there is an urgent need to address the lack of guidelines and awareness in order to increase patient access to treatment to improve quality of life among adults with hearing loss

Professor Craig Buchman, Chair, Delphi Group
International Consensus Paper (ICP)…12 months on...

Since the first global consensus on the use of CIs for the management of adults living with hearing loss, there has been unprecedented activity to drive awareness around the findings from the ICP.

This year in review brings you examples from around the world of the initiatives driving towards the goal for cochlear implants (CIs) being recognised and accepted as the Standard of Care for adults.

LANDMARK PUBLICATION sets minimum standards for cochlear implantation in adults

Figure 1: Delphi voting process

VOTING ROUND 1
Online questionnaire #1
- 75% agree with feedback = include in final list of statements
- 75% agree with feedback for improvement
- 75% agree with no feedback = revise statement

Discuss feedback, revised and revise statements as needed. Vote on revised statements at face-to-face meeting.

VOTING ROUND 2
Online questionnaire #2
- 75% agree with feedback for improvement
- 75% agree with no feedback = revise statement

Discuss feedback, revised and revise statements as needed. Vote on revised statements at face-to-face meeting.

Include in final list of statements the version that receives most votes.

VOTING ROUND 3
Face-to-face meeting
- 75% agree = include in final list of statements
- 75% agree = revise statement
- 75% agree = exclude statement

The first step towards clinical practice guidelines addressing cochlear implantation for adults. For more information visit www.adulthearing.com

How has the ICP made an impact?

- 6,834 consensus paper downloads, influencing 13 citations and 323 media articles
- An evolution in unified global advocacy for first time from the seven advocacy groups involved in the ICP process to the CIICA* network
- The evidence from the ICP has provided education to thousands of professionals globally
- The call to action has resulted in subject matter experts signing up to advisory groups around the world to tackle Hearing Health for adults

*CIICA
CI International Community of Action

Hearing Health Collaborative, a US Standard of Care Initiative
1. World Report on Hearing 2021

**Background**

Hearing impairment is one of the leading causes of overall disability worldwide. 1 in 5 people globally experience hearing loss. This is expected to rise to 1 in 4 by 2050.[1] Hearing impairment has a substantial impact on people’s lives, including, but not limited to, communication difficulties, increased risk of dementia and reduced well-being.

Hearing loss is the single largest modifiable risk factor for dementia[2].

Cochlear implantation has been available for 40 years across the world. In many developed countries, CIs have become established as Standard of Care (SoC) for newborns with severe to profound sensorineural hearing loss (SPSNHL). In adults, however, cochlear implantation is often seen as a last resort option and penetration remains low. During this time, clinical practice and evidence have evolved considerably. The next logical step is for cochlear implantation to become the SoC for adults with SPSNHL.

The global prevalence of hearing impairment is substantial and increasing. For adults, healthy ageing is a key public health issue.

**About The Consensus Paper**

Numerous medical specialties that have achieved Standard of Care publish an international consensus paper as an initial step to inform treatment and clinical guidelines. In the absence of clear clinical practice guidelines for the diagnosis and treatment of adult hearing loss, the Standard of Care consensus paper aims to be a step towards establishing clear, consistent, global treatment guidelines and best practice aftercare for CI patients to reach their optimal hearing outcome and quality of life. This international paper is focused on unilateral implantation for bilateral SPSNHL in adults.

**Process**

The international consensus paper contains widely accepted clinical guidance on medical criteria for assessing whether CI surgery is indicated as the most beneficial treatment option for severe and profound sensorineural hearing loss, compared to other treatment options (adults).

The first step in the process was a thorough literature review to inform draft consensus statements. Three rounds of voting on consensus statements (Delphi process*) followed. The categories from the search were:

- Awareness of CIs
- Best Practice: Diagnosis of SNHL / CI-candidacy Evaluation
- Best Practice: CI Surgery
- Best Practice: Clinical Effectiveness / Influencing Factors of CI
- Best Practice: Follow Up/Rehabilitation
- Association of SNHL: Depression / Well-being / Loneliness
- Association of SNHL: Cognitive function & Dementia
- Cost of Unilateral CI

Following the Delphi process, an international consensus paper was developed. This contained clinical guidance on the consensus for medical criteria for assessing whether CI surgery is indicated as the most beneficial treatment option for an adult with bilateral SPSNHL, compared to other treatment options.
The ICP in a tiny nutshell!

