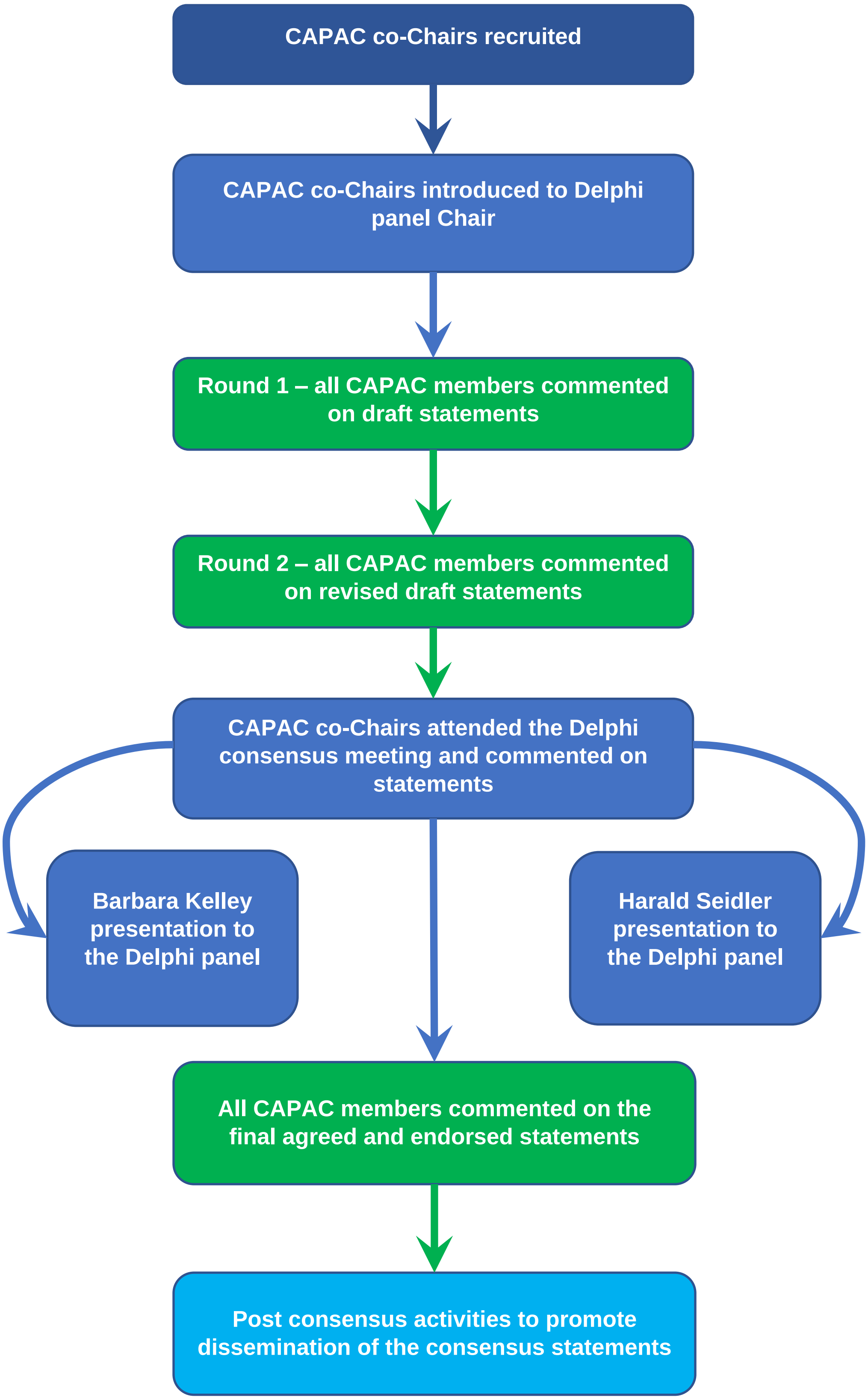
*Table 4-1 Members of the CAPAC*

| Name | Affiliation | Role |
|---|---|---|
| Barbara Kelley | Executive Director of Hearing Loss Association of America | CAPAC co-Chair |
| Harald Seidler | President of the German Hard of Hearing Association | CAPAC co-Chair |
| Leo De Raeve | European Association of Cochlear Implant Users | CAPAC member |
| Bernard Fraysse | International Federation of Otorhino Laryngological Societies | CAPAC member |
| Darja Pajk | European Federation of Hard of Hearing People | CAPAC member |
| Donna Sorkin | American Cochlear Implant Alliance | CAPAC member |
| George Tavartkiladze | International Society of Audiology | CAPAC member |

During the Delphi process, the CAPAC had a non-voting role, but provided individual comments and feedback on the statements that were taken into account by the Delphi panel chair when revising the statements (Figure 2). Following voting round 3, all CAPAC members were asked to comment on the final statements.

The full CAPAC comments for voting round 1 are shown in Table 8-1 and for voting round 2 in Table 8-2 in the appendices.

*Figure 2 Outline of the CAPAC process*



# 5 DELPHI CONSENSUS MEETING

## 5.1 SUMMARY OF PRESENTATIONS

### 5.1.1 Clinical need for the Delphi consensus process – Craig Buchman

Professor Craig Buchman, Delphi Panel Chair and Lindburg Professor and Chair at Washington University School of Medicine, discussed the clinical need for the Delphi consensus process. The overall goal is to expand access to CIs to all patients who may benefit from them. In particular, there is an unmet need in adults for whom CIs may be viewed as a last resort option.

Globally, there are 432 million adults with disabling hearing loss. Estimates have shown that approximately 15 million adults are potential CI candidates. However, penetration (i.e. uptake in those eligible to receive a CI) is estimated to be as low as 5%. Penetration is influenced by various factors, including lack of awareness of implants among those with hearing loss and healthcare providers, lack of referral for CIs, financial factors related to funding cochlear implantation, lack of "best clinical practices", the political landscape, and the paucity of dedicated organizations focused on cochlear implantation. Figure 3 Why is penetration of cochlear implants low? illustrates the key factors limiting penetration of CIs.

***Figure 3 Why is penetration of cochlear implants low?***

| | ***KEY FACTORS*** | | | | | |
|---|---|---|---|---|---|---|
| ***Low awareness*** | ***Referral networks not referring*** | ***Clinic/hospital financial viability*** | ***Lack of "best clinical practice" guidelines*** | ***Lack of current cost-effectiveness data*** | ***Political landscape*** | ***Lack of dedicated organizations focused on CIs*** |

Professor Buchman said that the initial goal should be to make CIs the standard of care in adults with severe to profound SNHL. For an intervention to become the standard of care, there must be comparative evidence on a range of outcomes (e.g. efficacy, QoL, cost-effectiveness) and consistent opinions of the intervention's benefits among key stakeholders, especially at the local level. To reach these stakeholders, the Delphi panel will publish an international consensus paper on unilateral implantation in adults. This will serve as a step towards establishing clear, consistent, international clinical guidelines.

Key to the success of the project will be actions consequent of the international consensus paper, which lead to greater awareness of and access to CI for those with hearing loss. Actions that lead to greater awareness and access to CIs for those with hearing loss following the publication of the international consensus paper will be key to the success of the project. Some measures of success to consider are number of citations, downloads and endorsements of the publication, and whether referrals increase. Changes in access and awareness are likely to take place over many years. Success is dependent on endorsement and continued commitment.

