

Cochlear Implants: Bi- Versus Unilateral

Final Key Questions - Public Comments

January 10, 2013

Health Technology Assessment Program (HTA)

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Cochlear Implants: Bilateral Versus Unilateral

Response to Topic and Public Comments on Key Questions

January 10, 2013

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Response to Public Comments, Topic and Key Questions Cochlear Implants: Bilateral Versus Unilateral

Hayes, Inc. is an independent vendor contracted to produce evidence assessment reports for the WA HTA program. For transparency, all comments received during the comments process are included in this response document.

Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only. When comment cite evidence, the information is forwarded to the vendor for consideration in the evidence report.

This document responds to comments from the following parties:

- David R. Nielssen (American Academy of Otolaryngology-Head and Neck Surgery [AAO-HNS])
- Dr. Gerhard Roehrieien (Advanced Bionics, LLC), Chris Smith (Cochlear Americas), and Richard Collette (Med-EL)
- Lise Hamlin (Hearing Loss Association of America)
- Teresa Zwolan and Donna Sorkin (American Cochlear Implant Alliance)
- Donald Goldberg, Ph.D. (Alexander Graham Bell Association for the Deaf and Hard of Hearing)
- Melissa Uhlman (University of Iowa Hospitals and Clinics)
- Kami Fehlig (Spokane ENT)
- Kevin Franck, Ph.D. (Artisan Healthcare Consulting)
- Jay T. Rubinstein, M.D., Ph.D. (Virginia Merrill Bloedel Hearing Research Center; Professor of Otolaryngology and Bioengineering, University of Washington)
- Gina Casa
- Ashley Johnson
- Geri Ann Pelechaty
- Tricia Allen
- Julie Olson
- Emily Mandelbaum
- Michelle Benavides

Table 1 provides a summary of comments with responses. No other parties submitted comments.

Table 1. Public Comments on Topic and Key Questions for Cochlear Implants

Comment and Source	Response
Comments on Topic	
June 13, 2012 Letter from David R. Nielsen, M.D., Executive Vice President and CEO of AAO-HNS, with separate response document	
<p>Appropriate population “Cochlear implants are appropriate for children and adults with severe to profound bilateral sensorineural hearing loss. In general, this population gains little to no benefit with the use of conventional hearing aids . . . children [with prelingual severe to profound sensorineural hearing loss] implanted with a cochlear implant at a young age will have an excellent chance of developing advanced auditory and speech skills.”</p> <p>Other information:</p> <ul style="list-style-type: none"> • FDA approvals • Outcome measures used to assess adult patients with moderate to profound sensorineural hearing loss (SNHL) • Advantages of bilateral implantation • Citation of two consensus statements (international and U.S.) <p><i>(See pages 1-3 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Topic.</p>
<p>Effectiveness for clinical conditions and quality of life (QOL)</p> <p>“The efficacy of cochlear implantation on speech discrimination has been well documented and studied, particularly in postlingually deafened adults.”</p> <p>Other information:</p> <ul style="list-style-type: none"> • Benefit has been demonstrated for multiple languages <p><i>(See pages 3-6 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Topic.</p>

<p>Patient evaluation</p> <ul style="list-style-type: none"> • Patient history • Unaided audiologic testing • Audiologic testing with hearing aids and real ear measurement to verify appropriateness of hearing aid settings • Vestibular work-up if there is a complaint of dizziness • Possible imaging to assess for cochlear dysplasia/ossification and retrocochlear processes <p>No references cited.</p> <p><i>(See pages 6-7 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>No change to Topic.</p>
<p>Key benefits</p> <p>“Even with the heterogeneity of the scientific literature, the clinical and scientific findings of benefit are consistent.”</p> <p>Other information: description of specific benefits to prelingually deaf children, postlingually deaf children and adults, prelingually deaf adults, and geriatric versus younger adults.</p> <p><i>(See pages 7-8 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Topic.</p>
<p>Clinical role and implications</p> <ul style="list-style-type: none"> • Hearing loss that is not profound (some degree of residual hearing) may respond to acoustic amplification. • Electroneural stimulation is the only solution for severe or profound deafness. • Neural pathways for speech are developed almost exclusively in early childhood. • Individualized programming is required following implantation. 	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Topic.</p>