### The panel members consisted of 26 Audiologists and ENT Surgeons across 13 countries:

- Dr. Oliver Adunka, Ohio State University Wexner Medical Center, US
- Allison Biever, Au.D., Rocky Mountain Ear Center, Colorado, US
- Associate Professor Robert Briggs, Royal Victoria Eye and Ear Hospital, Royal Melbourne, Australia
- Dr. Matthew Carlson, Vanderbilt University, New York State, US
- Dr. Pu Dai, Chinese PLA General Hospital, Beijing, China
- Dr. Colin Driscoll, Mayo Clinic School of Medicine, New York State, US
- Dr. Howard Francis, Duke University School of Medicine, North Carolina, US
- Dr. Bruce Gantz, University of Iowa Health Care, Iowa, US
- Dr. Richard Gurgel, University of Utah Hospitals and Clinics, Utah, US
- Professor Marlan Hansen, Institute for Clinical 
  & Translational Science, The University of Iowa, Iowa, US
- Assistant Professor, Meredith Holcomb Au.D., Medical University of South Carolina, US
- Dr. Eva Karltorp, Karolinska University Hospital, Sweden
- Dr. Milind Kirtane, P.D. Hinduja Hospital & Medical Research Centre, India
- Jan Larky Au.D., Stanford University School of Medicine, San Francisco, US
- Dr. Emmanuel Mylanus, Radboud University Nijmegen Medical Centre, Nijmegen, Netherlands
- Professor Tatsuya Yamasoba, University of Tokyo, Japan
- Dr. Thomas Roland, NYU Langone Medical Center, New York State, US
- Professor Shakeel Saeed, University College Hospital National Hospital for Neurology and Neurosurgery; Royal National Throat, Nose and Ear Hospital, London, UK
- Professor Henryk Skarzynski, Institute of Physiology and Pathology of Hearing of the Ministry of Health, Poland
- Associate Professor Piotr Skarzynski, Institute of Physiology and Pathology of Hearing of the Ministry of Health, Poland
- Dr. Mark Sym, Arizona Hearing Center, Arizona, US
- Associate Professor Holly Teagle, The University of Auckland, New Zealand
- Professor Paul Van De Heyning, The Antwerp University Hospital – UZA, Belgium
- Professor Christophe Vincent, Centre Hospitalier Régional Universitaire de Lille, France
- Dr. Hao Wu, Xinhua Hospital, Shanghai, China
- Professor Terry Zwolan, Michigan Medicine, University of Michigan, Michigan, US

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### The consensus statements are important in providing an evidence based approach to establishing cochlear implantation as the standard of care for adults with bilateral severe to profound hearing loss and illustrating what good practice should be in several key areas.

The huge underutilization in health systems of the life changing technology of cochlear implantation across the world results in poorer health and wellbeing for individuals and enormous additional costs for health systems.

### Who was involved?

To lead the international consensus paper, a dedicated Steering Committee and Panel, was formed, chaired by Dr. Craig Buchman, Washington University (St Louis, US), steering committee members consisting of Professor Thomas Lenarz (Hannover, Germany), Professor Rene Gifford (Vanderbilt, US), Dr. David Haynes (Vanderbilt, US) and Professor Gerard O’Donoghue (Nottingham, UK).

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**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.**

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1. GLOBAL GUIDELINES ON STANDARDS OF CARE FOR ADULT COCHLEAR IMPLANTATION. Sue Archbold, Brian Lamb and Leo De Raeve
Why was it important?

Up until now, there has never been any international consensus on the appropriate diagnosis, referral, treatment and aftercare for adults living with SPSNHL. These statements are an important milestone in establishing clinical best practice for adults living with SPSNHL in line with best available clinical evidence. They represent the first step toward the development of international guidelines on best practices for cochlear implantation in adults.

How were the industry sponsors involved?

This process was the first time in the history of the cochlear implantation that all CI manufactures came together to support the process and align on the need to address adult hearing loss.*

Advanced Bionics, Cochlear Ltd, MED-EL, and Oticon Medical had no input to the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. The manufacturers did not participate in selection of the Delphi consensus panel members or in the voting rounds of discussions at any stage in the consensus process. There was no remuneration paid to the Delphi consensus panel members, including the chair and committee members.

Consumer and Professional Advocacy Committee

To ensure the user and CI candidate perspectives were taken into account in the development of the consensus paper, a Consumer and Professional Advocacy Committee (CAPAC) was formed with perspectives of respected international user and professional organisations. The committee made suggestions to the Chair of the Delphi process to ensure:

- Relevance and acceptability of the consensus statements to cochlear implant users and candidates, ensuring a focus on the user experience and that the perspectives of deaf and hard of hearing people have been taken into account in the process.
- The process and outcomes have the confidence of international user and professional advocacy organisations.
- The process and outcomes have the confidence of healthcare providers and their professional organisations. The CAPAC will be invited to provide advice on acceptance and dissemination by professional organisations.