### 5.1.2 A real-world view of cochlear implant use – Barbara Kelley

CAPAC co-Chair Barbara Kelley presented a real-world view of CI use in the USA. As Executive Director of the Hearing Loss Association of America (HLAA), Barbara described how the organization has been assisting those with hearing loss for 40 years, with a mandate to open the world of communication to people with hearing loss through information, education, support and advocacy. The HLAA organizes a series of Walk4Hearing events to raise awareness of hearing loss, at which screening for hearing loss is also available.

Barbara said that, whereas HAs provide important benefit for the majority of people with hearing loss, CIs provide meaningful access to sound for those with more severe hearing loss. In the USA, the average primary care medical practice includes eight adult patients who would benefit from a CI.

There are several ways in which the HLAA can facilitate spreading the word about the consensus statements; the HLAA has an extensive and well-used website with resources for those with hearing loss, as well as a monthly magazine publication entitled 'Hearing Life'. It is anticipated that sharing information about the consensus statements via these routes would be an effective way for reaching the hearing loss community. In addition, in 2023 the HLAA Research Symposium on Cochlear Implants will be held (funded by the National Institute on Deafness and Other Communication Disorders – NIDCD), which will offer excellent opportunities to promote the message of the consensus statements.

### 5.1.3 Helping people to help themselves – Harald Seidler

CAPAC co-Chair Harald Seidler represents Deutscher Schwerhörigenbund – the German Hearing Impaired Association and the Bosenberg Kliniken St Wendel in Saarland, Germany. Harald described the current situation in Germany where 19% (~13.4 million) of the population above 14 years of age have hearing loss, with moderate to profound hearing loss accounting for 43.5% of cases. In Germany, there are more than 120 CI clinics with approximately 5000 surgeries conducted in 2017, and a total of approximately 50 000 CI users. There is a strong focus on the importance of patient rehabilitation post-implantation, for both quiet and noisy environments. This is centered on rapid occupational rehabilitation (3–6 months) and reintegration into family and social life. In Germany there is no age limit (0 to 80+ years) on eligibility for a CI, and longstanding deafness is no longer contraindicated. New CI guidelines in Germany are due to be published in 2019.

Dr Seidler explained that a rehabilitation team should be composed of audiologists, speech therapists, audio therapists and psychologists with experience in hearing loss. Table 5-1 shows the care model for adult patients undergoing cochlear implantation in Germany.

*Table 5-1 Inclusion for Hard of Hearing Phase Model in the CI (Adult Care)*

| Stage of Care | Phase |
|---|---|
| Pre-op | Phase A: diagnosis (clinical) |
| 0 | Phase B: surgery (clinical) |
| 2–12 weeks | Phase C: initial CI adjustment of speech processor (in the clinic as an outpatient, inpatient rehabilitation, outpatient CI centers) |
| 12 weeks–6 months | Phase D: rehabilitation (communication skills, rehabilitation verbal and non-verbal characteristics) |
| Every 3 months | Phase E: outpatient care (hospital, outpatient, CI centers) |
| Lifelong care | Phase F: recovery of resources, culture, recreation, self-help group |

Dr Seidler said that there are several professional and patient associations and CI suppliers in Germany that could assist with championing the consensus statements. These include the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery (DGHNO), the German Society of Audiology (DGA), the Working Group of German-speaking Audiologists, Neurotologists, and Otologists (ADANO), the Professional Association HNO (BV HNO), the Federal Guild of Hearing Aid Acousticians (BIHA), the German Association of the Hard of Hearing People (DSB), the German Association of CI Users (DCIG), the Hannover Association of CI Users (HCIG), and journals such as Schnecke and Spektrum-Hören.

### 5.1.4 Endorsement and roll-out strategy – René Gifford and David Haynes

Dr David Haynes and Dr René Gifford, both members of the Delphi steering committee and affiliated with Vanderbilt University Medical Center, Nashville, Tennessee, discussed their plans to obtain endorsement of the final consensus statements.

Many of the consensus statement recommendations are already in place in their region, and they are committed to advocating the recommendations in the statements; their ideas for outreach in their region include lecturing at Vanderbilt's grand rounds in pediatrics, geriatrics, primary care and family medicine, and submitting abstracts to speak at regional and/or national conferences. Opportunities may also be found to speak at local, state or national audiology and ear, nose and throat (ENT) meetings, and to promote awareness on social media.

To have an impact in other regions, a lot of work is needed to address awareness of CIs among primary care providers, audiologists and ENT physicians not working in a CI program. Other considerations are how to ensure adequate assessment of QoL before and after implantation, and hearing screening for older adults outside audiology and ENT clinics.

# 6 AGREED AND ENDORSED CONSENSUS STATEMENTS

The final agreed and endorsed Delphi consensus statements on unilateral CI use in adults with bilateral moderate sloping to profound SNHL are shown in Table 6-1.

***Table 6-1 Agreed and endorsed Delphi consensus statements***

| **Awareness of cochlear implants** |
|---|
| **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. |
| **Best practice for diagnosis** |
| **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. |
| **Best practice for surgery** |
| **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. |
| **Clinical effectiveness of cochlear implants** |
| **Statement 7:** Cochlear implants significantly improve speech recognition in both quiet and moderate noise in adults with bilateral severe, profound, or moderate sloping to profound 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 postimplantation 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. |
| **Best practice for rehabilitation after cochlear implantation** |
| **Statement 14:** Adults who have undergone cochlear implantation should receive programming sessions as needed to optimize outcomes. |
| **Association of hearing loss with cognitive disorders, depression and loneliness/social isolation** |
| **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. |
| **Cost of cochlear implants** |
| **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. |

## 6.1 COMMENTS FROM CAPAC ON THE FINALIZED STATEMENTS

Following the final voting round, the CAPAC members were asked to give any comments or feedback they had regarding the finalized statements. These are show in Table 6-2.

*Table 6-2 CAPAC comments on the final agreed and endorsed Delphi consensus statements*

| CAPAC member | Comments |
|---|---|
| Barbara Kelley | Full agreement. |
| Harald Seidler | No comments. |
| Leo De Raeve | **Statement 14: Adults who have undergone cochlear implantation should receive programming sessions as needed to optimize outcomes.**<br>Rehabilitation is more than programming, it should also include auditory training and for some patients also psychological support, because they have some social or psychological difficulties. |
| Bernard Fraysse | No comments. |
| Darja Pajk | **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."**<br>Not only deafness, but also an understanding of the possibilities of CIs and their limitations is important. It's also important that they understand that in the beginning maybe CI will not work as they expect, and people understand that side effects are possible. The motivation to hear is also essential. People should appreciate that they need to train to understand speech again in different situations, and that is still a problem in some environments.<br>**Statement 14:** "**Adults who have undergone cochlear implantation should receive programming sessions as needed to optimize outcomes."**<br>I miss where there are recommendations about rehabilitation after implantation. Not only about programming but also speech therapy, psychological support and information about training speech recognition, and using assistive listening device (ALD) in combination with a CI. Information about the possibilities and recommendations about existing support.<br>CIs are virtually perfect, but they do have limitations and people need to know what these are and understand them. |
| Donna Sorkin | Full agreement. |
| George Tavartkiladze | No comments. |

# 7 NEXT STEPS

Sharing of the Delphi consensus statements by congress poster and publication in a peer-reviewed journal is the primary next step. The manuscript will describe the entire Delphi process, from the systematic literature review that identified supporting evidence to the final voting round. The final statements will be presented with accompanying discussion of each statement, incorporating comments from both the Delphi panel members and CAPAC members.

The Delphi panel members have made individual commitments to specific actions to promote the Delphi consensus statements; these are outlined in Table 8-3.