<ul style="list-style-type: none"> • Prelingual children who receive implants then require years of speech training and audiologic support. • Implants increase the risk of otitis media, which may require surgical treatment. <p><i>(See pages 8-9 of the comment document.)</i></p>	
<p>Measurable clinical outcomes based on clinical experience and peer-reviewed evidence</p> <p>Commenter notes that there are few RCTs but contends that given the evidence suggesting efficacy, it would be unethical to withhold cochlear implants from eligible patients. Research showing an impact on objective outcomes and quality life is described separately for <u>pediatric and adult</u> patients for these comparisons:</p> <ul style="list-style-type: none"> • Unilateral CI versus no acoustic support • Unilateral CI versus hearing aids • Unilateral versus bilateral CI <p><i>(See pages 9-16 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Topic.</p>
<p>Cost-effectiveness/cost-utility</p> <p>Description of numerous economic evaluations. Commenter asserts that recall bias is not a serious issue in studies assessing QOL measures since “cochlear implant patients are not cured of their deafness and revisit their ‘deficit’ whenever they remove the sound processor.”</p> <p><i>(See pages 16-18 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Topic.</p>
<p>Safety</p> <p>Information provided:</p> <ul style="list-style-type: none"> • In 2010 the FDA asked the Association for the advance of Medical Instrumentation (AAMI) to develop a new standard for performance, safety, and reliability of cochlear implants. A European standard has been published. A committee of U.S. stakeholders is expected to issue a preliminary draft for use in 	<p>Thank you for this background information. The cited references will be considered for inclusion, and current information on standards development and recalls will be sought.</p> <p>No change to topic.</p>

<p>the U.S. in December 2012.</p> <ul style="list-style-type: none"> • Cochlear implants are Class III devices. • Complications that may necessitate a re-implantation procedure: hard failure, soft failure, implantation site infection, soft tissue complications and/or device extrusion, improper electrode placement, upgrade of CI technology • Other complications have been reported, the most serious of which is meningitis. • Device recalls have occurred. <p><i>(See pages 19-21 of the comment document.)</i></p>	
<p>Comments on Key Questions</p>	
<p>November 28, 2012 Letter with attached comment document from representatives of 3 manufacturers: Advanced Bionics, LLC (Dr. Gerhard Roehrieien), Cochlear Americas (Chris Smith), and Med-EL (Richard Collette)</p>	
<p>KQ #1, part 1. Review of rationale for bilateral as opposed to unilateral implantation and the particular needs of children. Description of research findings from studies evaluating the effects of hearing loss and from clinical studies of cochlear implantation (CI) with respect to sound detection/perception, neurocognitive development, speech production, functional status, and quality of life (QOL). Citations include two consensus statements (U.S. and Europe) endorsing bilateral CI in adults and children.</p> <p><u>Selected excerpts:</u> “Speech production and/or expressive language outcomes have not been studied directly to date in the pediatric bilateral cochlear implant research literature. However, outcome data can be extrapolated from existing pediatric studies of children with unilateral cochlear implants . . . The unilateral cochlear implantation literature shows that the younger a child is implanted, the better and more likely they will perform in line with normal hearing peers. .”</p> <p><i>(See pages 1-3 and pages 7-9 [reference list] of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>KQ #1, part 2. Review of rationale for bilateral CI as opposed to unilateral CI plus hearing aid (HA) with emphasis on the significance of the degree of residual hearing in the ear fitted with a HA. Description of research findings from clinical studies of cochlear implantation (CI) with respect to sound detection/perception, neurocognitive</p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p>

<p>development, speech production, functional status, QOL.</p> <p><u>Selected excerpt:</u> “Some studies have also alluded to the possibility of ‘binaural interference’ in rare cases while an individual is trying to process both acoustic [hearing aid] and electric [CI] precepts. Specifically, these individuals demonstrated a performance decrement with bimodal stimulation and/or differences in pitch, and in dynamic range and shape of the iso-loudness curves across the HA and CI ears.”</p> <p><i>(See pages 3-6 and pages 7-9 [reference list] of the comment document.)</i></p>	<p>No change to Key Questions.</p>
<p>KQ #2. General review of FDA approvals. Citation of studies showing implantation of a second device to be safe. Reference to National Institute of Health and Clinical Excellence (NICE) recommendation that hearing-impaired children have the option of two implants.</p> <p><u>Selected excerpt:</u> “Outcomes support a reduction in analgesia and antiemetic requirements when compared with sequential bilateral implantation, and a shorter cumulative/total hospital stay than the sequentially implanted children. Complications related to simultaneous bilateral CI surgery were not increased nor was there greater morbidity compared with single-sided implantation.”</p> <p><i>(See pages 9-11 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>

