OUR MISSION:

To advance access to the gift of hearing provided by cochlear implantation through research, advocacy and awareness.

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Washington State Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42682
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To Whom it may concern:

The American Cochlear Implant Alliance (ACI Alliance) is pleased to submit comments on the Washington State Heath Technology Assessment on Bilateral Cochlear Implants.

The ACI Alliance is a newly established non-profit organization of clinicians, scientists, and educators who work in the field of cochlear implantation as well as parent and consumer advocates. Our mission is to advance the gift of hearing provided by cochlear implantation through research, advocacy and awareness.

Our membership includes physicians, audiologists, speech language pathologists, teachers of deaf children, researchers, parents of children with cochlear implants and adult cochlear implant recipients. We address issues impacting access to, and quality of, health care relating to cochlear implantation.

1. Compared with unilateral CI or with unilateral CI plus acoustic hearing aid, does bilateral CI for hearing loss improve detection of sound, neurocognitive development, perception or production of speech, functional status, quality of life, or other patient-important outcomes?

Binaural hearing is a fundamental property of the human auditory system; numerous studies have demonstrated that two ears are better than one (Colburn et al., 2006). Listening with two ears provides important benefits, such as the ability to tell the direction from which a sound is coming (localization), enhanced listening with two

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ears when compared to one ear (binaural summation), and improved speech recognition in the presence of background noise, particularly when the speech and noise are spatially separated, causing each ear to have a different signal to noise ratio (also known as the head shadow effect). Additionally, when listeners use two ears, the central auditory system compares level and timing differences between the two ears to improve speech recognition in noisy situations (also known as binaural squelch). Numerous investigators have demonstrated that these benefits hold true for patients who utilize two hearing aids (Noble, 2006) and for those who utilize bilateral cochlear implants, which is the focus of this response.

When a child is only able to hear in one ear (unilateral hearing loss), they lose these binaural benefits and often experience speech perception and language acquisition difficulties (Bess & Tharpe, 1984; Ruscetta, Arjmand, & Pratt, 2005). Children who receive a unilateral implant are similar to those with a profound unilateral hearing loss in that they, too, are unable to take advantage of the benefits associated with binaural hearing.

There is a vast amount of peer-reviewed literature that supports the benefits of bilateral cochlear implants (see below).

Improving detection of sound

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. This improved ability to localize has been found to be true when bilateral CIs were compared to a unilateral CI (Dunn et al., 2008; Litovsky et al, 2004, 2006a; Laszig et al, 2004; Tyler et al., 2003) and when bilateral CIs were compared to a unilateral CI plus a hearing aid (Noble et al., 2008).

Perception or production of speech

It has been documented that use of bilateral CIs results in improved speech understanding in quiet (Litovsky et al., 2006; Laszig et al, 2004; Tyler et al, 2003) and in background noise (Litovsky et al, 2006; Laszig et al, 2004; Tyler et al, 2003). Schoen et al (2002) demonstrated that subjects heard significantly better in the

bilateral condition when compared with results obtained with their better hearing unilateral CI ear.

Functional status

Provision of bilateral cochlear implants provide 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 (Litovsky et al., 2004;Bichey & Miyamoto, 2002; Litovsky et al., 2006).

Quality of life

Numerous researchers have found that bilateral CI users demonstrate improvements in quality of life. Bichey et al. (2008) performed a prospective case-control study of 23 bilateral cochlear implant patients and found a 0.48 mean gain in health utility after bilateral cochlear implantation and a discounted cost per quality adjusted life year of $24,859. When patient scores for unilateral and bilateral use were compared, improvements in the domains of hearing, speech, emotion, and cognition were noted, resulting in a mean gain in health utility of 0.11. .Sparreboom et al. (2011) assessed quality of life before children received a second implant and after 12 and 24 months of using two implants. Disease-specific questionnaires indicated that unlike the children with a unilateral implant, quality of life measures continued to improve with longer durations of bilateral implant use. The age at second implantation had no influence on the gain in quality of life, the researchers found.

Other patient-important outcomes

Presently, there is no way to preoperatively predict which ear will stimulate optimally to a cochlear implant when only one ear is selected to receive a cochlear implant. Thus, implanting both ears ensures that the optimal ear is implanted, maximizing outcomes.

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2. Is bilateral CI safe?

