

Cochlear Implants: Bilateral versus Unilateral

Draft Report - Public Comments

April 17, 2013

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Bilateral Versus Unilateral***

Response to Public Comments on First Draft

April 17, 2013

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

This document responds to comments from the following parties:

- Washington Health Care Authority (WA HCA) Agency Medical Directors
- Melissa Larson, parent of a child who has received bilateral cochlear implants (CI)
- John K. Niparko, MD, Chairman of the Board; Donna L. Sorkin, Executive Director, American Cochlear Implant Alliance
- Susan J. Norton, PhD, Co-Director of the Seattle Children’s Hospital Pediatric Cochlear Implant Program
- Rainer Platz, President, Advanced Bionics, LLC; Chris Smith, President, Cochlear Americas; Richard Collette, President/CEO, Med-El Corporation
- Patricia A. Prelock, PhD, CCC-SLP, President of the American Speech-Language-Hearing Association
- Jay T. Rubinstein, MD, PhD, Director of the Virginia Merrill Bloedel Hearing Research Center; Professor Of Otolaryngology & Bioengineering, University of Washington; clinical expert assigned by Washington HTA to this report (email messages).
- Kathleen Sie, MD and Susan Norton, PhD, Co-Directors of the Cochlear Implant Program; Seattle Children’s Hospital

Table 1. Public Comments on the Final Report, *Cochlear Implants: Bilateral Versus Unilateral*

Comment and Source	Response
WA HCA Agency Medical Directors	
<p>“Unilateral cochlear implantation for select populations of patients, particularly prelingual pediatric patients with severe to profound hearing loss, is accepted as a standard of care. However, bilateral cochlear implantation, either simultaneous or sequential, remains controversial. While speech perception in noise and left-right sound localization are improved with bilateral cochlear implantation, these measures are surrogate markers of hearing-related function, overall health and quality of life. In addition, reported utility gains from unilateral to bilateral cochlear implantation vary widely in the literature and subsequently challenge all cost effectiveness analyses. The differential effectiveness of bilateral as opposed to unilateral cochlear implantation must be considered in the framework of additional risks associated with the second procedure, as well as additional associated costs of both the procedure and replacement hardware. “</p>	<p>This is a good summary of the background material and is consistent with the evidence reviewed for this report. The issue of surrogate measures for functional outcomes is discussed in the report. Changes have been made in the report to better highlight the safety risks.</p>
<p>“This technology assessment report is further challenged by the various comparator groups and study designs, and this report would benefit from reorganization. As presently structured the report is very difficult to read. For example, some of the key questions are split between “children” and “adult,” and others are not.</p>	<p>Thank you for this feedback. Subheadings have been altered.</p>
<p>“In addition, the comparator group is not always clear, i.e. same patient with unilateral implant with repeat testing following second implant, unilateral implant with hearing aid versus separate group with bilateral implant. While the study design is clearly outlined in Table 1, this table is not consistently</p>	<p>The comparator group is indicated for each study in the evidence tables (Appendices IV and V). Since the findings were typically consistent across comparators, findings were not generally discussed or analyzed by comparator. However, in those few places where there was some inconsistency across</p>