<p>KQ #3. Description of research, or lack thereof, investigating the relationship between outcomes and age at implantation, prelingual versus postlingual onset of hearing loss (and the relevance of brain plasticity in children), choice of implanted ear, time interval between implantations, specific device, and provider characteristics</p> <p><u>Selected excerpts:</u> “While the current FDA-approved age for cochlear implantation is ≥ 12 months old, implantation has reportedly occurred globally in even young children. A few studies have addressed outcomes with this younger population.” “. . ., the industry has been moving away from prelingual onset as a candidacy factor since it provides little predictive value in children.” “There is no clinical or research literature consensus regarding which ear to implant.” “Scientific publications regarding bilateral cochlear implantation in children generally do not address specific details pertaining to provider characteristics. Some statements have appeared regarding appropriate staff and facilities that are equipped and accustomed to dealing with children with complex needs. Other variables alluded to are multi-disciplinary teams to accommodate the child as a whole. Specifically, aural rehab team/therapist, psychologist and/or social worker to facilitate varying socioeconomic factors were among characteristics cited.”</p> <p><i>(See pages 11-16 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>KQ #4. Citation of a 2000 study estimating lifetime costs of \$1,000,000 (1998 US dollars) for deafness in young children; a study showing cost savings from unilateral pediatric implantation; and a study showing lower costs/QALY for CI compared defibrillator and with knee replacement. Statement that cost-effectiveness studies specific to bilateral CI are lacking but that an analysis conducted by NICE (2009) concluded that simultaneous bilateral CI is considered cost-effective.</p> <p><i>(See pages 16-18 of the attached comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>November 28, 2012 letter from Lise Hamlin (Hearing Loss Association of America)</p>	
<p>“The Hearing Loss Association of America (HLAA) is the nation’s leading organization representing people with hearing loss. According to the National Center for Health</p>	<p>Thank you for your comment.</p>

<p>Statistics 36 million (17 percent) Americans have some degree of hearing loss making it a public health issue third in line after heart disease and arthritis. We are well acquainted with cochlear implants from the perspective of the consumer: many of our constituents are recipients of or candidates for cochlear implants or are parents of children with cochlear implants. We provide consumer-oriented information about cochlear implants to consumers via our website, brochures, workshops and seminars during our annual conventions.</p> <p>HLAA hears regularly from people with cochlear implants and parents of children with cochlear implants about the value of implantation. Recently, we have been hearing more about the benefits of bi lateral implantation. For children, cochlear implants can provide access to sound needed to fully develop an individual’s potential for spoken language and improve access to reading, music, higher education, and employment opportunities. Having access to sound bi laterally increases a child’s ability to function with their hearing peers.</p> <p>In short, Hearing Loss Association supports the inclusion of bi lateral cochlear implants for children who qualify for implantation. There is no other medical intervention that will provide the same level of enhancement of communication for people with severe to profound hearing loss.</p> <p>We thank you for the opportunity to comment in this matter.”</p>	<p>The linked information sources will be reviewed.</p> <p>No change to Key Questions.</p>
<p>November 29, 2012 letter from Teresa Zwolan, Ph.D. and Donna Sorkin (American Cochlear Implant Alliance)</p>	
<p>KQ #1, part 1. Discussion of the effect of bilateral cochlear implants on the detection of sound.</p> <p><u>Excerpt:</u> “Persons with bilateral cochlear implants often demonstrate improved detection of sound when compared to patients with a unilateral CI or with a unilateral CI plus acoustic hearing aid, especially when sound detection is measured at various angles around the listener’s head due.”</p> <p><i>(See pages 1-2 and 4-5 [reference list] of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>

