Consumer and Professional Advocacy Committee – Summary Report

Prepared by:

Value Demonstration Practice

Oxford PharmaGenesis

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Contents

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 7.1 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 Cochlear Ltd, Advanced Bionics and Oticon.

This report summarizes the outcomes of the Delphi consensus process, the development of the 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

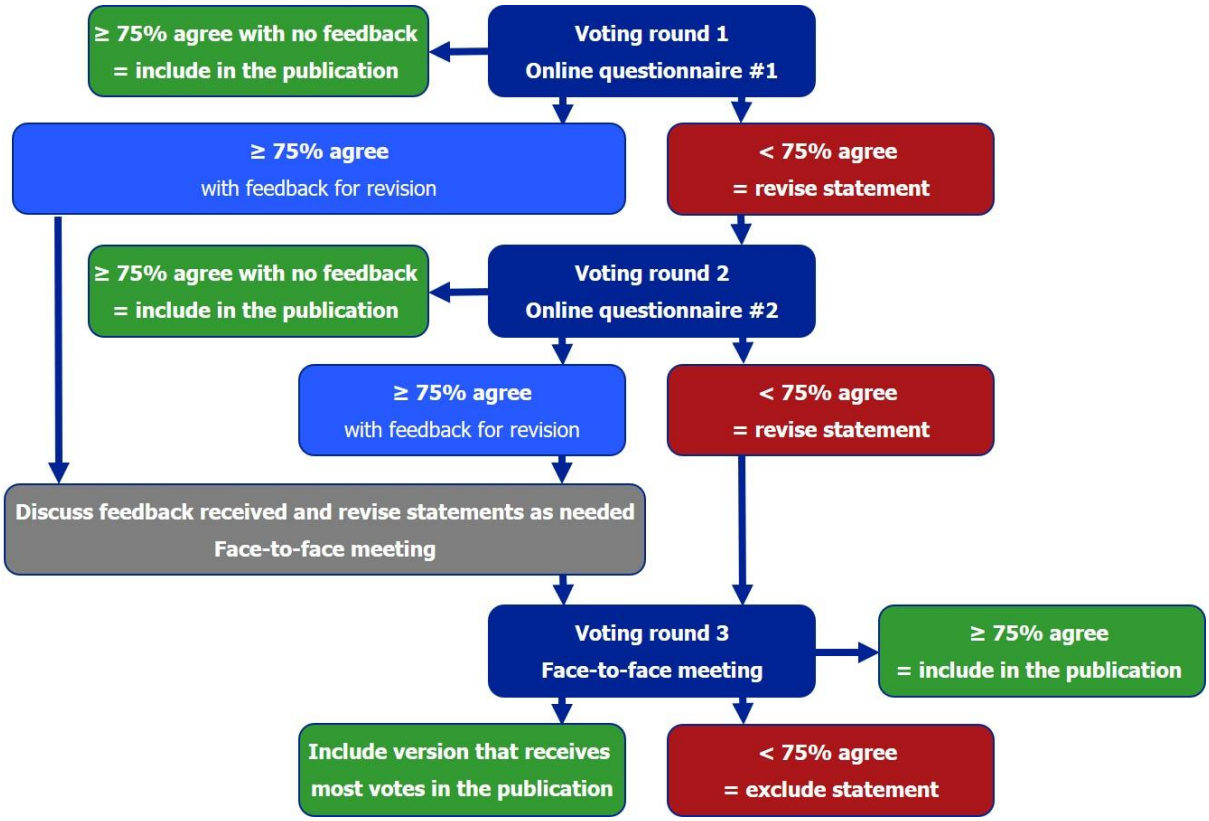
4.1 DELPHI PROCESS

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

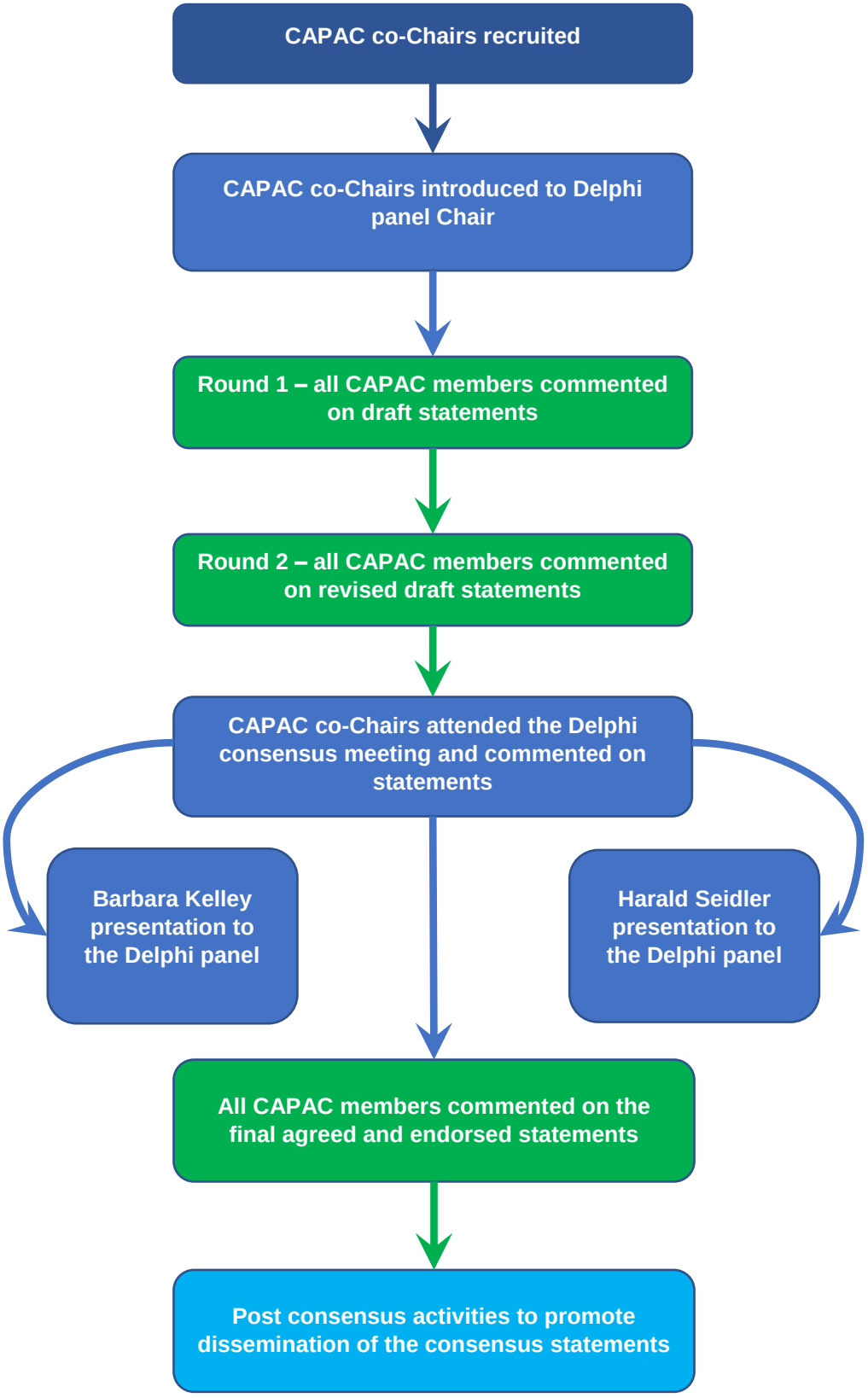
The CAPAC is composed of seven CI users and user representatives (Table 4-1).

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.

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 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.

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.

7 APPENDICES

7.1 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

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