Comment and Source	Response
referenced throughout the report.”	studies, comments were made in the Literature Review discussion about whether the inconsistency followed a pattern according to comparator and study design. Links to Table 1 have been added throughout the report.
<p>“The hyperlinks are not helpful. Linking to summary tables and appendices would be helpful, or having links in the table to the original articles would be helpful. The present hyperlinks to later sections in the report are particularly confusing because the link takes the reader to a section which has a different title, i.e. “In Noise” on p. 52 links to “Speech Perception in Noise” on p. 20. This section also references Appendix IV-B. The information in Appendix IV-B is useful, would recommend either the addition of a hyperlink to Appendix IV-B or moving this table into the body of the report.”</p>	<p>Thank you for these suggestions. Linked headings have been made consistent and links to the evidence table appendices have been added to the EVIDENCE SUMMARY. Copyright law does not permit Hayes to make published articles available.</p>
<p>“p. 2 The authors of this report reveal their biases throughout. Please justify this declarative statement, “This suggests that unilateral implantation in children with bilateral hearing loss may not afford optimal benefits.” The statement appears to be the opinion of the authors of this report rather than an unbiased summary of the background information upon which this report is based. Please clarify how this conclusory statement was derived.”</p>	<p>The text has been altered to read: “In describing the rationale for exploring the effect of a second CI, one group of researchers (Nittrouer et al., 2009) cited studies assessing children with untreated unilateral hearing loss and described these studies as having shown that compared with normal hearing children, such children have deficits in language learning and speech perception. Nittrouer and colleagues suggest that unilateral implantation leaves children with bilateral hearing loss in a condition comparable to unilateral hearing loss.”</p>
<p>“. Please also clarify this conclusory statement: “situations in which the benefits of bilateral implantation may be especially critical include noisy classroom settings for school children and outdoor settings that involve hazards such as those associated with crossing the street.” Please provide the evidence basis</p>	<p>The text has been changed to read: “The expectation of researchers interested in bilateral CI is that the benefits would be especially critical in noisy classroom settings for school children and in outdoor settings that involve hazards such as those associated with crossing the street.”</p>

Comment and Source	Response
for this statement; references are included on p. 38 but not on p.2.”	The authors cited at the end of the paragraph on p. 38 are representative of the expectations described in this paragraph. References were omitted from the EVIDENCE SUMMARY, in keeping with the standard style for executive summaries.
““Simultaneous implantation, or sequential implantation with little delay between the procedures, is potentially more advantageous in that it prevents a lack of coordination between the two devices that could diminish binaural cues and avoids timing differences in auditory brainstem activity that can develop during the time between implants.” Please provide the evidence basis for this statement.”	The references, which were inadvertently omitted, have been added, and the text slightly altered: “. . . some experts believe that simultaneous implantation, or sequential implantation with little delay between the procedures, is potentially more advantageous in that it may prevent a lack of coordination between the two devices that could diminish binaural cues and avoids timing differences in auditory brainstem activity that can develop during the time between implants (Smulders et al., 2011).”
“p. 22 Table difficult to interpret, could be helped by addition of p values, i.e. “In Quiet” has SRT of 71% for both comparator and bilateral CI results, with ranges 42-45 dB for comparator and 42-48 dB for bilateral. How is this significantly different?”	We appreciate the challenges this table presents to the reader and the comments on points of possible misinterpretation are very helpful. This table is a first attempt to include, at the request of the HTCC, a Summary of Findings table similar to what is currently recommended for the GRADE system. Unfortunately, the data from the studies in this report do not lend themselves to simple aggregation. A text reference to the footnotes has been added to the column headings; one of the footnotes explains the meaning of the SRT-71% results. Omitting <i>P</i> values was felt to be necessary to keep from further detracting from the at-a-glance purpose of the table by excessive detail. The evidence tables in Appendices IV and V show <i>P</i> values. The 42-45 and 42-48 dB ranges are not meant to suggest significance; additional explanation has been added to the column headings.

