Global regulatory review needed for cochlear implants: A call for FDA leadership

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Abstract

Using the United States Food and Drug Administration (FDA) as example, we argue that regulatory agencies worldwide should review their guidance on cochlear implants (CIs). The FDA's original approval of implantation in prelingually deaf children was granted without full benefit of information on language acquisition, on child-caregiver communication, and on the lived experience of being deaf. The CI clinical trials, accordingly, did not address risks of linguistic deprivation, especially when the caregiver's communication is not fully accessible to the prelingually deaf child. Wide variability in the effectiveness of CIs since initial and updated approval has been indicated but has not led to new guidance.

Children need to be exposed frequently and regularly to accessible natural language while their brains are still plastic enough to become fluent in any language. For the youngest infants, who are not yet producing anything that could be called language although they might be producing salient social signals (Goldstein et al. 2009), good comprehension of communication from caregiver to infant is critical to the development of language. Sign languages are accessible natural languages that, because they are visual, allow full immersion for deaf infants, and they supply the necessary support for this comprehension. The main language contributor to health outcomes is this combination of natural visual language and comprehension

in communication. Accordingly, in order to prevent possible language deprivation, all prelingually deaf children should be exposed to both sign and spoken languages when their auditory status is detected, with sign language being critical during infancy and early childhood. Additionally, all caregivers should be given support to learn a sign language if it is new to them so that they can comprehend their deaf children's language expressions fully. However, both languages should be made accessible in their own right, not combined in a simultaneous or total communication approach since speaking one language and signing the other at the same time is problematic.

We call for the FDA (and similar agencies in other countries) to review its approval of cochlear implantation in prelingually deaf children who are within the sensitive period for language acquisition. In the meantime, the FDA should require manufacturers to add a highlighted warning to the effect that results with CI vary widely and CIs should not be relied upon to provide adequate auditory input for complete language development in all deaf children. Recent best information on users' experience with CIs (including abandonment) should be clearly provided so that informed decisions can be made. The FDA should require manufacturers' guidance and information materials to include encouragement to parents of deaf children to offer auditory input of a spoken language and visual input of a sign language and to have their child followed closely from birth by developmental specialists in language and cognition. In this way parents can align with providers to prioritize cognitive development and language access in both audio-vocal and visuo-gestural modalities.

Keywords: deaf children and sign language, cochlear implants, sensitive period for first language acquisition, Federal Drug Administration as regulator of cochlear implants

Significance: Cochlear implants have variable effectiveness and cannot be relied upon to provide access to language for prelingually deaf children and to support mutually comprehensible communication between child and caregiver. Yet the manufacturers' materials do not include warnings to this effect nor a check list of developmental milestones that might indicate delays and cognitive deficits due to inaccessibility of natural language. This article pulls together recent research into a cogent argument that a change is needed in FDA requirements regarding CI packaging and guidance and recommends a review of FDA approval of CIs for prelingually deaf children.

Introduction

As of 2014, 40% of prelingually deaf children worldwide receive a cochlear implant (CIs) (NIDCD 2014; throughout we refer readers to citations within our citations). That percentage climbs higher in affluent countries (Mowry et al. 2012). However, CIs carry a risk of language deprivation if mutual comprehension of communication between child and caregiver is not supported. We call upon medical professionals and speech therapists to petition regulatory agencies to address and alleviate these risks. In the USA, that would mean petitioning the United States Food and Drug Administration (FDA).

Background information

Three facts are essential to our argument: sign languages are bona fide languages, there is a sensitive period for language acquisition, and mutually comprehensible communication interaction between child and caregiver is necessary for language development and good health outcomes. Throughout we use the term *caregiver* to include family members as well as non-family members who assume the primary responsibility in caring for the child. Too often medical professionals equate speech with language, dismiss sign languages as cognitively impoverished, and ignore or devalue the importance of the child and caregiver fully understanding each other. Such positions are outdated and scientifically incorrect. They reflect lack of knowledge about first language acquisition and prejudice among medical professionals against both sign languages and the lived experience of deaf people, particularly with respect to the need to fully understand and be fully understood by caregivers in order to realize healthy outcomes (Humphries et al. 2017; Kushalnagar et al. 2020). Language is a cognitive activity

realized in at least two modalities: audio-verbal and visuo-gestural (the tactile language of deaf-blind people is also worthy of study). Both modalities have equal capacity linguistically (Anderson and Reilly 2002; Emmorey 2002; Meier et al. 2002; Emmorey and McCullough 2009; Klima and Bellugi 1979; Kovelman et al. 2014; Sandler and Lillo-Martin 2006), cognitively (Campbell et al. 2014), and psychosocially (Hintermair 2015). All children need language; speech is only one of the forms of language, with sign being another (Hall et al. 2019). Importantly, the presence of sign language and spoken language by themselves are not enough to ensure healthy development; the deaf child and caregiver must also be able to fully understand each other (Kushalnagar et al. 2020).