To maximize the reach of the consensus statements and to ensure that they have the greatest impact, it is essential that the CAPAC members consider how they can champion the statements; through their own organizations, by speaking at key user and professional conferences, and by acting as ambassadors verifying and promoting the importance and credibility of the international consensus paper at the regional, national and international level.

# 8 APPENDICES

## 8.1 DELPHI FACULTY

| | |
|---|---|
| **Chair:** | Dr Craig Buchman, Washington University School of Medicine, St Louis, MO, USA |
| **Steering committee:** | Dr René Gifford, Vanderbilt University, Nashville, TN, USA |
| | Dr David Haynes, Vanderbilt University, Nashville, TN, USA |
| | Professor Thomas Lenarz, Medical University of Hannover, Hannover, Germany |
| | Professor Gerard O'Donoghue, University of Nottingham, Nottingham, UK |
| **Delphi panel:** | Dr Oliver Adunka, Ohio State University, Columbus, OH, USA |
| | Dr Allison Biever, 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, 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 |
| | Dr Meredith Holcomb, Medical University of South Carolina, Charleston, SC, USA |
| | Dr Eva Karltorp, Karolinska University Hospital, Stockholm, Sweden |
| | Dr Milind Kirtane, Seth GS Medical College and KEM Hospital, Parel, Mumbai, India |
| | Dr Jan Larky, Stanford University School of Medicine, Stanford, CA, USA |
| | Professor Emmanual Mylanus, Radboud University Medical Center, Nijmegen, the 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 Henrich Skarzynski, Institute of Physiology and Pathology of Hearing, Warsaw and Professor Piotr Skarzynski, Institute of Physiology and Pathology of Hearing, Warsaw, Poland (working jointly with contribution equivalent to one panel member)

Dr Mark Syms, Arizona Hearing Center, Phoenix, AZ, USA

Dr Holly Teagle, University of Auckland, New Zealand

Professor Paul Van De Heyning, Antwerp University Hospital, Edegem, Belgium

Professor Christophe Vincent, Centre Hospitalier Regional, 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

## 8.2 FULL CAPAC COMMENTS ON DRAFT STATEMENTS AT ROUND 1

*Table 8-1 Full CAPAC comments on draft statements at round 1*

| | **CAPAC Participants** | | | | | | |
|---|---|---|---|---|---|---|---|
| Delphi Consensus Statements | **Leo De Raeve** | **Bernard Fraysse** | **George Tavartkiladze** | **Darja Pajk** | **Donna Sorkin** | **Barbara Kelley** | **Harald Seidler** |
| Statement 1: "Awareness of cochlear implants among physicians is inadequate, leading to under-identification of eligible candidates. Clearer referral and candidacy pathways would help increase access to cochlear implants." | Yes I agree, but it is not only a problem among physicians, also among other professionals supporting people with a hearing loss, including audiologists, teachers of the deaf, speech and language therapists, and also among deaf and hard of hearing people themselves. | Yes. | Agree, physicians need clearer referral and candidacy pathways. | In particular, it is inadequate knowledge of what the implant essentially is and also limited otorhinolaryngologists' knowledge of cochlear implants, as they do not directly deal with them, that is the issue. | Agree with the statement. Physician should be broadly defined to include both general ENTs and primary care physicians. Both should know enough to make a referral to a cochlear implant center – not a "hearing care" center where an individual might be fitted with another set of hearing aids. | Agree with this statement. Hearing health in general is not promoted in regular medical and wellness visits. Primary care physicians often dismiss hearing loss as a normal part of aging, and nothing can be done about it. To think that physicians have information about referring for implants is unrealistic given they rarely address hearing loss. | I agree with this statement. We observe that many physicians consider CI fitting as a technical problem for hard of hearing people, not as a rehabilitation. This means there is not enough space for explaining the new way of hearing. We see that results of better reintegration of deaf people depends on the rehabilitation system which is being offered. |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Statement 2: "Early screening for hearing impairment in adults is important and cost-effective; 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." | Pure tone audiometry in a silent room is not a good screening method. It is not quick, and assessments only in good listening conditions do not show the impact of hearing loss in daily life.<br>In Flanders, Belgium we use the Dutch version of the 'triple digit test with and without background noise', which is developed by the University of Leuven (Belgium). This test is now used for public hearing screening of all children at age 4, 6, 10 and 15, with a lot of success. Same screening can be used for adults too (after some small adaptations). | Yes. | Agree. | Early screening is important for the whole population, including older people. Awareness about what hearing loss is also important. I think that the addition of an interview to the screening can improve the detection of sensorineural hearing loss. | While I agree with the statement that early screening is important, I am not sure where the pure tone audiometry screening is to be done. In the primary care office? In the hearing aid audiologist's office? I am not sure that pure tone audiometry is designed to move someone into the evaluation channel for cochlear implantation. Shouldn't we be considering measures of function for people who are already fitted with hearing aids? Does someone properly fitted with hearing aids still have difficulty in conversation in quiet or noise? Does someone properly fitted with hearing aids have difficult on the telephone, or when the person cannot see the speaker's face? A hearing care professional outside of CI or a primary care physician could make those determinations. | Early screening is important as the earlier it is detected and treated, the better the person is. According to the National Academies of Sciences, Engineering and Medicine, untreated hearing loss can lead to falls, isolation, depression and anxiety, and there is a cognitive link. I do not have the expertise to know about screening methods; however, most patients can relate to real-world questions like, "Do you have trouble hearing on the phone, and in restaurants?" “Do you tend to choose staying at home rather than going to social events?” These types of questions can augment the audiogram. Loss of audibility doesn't necessarily translate into one's ability to communicate. "A multifactorial domain of function, hearing access depends on these interconnected variables: auditory integrity, | Early hearing diagnosis is important, but in addition to the pure tone audiogram, in my experience, the evaluation of the candidate's previous daily routine is extremely important. The audiogram provides insufficient information about the communication competence and the listening effort in everyday life. |

amplification integrity, individual factors, and listening environment." (Barbara Weinstein, PhD, The Hearing Journal, December 2018).

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| Statement 3: "The preferred speech recognition tests for cochlear implant candidacy in adults are the monosyllabic word test (CNC, Freiburg, etc.), the AzBio sentence test, and the Hearing In Noise Test*. Further standardization of speech recognition tests is needed to facilitate comparison of outcomes across studies and countries."<br>*In the USA, HINT is no longer listed in the minimum speech test battery for adults. | It is important to have speech recognition scores at word level (using monosyllabic words), but not only in quiet, also in noise. A sentence test has little or no additional value because it measures not only speech perception, but also cognition and language. | Yes. | Agree. | Before implantation, I did not complete the speech recognition test. I could not understand (I used a HA) the speech of people at a distance of more than 80 cm in a quiet environment and relied on lipreading. If a person cannot understand speech normally with a HA at less than 2 m, that means that he/she has a major problem in normal life activities. Before I got a CI, I had terrible problems in my life because I could not understand, and I had to ask people about what was going on. However, it depends on the individual and how demanding the environment in which they live in is. Personally, I think it is imperative to understand speech at a distance of 2 m or more for QoL. | Agree. | Not qualified to answer. | Yes, the Freiburger test is in addition to the Oldenburg test an important decision-making aid. These should be measured in silence and in noise 60/65 dB. |
| Statement 4: "Age 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." | Totally agree. | Yes. | Agree. | I totally agree. Just as there are no restrictions on the replacement of the heart valves or artificial hips. Quality communication allows for normal aging. Older people of course want to hear and be involved in society. In addition, most of us all become old and I assume that most people want to hear and communicate individually. If there is an age limit, then this is discrimination. I just cannot imagine being without a CI and also older people around me being without a CI. They are so happy because they (and me too) get our lives back. | Agree. | Agree with statement. | I agree with this statement. |