Comment and Source	Response
<p>“p. 22 Summary of findings table, footnotes: Numerical scores for some studies were missing and/or “Where possible, scores were estimated from bar graphs,” how was a moderate level of evidence rating derived if scores were missing or estimated? In addition it appears that all comparators were internal (single cochlear implant prior to implantation of second cochlear implant) and none of the comparators included a contralateral hearing aid?”</p>	<p>Only a couple of studies failed to provide any quantitative information at all. Several represented magnitude of benefit with bar graphs. Even where numerical data were missing, statistical testing based on quantitative data was usually reported. Lack of numerical results may be considered poor reporting and may make precise estimates more difficult but does not diminish our confidence in the internal validity of the study or affect interpretation of the direction of findings.</p> <p>The phrase “all forms of comparison” has been added to the column heading.</p>
<p>p. 23 Specify the utility instrument for “Disease-specific scale” rather than list “Disease-Specific scale” on multiple lines. It would be helpful to add a p value rather than the additional text at the bottom stating the “statistically significant absolute differences.”</p>	<p>All scales and tests are named in the evidence tables (Appendices IV and V). Multiple <i>P</i> values, not just one, would have to be added at the bottom sections of the results cells. <i>P</i> values do appear in the evidence tables.</p>
<p>p. 37 “Hearing loss may cause serious linguistic, cognitive, emotional, educational, social and employment problems.” This statement conflicts with the statement on p. 20: “Neurocognitive development: No studies evaluated this type of outcome.” This statement also conflicts with the statement on p. 33: “Long-term impact on educational achievement or employment has not been studied.”</p>	<p>The first statement refers to the effects of <i>hearing loss</i> and appears in the BACKGROUND section.</p> <p>The other two statements appear in the context of findings from studies exploring the benefits of <i>bilateral CI</i>. The last sentence has been modified to read “The long-term impact of <u>bilateral CI</u> on . . .”</p>
<p>pp. 36-48. Background, Technology description, Outcome measures, PICO and key questions are listed twice in this report. These sections should be combined to help the overall organization of the report and included either before or after the summary section. Some of the sentences are identical; these sentences do not need to be repeated in the report.</p>	<p>The sections named in the comment appear in the front part of the report in summary form and in the back part of the report with more detailed information, in keeping with the guidance that has been given to evidence vendors.</p>
<p>“p. 38 Example of bias of the authors of this</p>	<p>The text explains that these effects are</p>

Comment and Source	Response
report. Retitle Box 1 from “Elements of the Bilateral (Binaural) Advantage” to “Definition of Binaural effects.”	phenomena that humans benefit from because they have 2 ears. The phrase “in Normal Hearing Individuals” has been added to the Box title.
<p>“p. 60 The harms and risks associated with cochlear implantation is underemphasized in this report. A major complication rate of 6.8% in pediatric procedures is significant; please elaborate on these specific complications. Minor complication rates of 34.7% in pediatric procedures and 35.3% in adult procedures is significant, please elaborate. Major complications rates of 8.9% and minor complication rate of 7.8% are significant; please elaborate on these specific complications. Facial nerve paralysis (damage used on p. 16), prosthesis rejection, vestibular symptoms, no improvement in hearing, CSF otorrhea, and permanent explantation have been reported in the literature and were not mentioned in this report. The committee will need to decide about an acceptable complication rate for a procedure which is life altering but not life-saving and insufficient evidence was provided in this report.”</p>	Thank you for calling attention to the unclear presentation of safety data. The section on Key Question #2 in both the EVIDENCE SUMMARY and the FULL REPORT has undergone significant revision, and statements about safety throughout the report have been modified.
<p>“p. 64 The cost analyses utilize wide ranging utility gains (the multiplier), which ranged from .63 to .03. Given the broad range of quality of evidence listed in Appendix IV-E and V-D, how useful is this cost effectiveness analysis and how reliable are the ICER calculations?”</p>	The ICER calculations are indeed unreliable and thus the Overall Summary paragraphs for children and for adults include this statement: “The cost-effectiveness of bilateral CI in [children and adolescents/adults] is unknown because no cost-effectiveness studies using a reliable estimate of effectiveness have been published.” (‘0.63’ is a typographical error and has been amended to 0.063.)
Melissa Larson (parent)	
The commenter’s daughter was born with profound hearing loss due to a genetic cause, did not benefit from hearing aids, and underwent simultaneous bilateral CI at age 9.5 months. The commenter is very happy with	Thank you for this real-life illustration.

