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Cochlear Implants Standards of Care: An International Consensus

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

Guest Speaker:

Craig A. Buchman, MD
Lindburg Professor and Chair, Otolaryngology, Washington University in St. Louis

For the Delphi Consensus Group
Disclosures

- Consultant for: Advanced Bionics, Cochlear, IotaMotion, Envoy
- Equity Interest: Advanced Cochlear Diagnostics, LLC

- The consensus process was independently facilitated by Oxford PharmaGenesis, a Health Science communications consultancy providing services to the healthcare industry, professional societies and patient groups through specialist practices

- Support for this project provided by: Advanced Bionics, Cochlear, MedEL, Oticon
Geographic spread of Delphi panel members

• The Delphi panel and steering committee bring together clinical experts, ENTs and audiologists from across the globe.

• 1 Chair
• 4 steering committee members
• 25 additional panel members
• 13 countries represented
CONSUMER & PROFESSIONAL ADVOCACY COMMITTEE (CAPAC)

**CAPAC Co-Chairs**
Barbara Kelley – Executive Director, Hearing Loss Association of America
Dr. Harald Seidler – President, German Association of Hearing Impaired Persons, also representing International Federation of Hard of Hearing People (IFHOH)

**Professional Organisations**
- Professor Bernard Fraysse - President, International Federation of Otorhino Laryngological Societies (IFOS)
- Professor George Tavartkiladze - Secretary General, International Society of Audiology (ISA)

**User Advocacy Organisations**
- Leo De Raeve, special advisor to the board - European Association of Cochlear Implant Users (EURO-CIU)
- Donna Sorkin – Executive Director, American Cochlear Implant Alliance (ACIA)
- Darja Pajk, Treasurer - European Federation of Hard of Hearing People (EFHOH)

**Role in advocacy**
- Communication through their organizations about the Consensus Paper and why it is being published
- Speaker at key user and professional conferences.
- Verify the importance and credibility of the paper at the international, regional, and country level.

**Future role**
- If the CAPAC is successful it may have an ongoing role in the field of global CI advocacy. For example, they could form the basis of a global CI advocacy alliance.
Global burden of hearing loss

- Hearing loss is one of the leading causes of overall disability worldwide

- Globally, approximately **466 million** adults and children (6%) have a disabling hearing loss
  - This is projected to rise to **630 million** by 2030 and to **over 900 million** by 2050

- Hearing loss has a substantial impact on people’s lives (e.g. communication difficulties and reduced well-being\(^1\))

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Hearing loss and dementia

Evidence has indicated that the risk of dementia and Alzheimer’s disease increases with hearing loss severity\(^1\)

- In 2017, findings from a commission on dementia prevention, intervention and care stated that **hearing loss is the single largest modifiable risk factor for dementia**\(^2\)
- Dementia incidence could be reduced with the treatment of hearing loss\(^2\)

Cochlear implant use in adults

- Cochlear implantation has now been available for more than 30 years in many countries

- Cochlear implants (CIs) are standard of care for newborns with severe to profound sensorineural hearing loss (SNHL) in many developed countries
  - In children, penetration of CIs is high (>50%)

- In adults, cochlear implantation is often seen as a last resort option
  - Many adults who could benefit from a CI do not receive them
  - As in children, CI use in adults has potential to become standard of care
What do we know?

Benefits have been demonstrated but adoption is low

- Adults using CIs experience improvements compared with hearing aid only or no treatment, in terms of:
  - Very safe
  - Speech perception in quiet and noise\textsuperscript{6,7}
  - Educational\textsuperscript{8} and employment\textsuperscript{9} opportunities
  - Quality of life\textsuperscript{6,10}
- CIs have been shown to be cost effective\textsuperscript{11}
- However, penetration of CIs in eligible adults is as low as 5%

*Eligibility for CIs varies according to country-specific guidelines


CI, cochlear implant; M, millions

HLAA
Hearing Loss Association of America
What does **standard of care** mean for the patient?

**From the patient’s perspective**, achieving standard of care can lead to:

- More **consistent medical diagnosis, referral** and **treatment guidelines**
- Better access to CI treatment and **aftercare**
- Improvements in **quality of life** and health, through **optimizing hearing function**, social participation and engagement

Standard of care will also raise **awareness**, making the care pathway more transparent and educating a wider audience about the effectiveness of CI treatment.
Consensus to achieve standard of care in CI treatment for adults

- Comparative data
  - Risks versus benefit across:
    - treatment options
    - patient populations
    - affected groups and over time

- Body of evidence

- Consistent opinions
  - Consensus at all levels, especially local level, among:
    - clinical experts
    - specialty societies
    - patient advocacy groups
    - political channels
    - administrative arm of government

- Standard of care
SYSTEMATIC REVIEW AND CONSENSUS:

Unilateral cochlear implants for bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss

What is a Delphi consensus process?