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| Statement 5: "Both curved (perimodiolar) and straight electrodes are clinically effective for cochlear implantation, with a low rate of complications, in adults of all ages." | No comments. | Yes. | Depends on cochlear anatomy. | I do not know this area so I cannot answer. | Agree. | Not qualified to answer. | I agree with this statement. |
| Statement 6: "Older perimodiolar electrodes are not optimum for achieving hearing preservation in those with residual hearing before implantation, and newer perimodiolar or straight electrodes should be used." | No comments. | Yes. | Agree. | It is important to use such electrodes to achieve hearing preservation in those with residual hearing before implantation. As a CI user I would be happy if I still had some of my own hearing. | Don't feel comfortable responding on this statement. | Not qualified to answer. | No comment. |
| Statement 7: "Unilateral implants significantly improve speech recognition in both quiet and noise conditions in adults of all ages with bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss; these gains in speech recognition are likely to remain stable in the long term." | Unilateral implants have less impact on speech recognition in noisy conditions in cases of bilateral profound hearing loss. Results also depend on the hearing device fitted in the second ear. Is the patient still wearing a hearing aid or not on the second ear?<br>I can agree that in general (there are always exceptions) the speech recognition outcomes remain stable over time. | Yes. | Agree. | From my own experience, I have one implant and with it I have significantly improved speech recognition in both quiet and noise conditions. So, I suppose that this is true, but not in all circumstances (in some circumstances a CI does not work so perfectly). In adults of all ages with sensorineural hearing loss it is important to save residual hearing, if that is possible, and that these gains in speech recognition are likely to remain stable in the long term. | Agree. This finding has been confirmed by a large body of published research. | Not qualified to answer. | Unilateral implants are useful in cases with symmetric hearing levels, fitted with a hearing aid or with single-sided deafness (SSD). |
| Statement 8: "Word recognition tests, rather than sentence recognition tests, should be used to evaluate speech recognition performance in the period following cochlear implantation." | Agree, but add word recognition tests in noise (sometime after implantation, not in the early months after implantation, for example 6 months after CI use). | No. | Agree. | Both of them should be used. In the first phase word recognition tests should be used, and in the later stages sentence recognition tests should be used. Both should be used in different environments (quiet, noisy and outside in real life situations). | Agree. | I am not qualified to answer, but it seems to be that people talk in sentences. So sentence recognition would be just as important as word recognition, and would give a more | I agree with this statement. |

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| Statement 9: "Unilateral implants significantly improve overall and hearing-specific quality of life in adults with bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss. Further research is needed to develop more quality of life metrics specific to cochlear implantation." | I totally agree with statement 9. | Yes. | Agree. | I have one CI and for me my hearing is very good, I can say normal. But in many situations, I am not able to hear on both sides of my head (both ears). Often, I am not able to participate because I hear only from one side (meetings and so on, where people speak just to one side of me and they are not near me). I think it is clear that with two CIs we can hear better, but for me it is not so comfortable to have two for now. I do not only consider the impact on hearing, but also on the comfort of use and way of life with two CIs. | Agree. It is important to capture and document the wide-ranging ways in which cochlear implants impact on an adult's life including, but not limited to, work, family, socialization, culture, and general health. | Agree. | In my opinion unilateral implantation is the first step to improve the QoL in adults with bilateral severe, profound hearing loss. But after this, this group regularly needs bilateral implantation of cochlear implants. |

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| Statement 10: "Adults who are eligible for unilateral cochlear implants should receive the implant at the earliest age possible to maximize their postimplantation speech recognition; however, adults identified at an older age may still receive benefit from a cochlear implant." | I also agree with statement 10, but I even prefer (in case of a sudden or progressive hearing loss) that two CIs be fitted at the earliest age possible. | Yes. | Agree. | It depends on the age of the adult who loses the hearing, and what is being prepared to be able to hear again. Also, if they understand what the CI really is. Even if we have a CI we are still deaf and sometimes you simply cannot understand the speech because we are so tired. It is not so easy to listen and focus on the environment.<br>It is not so important at what time after losing hearing you receive a CI, but it is important if the individual was used to using a HA beforehand and if they have environmental support and good rehabilitation. Also, if the individual is preparing for training to hear, and now I'm talking about if people need to hear again. For example if they live in a deaf community and are used to communicating by sign language, then the results of CI are not as good because they are used to an easier way of communicating.<br>In my situation I need to communicate because I work in an area where I need to communicate all day and also live in the hearing world. So again, it is important to consider the environment, the wishes and needs of adults to hear and communicate in an oral way. | Agree, though adults who wait may not experience the same level of outcome. | Agree. | I agree with this statement. |

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| Statement 11: "Individuals should continue to use a contralateral hearing aid with their unilateral cochlear implant in order to achieve the best possible speech recognition and quality of life outcomes." | Hard to answer this question in general, because the effect of the contralateral hearing aid can differ from patient to patient. It is something you have to try and have to measure after CI.<br>Also fitting a hearing aid well, in combination with a CI, is still a problem for a lot of audiologists. Often a hearing aid is fitted by a local audiologist and CI is fitted in the CI clinic.<br>There are also cases in which the hearing aid disturbs speech recognition with the CI. | Yes. | Agree. | Sometimes it's hard to get used to hearing with two different devices because the sound is not the same, some may find this difficult to accept. In my case, the sound was completely different. | Adults who benefit should continue to use a hearing aid. Not all adults necessarily benefit from a contralateral hearing aid. | Not qualified to answer but it seems this is the prescribed treatment today, more so than 20 years ago. | I agree with this statement. The benefit of the contralateral hearing aid is undoubtedly very high. |
| Statement 12: "Age, duration of hearing loss, education level, and preimplantation speech recognition may all be used to give an indication of postimplantation performance." | Yes, these factors can predict some outcomes, but variation within the outcomes is very big. So, you may not be able to use this to exclude patients. Their motivation and cognitive skills are even more important. | Yes. | Agree. | Also motivation. | Don't agree with this statement. What constitutes "performance?" | Agree. | Yes, and in our experience the limits are increasingly expanding. We have good results with patients with long time deafness (> 20 years). |