Comment and Source	Response
<p>her daughter’s progress. She writes “We have always had bilateral CI’s, so I can’t comment on 1 vs 2 implants, but I know that when she was only activated on 1 side, she was not able to localize sound at all. She could hear a sound and even if it was on the side she could hear, she would do a full 360 degrees turning to find it.”</p>	
<p>John Niparko and Donna Sorkin (American Cochlear Implant Alliance)</p>	
<p>“We believe that our original comments, filed on behalf of ACI Alliance by Dr. Zwolan and Ms. Sorkin, were a comprehensive and accurate summary of the published literature on bilateral cochlear implantation as related to patient outcomes, safety, and cost effectiveness.”</p>	<p>Thank you. Comments submitted and references cited in the Alliance’s response to the Key Questions were taken into consideration in the preparation of this report.</p>
<p>“The cost effectiveness of cochlear implants has been demonstrated by numerous studies. Mohr et al (2000) calculated the lifetime cost to society for a child born with prelingual onset deafness to exceed \$1 million. An average societal cost of deafness for individuals of all ages was determined to be \$297,000. Most of this cost—67%—was attributable to reduced work productivity. The additional cost of a second (bilateral) cochlear implant is relatively small given the dramatic positive effect of restored hearing on an individual’s ability to function in high communication settings, such as educational venues or the workplace. Workplace impacts are significant for working age adults with severe to profound hearing loss, a demographic that has traditionally experienced high unemployment as well as underemployment due to their deafness.”</p>	<p>The study by Mohr and colleagues appears to be an assessment of the economic burden of hearing loss. The commenters do not indicate whether the authors assessed the cost consequences of CI. Only cost analyses comparing the cost consequences of unilateral and bilateral CI, or assessing the cost-effectiveness of bilateral CI compared with unilateral CI, were eligible for review in this report.</p>
<p>“Recent work by Sevenov et al (2013) [should be Semenov] assessed 175 children who had received unilateral and bilateral cochlear implants. The study determined that unilateral and bilateral cochlear implants in children was</p>	<p>Assessing the cost-effectiveness of CI compared with no CI was not within the scope of this report. The Semenov study includes bilateral CI as an explanatory variable in the model but does not assess the cost-</p>

Comment and Source	Response
<p>highly cost effective, with the greatest cost effectiveness found in the children who were implanted at the youngest age. Over the lifetime of the child, the cost of the implant is relatively small given the important benefits provided by bilateral hearing.”</p>	<p>effectiveness of bilateral CI compared with unilateral CI.</p>
<p>Susan Norton (Seattle Children’s Hospital)</p>	
<p>“For at least the past two years the Medicaid program has refused to cover bilateral cochlear implantation either simultaneous to sequential for children in Washington State. This appears to be an absolute rule with no exceptions for children with deafness due to meningitis where the risk of cochlear ossification is high or children with Usher’s syndrome who suffer from progressive vision loss in addition to deafness.”</p>	<p>Thank you for these insights. A reference to visual impairment as a possible concomitant disability has been added to the statement in the OVERALL SUMMARY about the subpopulations who have not been well studied.</p> <p>The issue of possible meningitis-induced ossification in children where meningitis was the cause of hearing loss appears to be relevant for choosing simultaneous over sequential bilateral CI but does not seem to speak to the effectiveness of bilateral CI over unilateral CI.</p>
<p>“Cochlear implant technology has improved greatly in subsequent years. At the present time infants who are implanted early and receive appropriate therapy and educational intervention are expected to achieve age appropriate auditory-oral speech and language and academic outcomes.”</p>	<p>The available evidence for this report does not permit conclusions specific to bilateral CI in infants. No unilateral-bilateral comparative studies were restricted to infants and studies that reported outcomes according to age at second implant used higher age cutoffs. None of the studies excluded because of sample size <20 provided data specific to infants.</p>
<p>“ . . . we know that the first three years of a child’s life are critical for acquisition of speech and language and other skills. Without access to sound during this critical period the likelihood of normal auditory-oral language development decreases. Thus, for pre-lingually deaf and hard of hearing infants waiting [for future development of treatments that can induce hair cell regeneration] to intervene is not an option. “</p>	<p>The report acknowledges in the BACKGROUND and LITERATURE REVIEW sections that there is reason to expect that CI might be more effective the earlier it is performed, and Key Question #3 attempts to address this very important issue. The studies that evaluated either age at first implant or age at second implant as a modifier of the effect of bilateral CI or as a treatment success predictor in children receiving bilateral CI reported conflicting findings. The report acknowledges that “given the very poor quality of the</p>

