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The Readability of Cochlear Implant Brochures: A Potential Factor in Parent Choice

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THE READABILITY OF COCHLEAR IMPLANT BROCHURES: A POTENTIAL FACTOR IN PARENT CHOICE

by

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Abstract

The early diagnosis of hearing loss can be a life-changing event for families. Parents are required to make several prompt decisions where they might be overwhelmed with all the information being shared with them. Patient education materials (PEMs) are often provided by clinical health professionals – yet these materials are often written above the average reading level of adults in the United States, thus presenting an additional challenge to many parents.

The purpose of this study was to examine the ease of reading cochlear implant (CI) brochures that are provided to parents who are making informed decisions about the management of their child's hearing loss. The CI brochures analyzed include those from three Food and Drug Administration (FDA)-approved CI manufacturers: Advanced Bionics, Cochlear Americas, and MED-EL. Reading grade levels were analyzed using a commercially-available computer software program, applying six readability formulas commonly used to examine PEMs. Analyses revealed that the readability of the three CI brochures exceed the fifth- to sixth-grade reading levels recommended by health literacy experts. Audiology-focused PEMs continue to be created without full consideration of their reading grade level despite health literacy initiatives. Researchers should consider the health literacy skills of the reader when creating or revising PEMs such as CI brochures.

Dedication

For everyone who makes decisions about their own healthcare or for their loved ones, and for all the first-generation and lifelong learning scholars.

“The most important journey of our lives doesn't necessarily involve climbing the highest peak or trekking around the world. The biggest adventure you can ever take is to live the life of your dreams”
- Oprah Winfrey

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#Thriving

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CHAPTER ONE: REVIEW OF LITERATURE

The early diagnosis of hearing loss can be a life-changing event for families. After the diagnosis of hearing loss, parents are faced with having to make decisions about amplification and communication. This decision-making usually takes place as they meet with a variety of professionals (e.g., physicians, audiologists, early intervention providers, speech-language pathologists [SLPs]). Parents are often required to make decisions as they experience a range of emotions associated with learning about their child's diagnosis of hearing loss (Kübler-Ross & Kessler, 2005; Luterman, 2021). The emotions experienced by parents often parallel the five stages of grief as depicted by the Kübler-Ross model (Kübler-Ross, 1969). The stages of grief are described as denial, anger, bargaining, depression, and acceptance (Kübler-Ross, 1969) and are used to describe the reactions by family members to the diagnosis of hearing loss due to its impact on communication and language development (Kübler-Ross & Kessler, 2005). Additionally, during this time parents receive much information while required to make decisions that will have major impact on the child's use of amplification, speech-language development as well as communication mode (Kübler-Ross & Kessler, 2005; Kurtzer-White & Luterman, 2003; Luterman, 2017).

As parents meet with different professionals, they are often provided with patient education materials (PEMs). These materials serve to provide information to parents regarding hearing loss and are used to guide them in considering a variety of amplification options (e.g., hearing aids, bone anchored hearing aids, cochlear implants). PEMs may provide visual aids by including images or illustrations of products so readers can visualize the product, understand available features, and learn about the benefits of different technology. However, some of these

materials may be challenging for several reasons, such as the use of complex terminology, or simply, that too much information is provided at a time when parents are still processing the diagnosis of hearing loss. Parents are required to understand complex information and to make decisions in a short amount of time. As such, they seek simple and convenient information from other resources (e.g., the internet) to help them make decisions in the hopes of creating a positive outcome in their child's development and academic success (Scarinci, Erbasi, Moore, Ching, & Marnane, 2018; Decker, Vallotton, & Johnson 2012). While some useful information about hearing loss and its impact can be found on the internet, it may not be supported by evidence and parents may find it difficult to read and understand (Laplante-Lévesque, Brännström, Anderson, & Lunner, 2012; Manchaiah, Dockens, Flagge, Bellon-Harn, Azios, Kelly-Campbell, & Andersson, 2019). Furthermore, printed and web-based resources often include complex technical words, and medical terminology that may be challenging for parents as they are making important decisions about their child (Fitzpatrick, Angus, Durieux-Smith, Graham, & Coyle, 2008). Given some of these concerns, this study examines the readability of cochlear implant (CI) brochures provided to parents considering a CI for their child diagnosed with a hearing loss.

What Is Hearing Loss?

Hearing loss is prevalent in one to two per 1,000 babies born in the United States and its territories ("2018 Annual", 2020) and occurs when there is an abnormality or damage in one or more structures of the ear/auditory system. There are three types of hearing loss: conductive, mixed, and sensorineural (American Speech-Language-Hearing Association [ASHA], n.d.c).