An **established consensus-based technique** that allows for the collection and aggregation of informed judgements from a **group of experts**

- Uses several rounds of questionnaires to seek anonymous responses, which are then aggregated
- Seeks to reach the correct response through consensus
- The result is a series of consensus statements about a clinical area that have been agreed on by experts in the field
Achieving standard of care with the consensus process

• The Delphi consensus process provides a summary of clinical evidence and expert opinion on cochlear implantation

Findings from the Delphi process have the potential to:

• Establish CIs as the standard of care for adults with severe to profound SNHL
  – Improve access to CIs for patients
  – Improves the individual’s hearing function, communication and QoL
Literature review to inform statements

- A systematic literature review was used to obtain evidence relevant to adults with bilateral moderate sloping to profound SNHL or worse receiving and unilateral CIs
- Searches were conducted in MEDLINE, Embase, and Cochrane Library, on 18 July 2018

- Identified studies were screened for relevance
- Included studies were quality-assessed using a recognized method (Eubank et al. 2016)\(^1\)

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\(^1\)Eubank BH et al. BMC Med Res Methodol 2016;16:56
PRISMA diagram of included and excluded studies in the systematic literature
Delphi voting process

- The action for each statement for the subsequent round was determined by:
  - the 75% consensus threshold, and/or
  - provision of text feedback from the voter
- Wording of statements could still be revised even if the statement had reached at least 75% consensus
- At the end of voting round 3, statements that had reached at least 75% consensus were included in the final list to be published
Consensus Statement Categories

1. Level of awareness of CIs
2. Best practice clinical pathway for diagnosis
3. Best practice guidelines for surgery
4. Clinical effectiveness of CIs
5. Factors associated with post-implantation outcomes
6. The relationship between hearing loss and depression, cognition, and dementia
7. Cost implications of CIs
Consensus Statement Categories

1. Level of awareness of CIs
2. Best practice clinical pathway for diagnosis
3. Best practice guidelines for surgery
4. Clinical effectiveness of CIs
5. Factors associated with post-implantation outcomes
6. The relationship between hearing loss and depression, cognition, and dementia
7. Cost implications of CIs
Consensus 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.

*Delphi Consensus Group on Cochlear Implantation in Adults*
Consensus Statement Categories

1. Level of awareness of CIs
2. Best practice clinical pathway for diagnosis
3. Best practice guidelines for surgery
4. Clinical effectiveness of CIs
5. Factors associated with post-implantation outcomes
6. The relationship between hearing loss and depression, cognition, and dementia
7. Cost implications of CIs
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.¹

¹Delphi Consensus Group on Cochlear Implantation in Adults;
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.\textsuperscript{1}

\textsuperscript{1}Delphi Consensus Group on Cochlear Implantation in Adults;
Consensus 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.¹

¹Delphi Consensus Group on Cochlear Implantation in Adults;
Consensus Statement Categories

1. Level of awareness of CIs
2. Best practice clinical pathway for diagnosis
3. **Best practice guidelines for surgery**
4. Clinical effectiveness of CIs
5. Factors associated with post-implantation outcomes
6. The relationship between hearing loss and depression, cognition, and dementia
7. Cost implications of CIs
Consensus Statement

5. Both curved (perimodiolar) and straight electrodes are clinically effective for cochlear implantation, with a **low rate of complications**.

6. When possible, hearing preservation surgery can be beneficial in individuals with substantial residual hearing.¹

¹Delphi Consensus Group on Cochlear Implantation in Adults;
1. Level of awareness of CIs
2. Best practice clinical pathway for diagnosis
3. Best practice guidelines for surgery
4. **Clinical effectiveness of CIs**
5. Factors associated with post-implantation outcomes
6. The relationship between hearing loss and depression, cognition, and dementia
7. Cost implications of CIs
Consensus Statements

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\(^1\)

8. Both word and sentence recognition tests should be used to evaluate speech recognition performance following cochlear implantation\(^1\)

\(^1\)Delphi Consensus Group on Cochlear Implantation in Adults
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.¹