The FDA regulates cochlear implants by requiring manufacturers to conduct clinical trials prior to receiving approval for widespread use. All three brands of present day cochlear implants have been through FDA clinical trials for both adults and children and were found to be safe and effective for both the adult and pediatric populations.

There is no reason to believe that provision of 2 implants would be less safe than provision of one implant and the literature supports this. Studies have examined possible side effects including vestibular function, prolonged operative time (in simultaneous surgeries), additional blood loss (especially in young children), and surgical complications. All such studies have concluded that bilateral implantation in children is a safe procedure (Barton et al 2006, Kawano et al 1998, Ramsden et al 2009, Grainger et al 2012).

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. Ultimately, the decision on whether to utilize simultaneous versus sequential provision of cochlear implants should be based upon the individual clinician's medical assessment of a particular child. 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 (Basura et al 2009, Migirov et al 2009, Ramsden et al 2012).

A forthcoming publication (Semenov et al) evaluates the effectiveness of implantation at various, early childhood ages. The authors observed that implantation of children with bilateral implants had no more complications than children with unilateral implants.

Both simultaneous and sequential cochlear implantation are safe for children.

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3. Does the effectiveness or safety of bilateral CI vary according to age at implantation, prelingual vs postlingual onset of hearing loss, duration or

degree of deafness, choice of implanted ear, time interval between implantations, specific device, or provider characteristics?

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. In regards to age at implant and time interval between implantations, Peters et al (2008) found that children implanted sequentially acquire open-set speech perception in the second ear relatively quickly (within 6 mo). However, children younger than 8 years do so more rapidly and to a higher level of speech perception ability at 12 months than older children. Conversely, Zeitler et al (2008) found that, on average, the speech recognition skills of patients with sequential bilateral cochlear implants improved over time, despite length of deafness, time between implants, or age at implantation. To our knowledge, bilateral cochlear implants have not yet been investigated as they relate to specific device (manufacturer) or provider characteristics.

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4. What are the cost implications, including cost effectiveness of bilateral CI?

The cost effectiveness of unilateral cochlear implantation has been extensively studied and documented for both children and adults. For children, the lifetime cost benefit for a young deaf child provided with access to sound via one cochlear implant, considering educational savings and potential job earnings, exceeded $1 million (Cheng et al 2000). Given that the lifetime costs of deafness estimated by Cheng are so high, even allowing for a doubling of the cost of the surgery and follow-up from $60k to $120k (Cheng et al 2000), would yield a favorable cost effectiveness outcome and societal benefit. Other studies have also confirmed the cost effectiveness of unilateral CI (Mohr et al, NICE).

Studies have also looked at bilateral CI in a cost effectiveness framework. A prospective study (Bichey and Miyamoto 2008) of 23 bilateral patients utilized the Mark III health utility index and found a 0.48 mean gain in health utility after bilateral

cochlear implantation and a discounted cost per quality adjusted life year of $24,859. Improvements from unilateral to bilateral use indicated a mean health utility index improvement of 0.11.

A study from the UK (Barton 2006) of 403 implanted children also used the Mark III index and found that the cost utility index for bilateral CI fell within the acceptable limits overall with some variability depending upon child characteristics. The study found it was important to view outcomes over the longer term (i.e., at least15 years). Higher indices were associated with children who received CI at a younger age and had a worse preoperative hearing level. The latter factor makes sense; in general individuals who derive significant speech and environmental perception information from a hearing aid contralateral to a CI, benefit from continued hearing aid use on that side.

In an in press publication by Semonov et al that evaluated the cost-effectiveness of implantation at various, early childhood ages the authors found that children implanted at ages under 18 months achieved greater QALY gains across their expected lifetime without increased costs of care when compared with children implanted at older ages. Children implanted at ages under 18 months of age were integrated into mainstream classrooms at an earlier age than children implanted later. A key conclusion of this work is the observation of a net societal savings with cochlear implantation in children. That is, for each child who has received a cochlear implant in the CDaCI Study (Niparko et al), societal savings range from approximately $30-60K per child (with greater societal savings for children implanted at early ages).

When these observations are paired with observations of greater language learning potential in younger implant recipients, and those who receive bilateral cochlear implantation (Niparko et al), a direct conclusion is that early, bilateral implantation yields substantial rehabilitative and educational benefits, representing high value for the healthcare dollar.

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Thank you for the opportunity to comment.

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