Comment and Source	Response
	available evidence, future findings could alter the conclusions that are possible at this time.” (See FULL REPORT, LITERATURE REVIEW, (Children) Findings, Key Question #3.) The report also acknowledges this issue in the Gaps in the Evidence section (see EVIDENCE SUMMARY, OVERALL SUMMARY AND DISCUSSION).
“Finally, there is an increasing body of evidence indicating that the lack of binaural hearing leads to academic and social-emotional delays (for a review see Lieu, 2004).”	The commenter does not provide a full reference to this review article and does not identify individual studies that should have been included in the report but were not.
<p>“Binaural hearing is critical for spatial hearing . . . Even in normal hearing listeners the binaural advantage for thresholds is only 3dB so looking at threshold changes wearing two implants compared to one implant is not a reasonable question. Studies looking at skills and tasks known to require binaural hearing such as localization is more meaningful.”</p> <p>A study (Murphy et al., 2011) is cited, and results are described as showing that speech perception in noise and localization were superior in bilateral CI users compared with unilateral CI users.</p> <p>“Other groups including Litovsky and colleagues at the University of Wisconsin (2012) report similar findings.”</p>	<p>Thank you for this reminder of one of the key benefits to bilateral CI. The particular potential benefit of bilateral, as opposed to unilateral, CI to localization is acknowledged in the BACKGROUND section of the report, and the report concludes that there is “moderate-quality” evidence showing an association between bilateral CI and improved localization in children, with the small quantity of data (5 studies, 170 participants) cited as the chief limitation in this body of evidence.</p> <p>Additional language highlighting magnitude of improvement in localization over unilateral CI has been added to the discussions of study findings in the FULL REPORT and in the EVIDENCE SUMMARY, as well as in the OVERALL SUMMARY AND DISCUSSION (see Overall Summary and Discussion; also, Other Considerations).</p> <p>The study by Murphy et al. was excluded because of sample size, but its inclusion would not have altered conclusions. The 2012 article by Litovsky and colleagues appears to be primarily a review article; the commenter does not identify any omitted primary studies.</p>
Rainer Platz, Chris Smith, and Richard Collette (CI manufacturers)	
“One of the benefits of binaural hearing is	This is an important point and is reflected in