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| Statement 13: "Individuals may still experience improvements in speech recognition if they receive an implant in an ear that was previously unaided for a long duration (more than 15 years), rather than receiving an implant in the previously aided ear." | Yes, even after 15 years of auditory deprivation, it is still possible to stimulate that ear (in cases of progressive or sudden deafness), but it does not mean that this is always better than receiving an implant in the previously aided ear.<br>In cases of unilateral implantation, it also depends on the current hearing thresholds in the patients best ear. Is the hearing aid still adding some value or not?<br>Often you even don't know beforehand which ear will be best. Also, for that reason, it is best to fit two implants. | Yes. | Disagree. | I think so, but it also depends on their way of living (hearing world), their own motivation to work on rehabilitation, and needs that they have. | Yes, though the outcomes may be less robust than if the aided ear were implanted. That should be highlighted. | I agree with this because I have seen it (anecdotal evidence). | I agree completely with this statement. |
| Statement 14: "Adults of all ages who have undergone cochlear implantation should receive weekly programming sessions for the first 1–2 months after ‘switch on’ to check threshold levels and comfort levels, followed by periodic sessions for up to 2 years, in order to maximize benefits." | I agree with the first part of statement 14 that all patients should receive a minimum of 2 months of rehab after CI. But it is hard to say how long it should take, because it depends on the patient. For some patients 6 months is enough, for others 2 years is even not enough.<br>A question is also: what is the level patients have to reach to decide to stop rehabilitation? Some therapists stop when the patient has a word recognition score > 80% at 60 dB (in a silent environment), but others want to work also on speech perception in | Yes | Weekly programming sessions for the first month after 'switch on'. | Agree. I had about 10 fittings in 2 months, and after about 6 months I had once every month and then every 3 months or less. Depends when I feel I need fitting again. Also, usually I need fitting after I change the power in my processor. After I change the programme (loudness) I am likely not able to hear again in quieter programme. Also, it is very important to speak in fittings with professionals. After 2 or 3 years fitting, programming sessions once a year or when it is necessary until the end of life is suggested. | Disagree. Weekly programming sessions are excessive/unnecessary. | Agree. | In our experience we see even daily fitting in the first 4 to 6 weeks most effective to maximize benefits. |

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|  | noise and on more difficult listening situations. There is huge variation between therapists. It would be nice to have a consensus statement on this topic too.<br>Another question: what happens in cases of reimplantation? There should be the possibility to restart with rehabilitation after reimplantation, but this is often not the case (in a lot of countries there is no reimbursement for rehabilitation after reimplantation). |  |  |  |  |  |  |
| Statement 15: "Adults with hearing impairment are substantially affected by social isolation, loneliness, and depression: emerging evidence suggests that treatment with cochlear implants may lead to improvement in these aspects of well-being and mental health." | I totally agree. Also, for this reason: the sooner the CI is fitted, the better. | Yes. | Strongly agree. | Of course. It is nice to live in society and participate in normal events and so on. However even if we have a CI we still need support with speech-to-text (STT), subtitles and sometimes loops. I just cannot imagine myself not living in the hearing world and being able to communicate with others and working in my job. | Agree. | Agree. | This is completely correct. The side effects of isolation and loneliness are more expensive in our health systems. |

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| Statement 16: "The risk of social isolation and depression is higher in women with hearing impairment than in men with hearing impairment, and this difference in risk should be taken into account when assessing individuals with hearing impairment." | I don't agree. This is not gender specific. | No. | Agree. | I do not think so. I think it is greater in men with hearing impairment, because they usually find it harder to accept difficulties with hearing loss and also accept that they do not hear. But in fact, that depends on what kind of person you are, how strong you are and what you expect from life. It also depends on which country you are from – what kind of possibilities to communicate without HA or CI you have (STT reporters, subtitles). | I don't agree that the risk is higher for women, if there is such a higher risk it should be taken into account during the assessment. | Not sure I agree with the gender difference even though isolation and depression are higher in women, shouldn't it be taken into account for both genders? | I cannot agree with this. I think both genders suffer from isolation and depression. |
| Statement 17: "The risk and degree of hearing impairment is increased in individuals with cognitive impairment, and hearing impairment has been shown to be a marker for memory impairment." | Yes, I agree. We have to focus more on (higher) cognitive skills including working memory, attention span and planning. | Not exactly. | Agree. | It is logical that people with hearing loss are not so active in the environment within which they live. Also, many older people also have problems with vision, not only problems with hearing. So, there are problems with reading and hearing – communication in both areas, and this in fact can lead to other problems. When people do not have the possibility to actively participate, this leads to problems with cognition and memory. Of course, if somebody is not able to hear others may think he/she is a person with cognitive problems. People may just live in their own world and try to survive. This adds to the importance in raising awareness about hearing problems. | I don't understand the first part of the statement: "The risk and degree of hearing impairment is increased in individuals with cognitive impairment." What are you intending to say there? And hearing impairment is “a marker for” memory impairment is an odd phrase. Shouldn't it be “associated with"? | Not qualified to respond. | I agree with this statement. |

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| Statement 18: "Further research is required to confirm the nature of cognitive impairment in individuals with hearing impairment, and its potential reversibility with treatment." | I totally agree. We still don't know enough about the impact of specific higher cognitive functions on the outcomes after implantation. This is also a topic of research which falls within our interests (of our research center ONICI). | Yes. | Strongly agree. | Agree. If a person uses a HA or CI all of his life there is, in my opinion, no reason to have any cognitive problems. But if there is no possibility for that, then hearing loss can cause some of problems in this area. But of course, you may have cognitive problems if you have problems in a psychological sense, including if you are deaf or you lose your hearing in adulthood and this is not easy to accept. The fact is that when you lose your hearing there is no psychological support and very little understanding of what kind of trouble you actually have. | Yes, that will help demonstrate cost-effectiveness and QoL factors. | Agree. | I agree with this. |
| Statement 19: "The use of unilateral cochlear implants may improve cognition in older adults with bilateral severe to profound sensorineural hearing loss." | I agree, but it also depends on what you understand by 'cognition'. It is an umbrella which covers different functions, and unilateral CI can influence several of these functions, but not all. | To be confirmed. | Agree. | Unilateral or bilateral. Of course, people want to hear and participate in daily life as before. If you lost your hearing as an adult this is not easy, and you can become alone very quickly. As an adult you can have a lot of psychological problems because of your hearing loss. It is really necessary for people who become deaf as an adult to have access to a CI. | Agree. | Not qualified to answer. | This is not enough! We need bilateral CI fitting to improve hearing skills in work and society. |
| Statement 20: "Hearing impairment is not a symptom of dementia; however, treatment of hearing impairment may reduce the risk of dementia, which is greater in women with hearing impairment than in men with hearing impairment." | We need more research to prove this statement, not only on the impact on dementia, but also on the gender difference.<br>We can now only say that treatment of hearing impairment will reduce the risk for dementia. | Not exactly. | Strongly agree. | As I mentioned before, if people are not active this can cause problems in their lives, not necessarily dementia. Also, I do not think the risk of dementia is greater for women, women live longer than men and of course more of them have problems. It also depends of course on the way of life of individuals. So if people can hear they can live more actively, and they are happier and healthier too. | I am not familiar with the greater risk in women. It may be true, I am just not familiar with the research. | Agree. | I agree with the first part of this statement. See my comment on gender. I think we can't differentiate between genders. |

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| Statement 21: "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." | Yes, totally agree. | Yes. | Agree. | Yes, I agree. My example: If I had lost my hearing and did not get a CI I would probably be depressed because of my hearing loss. This means that I would not be effective at work, which would result in a worse job with a lower salary. I would very much distance myself from society, and my children would suffer very much due to my condition. Everyone would need a lot of medical and social assistance.<br>However now, after being fitted with a CI (I got it 4 years ago) I am active in society, I support CI users, I am successful at work and of course a good mum. | Agree. | Agree. | I agree with this. But I argue for bilateral fitting if it is indicated. |

**Please note, in the final version of the consensus statements *hearing impairment* was replaced with *hearing loss* at the request of the Delphi panel.**