The Co-Chairs of the CAPAC were:

- Barbara Kelley (BA) - Executive Director of Hearing Loss Association of America
- Dr. Harald Seidler - President of the German Hard of Hearing Association and representative of the International Federation of Hard of Hearing People

The CAPAC Members were:

- Darja Pajk (OT) - European Federation of Hard of Hearing People (EFHOH)
- Donna Sorkin (MA) - American Cochlear Implant Alliance (ACIA)
- Dr. Leo De Raeve (PhD, in Medical Sciences) - European Association of Cochlear Implant Users (EUROCIU)
- Professor George Tvtirkldadze - International Society of Audiology (ISA)
- Professor Bernard Fraysse - International Federation of Otorhino Laryngological Societies (IFOS)

*The consensus paper and clinical guidelines were developed independently from industry representatives. No industry representatives were part of the voting, development or submission of the international consensus papers.
Key insights in the statements from Sue Archbold, Brian Lamb, and Leo De Raeve*

**Level of 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.

- Key insights for policy: Lack of referral pathways to cochlear implantation leads to a substantial unnecessary burden to the individual with hearing loss, with a poorer quality of life. We know that lack of referral and awareness of the benefits of cochlear implantation are the major reasons for under-identification of the many who could benefit.

- Estimates suggest that in many countries only 5-10% of potential candidates are implanted. More awareness in primary health care and audiology of the benefits of CIs needs to be promoted to improve access. More knowledge among health professionals about Standards of Care and best practices in CI diagnosis, earlier referral, treatment and aftercare will help many people live healthier and more fulfilled lives.

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**Best practice clinical pathway 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.

- Key insights for policy: Screening for hearing loss in adults is important for the identification of potential candidates for cochlear implantation. Clearer and appropriate criteria for diagnosis of those who may be a candidate for cochlear implants will help create a clear pathway to implantation and improve understanding of the benefits and appropriateness of CIs by health professionals and the general public. The guidelines and evidence are clear that older age should be no barrier to cochlear implantation.

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**Best practice guidelines for surgery**

- Factors associated with post-implantation outcomes

- The relationship between hearing loss and depression, cognition and dementia

- Clinical effectiveness of cochlear implants

*GLOBAL GUIDELINES ON STANDARDS OF CARE FOR ADULT COCHLEAR IMPLANTATION, Sue Archbold, Brian Lamb and Leo De Raeve*
**CLINICAL EFFECTIVENESS OF COCHLEAR IMPLANTS**

**Statement 7:** Cochlear implants significantly improve speech recognition in both quiet and moderate noise in adults with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss; these gains in speech recognition are likely to remain stable over time.

**Statement 8:** Both word and sentence recognition tests should be used to evaluate speech recognition performance following cochlear implantation.

**Statement 9:** Cochlear implants significantly improve overall and hearing-specific quality of life in adults with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss.

**Key insights for policy:** CIs are effective in improving quality of life due to improved hearing, and the wider impacts of better communication and connection with the world. CIs are safe with low rates of complications and can also be done while preserving any residual hearing. CIs should be the accepted standard of care for severe and profound deafness in adults.

**FACTORS ASSOCIATED WITH POST IMPLANTATION OUTCOMES**

**Statement 10:** Adults who are eligible for cochlear implants should receive the implant as soon as possible to maximize post-implantation speech recognition.

**Statement 11:** Where appropriate, individuals should use hearing aids with their cochlear implant in order to achieve bilateral benefits and the best possible speech recognition and quality of life outcomes.

**Statement 12:** Many factors impact cochlear implant outcomes; further research is needed to understand the magnitude of the effects.

**Statement 13:** Long durations of unaided hearing loss do not rule out potential benefit of cochlear implants: individuals who receive an implant in an ear that was previously unaided for more than 15 years have been shown to experience improvements in speech recognition.

**Statement 14:** Adults who have undergone cochlear implantation should receive programming sessions as needed to optimize outcomes.

**Key insights for policy:** It is important that for those who are identified as being able to benefit from CIs are provided with an implant as soon as possible to ensure the best possible outcomes. Using hearing aids with CIs also delivers positive outcomes for communication and quality of life. Ongoing support to optimise the functioning and use of the implant is necessary.