Conductive hearing losses can occur when there is an occlusion in the outer or middle ear structures preventing the energy created by soundwaves from continuing to the inner ear.

Conductive hearing losses are often temporary and can be treated with medications, removal of cerumen, and insertion of surgical pressure equalization (PE) tubes to drain excess fluid from the middle ear. Permanent conductive hearing losses can be managed with surgical interventions as well as with the use of hearing aids (Hall, 2014, pp. 318-333).

Mixed hearing losses occur when there is a temporary or permanent conductive hearing loss in conjunction with a permanent sensorineural hearing loss. Treatment options for mixed hearing losses vary and include surgical and non-surgical interventions as well as use of hearing aids (American Academy of Audiology [AAA], 2013).

Sensorineural hearing loss occurs as a result of permanent damage to the structures in the cochlea within the inner ear or to the vestibulocochlear nerve. Congenital sensorineural hearing loss in children are present at birth as a result of genetic or fetal developmental complications in utero, a familial hereditary condition, or an illness passed from the mother during gestation (Hall, 2014, pp. 333-350). In addition, acquired sensorineural hearing losses due to other conditions may also occur following birth (American Speech-Language Hearing Association, [ASHA] n.d.b). Management of sensorineural hearing loss include use of hearing aids, CI or both technologies, depending on the degree of hearing loss (Hall, 2014, pp. 382-417).

Early Identification and Diagnosis of Hearing Loss in Children

The early identification and diagnosis of hearing loss is vital to the child's development. Early Hearing Detection and Identification (EHDI) programs working with the Joint Committee on Infant Hearing (JCIH) and Universal Newborn Hearing Screening (UNHS) programs have established goals pertaining to initiation of appropriate intervention(s) by six-months of age to maximize the potential for language development (American Academy of Audiology [AAA],

2020). Guidelines from the JCIH and UNHS programs have been instrumental in the early identification of hearing loss to provide the best outcomes for the child (AAA, 2020).

Early identification of hearing loss is also an important first step to choosing appropriate hearing technology (Joint Committee on Infant Hearing, 2007). Early identification and intervention of hearing loss prior to 12 months of age (Zwolan & Sorkin, 2016) are central to language development, particularly speech and social-emotional variables, in infants and toddlers (Yoshinaga-Itano, 2003). When benchmarks are met, as outlined by UNHS, EHDI and JCIH, there is an increase in potential to lower the age of intervention equating to potential for better outcomes (AAA, 2020). Families who are informed of hearing loss early can seek information, obtain second opinions, begin intervention, and find support and services sooner. The outcome of a child's development of language, speech, and social skills is increased when intervention begins prior to six months of age (Ching, Dillon, Button, Seeto, Van Buynder, Marnane, Cupples & Leigh, 2017). Research shows that children who received amplification technology as early as 3-6 months have better vocabulary (Yoshinaga-Itano, Sedey, Wiggin & Chung, 2017) and language outcomes at age 5 as compared to those at receiving amplification technology at 24 months (Ching, et al., 2017).

Informed Decision-Making - Communication and Amplification

Parents who are informed that their child has a hearing loss must consider the best course of action for their child (Watermeyer, Kanji, & Sarvan, 2017). For example, in a survey conducted by Erbasi, Scarinci, Hickson & Ching, 2016, parents were surveyed about the nature of their involvement in the intervention of their child's hearing loss and the parents reported that the most important thing was to obtain information about communication options. Another concern parents may have, is being informed about best practices, and amplification options for

their child (Erbasi et al., 2016). These options may include evaluations for trial period with amplification devices such as a hearing aid and hearing assistive technology (HAT) (Hall, 2014, pp. 414-417). Cochlear implant (CI) candidacy is often an option discussed with parents, if the child demonstrates little or no progress with amplification and/or toward development of spoken language (Manrique, Ramos, de Paula Vernetta, Gil-Carcedo, Lassaletta, Sanchez-Cuadrado, Espinosa, Batuecas, Cenjor, Lavilla, Núñez, Cavalle, & Huarte, 2019). Results from a study which surveyed 78 parents who chose cochlear implantation, 96% responded that CIs met their child's expectation (Nelson, Herde, Munoz, White, & Page, (2017). Additionally, when asked whether parents would make the same choice in choosing a CI for their child, 99% indicated "yes" and 1% was "unsure" (Nelson et al., 2017).