First language acquisition and the sensitive period

Children acquire language without explicit teaching when exposed regularly and frequently to accessible natural language whether it is signed or spoken, an unsurprising fact given language's biological nature (Campbell et al. 2008; Capek et al. 2010; Petitto et al. 2012; Kovelman et al. 2014; Friederici 2017). However, if children do not gain a firm foundation in a language by 3 to 5 years old, that is, within the sensitive period of brain plasticity for language, a range of risks follow, including a reduced chance of achieving native language competency in sign or in speech (Mayberry 2010; Pakaluk and Neville 2010) and a greater chance of changes in brain architecture with adverse outcomes (Drury et al. 2011) such as disruptions regarding memory (Rönnberg 2003; Pisoni and Cleary 2003) and mathematical ability (Hyde et al. 2003). The importance of early acquisition of language prompted the development of universal newborn screening

and early intervention (Cunningham et al. 2003).

Too often professionals (medical, auditory, and speech) assume that if an implanted child is kept working in rehabilitative training with a focus on the child's comprehension of the caregiver, sooner or later the child will acquire a first language; and that if a child does not thrive developmentally with a CI only, at any point the child can fall back onto the option of signing regardless of whether the caregiver is skilled in the sign language. This option is not always reliable, as all languages – sign and spoken – are subject to the sensitive period, and children need regular, frequent exposure to an accessible language throughout that early period.

Typically with infants (newborns through toddlers), both deaf and hearing, many means of communication are employed. Caregivers engage and expose their child to language and communicative practices in creative ways during play and to everyday interactions that foster not only the development of the child but also the development of a strong social relationship and sharing of the daily home environment. Basically, both parties try, in whatever way they can, to get across their messages. For the deaf infant, access to visual language and the gestural system is critical for the development of cognitive, and much needed, social functions.

When bona fide language starts to develop, both parties involved in a communication event need to engage in a way that involves attention, interaction, reciprocity, and other elements foundational to language (Singleton and Morgan 2005); both parties must use

effort to engage in meaningful language exchange (Bloom 1993; Bloom and Tinker 2001). This reciprocal communication is critical for age-appropriate child development and for health outcomes of the deaf child (Kushalnagar et al. 2020); it is a critical part of first language acquisition.

Sign languages are available accessible languages that parents (hearing or deaf) can provide for their children with reasonable effort by seeking out sign language exposure (Schwartz and Verschik 2013; Humphries et al. 2019). Crucially, caregivers must also engage in learning to become fluent in a sign language along with the deaf child, so as to maximize successful communication. It is essential that caregivers and children have ease of communication both ways.

FDA approval and oversight

CIs are Class III medical devices, defined by the FDA in the United States as devices that "usually sustain or support life, are implanted or present a potential unreasonable risk of illness or injury" (Rabin and Picard 2019, p. 1). The approval process for CIs is meant to check for safety and efficiency; it includes premarket approval, clinical trials to inform about adverse effects, ongoing supplemental approval, post-market surveillance, and a complaint process including mandatory and voluntary reporters (FDA 2018a).

Clinical trials

CIs have been provided to adults (over age 18) since 1972, with FDA full approval in 1985. Based on perceived success with adults, CIs were provided to younger children

starting in 1985 with clinical trials, and in 1990 final full approval was given for children age 2 and up. In 2000, the minimum age was lowered to 12 months, but many doctors worldwide implant younger children at their own discretion (McKinney 2017).

The clinical trial that led to FDA approval of CIs in children in 1990 selected children over the age of two that were expected to have a high potential for success because they had been deaf only "a short while" and their home and educational programs were committed to oral communication that focused only on the child's reception of the caregiver's speech rather than considering the importance of the child being understood by the caretaker, as well (Sarant and Naz 2012). Children of varying ages came into the 5-year clinical-trial window (1985 to 1990) at varying times (Clark 1995; Donaldson 2011). We have found no information about the age of onset of deafness and the age of implantation, although the fact that these children had been deaf only a short while suggests few to no children in the trial were born deaf.

Clinical trials since 1990 have provided information about age of onset of deafness and age of implantation, but exactly how the information is used in determining effectiveness is not described in the literature we have found. Further, once a medical device has been approved, modifications and upgrades do not necessarily call for clinical trials (FDA 2017a, 2017b), but, instead, can be fast-tracked via a premarket submission (an FDA 510(k)) that demonstrates that the device to be marketed is "at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval" (FDA 2018b). Many CIs have been approved through this

premarket approval process (FDA 2018c, 2018d) and others have been approved through the humanitarian device exemption pathways; even those CIs that undergo premarket trials are often approved on the basis of studies of patients who are over age 18 and few post-market studies consider pediatric patients (Hwang et al. 2014). Even though later CIs have a significantly better quality of auditory input than earlier devices (Mowry et al. 2012; Roche and Hansen 2015), these improved devices have not undergone clinical trials to determine whether and to what extent they provide access to first language acquisition with opportunity to engage in mutually comprehensible communication between child and caregiver, nor whether language performance levels of children with these newer CIs have improved proportionately with technology improvements (Nittrouer and Caldwell-Tarr 2016).