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*GLOBAL GUIDELINES ON STANDARDS OF CARE FOR ADULT COCHLEAR IMPLANTATION, Sue Archbold, Brian Lamb and Leo De Raeve
ASSOCIATION BETWEEN HEARING LOSS AND DEPRESSION, COGNITION, AND DEMENTIA

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 wellbeing 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 or 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.

Key insights for policy: Addressing hearing loss is associated with improvements in overall wellbeing including mental health by enabling people to communicate more easily with others. This reduces the social isolation and mental health problems associated with hearing loss. Addressing untreated hearing loss improves cognition and may help reduce the risk of dementia. Further research is needed, and being carried out, on the impact of CIs in addressing cognitive impairment and mitigating the risk of dementia.

COST IMPLICATIONS 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.

Key insights for policy: Ensuring that people with hearing loss who could benefit from a CI receive one is not only beneficial for the individual’s wellbeing but improves their chances of employment. This reduces the cost of social care and welfare budgets. It is a cost effective intervention for health systems and has the potential to save money on other health related costs.

*GLOBAL GUIDELINES ON STANDARDS OF CARE FOR ADULT COCHLEAR IMPLANTATION, Sue Archbold, Brian Lamb and Leo De Raeve*
ICP IN THE MEDIA

Global media coverage and digital platforms

GLOBAL MEDIA COVERAGE SPREADS MESSAGE ACROSS PROFESSIONAL AUDIENCE OF MORE THAN 55 MILLION

Media exposure for the consensus paper saw an unprecedented level of attention from outlets around the world.

The hearing community were informed and motivated to use standard language to describe the narrative from the ICP to drive referrals.
Coverage highlights...

Forbes
Consensus Study Says Cochlear Implants Can Help People With Severe Hearing Loss Today

HLAA
Cochlear Implants Standards of Care: An International Consensus

Medscape
International Consensus Supports Wider Use of Cochlear Implants

News Medical
Life Sciences
Cochlear implants should be offered to adults with moderate to severe or worse hearing loss

The Hearing Review
‘First Global Consensus’ on Cochlear Implant Treatment for Adults with Hearing Loss Published

Audiology World News
Global Consensus can improve adult CI care, but professionals must boost awareness

Washington school of medicine
Cochlear implants should be recommended for adults more often

Gold Coast Bulletin
“It’s worth hearing: Surgeon voices concern over Coast’s lack of public cochlear service”

WA Today
“How a Perth mother can choose to silence her world - or tune in to what’s going on around her”

Click here for more recipient stories.

Diane from Rotherham UK shares her experience with being given back her sounds

80 year old Malcom redisCOVERS favourite activities after implantation

See how Karl, a cochlear implant recipient from Kaukapakapa New Zealand got a new lease on life
Podcasts via Hearing Health Today and JAMA explore why SoC is crucial in addressing the growing hearing loss epidemic.

International professional media highlights the need for improved access to cochlear implantation.

- **Physician’s Briefing**
  - Consensus Statements Issued for Adult Cochlear Implantation

- **Science Daily**
  - Cochlear implants should be recommended for adults more often

- **Medscape**
  - International Consensus Supports Wider Use of Cochlear Implants

- **Audiology Online**
  - JAMA Otolaryngology Publishes Consensus Statements on CI in Adults

- **AusDoc**
  - Age alone not a barrier for cochlear implant, say otolaryngologists
ICP messages reaching a broad social media audience

Awareness whitepaper published via Audiology Online
ADVOCACY

UNIFIED ADVOCACY VOICE ACROSS CONTINENTS AS TO THE IMPORTANCE OF IMPROVING REFERRAL PATHWAYS AND ADULT CI ACCESS

Landmark Consensus on Treating Adult Hearing Loss with a Cochlear Implant Published by International Hearing Experts

August 27, 2020

Nordic Advocacy Meeting
Author and advocacy organisations spread news to key stakeholders via owned channels

Government & policy activity: evidence into action

Convergence of activity focused on SoC influencing policy locally with the ICP and WHO World Report on Hearing providing a flow on effect to local Government.

German Government Parliamentary Meeting

- “The German Hard of Hearing Association calls for better access to cochlear implants for people with severe to profound hearing loss.”

AUS CEO forum submits Hearing Services Program Review to Govt.

- Recommendations for referral and candidacy pathways and increased awareness

Italian Society of Otorhinolaryngology lobby effort

- “This webinar was a unique chance to realize that we need a joint approach to move toward new national guidelines”

US FDA ICD code effort for severity of hearing loss & “Know your PTA” campaign in collaboration with Johns Hopkins.