<p>KQ #1, part 2. Discussion of the effect of bilateral cochlear implants on perception or production of speech.</p> <p><u>Excerpt:</u> “It has been documented that use of bilateral CIs results in improved speech understanding in quiet and in background noise.”</p> <p><i>(See pages 2-3 and 4-5 [reference list] of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>KQ #1, part 3. Discussion of the effect of bilateral cochlear implants on functional status.</p> <p><u>Excerpt:</u> “Provision of bilateral cochlear implants provides several functional benefits for the implant user. An improved ability to localize sound results in improved safety, and improved speech perception and speech production results in an overall improvement in communication. Bilateral CI users report significantly decreased social restriction, reduced perception of hearing disability, and a trend toward reduced emotional distress compared to the unilateral implant condition.”</p> <p><i>(See page 3 and pages 4-5 [reference list] of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>KQ #1, part 4. Discussion of the effect of bilateral cochlear implants on quality of life.</p> <p><u>Excerpt:</u> “Numerous researchers have found that bilateral CI users demonstrate improvements in quality of life.”</p> <p><i>(See page 3 and pages 4-5 [reference list] of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>KQ #2 Discussion of the safety of bilateral cochlear implants. All three devices on the market are FDA-approved and are safe and effective for adult and pediatric use.</p> <p><u>Excerpt:</u> “Both simultaneous and sequential cochlear implantation are safe for children. . . With current widespread provision of simultaneous cochlear implantation in children, we now have extensive experience with the provision of two implants being provided during one hospital stay. . . Overall, peer reviewed studies and expert opinion of clinicians indicates that simultaneous CI allows for shorter periods of time in the hospital compared with sequential while not increasing complications.”</p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>

<p><i>(See pages 5-6 of the comment document.)</i></p>	
<p>KQ #3 Description of research investigating the relationship between outcomes and age at implantation and time interval between implantations.</p> <p><u>Excerpt</u>: “The safety of bilateral cochlear implants has not been reported to vary according to the factors mentioned above. Effectiveness of cochlear implantation has, however, been found to be minimally influenced by these factors.”</p> <p><i>(See page 7 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>KQ #4 Discussion of the cost implications for bilateral cochlear implantation. Citation of a 2000 study estimating lifetime cost benefit of unilateral cochlear implant of \$1,000,000 per young deaf child; a 2008 study estimated a 0.48 mean gain in health utility after bilateral cochlear implantation; and an in press study estimated \$30,000 to \$60,000 societal savings per child for cochlear implantation.</p> <p><u>Excerpt</u>: “When these observations are paired with observations of greater language learning potential in younger implant recipients, and those who receive bilateral cochlear implantation . . . a direct conclusion is that early, bilateral implantation yields substantial rehabilitative and educational benefits, representing high value for the healthcare dollar.”</p> <p><i>(See pages 7-9 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>November 29, 2012 letter from Donald Goldberg, Ph.D. (Alexander Graham Bell Association for the Deaf and Hard of Hearing)</p>	
<p>Discussion of the benefit of bilateral over unilateral cochlear implants. Requests the State of Washington Health Care Authority to support appropriate and early intervention for children who are deaf and hard of hearing through access to cochlear implants. Provided references to support statements.</p> <p><u>Excerpt</u>: “When children receive only a unilateral cochlear implant, they are able to hear in only one ear and have single-sided deafness. This does not provide sufficient intervention for auditory brain development and the full ability to acquire listening and</p>	<p>Thank you for your comment.</p> <p>The cited references will be considered for inclusion.</p> <p>No change to Key Questions.</p>

<p>spoken language. Unilateral hearing loss has adverse educational implications. . . Bilateral cochlear implants overcome the limitations of unilateral hearing loss and provide important benefits for children that are derived from binaural sensitive hearing. Bilateral cochlear implants can provide children with the ability to learn and function in the complex listening situations that are encountered in everyday life, such as noisy classrooms, playgrounds, and sports environments. Safety is also enhanced when there is a need to be aware of the sound of moving objects, such as traffic when crossing a busy street.”</p> <p><i>(See pages 1-3 of the comment document.)</i></p>	
<p>Melissa Uhlman (University of Iowa Hospitals & Clinics)</p>	
<p>KQ #1, part 1. Discussion of the effect of bilateral cochlear implants on the detection of sound.</p> <p>Excerpt: “Bilateral cochlear implantation does improve detection of sound. . . Lack of effective amplification, even in one ear (as would be the case in a unilateral cochlear implantation) may have significant impacts on patient safety. . . A unilateral lack of amplification may also negatively impact the patient in social and educational situations if he is unable to hear his name called from across a classroom or unable to soft-spoken words from a peer or teacher.”</p> <p><i>(See page 1 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>KQ #1, part 2. Discussion of the effect of bilateral cochlear implants on neurocognitive development.</p> <p>Excerpt: “Bilateral cochlear implantation may improve neurocognitive development. . . Unlike an acoustic hearing aid which only offer amplification and not improvement of clarity, cochlear implants may offer patients improved speech clarity. . . Bilateral implantation for patients in this age range necessarily means providing the best possibility for optimum neurocognitive development.”</p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>