Determination of effectiveness

CIs were originally designed to induce brain reactions to auditory stimuli. It seems the working assumption was that if CIs could stimulate receptive reactions to auditory input, they would naturally support language development, including mutually comprehensible communication between the deaf child and caregiver. With this assumption, the effectiveness studies were often irrelevant to language per se (and we have found no information on how the FDA defined "safe and effective" with respect to clinical trial assessment or premarket approval of CIs). Whether a child can tap in time to the beat of an auditory stimulus, for example, implies nothing about whether that child can distinguish words in a sound stream or whether the child can understand or by understood by the caregiver.

Clinical trials that measure only detection and production of speech are inadequate for judging the effectiveness and reliability of CIs as a tool for providing access to first language acquisition at all linguistic levels (phonetic-phonology interface, lexicon, morphology, syntax, semantics and discourse). Therefore, clinical trials in prelingually deaf children should include evidence of language acquisition and fluent child-caregiver communication as a result of implantation. In particular, these trials should evaluate open-set speech recognition, the complexity of expressive language, vocabulary/lexicon (including ability to name objects and to describe internalized concepts), the creative use of language – comparing to pre-implantation abilities as well as to abilities of non-implanted deaf peers and of hearing peers (Svirsky et al. 2000), and cognitive development of those abilities that rely on a firm foundation in a first language. This is critical for the foundation of child-caregiver communication, which then supports overall well-being of the child.

In the absence of adequate clinical trials involving well-designed studies with large numbers of implanted children, it is difficult to establish what percentage of prelingually deaf children receive adequate linguistic benefits from implants to ensure robust language development that will allow one to fully engage in daily home communication activities. The impact of a CI on the child's language development and engagement in daily home communication is highly variable, even tested in laboratory settings with no ambient noise and even with bilateral implantation (Sparreboom et al. 2010), and no one yet has found a sure way of predicting which children will do better with CIs despite

considerable research on potentially relevant variables (Fink et al. 2007; Giraud and Lee 2007; Pisoni et al. 2008; Bond et al. 2009; Meshik et al. 2010; Hyde et al. 2011; Boons et al. 2012; Black et al. 2011; Cruz et al. 2013; Antia 2015; Leigh and Marschark 2016). Children with CIs persistently lag behind hearing peers in speech production (Niparko et al. 2010; Geers and Sedey 2011), reading skills (Çizmeci and Çiprut 2018), academic performance in general (Sarant et al. 2015; Diaz et al. 2019), and emotional understanding (Wang et al. 2018). Children with CIs experience difficulties communicating in speech environments even after many years of rehabilitative training (Thoutenhoofd et al. 2005; Yoshinaga-Itano 2006; O'Reilly et al. 2008; Peterson et al. 2010; Martin et al. 2010). Many more studies raise concern about the absence of a firm first language foundation and successful child-caregiver communication.

Beadle and colleagues (2005) report that 60% of the implanted children in their study could use the telephone "with a familiar speaker". That implies 40% could not. We do not know what percentage in their study needed more than auditory information in order to decipher a stranger's speech and in order for a stranger to be able to decipher their speech on the telephone. In another study, face-to-face speech intelligibility with strangers is reported as 40% (Uziel et al. 2007).

In a recent study 87.7% of implanted children were still using their CI 10 years post-implantation (Contrera et al. 2014). We do not know how well that 87.7% were doing communication-wise through engagement in daily home communication. But 12.3% had stopped using the CI. Further, there has been a shift in how discussions of CI success are

framed, displacing responsibility for language access from the device onto the rehabilitative training post-implantation. This has resulted in children and their parents (typically mothers) assuming the blame when positive results are lacking (Mauldin 2014), which can prolong the use of the CI regardless of language access.

There are studies across a sufficient number of children to indicate that CIs do not "restore" hearing and do not assure deaf children's full participation in daily home communication as well as in the society. While restoration of hearing may not be the intention of CIs, it remains the responsibility of medical professionals and speech specialists to ensure that anyone seeking a CI understands this. CIs provide auditory input to the brain, which is not the same as hearing; hearing is a perception that allows the brain to receive and interpret auditory information in the way humans have evolved to do that and thus acquire language in the oral/aural modality. Detecting sound is not the same as receiving language input that allows for acquisition of that language and supports full participation in daily home communication. CIs alone have not been demonstrated to be effective in guaranteeing or even reliably providing what prelingually deaf children need with regard to language acquisition and engagement. Scientific information on language acquisition of the past several decades since initial approval of CIs now allows us to seek explicitly the relevant effectiveness a CI should exhibit. The FDA has standards of relevant utility for medical devices. For example, the FDA says the intention of hip-replacement devices is to "restore mobility and relieve pain" (FDA 2019a); if in clinical trials a device was shown to replace the hip without "reasonable assurance of safety and effectiveness" (Faris n.d.) – which, in this case, would mean