## 8.3 FULL CAPAC COMMENTS ON DRAFT STATEMENTS AT ROUND 2

*Table 8-2 Full CAPAC comments on draft statements at round 1*

| | CAPAC Participants | | | | | | |
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| **Delphi Consensus Statements** | **Leo De Raeve** | **Bernard Fraysse** | **George Tavartkiladze** | **Darja Pajk** | **Donna Sorkin** | **Barbara Kelley** | **Harald Seidler** |
| **Revised Statement 1: "Awareness of cochlear implants among primary healthcare providers, audiologists and otorhinolaryngologists is inadequate, leading to under-identification of eligible candidates. Clearer referral and candidacy pathways would help increase access to cochlear implants."** | In Belgium and in a lot of European countries (especially in those countries with a UNHS) there is a big difference between awareness of cochlear implants for children in comparison to adults or the elderly.<br>In these countries children are screened early, have hearing aids fitted early and, in case the hearing aids are not sufficient, they are referred to University hospitals (CI teams).<br>But for adults and the elderly the situation is totally different. A lot of local MPs and even ORLs are not aware of the current possibilities of CI. Also, audiologists often try too long with hearing aids instead of referring them for CI.<br>Also, the deaf adults themselves are not aware about the possibilities of CI. They miss a lot of information or their knowledge is not up-to-date. | Yes. | Agree it should be increased. | The statement is true. Healthcare providers, audiologists and otorhinolaryngologists, in my opinion, do not know CI very well (dependent on their area of work), and many times patients need to ask for CI or investigate how to get the implant and what the indications are. Unfortunately, they are not well aware of what hearing loss in practice means, and how the life of an individual can change positively if the rehabilitation after successful CI is successful. It is sad that doctors do not give adequate information about the implant, or they do not even know it – especially this is true for older doctors. Often, older people with hearing loss are not taken seriously by staff and it is believed that the implant would not affect their QoL. I think that implants should be understood, just like artificial heart valves, artificial hips, knees, etc., because this artificial gadget also returns the function in most cases or improves it at least substantially. It is also necessary to have rehabilitation after receiving the implant. | Agree with this statement, but I wonder if we should add the more generic term "hearing aid dispensers" after audiologists. A sizeable number of adults are seen by non-audiologist dispensers in the US. | Agree. | I completely agree with this statement. The reason is the lack of knowledge about CI indications and benefit for the patient, e.g. inclusion in professional and social life. We need more guidelines for patients and professionals. |

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| **Revised Statement 2: "Screening for hearing impairment in adults is important; pure tone audiometry screening and speech perception methods in quiet and noise are considered the most effective. The addition of a questionnaire or interview to the screening can improve the detection of sensorineural hearing loss."** | I don't agree with this statement. A questionnaire or interview is very time-consuming and very subjective. It is better to use a more objective and less time-consuming screening. For instance, an online screening (the triple digit test) for adults/elderly. Questionnaires can only be useful to detect hearing loss in young children. For instance, by using the Littlears Auditory questionnaire (from the MED-EL company). | Yes. | Agree. | I agree with addition of a questionnaire or interview to the screening can improve the detection of sensorineural hearing loss. | Suggest adding the word "undertreated" before the term sensorineural hearing loss at the end of the 2nd sentence. | Agree. | I agree with this statement. A questionnaire is quite necessary. In addition, case history of the hearing loss is indispensable. |
| **Revised Statement 3: "Preferred 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."** | I agree, but I want to add that it is also important that the speech recognition test is not only done at the intensity of 70 dB (as is the case in most countries today), but also at the softer intensity of 60 or even 50 dB. Because this is often the intensity they have to understand speech in daily life. | Yes. | Agree. | I think that when a person loses hearing to a level higher than 95%, understanding speech is already so difficult that it is necessary to think of the implant even if different tests are not done. The fact is that a person has to want to hear. On such occasions motivation is very high, and the person will try to learn to listen again. When the hearing impairment is very high, it is so difficult to understand speech in everyday situations that if a person expresses the need for a higher QoL, it is necessary to take this into account. Additional speech recognition tests do not seem to be necessary to me. But I am speaking from practical experience, because I lost my hearing gradually, and understanding speech at a loss over 95% despite the motivation and good hearing aids was very difficult. | Agree. | Not qualified to answer, but there was mostly agreement in round 1. | I agree with this statement. |

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| **Revised 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."** | I can only agree with this statement. | Yes. | Agree. | I totally agree. It is indispensable and in line with human rights, if the implant will improve (even if only partially) QoL of the person who loses hearing it is necessary to organize systems in such a way that people can access CI. As there is no restriction on other artificial devices, these restrictions should not be placed on cochlear implants. It is terrible if you lose your hearing as an adult and you are not able to participate in normal life. We live now much longer and somebody who is 80 is not old any more. | Suggest removing the word "alone" after the word age. Leaving that word in makes it seem like age is ever a criterion. It is not. | Agree. Statement did not change. | I agree with this statement. |
| **Revised Statement 6: "Straight and recently developed perimodiolar electrodes have been demonstrated to be effective for achieving hearing preservation in those with residual hearing before implantation."** | Hearing preservation depends not only on the electrodes but on a lot of other factors: (mal)formation of the cochlear, surgical technique (round window approach), experience of the surgeon (soft surgery). But the perimodiolar electrodes are often the best to preserve hearing. | No. | Agree. | I do not know this area very well, but I lost my hearing completely in both sides. As I know I was able to hear only very loud sounds (like gun) and in fact for normal life I do not need them. I do not know in fact how preserving residual hearing helps them to hear better with an implant. Without preserved residual hearing, I can hear perfectly with CI. | I am not familiar enough with the research on this issue to comment. | Not qualified to answer. | This is correct, but there may be a loss of residual hearing sometime after the implantation. We need more facts from the post-operative period. |
| **Revised Statement 7: "Unilateral implants significantly improve speech recognition in both quiet and moderate noise conditions in adults of all ages with bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss; these gains in speech recognition are likely to remain stable up to 10 years."** | In general, unilateral CI improve speech recognition in quiet and moderate noise. But noisy environments ask for much more listening effort. So listening in moderate noisy conditions is often only possible for a short time. Most gains remain stable over time for 10 years or more, but outcomes are very heterogeneous; not only their speech recognition in quiet and noise, but also their gain over time. To know the development of a CI user over time, it is necessary to monitor yearly. | No. | Agree. | I totally agree. You cannot, of course, hear, understand and live a normal life without CI if you are deaf. I only hope that even after 10 years, the understanding remains as on receipt, and that there is no change or deterioration. | I wonder why the last phrase is added, "these gains in speech recognition are likely to remain stable up to 10 years." This seems to imply that after 10 years they are not stable. Why is that statement there? | Not qualified to answer; however, I will assume that the revised statement on "...gains in speech recognition...likely to remain stable up to 10 years." is backed by research. | This is correct. As I explained before we have much better results with bilateral fitting with CI, as both ears show profound sensorineural hearing loss. |