10. Adults who are eligible for cochlear implants should receive the implant as soon as possible to maximize post-implantation speech recognition.¹

¹Delphi Consensus Group on Cochlear Implantation in Adults
Consensus Statement Categories

1. Level of awareness of CIs
2. Best practice clinical pathway for diagnosis
3. Best practice guidelines for surgery
4. Clinical effectiveness of CIs
5. **Factors associated with post-implantation outcomes**
6. The relationship between hearing loss and depression, cognition, and dementia
7. Cost implications of CIs
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.¹

12. Many factors impact cochlear implant outcomes; further research is needed to understand the magnitude of the effects.¹

¹Delphi Consensus Group on Cochlear Implantation in Adults
Consensus Statements

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.¹

14. Adults who have undergone cochlear implantation should receive programming sessions, as needed, to optimize outcomes.¹

¹Delphi Consensus Group on Cochlear Implantation in Adults
Consensus Statement Categories

1. Level of awareness of CIs
2. Best practice clinical pathway for diagnosis
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7. Cost implications of CIs
Consensus Statements

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.¹

16. There is an association between age-related hearing loss and cognitive/memory impairment.¹

¹Delphi Consensus Group on Cochlear Implantation in Adults
Consensus Statements

17. Further research is required to confirm the nature of cognitive impairment in individuals with hearing loss, and its potential reversibility with treatment. ¹

18. The use of cochlear implants may improve cognition in older adults with bilateral severe to profound sensorineural hearing loss.¹

19. Hearing loss is not a symptom of dementia; however, treatment of hearing loss may reduce the risk of dementia.¹

¹Delphi Consensus Group on Cochlear Implantation in Adults
Consensus Statement Categories

1. Level of awareness of CIs
2. Best practice clinical pathway for diagnosis
3. Best practice guidelines for surgery
4. Clinical effectiveness of CIs
5. Factors associated with post-implantation outcomes
6. The relationship between hearing loss and depression, cognition, and dementia
7. Cost implications of CIs
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.¹

¹Delphi Consensus Group on Cochlear Implantation in Adults.
Next steps
What will the Consensus Statements lead to?

• They mark the first step in raising awareness of the benefits of cochlear implantation in adults and in improving how potential CI candidates are identified and treated.

• The ultimate goal is to improve hearing and QoL in adults with SNHL who are eligible for unilateral cochlear implantation.
Maximizing the impact of the Delphi process

• An international consensus paper published in JAMA-Otolaryngology
• Following publication, the real work begins for all of us! Dissemination and promotion is key to help the statements influence awareness and referral behaviour

Engagement of professionals and community

Adoption of clinical practice guidelines

Development of country-specific clinical practice guidelines through national medical academies

Policy advocacy to positively influence decision-making for payers and policy makers
Working together towards the same goal

Greater access to CIs and better quality of life

CAPAC, Consumer and Professional Advocacy Committee; CI, cochlear implant
If you have any questions, please contact:

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Cochlear implants in adults

• Prior to Buchman et al. (2020), there have been no international guidelines on adult CI candidacy
• Varied indications across countries
• Poor utilization of CI technology
  • Barriers:
    • Public awareness
    • Knowledge about CI criteria
    • Lack of defined care pathways
Global burden of hearing loss
Cochlear implants: awareness & referrals

Adult CI criteria in the U.S. are broad

• **Conventional**: moderate sloping to profound SNHL
• **Hybrid/EAS**: normal to near-normal hearing in the LFs with severe-to-profound HF loss
• **Single-sided deafness (SSD)**: normal to near-hearing in the better ear

Even adults exceeding current criteria → significant CI benefit
(Cullen et al., 2004; Gifford et al., 2010; Mudery et al., 2017; Sladen et al., 2018; Dunn et al., 2020)
Cochlear implants: awareness & referrals

Perkins et al. (in review)
Cochlear implants: awareness & referrals

Perkins et al. (in review)
CI s are highly effective and underutilized

*Without additional action*, these consensus statements may not hold impact beyond the walls of progressive CI programs.

**We have a lot of work ahead of us:**

- CI awareness: public, primary care providers, audiologists, ENTs not working in a CI program, patient advocacy groups
- Assessment of QOL prior to and following CI
- Hearing screening for older adults outside audiology & ENT clinics

We must be committed to outreach!
If you have any questions, please contact:

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Questions?

Please use Q & A icon on meeting bar to ask a question.

Thank you.
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