restoring mobility and/or relieving pain – it likely would not receive approval from the FDA. Likewise, the FDA should clarify the intention of CIs with regard to providing a foundation for first language acquisition. If in clinical trials (or in their long history since 1990) CIs are shown to provide auditory stimulation to the brain without reasonable assurance of effectiveness in providing a foundation for first language acquisition, the FDA should reconsider its approval in prelingually deaf children (Duchesne et al. 2009; Davidson et al. 2011; Tobey et al. 2011; Lund 2015).

Evaluation of adverse effects and safety

The FDA's description of their approval process addresses adverse effects. For CIs, adverse effects that have come to light since FDA approval need to be examined, particularly effects related to language acquisition. And adverse effects studied before original approval need to be reassessed in view of new evidence on first language acquisition and the importance of mutually comprehensible communication between child and caregiver.

Most deaf people have residual hearing (Balkany et al. 2006). In many patients, CI surgery with a standard-length electrode and standard surgical techniques disables the cochlea, which destroys residual hearing (O'Reilly et al. 2008; Berrettini et al. 2008). A more recent option, for which only some CI patients are candidates, is to combine CIs with a low frequency sparing electrode array, conserving 50% to70% of low frequency residual hearing (Mowry et al. 2012) and only rarely resulting in total loss of residual hearing (Skarzynski et al. 2014). Since residual hearing is important in multiple ways,

especially in language discrimination in noisy environments (Miranda et al. 2014) and since it may affect candidacy for future regenerative hair cell therapy (Khater and El-Anwar 2017), a CI option presents a potential risk.

Other harms result from gaps in access to sound due to discontinuous use of the CI. Some complications from CI surgery require removal of the CI temporarily or permanently. In such instances, it is likely that the child is without full communication access for a variable amount of time. At a very early age, gaps in access to language can be critical. Even brief gaps in access to auditory stimulation that interrupt or degrade the comprehension of communication by the child and caregiver can result in setbacks in clinical performance regarding speech production and reception in 14% of children with CIs (Blanchard et al. 2015). Additionally, those gaps can leave the child feeling isolated and frustrated (as reported by parents, Zaidman-Zait 2007, 2008), where safety concerns arise when the child has no alternative means of communication.

Another cause for gaps in CI use, and, thus, in receptive auditory input, is when the CI becomes inoperative because of failure of external antenna, battery compartment, speech processor, microphone, transmission cables, controller, batteries, or battery charge (Pereira and Melo 2014). Likewise, when an implant is recalled, the child can be left without a CI and may have to undergo a second surgery to have it removed and perhaps a third to have another device implanted, with all the associated surgery risks and without auditory input for various lengths of time. The following is a list of recalls, halts, or delays in production through 2011 (Cochlear Implant HELP n.d.):

- Cochlear, CI500 series, 2011: Hermeticity failure. Moisture enters the implant, eventually causing an electrical failure in some cases.
- Advanced Bionics, HiRes90k, 2010: Latent short circuit in substrate, 2 devices affected. Substrate thickness increased to prevent short circuits.
- Advanced Bionics, HiRes90k, 2006: Hermeticity failure. Hermetic seals created by one of two specialty manufacturing companies (Vendor B) experienced a latent failure. Moisture entered the implant, eventually causing an electrical failure in some cases. Manufacturing process control implemented. Vendor A devices not affected.
- Advanced Bionics, HiRes90k, 2004: Moisture trapped inside of implant at time of manufacture. Manufacturing process control implemented.
- Advanced Bionics CII, 2002: Suspicion of electrode array positioner being correlated to risk of meningitis. Implant was recalled and subsequently resumed production without the positioner.
- Advanced Bionics 1.0, 1995: Cracked ceramic cases. Case design strength increased.
- Cochlear, 1995: Internal power supply failure, capacitors installed backwards. <10 devices explanted.

Sometimes these recalls are required by the FDA (FDA 2004, 2010). Other times a company voluntarily recalls the CI as well as being required by the FDA to do so (Advanced Bionics 2010). And, finally, sometimes a company voluntarily withdraws it (Cochlear® 2011). Voluntary recalls may be due to discussions with the FDA or internal discussion. When a device is recalled, ex-plantation can lead to severe pain, as documented for an Advanced Bionics device (model number CI-1400-02H). The same adverse effects occur when a CI malfunctions, whether or not it is recalled, as in the case where a child was severely shocked (Wolfson 2013).