Comment and Source	Response
<p>sound localization . . . there can be a difference in the time a sound reaches each ear.”</p>	<p>the BACKGROUND section of the report. No changes are required.</p>
<p>Functional abilities needed by people with hearing loss have been identified by the National Institute for Rehabilitation as including the ability to hear and recognize different sounds and noises, recognize direction from which a warning sound is coming, hear and understand isolated speech, pick out a single voice, discriminate and recognize individual voices, and discriminate and understand voices from electronic equipment.</p>	<p>These abilities are reflected in the tests and outcome measurement instruments that are described in the report.</p>
<p>“The deficits of hearing with only one ear are well-documented and well understood. Many adults with hearing in only one ear (monaural or unilateral hearing) report significant difficulty understanding speech in noise and localizing sounds. They also report that listening with one ear requires extra effort and leaves them fatigued by the end of the day. Studies have shown that children with unilateral hearing loss experience significant educational challenges.”</p>	<p>One of the references cited in this paragraph is a textbook, which is not accessible to the report author. Abstracts for the other two cited references suggest that these studies are not designed to demonstrate the statements made by the commenter. However, the report acknowledges in the BACKGROUND section that these types of assumptions have been cited by researchers as the rationale for studying the effects of bilateral CI.</p>
<p>“As with hearing, Vision is a two-sided, or binocular system . . .”</p>	<p>Thank you for this analogy. No changes in the report are required.</p>
<p>“Since 2000, recipients with severe to profound hearing loss (more residual hearing) have been implanted, and device technology has significantly improved, thus, ceiling effects have been observed on test measures even in the unilateral condition . . . Test materials with ceiling effects in the unilateral condition are not sensitive to binaural benefits. . . Most studies in the literature captured by the HTA report results from easier sentence materials in use prior to newer, more challenging test materials currently being adopted. Thus, the current evidence provides a highly conservative (likely underestimated measure</p>	<p>This is an important consideration. The report acknowledges ceiling effects as a possible limitation for certain studies and in the description in Appendix I of the reason for certain newly developed tests.</p> <p>Actually, in the selected studies of children, testing of speech perception was overwhelmingly conducted with the use of word recognition, not sentence recognition, tests.</p>

Comment and Source	Response
of binaural benefits from bilateral CI due to the lack of measurement sensitivity.”	
The commenters point out that the feasibility of randomized controlled trials is limited because of the small pool of participants and that while patient-blinded trials are not possible, there would be no placebo effect in individuals with profound hearing loss. The commenter notes that therefore, the most common study design is a single-subject design with repeated measures.	The report reviews the strengths and weaknesses of the commonly used study designs.
The commenters cite the UK technology assessment (Bond et al., 2009) and the cost-utility study by Semenov et al. (2013) as sources for the view that withholding CI from children is ethically unacceptable.	The comments in the cited sources refer to CI in general, not specifically to bilateral CI.
The commenters cite sources providing a rationale for early intervention in children with hearing loss (Sharma et al., 2005; Semenov et al., 2013).	The cited studies apply to CI in general, not specifically to bilateral CI.
The binaural benefits from head shadow and summation effects develop early following bilateral implantation while binaural squelch typically appears later at 6 to 12 months post op. While most studies follow subjects for only 12 months post-CI, one long-term study demonstrated that binaural squelch benefit continues to improve beyond 12 months as recipients gain experience with bilateral cochlear implants.”	The cited study (Eapen et al., 2009) was excluded from the report because of small sample size (n=9).
“Semenov concluded determined [sic] that cochlear implantation (unilateral and bilateral) was highly cost-effective and that the greatest cost effectiveness was associated with the children implanted at the youngest age.”	The study includes bilateral CI as an explanatory variable in the model but does not assess the cost-effectiveness of bilateral CI compared with unilateral CI.
The commenters cite Mohr et al. (2002) as evidence that “implants produce substantial savings from a societal perspective.	The study by Mohr and colleagues appears to be an assessment of the economic burden of hearing loss. The commenters do not indicate whether the authors assessed the cost

