Response to the MEDCAC Panel Voting Questions
Cochlear Implants for Sensorineural Hearing Loss

Alice E Holmes, PhD
American Academy of Audiology
University of Florida

1. How confident are you that there is adequate evidence to determine whether or not a unilateral (i.e., first) cochlear implant improves health outcomes for adults with hearing loss who have demonstrated a test score of:

- >40% and ≤50% -- 5 High confidence
- >50% and ≤60% -- 5 High confidence

Discussion for Question 1:

There are a number of speech perception tests available for use in evaluating candidacy for cochlear implant and post cochlear implant performance (i.e. HINT, Nilsson et al., 1996; CUNY sentences, Boothroyd et al., 1985; AzBio; BKB-SIN). Results are dependent not only upon the difficulty level of the test given, but also the intensity level of the presentation of the stimuli. With that being said, even with the easiest of these test measures, individuals who score <60% correct in the best aided condition in a quiet condition, in all likelihood will perform better with a cochlear implant. The minimum speech test battery recommended by the Committee on Hearing & Equilibrium of the AAO-HNS, recommends the use of the HINT sentence test given in quiet for implant candidacy evaluations[1]. Cochlear implants have improved dramatically in the last decade. In fact many studies have documented that ceiling effects are experienced using the HINT sentence test in quiet after the person receives their implants[2-4].

Is there an absolute or relative change in test scores that indicates a clinically meaningful difference in health outcomes for this population?

Again, because this is so dependent on the test material being used, it is not possible to give an absolute test score indicating a clinically significant difference. With the improvements in cochlear implants, a test battery that included a monosyllabic word test and sentence testing in noise may be more appropriate[4].

2. If the result of Question 1 is at least intermediate (mean vote ≥ 2.5) for either range of correct open set sentence recognition scores noted above, how confident are you that a unilateral (i.e., first) cochlear implant improves health outcomes for adults with hearing loss who have demonstrated a test score of :

- >40% and ≤50% -- 5 High confidence
- >50% and ≤60% -- 5 High confidence

Discussion for Question 2:

Numerous quality of life studies on cochlear implant patients have shown the benefits of the procedure in adults [5-10].

Are there any specific factors, other than test scores (e.g. anatomy, duration of hearing loss, characteristics of facilities/care providers, etc.), that can aid in the identification of those individuals most likely to attain improved health outcomes?

No one factor has been found to predict who may most likely benefit from cochlear implant surgery. Duration of deafness and amount of residual hearing have been cited as two important predictive factors to differentiate among the performance variations seen in cochlear implant users [11-14]. However, persons with profound losses and long term deafness have been very successful cochlear implant users; the length of deafness and severity of the loss should be considered in counseling the patients on expectations for their implant.

3a. How confident are you that there is adequate evidence to demonstrate whether or not the use of bilateral cochlear implants as compared to a unilateral cochlear implant improves health outcomes?

3.5 intermediate to high confidence

There is evidence that bilateral implantation provides improved health outcomes in terms of improved understanding in noisy backgrounds and improved localization abilities over unilateral implantation [15-22]. However, many of the benefits seen with bilateral cochlear implantation may also be gained with the use of a hearing aid in the opposite ear (bimodal stimulation) if the user has some residual hearing [23-30].

3b. If the result of Question 3a is at least intermediate (mean vote ≥ 2.5), how confident are you that the use of bilateral cochlear implants as compared to a unilateral cochlear implant improves health outcomes?

3 intermediate confidence

In my clinical experience, a second implant should be recommended if the person still meets the requirement for a unilateral cochlear implant within wear in the first device. For example, if the person had 20% speech recognition prior to the first CI with appropriately fit hearing aids, and, after three months of use his scores have increased to 40% with the CI and hearing aid in the opposite ear, a second implant should be considered. A second case where bilateral cochlear implants should be considered is when the hearing aid in the opposite gives no additional benefit using a test battery that includes speech in noise as listed in the explanation for question 4.

If the answer to question 3b is at least intermediate (mean vote ≥ 2.5), continue on to questions 4-9.

4. How confident are you that there is adequate evidence to determine whether or not a sequential bilateral cochlear implantation as compared to a unilateral cochlear implantation improves health outcomes for adults with hearing loss who have demonstrated a test score in the ranges below ?

- ≤ 40% -- 2

- > 40 % and ≤ 50%, -- 1.5
- > 50% and ≤ 60% -- 1

Low confidence, due to the fact these individuals have some hearing in the opposite ear and should try bimodal stimulation. With low frequency amplification a person can obtain prosody information from a hearing aid that is not available through current technology cochlear implants. This information can help in noise backgrounds, with melody.