<p><i>(See page 1 of the comment document.)</i></p>	
<p>KQ #1, part 3. Discussion of the effect of bilateral cochlear implants on perception or production of speech.</p> <p><u>Excerpt:</u> “Bilateral cochlear implantation may improve perception or production of speech . . . bilateral implantation (and simultaneous implantation more than sequential) offers pediatric and adolescent patients the highest possibility for improved speech perception and production. . . Research indicates that even a mild unilateral hearing loss (or in this case, inadequate aiding of an ear with hearing loss) can have significant negative effects for children in a classroom setting.”</p> <p><i>(See page 1 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>KQ #1, part 4. Discussion of the effect of bilateral cochlear implants on functional status and quality of life.</p> <p><u>Excerpt:</u> “Bilateral cochlear implantation may improve functional status and quality of life. . . Appropriate amplification can greatly affect a patient’s ability to function in all aspects of life. Bilateral cochlear implantation offers the highest level of help for children and adolescents with profound hearing loss, and this often translates to improved overall function and quality of life.”</p> <p><i>(See pages 1-2 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>KQ #2 “I am not a surgeon, so I will keep this comment to a minimum, but it is my understanding that for the typical patient, bilateral cochlear implantation is just as safe as unilateral cochlear implantation.”</p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>KQ #3, part 1. Discussion of the effect of age on effectiveness of bilateral cochlear implants.</p> <p><u>Excerpt:</u> “Cochlear implants, both unilateral and bilateral, are typically more beneficial if the recipient is younger. This is due to the fact that a younger brain is more plastic and therefore, more easily accepts and interprets new inputs such as those received from an</p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>

<p>implant.”</p> <p><i>(See page 2 of the comment document.)</i></p>	
<p>KQ #3, part 2. Discussion of the effect of language status on effectiveness of bilateral cochlear implants.</p> <p><u>Excerpt:</u> “Cochlear implants, both unilateral and bilateral, are almost always more beneficial if the patient is either pre-lingually deafened and implanted . . . or if the patient is post-lingually deafened and implanted. . . Cochlear implants offer the least amount of benefit for patients who are older than the typical window for developing language (1-4 years old) and who did not have access to adequate auditory stimulation in order to learn language during that time.”</p> <p><i>(See pages 2-3 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>KQ #3, part 3. Discussion of the effect of degree and duration of deafness on effectiveness of bilateral cochlear implants.</p> <p><u>Excerpt:</u> “In terms of duration, cochlear implants, both unilateral and bilateral, are almost always more beneficial for patients who have been more recently deafened.”</p> <p><i>(See page 3 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>KQ #3, part 4. Discussion of the effect of ear choice on effectiveness of bilateral cochlear implants.</p> <p><u>Excerpt:</u> “This decision should be based on the above outlined points, as well as patient preferences, and the patient should be led through this decision by her audiologist and surgeon.”</p> <p><i>(See page 3 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>KQ #3, part 5. Discussion of the effect of time between implantations on effectiveness of bilateral cochlear implants.</p>	<p>Thank you for your comment.</p>

<p>Excerpt: “In my experience, for patients with two implant-eligible ears, best outcomes with bilateral implantation occur with simultaneous implantation rather than sequential. . . In many cases, the amount of benefit received from the second implant diminishes as time between implantations increases.”</p> <p><i>(See page 3 of the comment document.)</i></p>	<p>No change to Key Questions.</p>
<p>KQ #4 Discussion of the cost implications of bilateral cochlear implantation.</p> <p>Excerpt: “As an audiologist and not a surgeon, I do not feel that I can comment about the cost implications in the operating room. . . In terms of other costs, bilateral cochlear implantation obviously incurs double costs with regard to the patient’s equipment needs. This includes doubling the cost of replacement equipment, which every cochlear implant patient will need eventually. Personally, I require up to 50% more appointment time (depending on the patient’s needs) to care for a bilaterally-implanted patient as opposed to a unilateral patient.”</p> <p><i>(See page 4 of the comment document.)</i></p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>November 21, 2012 letter from Kami Fehlig, AuD (Spokane ENT)</p>	
<p>“I want to put forth my opinions for the public comment period that is underway regarding the above issue under review. I have been working with pediatric cochlear implant recipients (both unilateral & bilateral) for the past 15 years.”</p> <p>KQ #1 “My opinion is that in most situations yes. (The exceptions to this are addressed in the answer to question #3).”</p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>KQ #2 “Yes. Bilateral cochlear implantation is safe. The only real additional risk (over single-sided cochlear implantation is when doing simultaneous bilateral CI's, a longer time under anesthesia). Cochlear implant surgery risks are minimal, about the same as tonsils & adenoids.”</p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>KQ #3 “It may affect the effectiveness of the highlighted factors. I think that it would be difficult to make a hard & steady rule & each case needs to be reviewed carefully.</p>	<p>Thank you for your comment.</p>