Comment and Source	Response
	consequences of CI.
<p>“In the UK, the National Institute for Clinical Excellence (NICE) reviewed bilateral vs unilateral cochlear implantation and notes that the use of the 0.03 cost utility estimate found for bilateral cochlear implantation in adults likely results in an underestimate of the cost-utility of bilateral cochlear implantation for children.”</p>	<p>The lack of a reliable utility estimate and the application to children of a utility value derived from adults are both acknowledged in the report.</p>
<p>The commenters quote a passage from the NICE guidelines about expert testimony concerning the importance of early stimulation and the NICE committee’s decision not to distinguish between prelingual and postlingual deafness in its guidance.</p>	<p>Thank you for pointing this out. A note about this has been added to the report’s discussion of the NICE guidelines.</p>
<p>“In addition, NICE supported coverage of bilateral implantation for adults with special needs requiring an additional dependence on their sense of hearing.”</p>	<p>This is covered in the report.</p>
<p>Patricia Prelock (ASLHA)</p>	
<p>Research has supported the benefits of bilateral cochlear implantation in children and adults with hearing loss who show no benefit from conventional amplification. Bilateral cochlear implantation has been shown to provide important benefits gained from the binaural stimulation of the auditory system. Particularly, studies show improved speech perception ability in quiet and in noise, greater ease of listening as well as improved localization to sound. ASHA is happy to endorse the findings of this report and encourage you to support access to binaural cochlear implantation for individuals who may benefit.</p>	<p>Thank you for your comment. No changes in the report are required.</p>
<p>Jay Rubinstein (clinical expert)</p>	
<p>Paraphrase:</p> <ul style="list-style-type: none"> • No comment on quality ratings, but 	<p>Thank you for your comment. No changes in the report are required.</p>

Comment and Source	Response
<p>overall sense of the conclusions is correct.</p> <ul style="list-style-type: none"> • Other benefits are possible, but improved localization is a virtually guaranteed benefit from bilateral cochlear implantation (CI). • Sound localization is of critical safety importance to the individual but this advantage may not be detected by general quality of life (QOL) measures of the benefits of CI. 	
Kathleen Sie and Susan Norton (Seattle Children’s Hospital), March 10, 2013	
<p>In response to each of the Key Questions, findings from a small number of studies or review articles are described.</p>	<p>Thank you for your comment. Most of the cited references are included in the report. A few of the cited studies do not appear in the report because they were excluded on the basis of sample size. An article (Nadege et al., 2011) cited by the commenters evaluates the methodological characteristics of cost studies but includes only one of the 6 available economic evaluations of bilateral versus unilateral CI. No additions were made to the report.</p>
<p>“We have performed 16 bilateral simultaneous cochlear implants in children with bilateral profound hearing loss. There has been one wound complication. Otherwise the bilateral procedure seems to be well tolerated and saves the expense and risk of two anesthetics and two hospitalizations.”</p>	<p>Thank you for your comment on practice experience at Seattle Children’s Hospital.</p>
<p>“Indirect support for the cost utility of bilateral cochlear implantation in children can be extrapolated from the European Bilateral Pediatric Cochlear Implant Forum consensus statement (Ramsden JD, et al. European Bilateral Pediatric Cochlear Implant Forum Consensus Statement. <i>Otolaryngology</i> 2012;33:561-565.). In fact they recommend bilateral simultaneous CI.”</p>	<p>Thank you for your comment. The referenced consensus document was not included in the Practice Guidelines section because it was not intended to provide guidance for practice in the U.S. and was not produced by an internationally recognized policy organization or health technology assessment (HTA) agency.</p>

Comment and Source	Response
<p>“As the benefit with unilateral cochlear implantation in young children has been well established, the incremental benefit of second side cochlear implant has been more recently studied. We recognize that there are limitations to many of the studies cited. Based upon our review of the literature and our team’s experience with bilateral cochlear implantation in children, we feel that children with severe to profound hearing loss and/or no demonstrable benefit with amplification in the non-implanted ear will likely benefit from second side cochlear implantation, regardless of the interval between first and second side surgery. Specifically, appropriately selected patients can expect to get improved access to speech information, improved speech in noise and localization, listening and patient satisfaction with second side cochlear implant.”</p>	<p>Thank you for your insights. No changes in the report are needed.</p>
<p>“The difference in performance between children receiving simultaneous versus sequential second side cochlear implants is not yet clear. Several authors have reported on the safety and cost savings of bilateral simultaneous CI in young children. However it is critical to verify the candidacy of young children before they undergo bilateral simultaneous CI, particularly with the evidence of the benefit of bimodal stimulation for children with any residual hearing.”</p>	<p>Thank you for your comment. No changes in the report are needed.</p>