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Regulatory Agencies and Cochlear Implants: Review is Imperative

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Abstract

The FDA has a means to reduce harms done by overreaching claims about linguistic benefits of CIs alone: the black box warning or BBW. BBWs call attention to drugs or devices with serious or life-threatening risks to patients. A prelingually deafened child who is implanted and from whom a sign language is withheld is at risk of linguistic deprivation. CIs must come with a BBW to the effect that the CI is part of a necessary bundle that includes sign language for the child.

Accompanying the BBW with printed guidelines that repeat the BBW and offer information on how to provide the child with a sign language plus resources about how the family can become fluent in a sign language is one way to protect deaf children while FDA review is being conducted. These printed materials should include a cognitive development check list, including language milestones (not simply responses to auditory input) and other cognitive benchmarks. The FDA must define as a priority the development of such a language-milestone list (useful material is found in 22-, and should be reviewed at regular intervals as research provides new information. Parents should be urged to seek close evaluation of their child's language and cognitive development milestones. These printed materials should outline the responsibilities of parents, medical professionals, educators, and other specialists to attend to the child's developmental milestones (in both spoken and sign language) as seriously as they do to hearing ability. Advisors of all specialties should review the guidance, including checklist and cautions, with families, who need assertive help and positive support in understanding what is reasonable to expect from CIs and how to enhance their effectiveness.

Keywords: Deaf children and sign language; Federal Drug Administration guidance on cochlear implants; Sensitive period for first language acquisition

Introduction

Clarifying evidence regarding sign languages

Cochlear implant (CI) companies are often the source of representations made to parents, as well as to medical professionals and auditory/ speech professionals, that language development will occur in a speech-only environment given proper rehabilitative practices and that sign languages will inhibit this development. They make these representations in the absence of confirming evidence and in the presence of contrary evidence. Multiple sources (brain imaging research, language acquisition studies, linguistic analysis) have established that sign languages are natural languages – they can and do allow normal language development in deaf children, and they do not inhibit the concurrent development of speech, but, rather, enhance it. Further, many books and articles offer evidence that deaf people who sign from early childhood enjoy better academic and professional achievements, personal satisfaction with self and life, and overall health [1-2].

Learning a sign language has multiple benefits for children with or without CIs that go beyond language per se. In mathematics, for example, comparing deaf children in signing families to deaf children in hearing (i.e., non-signing) families, we find that the former perform better on mathematics skills tasks [3]. Additionally, with regard to implanted children, comparing those in signing families to those in non-signing families, the intelligence quotients of the former are significantly higher [4]. These facts indicate that a foundation in a sign language – with all the communicative benefits that it affords – provides the necessary cognitive basis for the mathematics tasks examined in these two studies. Regarding general cognitive health, the brain benefits from bimodal-bilingualism (two languages, two modalities) in the same ways as from unimodal bilingualism (i.e., between spoken languages) [5,6]. Deaf children who are able to communicate fully in a sign language with their caregivers show better literacy and academic achievement [7-10]. Deaf children who acquire fluency in a sign language in early childhood demonstrate age-appropriate development of Theory of Mind [11-12].

But the single most important benefit of sign language is a firm foundation in language as early as possible so that the child can understand others and be understood by others, not just in requesting an object but in expressing inner feelings, hopes, dreams. Language is what binds us to the people around us. Caregivers need to understand that language development in the first year of life is substantial for children exposed to an accessible language. Leaving a child without appropriate communication between the child and caregiver in the months between birth and the time when cochlear implantation may provide linguistic benefit delays the child's exposure to language

[13]. The newly implanted child then has to work to 'catch-up' with hearing peers, and there is not sufficient evidence that they succeed in doing this. In fact, there is evidence that they frequently do not. A major concern about CIs without sign language is that there is great variability in the language exposure accessible to deaf children in early childhood [14].