<p>However, if a family is considering a 2nd CI for their child who is 15 or 16 & that child has been profoundly deaf since birth & had little or no hearing aid use, I would not feel that they would likely get much benefit from the second CI.”</p>	<p>No change to Key Questions.</p>
<p>KQ #4 “This needs to be examined closely. If question #3 is answered CORRECTLY, & only children who can truly benefit from a second CI are implanted, then the cost effectiveness will be good (i.e. impact to society vs. cost of second CI). However, that could go the other direction if children who are not good candidates receive a second CI. In terms of the costs, it will be less if they are done simultaneously but in most of these cases, I believe they will be done sequentially.”</p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>November 21, 2012 letter from Kevin Franck, Ph.D. (Artisan Healthcare Consulting)</p>	
<p>“I am an audiologist who has worked with adults and children with unilateral and bilateral cochlear implants. I have seen the benefit they provide, and can advocate for benefits to be extended. However, an ex-employee of Cochlear Ltd, and as a health care consultant, I can see the how every industry is looking to extend benefits for each incredible intervention available. This is not sustainable. Comparative economic evaluations much be performed, and this is difficult to do.</p> <p>If you need help separating the p-value from the passion, and coming up with proposals that help provide care in a way that is fair - please let me offer my services.”</p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>
<p>November 29, 2012 letter from Jay T. Rubinstein, MD, Ph.D. (Virginia Merrill Bloedel Hearing Research Center; Professor of Otolaryngology & Bioengineering, University of Washington)</p>	
<p>KQ #1 “The answer to this question is complex as it depends on the degree of hearing loss in the unimplanted ear. If the unimplanted ear is unable to contribute usefully to speech perception by the implanted ear, and is unable to provide other auditory benefits such as music perception, than the answer is yes. Functional status, quality of life, sound detection and localization, and speech perception in background noise are all improved. It is not known if neurocognitive development or speech production is enhanced by a second implant.</p> <p>If the unimplanted ear has sufficient hearing that when aided it enhances speech perception by the implanted ear, or provides some other significant benefits such as music perception, it is best left unimplanted as it can still provide significant benefit through bimodal hearing.”</p>	<p>Thank you for your comment.</p> <p>The provided review article will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>KQ #2 “Bilateral cochlear implantation is unquestionably safe when performed by qualified teams of surgeons and audiologists.”</p>	<p>Thank you for your comment.</p>

	<p>The provided review article will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>KQ #3 “Effectiveness of bilateral cochlear implantation varies as does effectiveness of unilateral cochlear implantation with age of first implant for pre-lingually deafened children and duration of deafness for postlingually deafened adolescents. There is little evidence that interval between implants has any effect on monaural outcome with the second device. There may be emerging evidence that interval between implants does effect certain binaural outcomes in pre-lingually deafened children but this is still uncertain. Choice of implanted ear or device does not generally impact safety or efficacy. Experience and skill of the surgeon and the audiological team has significant implications for both safety and efficacy.”</p>	<p>Thank you for your comment.</p> <p>The provided review article will be considered for inclusion.</p> <p>No change to Key Questions.</p>
<p>KQ #4 “Bilateral implantation is significantly more costly than unilateral implantation due to the second device, as well as increased surgical and audiological time. Cost-efficacy of bilateral implantation increases with decreasing age of the patient. As a result of this the UK National Health Service provides bilateral implants for children but not for adults. This is a highly complex and controversial area and references are included in the attached paper.”</p>	<p>Thank you for your comment.</p> <p>The cited reference will be considered for inclusion.</p> <p>No change to Key Questions.</p>