Cochlear Implants

A CI is a medical device, approved by the FDA as a treatment option for bilateral severe to profound hearing loss (American Academy of Audiology [AAA], 2019). In the pediatric population, CIs received FDA approval in 1990 for those who were at least 24 months old. In 2000, the FDA lowered the age limit to 12 months old. As of June 2020, Cochlear Limited, the parent organization of Cochlear Americas, received FDA approval for implantation of their Cochlear Nucleus system for children as young as 9 months old (American Speech-Language-Hearing Association [ASHA], 2020; Holcomb & Smeal, 2020). Based on CI manufacturer's reports as of December 2019, the FDA estimates that approximately 65,000 children in the United States have CIs (U.S. Department of Health and Human Services, 2021). The CI delivers stimulation to an electrode array surgically placed in the inner ear. This electrode array circumvents damaged inner hair cells of the cochlea and transmits the signals directly to the

auditory nerve and to the brain for processing and potential interpretation of the perceived sounds (American Speech-Language-Hearing Association [ASHA], 2004).

Selecting the most beneficial CI technology and management options for a child is not a simple decision for parents. Options depend on if one (unilateral) or both (binaural) ears were at severity levels indicative of implantation and/or use of bimodal technology (hearing aid on one ear and CI for the other ear) (Fitzpatrick, Cologrosso, & Sikora, 2019). In addition, parents must weigh the surgical information/considerations, technology available from three different CI companies, as well as potential benefits of CIs in deciding whether it will greatly improve their child's quality of life.

As with many medical procedures, the decision to pursue CI technology and implantation should be extensively explored/discussed to understand realistic expectations following the surgery (Aarthun, Øymar, & Akerjordet, 2018). Furthermore, the choice also includes the family's commitment to the surgery and potential financial obligations, commitment to following all recommendations for post-surgical appointments such as initial activation/MAPPING of the implant with the external processor(s), frequent subsequent re-MAPPING appointments, participation in Aural Habilitation/Rehabilitation, and various auditory learning with the audiologist and SLP (AAA, 2019). At a minimum, it is critical that the family adhere to the MAPPING and Aural Rehabilitation commitments, especially throughout the first year of use with the CI (ASHA, 2004).

Making Decisions, The Parent's Journey

Working with an Interdisciplinary Team

Parent choice regarding their child's hearing loss is an ongoing, multifactorial process motivated by a parent's expectations and objectives for their child's quality of life and planning

for their future (Dillon & Pryce, 2020). An interdisciplinary team consists of the audiologist, SLP, early interventionist, physicians, and other professionals. The professionals provide the parents with education and counseling on hearing loss and possible treatments (Hyde, Punch, & Komesaroff, 2010). Parents work with the interdisciplinary team to make the best decisions for their child. Practitioners have a responsibility to provide unbiased, information and resources that may be important to patients and their families in the decision-making process (Seymour, Lakhani, Hartley, Cochrane & Jephson, 2015). Research shows that during this emotional and challenging time, the practitioners should be empathic and skilled to counsel the families within their scope of practice (Scarinci et al., 2018a).

Role and Responsibilities of Team Members

Audiologist. Often the first professional that the parents meet with are the audiologists. The audiologist conducts newborn hearing screenings, as well as identifies and diagnoses hearing loss across the lifespan, advises patients and parents on possible treatment options, provides CI candidacy assessments, fittings for amplification technology, and provides audiologic treatment/management of selected technologies. Audiologists also initiate referrals to other key interdisciplinary professionals as well as provide continuity of care between the interdisciplinary professionals.

Speech-Language Pathologist. Parents work with the SLP to discuss and consider all communication options for their child. SLPs assess communication skills, provide speech-language services, aural (re)habilitation/auditory learning, and conduct visual inspections and listening checks of amplification devices. Following the implantation of the hearing aid and/or

CI technology, the SLP works collaboratively with the audiologist to develop and monitor goals for amplification and speech-language outcomes.

Other Professionals. Parents work with pediatricians, family physicians, otolaryngologists, surgeons, early interventionist, teachers of the deaf and hard of hearing, and other professionals who provide services and information within their specialties and scope of practice. In a study where 64 families were surveyed about who was involved in the decision-making of choosing CI technology for a child, 75% included a parent, 28% included the CI team, and 14% included the child (Clamp, Rotchell, Maddock & Robinson, 2013). After interviewing the parents of seven children with mild to profound hearing loss, Scarinci, Gehrke, Ching, Marnane, & Button, (2018) suggest that the family's characteristics, strengths, beliefs, access to information, and family-centered practice are the main themes that influence the parent decision-making process. Parents of 50 children with profound hearing loss reported that their decision was influenced by the recommendation of professionals, availability of services close to home, recommendation of a friend, cost of services, and services provided by their local school district (Li, Bain & Steinberg, 2004). One major challenge professionals face is making sure that all the information provided is understandable and that parents are well-informed of the various options available to their child. Professionals who promote and support parents' participation in the decision-making process have been found to recognize the parents' need to understand the information provided. Thus, parents who have relevant information regarding their child's diagnosis and treatment, have improved confidence in their choice(s) while influencing and overseeing their child's healthcare (Aarthun et al., 2018).