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| **Revised Statement 8: "Both word and sentence recognition tests should be used to evaluate speech recognition performance in the period following cochlear implantation."** | I agree, although we don't have to 'overtest' our CI patients. So three times in year one, and later on once a year is enough. | Yes. | Agree. | Of course. And also speech recognition in "normal life situations" because CI are devices which we use in everyday life. But also people with CI need good rehabilitation, psychological support, peer support and coaching in many situations when they are down if they do not understand. Also, people need to understand limits of CI. | Agree. | Agree, based on discussion during round 1. | I agree with this statement. |
| **Revised Statement 10: "Adults who are eligible for unilateral cochlear implants should receive the implant at the earliest age possible to maximize their postimplantation speech recognition; however, even if adults are identified at an older age they can still receive benefit from a cochlear implant."** | I agree, the younger you receive the CI the better (if you meet the criteria). If adults are identified at an older age they still can benefit from a CI, but they have to know that their outcomes will be less than those who have received their CI earlier in life. So they need the information to come to correct expectations. A special group are the prelingual deaf adults (often without hearing aids for many years and visual communicators) who want a CI later in life. Selection should be done very carefully on this group, because most non-users are located in this population. | Yes. | Agree. | If you are able to hear better than with HA then you have benefits anyway. And if you hear through all of your life and at the end no more then you are in very bad position. If you are not able to hear that means you are very dependent on others, and depend on how much and in what way they will tell you. Even if you can read, if there is possibility to use STT or other methods there is so much sounds information around that the quality of your life is not very nice. And also CI is so simple to use. I feel with CI so normal. | Suggest adding the word "important" before benefit in the last line. | Agree. | I agree with this statement. |
| **Revised Statement 11: "Individuals should continue to use a contralateral hearing aid with their unilateral cochlear implant, where appropriate, in order to achieve the best possible speech recognition and quality of life outcomes."** | In general, I should give this advice, but in case you measure over time that the hearing aid is not adding any value and the patient does not like to wear the hearing aid, it is better not to use (and buy) a hearing aid. The problem is also very often that the hearing aid and the CI are not fitted by the same audiologist. The local audiologist fits the hearing aid and the | Yes. | Agree. | It is ok if you are able to hear with both ears (or with help of two devices from both sides of your head). Nature made us in that way, so it is very useful if you are able to hear from both sides. Also, if you use only one CI you are always turning your head around to try to hear, it is not the same if you hear with both sides. I miss my other side, unfortunately I am completely deaf in both sides and HA is not useful for me. Individuals need support that they decide to use | Agree. | Agree but think it needs to be emphasized more that it's on an individual basis, and not all adults benefit from a contralateral hearing aid. This revised statement only added the words, "where appropriate" which I don't feel captures | I agree with this statement. Many studies show a high benefit of contralateral hearing aid use. Even if there are only poor hearing results in this ear. |

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| | audiologist of the CI team fits the CI, and there is little or no cooperation between the two. To maximize the value of both devices, the audiologists need knowledge of both devices and they have to communicate on 'who is doing what'. Also, often the patient is not coming to binaural hearing with two different devices (they have asymmetric hearing) and the added value is limited. So the patient should be motivated to wear both devices. If the patient does not like one of the devices, it will be hard to motivate him/her to wear them both. | | | also their HA after they have a CI. But if they are able to see differences and positive effects of using both sides, I think there is no longer a problem with using both. | | what we discussed in round 1. | |
| **Revised Statement 12: "Various factors, including age, duration of hearing loss, and preimplantation speech recognition, may impact on speech recognition or quality of life; however, further research is needed to identify predictors of outcomes of cochlear implantation."** | We already know a lot concerning impacting factors on speech recognition and QoL, but we need more information on rehabilitation. We know that rehabilitation (and I mean auditory training, not fitting) is also a factor with a big impact on the outcomes, but we don't know what kind of rehabilitation (auditory training) is most effective (for this patient). So we especially need research on the topic of 'rehabilitation' (auditory training). | Yes. | Agree. | I am not completely agreed with you. It is important but not so much, especially age if people are active in life. I think that an important factor is the motivation, the desire to hear, good rehabilitation, support in the environment, and the understanding of hearing loss and the limits set by the CI. It is also important whether the person was hearing-active before implantation, using a hearing aid to keep hearing center active. | Agree. | Agree. I think the revised statement captures our concern about the original statement in round 1 concerning what constitutes "performance." I wonder if others think this statement reflects that clearly. | I agree with this statement. |
| **Revised Statement 13: "Individuals may still experience improvements in speech recognition if they receive an implant in an ear that was previously unaided for a long duration (more than 15 years)."** | Yes it can happen, but the problem is that this is not always the case, and we don't know yet what predicts the outcomes exactly in these cases. | Yes. | Possible but questionable. | Probably yes. People are talking about that in different groups and some report they are very successful. I think if your hearing nerve and center is ok you can have some positive results. And of course if you are motivated. And also you need support and good rehabilitation. | Agree. | Agree. | I completely agree with this statement. We have many patients with improvements even after 20 or 30 years unaided duration. |

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| **Revised Statement 14: "Adults of all ages who have undergone cochlear implantation should receive regular programming sessions as needed for up to 2 months after ‘switch on’ to check threshold levels and comfort levels, followed by periodic sessions as needed, in order to maximize benefits."** | In general I agree, but you have to adapt the number of fitting sessions to the patient. But for me rehabilitation is much more than 'programming the device'. We also have to know the best practise for auditory training for each specific patient (because it can differ from patient to patient). So all patients should also receive auditory training for a minimum of 2–3 months and later as needed, to maximize their benefits. | Yes. | One month will be fine. | Absolutely. You need a lot of programming sessions at the beginning to find out which sound is perfect for you. It is not so simple to find the level or sounds in which you are comfortable and also to find sounds as natural as possible. This takes time. People need to understand that hearing is a brain process and it is complicated for individuals to understand specific sounds and small differences in programming. Also, after changing the level of power of your CI you may need programming multiple times. It is individual how much programming a person needs, but I think that this must to be well supported. Such support will make it easier for people to make the decision to get a CI. I think programming sessions are necessary through whole life with CI. | Agree. | Agree. Note revision from "weekly" programming to "regular" programming. However, I am not qualified to judge this as I don't know what the research shows for time periods of benefits. | In our clinic we fit patients 7 days after CI implantation with very good results. After first fitting an intensive rehabilitation is required to reduce the period of reintegration and inclusion in social or occupational environments. |
| **Revised Statement 15: "Adults with hearing impairment are substantially affected by social isolation, loneliness, and depression: emerging evidence suggests that treatment with cochlear implants leads to improvement in these aspects of well-being and mental health. Longitudinal studies are needed to obtain further knowledge in this area."** | In general I agree, although there are again big individual differences. We especially need more research on the broad impact of cochlear implantation (not only the impact on hearing and on communication, but also impact on an individual’s work, social, emotional development, self-esteem, independent living or absence at work). | Yes. | Absolutely agree. | Of course. It is normal if you lose your hearing as an adult then you will not be able to communicate and participate in your environment (job, children, family, social life, friends, shops, sports ...); you are likely to feel down. You are withdrawn from all these environments and consequently you become lonely. And the depression can occur. You need a lot of power to be involved in society. With CI it's all much easier and you can live your life again. I myself experienced depression due to loss of hearing and I needed a lot of power to climb and normalize my life. Of course, studies are ok, but we know that without them too. Just imagine you are not able to hear, and you are in your life. Some studies have already been done and people said | Agree. | Agree. | I agree with this statement. |