Facial palsy can result from CI surgery (Berrettini et al. 2011; Thom et al. 2012; Daneshi et al. 2015; Alzhrani et al. 2016; Rah et al. 2016). Though the incidence is extremely low, such palsy is “devastating” (Hsieh et al. 2015) and can, though rarely, be permanent, resulting in full paralysis of the same side of the face as the implant (Thom et al. 2012),

thus impeding speech. Should the patient ever want/need to rely on a sign language for communication, facial palsy would also affect communication since sign language grammars make critical use of facial articulations.

Post-cochlear-implantation vestibular dysfunction, as measured in the laboratory, is clinically significant, and is increased in patients with bilateral implantation (Licameli et al. 2009), where such dysfunction can result in vertigo and dizziness. Jacot and colleagues (2009) find an estimated 10% additional risk of post-operative vertigo, directly related to damage of sensory cells in the inner ear (the saccule) due to implantation. This post-operative vertigo results in persistent nausea and imbalance (Martin et al. 2012; Psillas et al. 2014), as well as gross motor developmental delay (Inoue et al. 2013; Maes et al. 2014). It also results in abnormal visual acuity (Martin et al. 2012), associated with poorer reading acuity (Braswell and Rine 2006). Vertigo and its associated problems can last or even worsen in older children (Rine et al. 2004; Janky and Givens 2015). Since the early years are a time of maximal cognitive development, significantly fed by physical exploration (Hackett 2014), limiting activity due to vertigo may put deaf children at additional disadvantages cognitively, aside from compromising their quality of life.

One critically important adverse effect of CIs on language acquisition stems from withholding sign language from a deaf child and not expecting the caregiver to share the learning accountability to ensure full inclusion in daily home communication. This withholding is due to representations to parents frequently provided by CI companies,

medical professionals and auditory/ speech professionals to the effect that language development will occur in a speech-only environment given proper rehabilitative practices (Mathews 2011; Mauldin 2014, 2016). These representations are not guaranteed, whereas many studies show robust language development in deaf children within a signing environment that is inclusive of the deaf child in daily home or group communication. Often parents are instructed to withhold sign language exposure (and to sign "contracts" to not sign with their children), with the claim that signing impedes speech skills (White 2008). Such instructions contradict research: learning a sign language does not impede success with CIs (Giezen 2011; Lyness et al. 2013; Campbell et al. 2014; Corina et al. 2017). To the contrary, implanted children who sign and fully understand and are fully understood by their caregivers exhibit more advanced spoken language development than nonsigners who are not able to fully understand or by understood by caregivers or fully participate in daily home communication, whether their caregivers are deaf or hearing (Hassanzadeh 2012; Davidson et al. 2014). First language acquisition in a sign language provides a foundation for communication (Rinaldi and Caselli 2014; Hall 2017).

Sign languages aid children with CIs in multiple other ways. Deaf children of deaf parents perform significantly better on mathematics skills tasks than deaf children of hearing parents (Kritzer 2009). Further, the intelligence quotients of implanted children with deaf parents are significantly higher than those of implanted children with hearing parents (Amraei et al. 2017). Both facts indicate that having a foundation in a sign language and full ability to understand and be understood by caregivers provides the

necessary cognitive basis for the tasks examined in these two studies. Bimodal-bilingualism benefits the brain in the same ways bilingualism between spoken languages does (Kushalnagar et al. 2010; Bialystok 2011). Sign language proficiency in deaf children who are able to communicate fully with their caregivers correlates positively with literacy and academic achievement (Rinaldi et al. 2014; Marschark and Lee 2014; Clark et al. 2016; Hrastinski and Wilbur 2016), and aids proper development of a Theory of Mind (Schick et al. 2007; Meristo et al. 2016). Social isolation due to inability to fully communicate with those they live with and peers has led to psycho-social harms among deaf children (Most 2007), even psychoses (van der Werf et al. 2010). What is of great importance psychosocially is full child-caregiver communication in addition to full participation in daily home communication; this is critical for healthy outcomes (Kushalnagar et al. 2011; Kushalnagar et al. 2020). Further, language development in the first year of life is substantial for children exposed to an accessible language. Without appropriate communication between the child and caregiver (which includes accessible language from the caregiver), the months between birth and cochlear implantation delay the implanted child's access to any form of language (Levine et al. 2016), putting the newly implanted child immediately in a situation of 'catch-up' with hearing peers.

It is important to acknowledge that implantation carries a range of risks beyond linguistic deprivation, and patients' families should be informed of the total risk, to help in evaluating short and long-term benefits (Riggs and Segal 2016). Likewise, the FDA needs to consider the total risk when reviewing its approval of cochlear implantation. Post-surgery complications with CI are common and persistent (Loundon et al. 2010;

Ciorba et al. 2012; Tarkan 2013; Farinetti et al. 2014), and higher for children who have a variety of other disabilities and syndromic illnesses (Chilosi et al. 2010; Birman et al. 2012; Broomfield et al. 2012) and for the youngest babies (McJunkin and Jeyakumar 2010). The presence of this medical device in the skull may inhibit a child's ability to have certain medical examinations and treatments (FDA 2018c; Shew et al. 2019), as well as lead to lifestyle limitations (FDA 2018c).