Local consumer and advocacy groups drive transformation of CI-care

Parliamentary evening on World Hearing Day!
Multi-channel dissemination to drive awareness and engagement for adult hearing opportunity in China

Highlights:

**Advocacy partnership** with the China Deaf People Association to share awareness of the Consensus Statement and gaining commitment to deliver seminars to promote the ICP to deaf adults in the community and raising as evidence in helping support formulation of policy.

**Professional activation** with support from Prof Wu Hao – Consensus Paper co-author and Delphi panel member and Chairman of Chinese ENT association to introduce the ICP during the National Ear Conference in October.

**Consumer reach** via Cochlear WeChat with >1100 views.

German advocacy group endorsement!

German Assoc of hearing (DSB) integrated ICP in policy website.

DSP and leading otologist accepted parliament evening 03.03.21

Dr Harald Seidler provides his perspective from a consumer and advocacy perspective as to the significance of the International Consensus Paper and the next steps in reaching standard of care.
Proactive adult ICP support | EURO-CIU, IFHOH, ACIA, HLAA

International Consensus on the Use of Unilateral Cochlear Implants for Bilateral Severe, Profound, or Moderate Sensorineural Hearing Loss in Adults

Endr Spender

Cochlear implants: Increasing Awareness and Access

Unified voice from our professional partners on the importance of SOC

Das Delphi Steering Committee ist ein Organ in einem so genannten Delphi-Prozess, der dazu dient, einen Konsensus herzustellen, in dem Sinne einen Standard zu definieren.
Journal clubs and editorials on the ICP make the news!

Michal Luntz in Milano: Spreading the SoC word!

Cochlear symposium @ online ENT congress: Prof. Timo Stöver on health policy recommendations to drive access to CI

CI Futures Forum series 1 & 2

12 webinar events

2,500 total registrations
EDUCATING OVER 6,000+ AUDIOLOGISTS VIA A SERIES OF PROFESSIONAL WEBINARS FOCUSED ON THE ICP CATEGORIES

COCHLEAR SCIENCE AND RESEARCH SEMINAR; SOC IN EMEA

Professional webinars continue...

STANDARD OF CARE WEBINARS IN ITALY

375 REGISTRATIONS | 222 ATTENDEES

L’impianto cocleare negli Adulti e Anziani: opinioni a confronto sul Consensus Delphi e prospettive di PDTA
Consensus statements should provide a stepping stone towards establishing clear, consistent, international clinical guidelines and best practice for patients.

The Delphi consensus process outcomes will provide a summary of clinical evidence and expert opinion on cochlear implantation in adults.

Findings from the Delphi process have the potential to:

- help establish CIs as the standard of care for adults with severe to profound SNHL
- raise awareness of CI as a treatment option and when it should be considered
- achieve appropriate improved access to CIs for patients who would benefit
- help optimize patient pathways, leading to treatment that improves the individual’s hearing function and quality of life
Greater access to CIs and better quality of life

Working together towards the same goal...

Manufacturers

Payers

CI users

CIICA

Hearing loss organisations

Living Guidelines ...Guidelines for the living

The publication was a world-first in recommending an international minimum standard of care for cochlear implantation and the first step in the long-term journey towards establishing best clinical practice in the use of CIs for adults.

We are due to embark on the next phase of this journey, with the development of a sophisticated resource of living guidelines, one that we hope will ultimately be used to change or develop clinical practice guidelines across a large geography.

More details will be made available on this topic very soon.

Creation of guidance and guidelines to optimise the standard of care for adults eligible for CI via an evidence based, real time repository under the governance of a coalition of the willing.
The call to action has resulted in subject matter experts signing up to advisory groups around the world to tackle hearing health for adults.

Objectives:
- Raise awareness of the benefits of CI in Adults, in the community, among audiologists and primary health care professionals and politicians.
- Create and ensure a person-centred and consistent referral pathway, which results in consistent diagnosis and more timely referral to CI specialists of candidates who may benefit.
- Sustainable funding and consistent standards of access, including consistent approaches to waiting times, access to a second implant and replacement sound processors.
- Enabling recipient and candidate-centred new models of care including through the development of tele-audiology
- Support CI user voices and those who would benefit from access to be heard in the community and by policy makers.

The goal:
Every adult with hearing loss in has timely and accurate diagnostic and treatment information required to make an informed decision to optimize their hearing.
Ongoing professional education to overcome awareness

Upcoming Webinar CI Futures Forum: Cost Implications of CIs

THANK YOU