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| | | | | that they feel depressed in such a situation. | | | |
| **Revised Statement 16: "Some evidence suggests that the risk of social isolation and depression is higher in women with hearing impairment than in men with hearing impairment; while this should not affect referral decisions, it should be taken into account when offering counseling to cochlear implant candidates."** | I think we need more research before agreeing to this statement. | Yes. | Agree. | I think that it depends on an individual's life and obligations they have. Women are usually work in "communications" and also they take more time for family than men (that is also in evidence). Because of their need to communicate more they can be in depression more often than men. And still in many occasions women are not so independent as men, this is often historically and socially conditioned. I think it is necessary to see the whole picture of the problem. | How? Why? I find this an odd statement. How does one take one's gender into account when making a referral? Would you say "Since you are a female, your risk of depression is greater so you REALLY should be a CI."? I actually think this is a silly statement. I can't imagine how to implement it. Plus, it is "some" evidence. Not compelling. Not useful. TAKE IT OUT! | Disagree. I don't know what this means; for example, if someone is female will she be counseled for a CI because she MIGHT be at risk for depression? I just don't see how this gender issue gets applied in the clinical setting. The statement also says this so-called risk factor should not affect referral decisions, so why is it included at all in these statements? | I do not agree with this statement. There are many other reasons for social isolation and depression than the gender. |
| **Revised Statement 17: "Findings from the literature have demonstrated an association between age-related hearing loss and cognitive/memory impairment."** | We have already a lot of research focusing on this topic, so I can agree with this statement. | Yes. | Agree. | It is also logical. Our body is older and functions are slower, and if our brains are not active all the time and we are deprived of the possibility of self-care we stop thinking and staying active. Of course there are differences if people are ill in any way. In my opinion if people have the ability to hear, see and be active their cognitive function is better than if there are not such possibilities. Then you just want to die in fact, in my opinion, if you are in a position not to hear and not to see. This is because the quality of anyone's life is highly connected with participation in everyday life. | Agree. Could be even stronger. | I somewhat agree; however, isn't it "untreated hearing loss" is associated with cognitive/memory impairment?" (not sure). | I partly agree with this statement, but there is a relevant share of older CI users with very good performance. |

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| **Revised Statement 20: "Hearing impairment is not a symptom of dementia; however, treatment of hearing impairment may reduce the risk of dementia."** | There is already a lot of research in this domain, but we need better (high level) research to come to this conclusion. | Yes. | Absolutely agree. | Of course. It is necessary to understand dementia as an illness, and chronic progressive brain disease that affects higher brain functions. It is logical that if an individual trains his brain all the time and has the possibility to hear (if we are speaking about people who lost their hearing as an adult and they are focusing on oral communication) on this occasion it is very important that there may be the possibility to slow down the problems related to dementia, but we should be careful to separate cognitive decline and dementia. | Agree. | I agree if it can be linked to the research (which I assume is why they included it...because it is backed by research. I just know the research is ongoing in this area and so far there is a link, not a cause and effect). | I agree with this statement. We need acoustic input for brain training, this may reduce the risk of dementia. |

**Please note, in the final version of the consensus statements *hearing impairment* was replaced with *hearing loss* at the request of the Delphi panel.**

## 8.4 DELPHI PANEL COMMITMENTS TO CHAMPIONING THE CONSENSUS STATEMENTS

*Table 8-3 Delphi panel member commitments to championing the consensus statements*

| Name | Affiliation | Top 3 ideas for championing the consensus |
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| Dr Colin Driscoll | Mayo Clinic School of Medicine, Rochester, MN, USA | As current Chair of the American Cochlear Implant Alliance (ACIA) we will use the consensus statements to inform:<br>- planned published clinical practice guidelines<br>- various discussions and meetings with politicians and policy makers<br>- discussions at the ACIA CI meeting this year<br>Dissemination of the consensus statements by:<br>- posting the consensus publication on the ACIA website (if open access)<br>- posting information relating to the statements on various social media accounts linked to our institution, for example as short video segments |
| Dr Howard Francis | Duke University School of Medicine, Durham, NC, USA | Promote the consensus statements by:<br>- participating in writing the consensus publication<br>- promoting the consensus statements regionally to primary care providers and audiologists<br>- advocating for consideration and dissemination of the consensus statements by the Lancet Commission |
| Dr Richard Gurgel | University of Utah Hospitals and Clinics, Salt Lake City, UT, USA | As current chair of the Hearing Committee of the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS), of which Oliver Adunka is Chair-elect, we can:<br>- present the consensus statements to the Hearing Committee for endorsement<br>- refer the consensus statements to the AAO-HNS leadership for consideration of their endorsement<br>Dissemination of the consensus statements by discussion/lectures given to:<br>- The American Neurotology Society (ANS) or Otological Societies (AOS), including an invited lecture at the annual AOS meeting in May<br>- The Ogden Surgical-Medical Society (regional medical society of physicians from all specialities) |
| Dr Marlan Hansen | The University of Iowa, Iowa City, IA, USA | Adding discussion of the consensus statements and their endorsement to the joint ANS/AOS council meeting agendas in early May |

| Name | Affiliation | Top 3 ideas for championing the consensus |
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| Dr Milind Kirtane | Seth GS Medical College and KEM Hospital, Parel, Mumbai, India | Dissemination of the consensus statements by:<br>- publishing a summary of the consensus publication in our journals<br>- publishing articles in the media (both print and electronic media) |
| Ms Jan Larky | Stanford University School of Medicine, Stanford, CA, USA | Dissemination of the statements by:<br>- partnering with the local Hearing Loss Association of America groups<br>- presenting at grand rounds at Stanford University and School of Medicine in various departments (including geriatric, primary care and pediatric departments)<br>- reaching out to area referring audiologists and ear, nose and throat specialists with a copy of the consensus statements and a one-page referral form including candidacy criteria<br>- summarizing the statements for publication in magazines with a wide readership including Reader's Digest, American Association of Retired Persons (AARP), Men's Health, Women's Health, Audiology Today, Hearing Journal and local newspapers |
| Professor Emmanual Mylanus | Radboud University Medical Centre, Nijmegen, the Netherlands | Dissemination of the consensus statements through:<br>- conferences, national ENT journal<br>- patient organizations<br>- working with governmental organizations, particularly those involved in prevention programs<br>- primary healthcare (primary care physicians, acousticians) |
| Dr Thomas Roland | New York University Langone School of Medicine, New York, NY, USA | Share consensus statements with:<br>- local regional hearing loss associations<br>- audiologists in the local regional area<br>- internal medicine and family practitioners at grand rounds |

| Name | Affiliation | Top 3 ideas for championing the consensus |
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| Professor Piotr Skarzynski | Institute of Physiology and Pathology of Hearing, Kajetany, Warsaw, Poland | The consensus statements may be presented at conferences and during meetings with stakeholders (depending on when and where the manuscript is published)<br>The consensus statements may be updated over time, cooperatively across different specialities |
| Dr Holly Teagle | University of Auckland, Auckland, New Zealand | As Clinical Director of The Hearing House, which is one of two CI programs in New Zealand, I will work towards including the content of the statements in the next round of strategic planning<br>I will work with colleagues at Cochlear Corporation in Sydney to explore further opportunities to share the consensus statements in Australia or Asia-Pacific countries<br>Dissemination of the consensus statements via presentation at the:<br>- American Speech Language Hearing Association (ASHA) annual national convention in November 2019<br>- PinDrop Foundation conference (https://www.pindrop.org.nz/) in November 2019<br>○ PinDrop is an advocacy group and works toward informing the general population and defining policy related to CI in New Zealand<br>○ The conference will be attended mainly by consumers and hearing health professionals, in addition to some general practitioners<br>- New Zealand Audiological Society annual conference in July 2019 |
| Professor Paul Van de Heyning | Antwerp University Hospital, Edegem, Belgium | Dissemination of the consensus statements through the general press (including newspapers, television news and social media)<br>The opportunity to disseminate the statements in this way will be improved by publication of the consensus manuscript in a high impact journal, such as the Lancet |

| Name | Affiliation | Top 3 ideas for championing the consensus |
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| Dr Terry Zwolan | University of Michigan, Ann Arbor, MI, USA | To aid in disseminating the consensus statements:<br>- a slide could be developed to summarize the statements, for use in outreach talks<br>- the statements can be referred to in upcoming publications and presentations<br>- the statements, including a brief summary, could be published on the Michigan Academy of Audiology website |

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