We are cognizant that *risk* is used in some professions in different ways. And risk is often defined vis a vis the perceived condition with which it is associated. Assessment of risk at its best is backed up with statistical probability. At its most problematic, risk is assessed subjectively and ideologically. For example, what level of risk is acceptable to the person undergoing a procedure (and risk to what)? In our discussion so far, we have listed adverse effects, giving statistical information when available. We note with concern, however, that risk tolerance for implanting deaf children is high compared to tolerance for other interventions and treatments that involve surgery, in-body implants, and the like. We also note that deafness is not a life-threatening condition, is not a safety issue, and is not classified as a debilitating illness. We argue that the relatively high risks of adverse effects related to CIs are much greater than other FDA approved applications. (Many have adverse effects of 1 in 100, 1 in 1000, 1 in 10,000 and so on). The risk of CIs to language acquisition alone is much greater than these thresholds. In contrast, the FDA needs to consider that there is no risk to language acquisition when deaf children are exposed to sign language from birth and when caregivers have the resources to fully engage them in daily home communication. The FDA needs to resolve the history of

high tolerance for risk in examining CI success as well as acknowledge that sign language exposure and mutually comprehensible communication between child and caregiver decreases the risk, not increase it as some CI manufacturers and CI professionals often tell families.

Re-examination of CIs relative to hearing aids

At the time of the 1990 approval and 2000 extension of CIs, a non-invasive alternative medical device existed: hearing aids (HA) (Tomblin et al. 2014). Since CIs are recommended for children with certain characteristics, including those who "demonstrate limited or no functional benefit from conventional hearing aid amplification" (American Academy of Audiology 2019), most studies of HA effectiveness concern children with mild to moderately-severe hearing loss, where consistent use of HAs is found to be beneficial to language development (Tomblin et al. 2015). However, some studies do compare HAs to CIs in children with severe hearing, and they show that these deaf children get auditory benefits from HAs just as from CIs (Most et al. 2010). Given the relative paucity of studies, we recommend considering findings regardless of whether children were provided a CI in an age range that runs older than the sensitive period.

For example, children with either device experience similar difficulties in vowel identification (Hedrick et al. 2019) and in distinguishing speech from noise (although influencing factors are different: Ching et al. 2018), and FM systems improve speech recognition in noisy environments for children with either device (Guarnaccia et al. 2018). Earlier fitting of either device correlates to better language benefits (Cupples et al.

2018), with the caveat that CIs are superior to HAs if the child has better hearing before the CI and the child's mother has extensive education (16 years or more) (Yoshinaga-Itano et al. 2010) and HAs are superior to CIs if the child has additional disabilities (Cupples et al. 2018). HAs were found to be superior to CIs with respect to perceiving the speech features of intonation, emphasis, and stress in one study (Most and Peled 2007) but not in a subsequent study (Most et al. 2010). HAs are superior in gaining print literacy (Harris and Terlektsi 2010) as well as in the domains of receptive vocabulary, phonological memory, and reading comprehension (Fitzpatrick et al. 2012). Usage patterns in both devices do not significantly differ (Marnane and Ching 2015). Children with CIs and HAs function equally well in daily situations, with the note that children with HAs have more hearing problems in team sports and outdoor activities than children with CIs (Anmyr et al. 2011). Children with either device who exhibit difficulties with paying attention and engaging in everyday home communication may have psychosocial problems, regardless of their language ability, age at hearing intervention, and severity of hearing loss (Wong et al. 2017).

Differences in the factors that influence how much benefit a child receives from HAs as compared to CIs in different areas of language development and use (as noted in these studies) suggest both that the two types of devices are not entirely interchangeable and that, for different children, one may be advantaged over the other. CIs have become the standard of care in many countries without sufficient comparative study. The continuing improvement in digital HA technology calls for more refinement of decision-making regarding use of CIs versus HAs, with the same kind of testing for language

development. There are risks of linguistic deprivation with both CIs and HAs, since neither technology as a stand-alone use provide complete auditory access to speech nor guarantee full child-caregiver communication as well as inclusion in daily home communication. Caregivers must do much more than provide the child with a CI or HA to ensure healthy development of the deaf child. Note that HAs should not be considered a fallback treatment if a CI fails, since CI surgery is shown to destroy or damage residual hearing (as noted earlier), which is needed for HA use.

While children with either device have deficits in vocabulary development in comparison to hearing peers (Percy-Smith et al. 2018), Yoshinaga-Itano and colleagues (2017) found that children with either device do better at vocabulary acquisition if there is a deaf adult in the household, a finding that leads them to suggest that deaf adults should be included in the intervention process for all deaf children, perhaps because deaf adults have life experience with effective communication strategies to maximize vocabulary acquisition. We second that recommendation and add the recommendation that the FDA review and clarify the comparative efficacy, safety, and risk of CIs vis a vis HAs, since HAs are an alternative to CIs and the implantation process has consequence for later HA use.