For individuals with ≤ 40%, bimodal stimulation should be tried to see if they receive benefit from a hearing aid in the opposite ear. For the cases in B and C, these individuals have some significant hearing in the opposite ear and should try bimodal stimulation. With low frequency amplification a person can obtain prosody information from a hearing aid that is not available through current technology cochlear implants. This information can provide better noise backgrounds, music appreciation with melody recognition and improved ability to hear emotion cues. In addition, many bimodal users can localize the sound source. The user should be evaluated after a trial with bimodal stimulation with and without the hearing aid using a test battery that includes both subjective and objective assessment of speech in noise, localization and music appreciation. If the hearing aid does not provide any improvement above that of the unilateral implant, bilateral cochlear implants should be considered [23-30].

5. If the answer to question 4 is at least intermediate (mean vote ≥ 2.5) in any of the ranges noted, how confident are you that a sequential bilateral cochlear implantation as compared to a unilateral cochlear implantation improves health outcomes for adults with hearing loss who have demonstrated a test score in the ranges below? *(Not Applicable)*

- ≤ 40%
- > 40 % and ≤ 50%
- > 50% and ≤ 60%

6. How confident are you that there is adequate evidence to determine whether or not a simultaneous bilateral cochlear implantation as compared to a unilateral cochlear implantation improves health outcomes for adults with hearing loss who have demonstrated a test score in the ranges below?

- ≤ 40% -- 3.5
- > 40 % and ≤ 50% -- 2
- > 50% and ≤ 60% -- 2

For individuals with no aidable hearing in either ear, bilateral cochlear implants are the only viable solution toe bilateral hearing. However, if the person has the possibility to try bimodal solution it should be encouraged.

7. If the answer to question 6 is at least intermediate (mean vote ≥ 2.5) in any of the ranges noted, how confident are you that a simultaneous bilateral cochlear implantation as compared to

a unilateral cochlear implantation improves health outcomes for adults with hearing loss with test scores in the ranges below ?

- ≤ 40% -- 3
- > 40 % and ≤ 50% -- 2
- > 50% and ≤ 60% -- 2

Bilateral cochlear implants can result in improvements in speech and noise and localization abilities, but the amount of additional benefit is not nearly as great in the average patient as that received from unilateral implantation compared to hearing aid use prior to the implant. Quality of life studies have again shown improvement with bilateral implants compared to unilateral but not to the extent of unilateral versus no implant [31].

8. How confident are you that there is adequate evidence to determine whether or not a simultaneous bilateral cochlear implantation as compared to a sequential cochlear implantation improves health outcomes for adults with hearing loss who have demonstrated a test score in the ranges below?

- ≤ 40% -- 2
- > 40 % and ≤ 50% -- 2
- > 50% and ≤ 60% -- 1.5

To my knowledge, no evidence-based study has shown health outcome benefits of simultaneous versus sequential bilateral implantation in adults. The only exception to this would be in the case of a disorder that may result in rapid ossification of the cochlea (i.e. meningitis), therefore possibly precluding a later second surgery. In this case simultaneous CIs should be considered.

9. If the answer to question 8 is at least intermediate (mean vote ≥ 2.5) in any of the ranges noted, how confident are you that a simultaneous bilateral cochlear implantation as compared to a sequential cochlear implantation improves health outcomes for adults with hearing loss who have demonstrated a test score in the ranges below?

- ≤ 40%
- > 40 % and ≤ 50%
- > 50% and ≤ 60%

10. What significant evidence gaps exist regarding the clinical criteria of individuals who should receive cochlear implants, either unilateral or bilateral?

More research needs to be done in developing test measures and protocols to demonstrate the benefits of both unilateral and bilateral cochlear implants. With improved technology, more people with significant residual hearing may benefit from cochlear implants. We must continue to improve test measures that provide results for a wide range of abilities without reaching a ceiling or floor effect.

It is also critical that we have evidenced-based research comparing the use of bilateral and bimodal modes of stimulation. Along with cochlear implants, digital hearing aids have also improved greatly and very little research has been completed to see the best method for fitting these devices when used in conjunction with cochlear implants. The manner in which the hearing aid is fit could tremendously affect the results of the bimodal stimulation.

11. How confident are you that these conclusions are generalizable to:
    - The Medicare patient population? 5
    - Community based settings? 5

In both my clinical experience, with over 100 elderly cochlear implant patients, and my review of the literature, older adults receive similar benefits with cochlear implants as their younger counterparts. The use of cochlear implants in this population can significantly improve their quality of life and their communication partners, [8, 32-43].

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