Language Acquisition and Cochlear Implants

Language is a cognitive ability that comes in at least two modalities: speech and sign. In order for a child to develop a firm foundation in language, mutual comprehension of communication between child and caregiver must be assured. Both parties involved in a communication event must engage with attention, interaction, and reciprocity. And both parties must enter into this communicative pact early. The human brain is ready to learn language from birth, and, so long as accessible language surrounds the child regularly and frequently from birth on, a child entering kindergarten, for example, will be producing and understanding sentences of significant complexity. That is, the child will simply acquire language under these typical and natural circumstances. However, the brain's plasticity changes as a child grows, with the result that, by the age of around three years old, a child who does not understand what a caretaker is trying to communicate and whose caretaker does not understand what the child is trying to communicate– that is, a child who is not exposed to accessible language– risks missing the opportunity to establish a firm foundation in language. This child might struggle to understand human language communication for the rest of their life. This child's language and cognitive functions may be compromised significantly during the most critical acquisition period. For this reason, anyone involved in raising and educating a deaf child needs to pay attention to the sensitive period for language development. This holds for all deaf children, even those with cochlear implants.

Cochlear implantation in deaf children is common worldwide, and growing in frequency in affluent countries. While CIs deliver audiological information to the brain via stimulation of the cochlear nerve, it seems to be universally agreed that the implanted child cannot be expected to then acquire spoken language the way hearing children do – that is, by simply being surrounded by it. There is a difference between the information the brain receives from a cochlear implant and the information the brain receives from passage of sound through the ear canal; the human brain evolved to naturally decode the latter but not the former. This means the child must be trained (the literature talks of "rehabilitation") to interpret the audiological information delivered by the CI – to distinguish non-linguistic ambient noise from linguistic noise, and then to negotiate their way through that linguistic noise to actual language comprehension and production. Thus, the implanted child does not "acquire" spoken language, but rather has to work at learning it with a regiment of help – sometimes in the form of heroic efforts – from family and from speech language pathologists. To repeat, there is great variability in this process. If the process does not work well, the child can be left linguistically deprived – that is, without sufficient early language that allows for typically appropriate cognitive development [15].

Linguistic deprivation is avoidable. Sign languages are accessible to all children, deaf and hearing. If the deaf child is exposed regularly and frequently to a sign language, they will acquire that language naturally. Acquisition of a sign language is developmentally the same as natural development of a spoken language. This foundation will then serve them as they learn the ambient spoken language– certainly the text of it, but, sometimes, also the speech. That is, fluency in a sign language correlates positively (more positively than any other factor) with a deaf child developing both literacy and the ability to converse in a spoken language.

Why, then, is any deaf child at risk of linguistic deprivation? In many countries, attitudes about sign language and overreliance on hearing technologies like CIs that do not replace lost hearing are left unexamined and uncorrected by regulatory agencies such as the Food and Drug Administration (FDA) in the USA and similar agencies in Europe, Asia, Africa, South America, and the Pacific. Alleviation of the risk requires accurate and realistic information as well as oversight. We use the FDA as our example of what has not been done and what needs to be done.

Regulatory responsibility and call for action

In 1985 the FDA first approved clinical trials of CIs in children aged 2 and up. In 1990, final approval was given. And in 2000, approval was given to implant children at 12 months old, but implantation of younger children does occur at doctor discretion. For several reasons the clinical trials were not adequate.

The trials from 1985-1990 did not provide adequate information on the age and linguistic experience of the children at the time of hearing loss. In fact, it's possible that no children in the initial trials were born deaf or were prelingually deafened. Once the FDA approves a medical device, modifications and upgrades can be fast-tracked to approval via a premarket submission that does not require the same scrutiny. With this fast-tracking, all a manufacturer need show is that the modified/upgraded device is "at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval" [16]. The upshot is that from the introduction of CIs and through to today, CIs have been implanted in very young children without clinical trials determining whether and to what extent the CI provides access to speech adequate for first language acquisition – access that allows opportunity to engage in mutually comprehensible communication between child and caregiver. The initial protection of children that is a normal responsibility of regulation was questionable, at best.