November 20, 2012 letter from Gina Casa (parent of child with cochlear implants)	
“Gianna Casa got bilateral cochlear implants at 9mths. They are MAGIC!!The Attach picture is of Gianna hearing the rain for the very 1st time!!”	Thank you for your comment. No change to Key Questions.
November 20, 2012 letter from Ashley Johnson (parent of child with cochlear implants)	
“My four year old daughter, Ryhan, has bi-later cochlear implants. She was born deaf due to genetic hearing loss. She received her first at one year old and her second at 16 months old. She loves wearing them. Every morning she can get them off of their charger, put them together, turn them on and put them on her head. She is now in pre-k in regular mainstreamed classes and is doing great and is on the same language level as her peers. No one can tell she has hearing loss and she does not have a speech impediment. I believe this was due to early implantation, and bi-lateral implants. She gets more sound with both. I really hope that more children that are deaf are able to get the opportunity to hear out of both ears, just like other hearing people have been blessed with the ability to do. I feel very blessed that Ryhan was able to receive her cochlear implants through Medicaid because we would have never been able to afford them for her. She can listen to music now (which she loves to sing along to), talk and listen to conversation, and hear all the sounds that are a part of life. It may not be life threatening being born deaf, but it is really awesome when the possibilities are endless for a child when they are given the ability to hear.”	Thank you for your comment. No change to Key Questions.
November 20, 2012 letter from Geri Ann Pelechaty (parent of child with cochlear implants)	
“Hi, I made a Picaboo photo book called “Michael's story book” and thought you’d enjoy seeing it. This is the book I have made telling my son's Journey with Bilateral Cochlear Implants.”	Thank you for your comment. No change to Key Questions.
November 20, 2012 letter from Tricia Allen (parent of a child with cochlear implants)	
“My name is Tricia M. Allen and I just got my daughter her second cochlear not even a week ago. Without this technology she would not be able to accomplish some of the things she has already. Yes one was a great milestone, but without the second one she would always have that delay in her speech as well as knowing exactly where sounds are coming from. She is 4 years old and is the light of my whole family's eyes she has been an inspiration to all of us who take hearing for granted. To not allow a child to get a second	Thank you for your comment. No change to Key Questions.

<p>cochlear due to the fact that insurance would have to deem it "necessary" would be devastating not only to their growth, but to their education as well. Imagine going through school with only 50% of your hearing would you have been able to function in a classroom with 20-30 students in it? I do not think so. Give the children a chance, yes ultimately it is our decisions as parents, but we do this not for our benefit but for theirs. I do not regret getting my daughter the other cochlear as much as some might not have agreed with me I did it so she would have the best possible future. Where do the insurance companies draw the line with "necessary"? They could say that not having hearing at all isn't a necessity because they could use ASL if Washington passes this law then there will be no telling what you pass a law on next. It should no ones choice whether a child can hear but theirs and their parents. My daughter will thrive with this technology and she will be the best of her "disability". Thank you for taking the time to read this and I hope you really hope you as a state do not pass this law. God Bless."</p>	
<p>November 20, 2012 letter from Julie Olson (parent of children with cochlear implants)</p>	
<p>"My name is Julie Olson and I have 2 boys both born with profound hearing loss. My son Jayden is 9 yrs old and he had unilateral done at the age of 9 months old, he was the youngest in New England at the time. Back then they did not believe in the bilateral so we went with the one and 3 years later the topic came up and the studies I was reading and learning about from the team of people Jayden worked with at school that the bilateral is more efficient and better to have done as a toddler. So I started to move forward for Jayden to have the second ear done. When Jayden had the second implant surgery he was 5 years old at a special school for hearing impaired kids with cochlear implants, today Jayden is 9 and back home in our local public school in second grade with outstanding grades. We also have a son named Jackson who is 4 on December 5th. Jackson was lucky that the policy changed and instead of having to put him through two surgeries and the healing process. He had the bilateral done at the age of 19 months he is doing wonderful wearing them full time and his vocabulary is still a little slow but it is so important to have the bilaterals done. The hearing paired have use of both there ears so why not the hearing impaired as well. I ask you to do what I was told to do from my sons audiologist she had me put cotton in my ear and then cover it, it was so much harder to hear what she was saying. It is a very safe procedure to have done both my</p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>