In sum, there is a clear need to examine when a CI is indicated for the deaf child through greater understanding of what the outcome will be for implantation, and whether HAs may be a better alternative. The FDA should address the process by which deaf children are chosen for implantation given the wide range of variation and rate of abandonment. Implantations are being performed on increasingly higher numbers of deaf children than

were recommended for implantation during initial FDA approval and there is a paucity of data for determining if implantation is justified in these higher numbers. Taken together, these points suggest that a review of present knowledge about this area is very important. It may be that for large numbers of deaf children now undergoing implantation, HAs are better indicated, safer, and more economical than CIs.

Conflicts of interest, legal and ethical

In 2010 Cochlear Americas (a subsidiary of Cochlear Limited) was fined $880,000 for paying illegal remunerations to health care providers whose patients purchased their CI systems (Department of Justice 2010). Such illegal incentives have a powerful effect on medical professionals' behavior, leading to overprescription (Hsiao 2008; Montero 2018, p. 86–87). Unfortunately, CI might be more vulnerable to overprescription than many other medical devices. The determination of HAs versus CIs is complicated in infants; speech scores after a prolonged period of using HAs are the best way to determine whether a HA is indicated, which is not possible for infants. Universal neonatal screening, genetic diagnosis, and neuroimaging can help (Paludetti et al. 2012), but subjective judgments also enter. Since the global market for CIs is huge and growing (Pikov 2015), the temptation to offer such remuneration and, accordingly, the temptation to overprescribe CIs, might also be growing. But even if such practices are rare, this conflict of interest should be acknowledged by the FDA and reviewed to identify such practices and give guidance on safeguards.

Conclusion and recommendation

No clinical trials have adequately tested the efficiency and safety of CIs in providing and protecting the foundation for first language acquisition and for effective child-caregiver communication. Studies show that CIs have afforded improved access to spoken language over time for many children who are also able to understand their caregivers and fully engage in daily home communication, but the rate of failure of CIs with a one-way communication (e.g. caregiver can understand the deaf child's developing speech, but the deaf child cannot understand the caregiver's spoken language) approach to first language acquisition in prelingually deaf children is higher than many might have anticipated, and the difficulty of predicting likelihood of success for an individual child is greater than many might have expected. Further, parents of small deaf children are often discouraged from signing with their children when, in fact, a sign language is not contraindicated, and would likely benefit all prelingually deaf children. Using a CI without assuring that the child fully understands and is understood by the caregiver amounts to taking a significant risk with the prelingually deaf child's cognitive and psycho-social health.

Thus far, with regard to clinical recommendations, neither the industry nor medical professionals have adequately developed comprehensive notions of effectiveness, addressed disparities, or included requirement for mutually comprehensible communication between child and caregiver, which is necessary for full inclusion in daily home communication. Protocols based on the types of evidence and issues presented in this article should be adopted in order to adequately protect the whole child. This begins with scrupulous regulatory review (Cortez 2014) of implantation in prelingually deaf

children at and during the sensitive period for language acquisition.

We point out two essential and related facts. First, original approval of CIs by FDA or similar agencies in other countries happened in an environment of competing social and political ideologies. Implications of the new technology's commercial possibilities played a role in overriding hesitations of scientists (Blume 2010). Overridden as well were the objections of Deaf communities that their language needs would be subordinated to the push for much less than perfect hearing restoration – an objection arbitrarily cast aside as identity politics (Blume 2010). Second, other medical devices regularly approved by the FDA or similar agencies in other countries do not generally have the potential to interrupt or impede cognitive development. CIs are unique in that they are relied upon to 'restore hearing', but when access to child-caregiver communication does not (fully) happen, cognitive development is threatened. If CIs are used to rationalize withholding language input in sign, they carry even greater risk. Engineers know about making technological devices; surgeons know about the physiology of head and brain; but the FDA (or similar agencies in other countries) approved a device when no one truly understood (or understands even now) how the technology and the brain interface and how imperfections in that interface affect cognitive development.

We call on medical professionals to help the FDA and its counterpart regulatory agencies around the globe to recognize and regulate these devices, with language acquisition outcomes as important measures of efficacy (as outlined in our section on determination

of effectiveness) and to ensure that these devices are not used to rationalize overlooking the role of sign languages in supporting child-caregiver communication and the cognitive development of deaf children.