The medical field in the 1980s on which the FDA relied had little understanding of language development. Generally, people did not understand how complex natural language acquisition is – neither CI developers nor regulators anticipated how hard it would be to train the brain to interpret the signals delivered by the CI. They may not have understood matters of brain plasticity that make the window of opportunity on first language acquisition critical and brief. CIs were designed to simply induce brain reactions to auditory stimuli (of any kind)– which, in fact, they did and do. The stimuli produced, however, is not the same as that experienced by normal hearing mechanisms. The assumption seemed to be that stimulation provided by the CI would naturally support language development. Evidence of detection of electronic sound provided by the implant in clinical trials, such as whether a child could tap in time to the beat of a stimulus, was presented as evidence of success, when, in fact, this behavior is irrelevant to language acquisition. A standard of evidence that was linguistic, such as that the child could distinguish words or features of words in a sound stream, would have been more relevant [17-18].

No trials since have examined whether CIs without sign language ensure robust language development that allows a prelingually deafened child to fully engage in daily home communication activities. Some trials have looked at speech comprehension in laboratory settings with no ambient noise – an unnatural environment compared to home or school communication environments. But even with such controlled conditions, children's performance has varied enormously, despite, in many cases, bilateral implantation. It is not yet possible to accurately predict which children will do better with CIs. It is still the case that even with CIs, deaf children lag behind hearing peers in speech production, reading skills, and overall academic performance, and they experience lifelong emotional and other health difficulties in greater frequency than hearing peers [19-20].

The past several decades have provided scientific information on language acquisition that now allows us to seek explicitly the relevant effectiveness a CI should exhibit. What is critically needed is clinical trials in prelingually deaf children that present evidence of language acquisition and fluent child-caregiver communication as a result of implantation. Adequate trials should evaluate open-set speech recognition, the complexity of expressive language, vocabulary/lexicon (including ability to name objects and to describe internalized concepts), and the creative use of language. These trials should compare a child's abilities to pre-implantation abilities as well as to abilities of non-implanted deaf peers and of hearing peers. These trials should also should show evidence of cognitive development of other abilities that rely on a firm foundation in a first language. However, because deaf children cannot wait for these trials, they are at risk with every passing day and week of language and cognitive delay. While new evidence is important for understanding the gain of CIs, ethically it is equally important to provide language exposure via an assured accessible modality, that is, the visuo-gestural modality [21].

The FDA has standards regarding utility of medical devices – standards concerning reasonable assurance of safety and effectiveness. It is our contention that prejudice against sign languages and against a deaf way of living compromises reasonable and wise discourse about CIs and their use. The history of CIs has been marked by CI producers and by many medical professionals recommending against a deaf child being offered a sign language, even though sign languages are cognitively accessible to all deaf children and would assure first language acquisition. Crucially, they fail to suggest that the deaf child be introduced to signing deaf people, their closest peers in the world. These recommendations and failures constitute a harm to the child by withholding from the child a secure route to first language acquisition. Since the FDA has the responsibility of regulating CIs and providing guidance on their use and limitations, the responsibility to avoid harms falls squarely on the agency. New and updated guidance is needed [22-23].

Conclusion and Recommendation

The FDA has a means to reduce harms done by overreaching claims about linguistic benefits of CIs alone: the black box warning or BBW. BBWs call attention to drugs or devices with serious or life-threatening risks to patients. A prelingually deafened child who is implanted and from whom a sign language is withheld is at risk of linguistic deprivation. CIs must come with a BBW to the effect that the CI is part of a necessary bundle that includes sign language for the child.

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We call upon medical professionals and CI advocates worldwide to encourage their regulatory agencies to conduct a broad review, including evidence from deaf consumers, language and cognitive development specialists, and parents of deaf children. The FDA is a telling example of a global failure that must be rectified.

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