<p>boys have Dr. Daniel Lee he is at Mass Eye and Ear Infirmary in Boston, MA. He is the best and as a Dr. he put both boys through testing to make sure they met the height, and weight criteria to have it done. He checked to make sure they would also be ok to be put under for the surgery. Please support the Bilateral implants for children its beneficial to them at such a young age the younger they are they grow into them and they don't try to take them off. Also studies show that 2-5 yrs of age is a childs most crucial time in learning and to talk. Jayden was delayed alot then after the surgery for the second one he caught right up to his age lvl. My husband and I never hesitated to have the procedure done it was the best thing for both of my boys, and when they were first activated and heard the words I love you from me for the first time it was such a feeling of complete aww. As parents we are the only ones to advocate for our children and I do just that. I am part of the Walk4hearing (Hartford, CT) Chapter who helps raise funds for advocacy, implants, equipment, educating, surgeries to those who can't afford it. Thank-you for your time.”</p>	
<p>November 23, 2012 letter from Emily Mandelbaum (cochlear implant recipient)</p>	
<p>“Altho I am 76, some benefits of my bilateral implantation likely apply to any age and my experience does address some issues posed in the DRAFT Key Questions. Because I was functionally deaf on both sides when I received the Nucleus22, that single implant initially seemed like a restoration of hearing. My unimplanted side was too deaf to benefit from a hearing aid Although a top performer, I soon learned the limitations of single sided “hearing”. Background noise, using the phone, sound location, the work required to understand, still limited my social life and caused stress. Often by evening I was too tired to listen and shut off my sound processor. Still I had difficulty believing a second implant would make much difference and wondered if these 2 very different implants would work well together. Having a second implant in case one failed was a major reason I finally applied to become bilateral. My internal N22 has never failed, nor the succession of sound processor upgrades, but my first processor, the Spectra, did quit once during a vacation. Abruptly returning to complete deafness was frightening. Without my husband’s presence, it would have been terrifying and left me unable to manage away</p>	<p>Thank you for your comment. No change to Key Questions.</p>

<p>from home.</p> <p>I qualified and received the Nucleus 5 in 2011. Altho the newly implanted ear hadn't been stimulated for about 20 years, I could hear and understand some speech with it almost immediately. I spent 3 months using it alone to bring the associated dormant part of my brain up to speed.</p> <p>At 3 months I comprehended with the new implant as well as with the old. I began using the 2 together and found, after a week or so, that they complemented each other. Each seemed to provide a different component, together giving me fuller, richer more complete sound. This was dramatic the first time I listened to music. On the bird walks I love, it was much easier to pick up songs and calls. People started telling me I heard them better. Although background noise was still a problem, I was more relaxed in all settings and sometimes at no more disadvantage than hearing people. I no longer needed to shut down in the evenings. I purchased a Bluetooth/telecoil/loop device which allowed me conduct phone calls using both sides without the tensing and dread I always experienced with the single implant. My ability to localize sounds improved just slightly. Thankfully I know that, if necessary, I can still function using just one implant. I also know that one implant now seems very inadequate for my listening and living needs."</p>	
<p>November 26, 2012 letter from Michelle Benavides (parent of a child with cochlear implants)</p>	
<p>Summary: Shared story of son's experience with bilateral cochlear implants.</p> <p><u>Excerpt</u>: "I am writing to explain why it is an absolute necessity to provide bilateral hearing to children with cochlear implants in Washington State. I cannot stress enough the importance and benefit of having bilateral hearing. . . If you do research you will find that a tremendous amount of language learned by toddlers is from 'incidental hearing' or 'incidental language'. Normal hearing toddlers pick up language by overhearing other conversations around them that they are not directly apart of. Children with hearing loss and limited hearing (such as only being allowed to have one cochlear implant) have a much smaller 'hearing bubble'. As a direct result they pick up very little, if any at all</p>	<p>Thank you for your comment.</p> <p>No change to Key Questions.</p>

<p>‘incidental language’ and miss out on so much language opportunity. . . Remember these children are still learning language, grammar, and oral communication. And remember they are delayed compared to hearing children and have a lot of work to do so we cannot afford to make their work more challenging. We cannot continue to minimize their hearing by only affording them one hearing ear. Our children need bilateral hearing. Please understand the vital need of bilateral hearing, especially in children that are still developing and learning.”</p>	
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