The FDA uses warnings on drugs and medical devices to protect the health of the user. Warnings on medical devices alert the user "against uses that may be dangerous to health or information that may be necessary for the protection of users" (FDA 1989). The FD&C Act requires both drugs and medical devices to have warnings "needed to ensure the safe and effectiveness [sic] use of the device" and warnings "against use in certain pathological conditions or by children where its use may be dangerous to health" (FDA 2008). The boxed warning (often called the "black box" warning or BBW) is the most serious. A BBW was first instituted in 1979 to call attention to drugs or devices with serious or life-threatening risks to patients (FDA 2012; Rice 2016). BBWs were used originally for drugs. Nearly half of all new BBWs have been added only after a drug has been on the market for 12 years. In recent years, the FDA has increased their speed in drug approval, which correlates (though not necessarily causally) with a high number both of BBWs (9,900 prescription drug labels carried such a warning as of 2014) and of the withdrawal of many drugs from the market (Frank et al. 2014).

Regulation of devices by the FDA has been less rigorous than that of drugs (Garber 2010), where some point to the fact that certain "high-risk" cardiovascular devices were approved between 2000 and 2007 with fewer than one third of them being subjected to a randomized trial (Dhruva et al. 2009). Besides cardiovascular devices (Dhruva and

Redberg 2012), approval of the birth-control device Essure has been criticized. In 2016 the FDA required the manufacturers of Essure to include a BBW (FDA 2016a, 2016b), after which the manufacturers voluntarily removed it from the USA market. Nevertheless, Essure is undergoing a post-market surveillance study (Voelker 2019), where the FDA order for this goes even further than the order for a BBW, requiring physicians to discuss a checklist of risks with the patient before prescribing the device (Bayer Healthcare 2018; for discussion see Gunn and Paasche-Orlow 2019). A more rigorous device-approval process could remedy some problems, while a more comprehensive post-marketing surveillance could remedy others (Garber 2010).

Importantly, the BBW is a tool the FDA has used to advise the public about health risks on devices (not solely drugs), and this tool should be used for CIs. The common assumption among medical professionals that linguistic deprivation is an inevitable and unfortunate consequence of deafness for a subset of patients is incorrect. Linguistic deprivation can be prevented with sign language access, allowing clear communication exchange between the child and caregivers. Doing anything less violates the Hippocratic Oath. If CIs are used in a prelingually deaf child without ensuring that the deaf child and caregiver always understand each other, irreversible and profound damage may be done to the child's cognitive abilities, including the child's ability to engage in daily home communication. CIs must be marketed as part of a necessary bundle that includes requirement for back-and-forth communication between child and caregiver that can allow for full engagement; inclusion of a sign language will protect against neglect of the cognitive health of deaf children and will help to ensure optimal effectiveness of CIs.

A BBW against use of the CI without a sign language should be accompanied by detailed guidance about how to provide the child with a sign language and resources to the caregiver about how to become fluent in this language (Weaver and Starner 2011; Schwartz and Verschik 2013; Humphries et al. 2019). Additionally, the FDA should require CI manufacturers to include printed guidelines in their packaging. These guidelines should repeat the BBW, stating that CIs cannot be relied upon to provide adequate auditory input for complete language development in all deaf children and that ensuring that deaf children fully understand and be understood by their caregivers can avoid linguistic deprivation and assure complete language development with healthy outcomes. The printed materials should include a cognitive development check list, including language milestones (not simply responses to auditory input) and other cognitive benchmarks. Development of that language-milestone list needs to be a priority (useful material is found in Joint Committee on Infant Hearing 2000, 2019; Muse et al. 2013; Simms et al. 2013), and that list should be reviewed at regular intervals as information about language development increases. Such a list should not be used in a reductionist way, however; parents should be urged, as part of the CI package, to have their child followed closely by developmental specialists in language and psychology, so they can align themselves with providers and prioritize cognitive development and language access over speech and hearing alone. CI teams that include an audiologist and/or a speech therapist but no language specialist (familiar with both spoken and sign language acquisition) are inadequate; the medical profession needs to expand these teams so that they can support inclusion in daily home group communication. These additions

will help to better inform professionals, caregivers, and the public about what to look for in monitoring a child's progress. Medical professionals should review the checklist and caveats with families, who need assertive help in heeding warnings (Karch 2006).

The FDA issues BBW based on the FDA Adverse Event Reporting System (FDA 2019b), which operates via an interactive web-based tool. We call on medical professionals to utilize this tool in two ways; the traditional way, of reporting adverse events they note among their patients, and the novel way of citing the evidence-based arguments in this article and accordingly requesting a BBW, as well as printed guidelines in CI manufacturers' packaging of the sort outlined in this article.

In closing, we are not suggesting an all or nothing decision about CIs from the FDA and similar regulatory agencies in other countries, nor suggesting that approval for CIs be rescinded. Rather, we call upon the FDA (and similar agencies in other countries) to ensure that CIs are more effective, better understood, and better prescribed, and in so doing, set an example for world leadership by rectifying fallacies, inappropriate practices, poor standards of care, conflicts of interest, and ultimately for doing no harm.

Disclosure: The authors declare that no conflict of interest exists regarding the publication of this paper.

Funding: This work received no external funding.

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