Parent Decision-Making about Communication Modality

Parents want to know how their child's hearing loss will affect their child's ability to speak and communicate with others, impact their academic performance, and how parents will communicate with their child. Almost immediately after diagnosis, parents must decide on their child's mode of communication (Scarinci et al., 2018b). They often rely on others to help inform their decisions.

Parents make an initial decision in communication modality based on the child's hearing loss at the time of diagnosis. (Scarinci et al., 2018b). Parents' choice of communication includes whether they want their child to use listening and spoken language (LSL) or a signed language such as American Sign Language (ASL). In 2017, Nelson et al., 2017 surveyed the parents of 16 preschoolers ages 0-5 and 100% responded that their child uses LSL exclusively in their academic instruction. Likewise, 90% of the parents of 5- to 18-year-old children in kindergarten through 12th grade (K-12) who were surveyed responded that their children also use LSL exclusively in their academic instruction (Nelson et al., 2017).

Additional Challenges in the Parents' Decision-Making Journey

There are multiple factors that play a role in a parent's decisions, such as learning and understanding the vast medical terminology regarding audiological testing, results, and intervention, and finding the support and services needed. These factors may impede their ability to obtain and understand the necessary information to make an informed decision. For example, accessibility to healthcare for treatment and services is necessary to obtain optimal outcomes. Families with limited resources, families from linguistically and diverse backgrounds, and those living in rural areas may be challenged to find the doctors, CI specialists, and therapists to provide optimum medical care (Liu, Rosa-Lugo, Cosby, & Pritchett, 2020). If families do not

live near healthcare providers, they may accumulate debt paying for healthcare and travel expenses (Steinberg, Bain, Li, Delgado, & Ruperto, 2003). An additional factor is the patient's use of the internet to seek information for medical conditions and treatments to help make health-related decisions. Although the internet has become an increasingly accessible and utilized resource, the content is sometimes too complex to understand. The above factors are all important considerations about parent decision-making; however, the purpose of this study was to examine the ease of reading CI brochures provided to parents to help them make informed decisions about the management of their child's hearing loss.

The Role of Patient Education Materials on Parent Decision-Making

Parents receive a variety of PEMs from healthcare professionals as soon as hearing loss is suspected and throughout the lifespan as new diagnoses, technologies and interventions are introduced (Matthijs, Loots, Mouvet, Van Herreweghe, Hardonk, Van Hove, Van Puyvelde, & Leigh, 2012). To avoid overwhelming the parents with too much information at the time of diagnosis, healthcare professionals provide the information that is relevant and necessary for the appropriate decision-making periods (Matthijs et al., 2012).

One of the challenges of PEMs is that they are difficult for the average reader to understand (Manchaiah, Kelly-Campbell, Bellon-Harn, & Beukes, 2020). Healthcare professionals who counsel parents during the decision-making process should be aware of:

- whether the health-related materials they provide have been created with or without consideration of the average health literacy skills of their target audience; and
- if the health-related materials are effective enough to be used in the decision-making process. Healthcare professionals can engage the parents by asking parents if they have questions or need further clarification.

To ensure that the parents understand the content provided, healthcare professionals should ask the parents to paraphrase what they understand about hearing loss, interventions, and their child's possible hearing-speech-language outcomes.

As the quantity of health information available on the internet increases, the quality and reliability of the information available varies greatly (Manchaiah et al., 2020; Seymour et al., 2015). After analyzing the top 40 relevant websites across three search engines, Seymour et al. (2015) discovered that a little more than one-quarter of CI websites have a target audience of healthcare professionals, raising the question as to whether a non-clinical healthcare professional could comprehend and use that information to make an informed decision. Web-based information can influence parents' decision-making for their child's care (Atcherson, DeLaune, Hadden, Zraick, Kelly-Campbell & Minaya, 2014) so the readability, relevance, and suitability of that information is an important factor in making an informed decision (Zraick, Azios, Handley, Bellon-Harn, & Manchaiah, 2021).

Health Literacy

In 2021, the Healthy People 2030 Initiative updated the definition of health literacy as "the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others" (https://health.gov/our-work/healthy-people/healthy-people-2030/health-literacy-healthy-people-2030). The American Speech-Language Hearing Association (ASHA) has a goal to "make effective communication, a human right, accessible and achievable for all" (ASHA, n.d.a). ASHA recognizes that audiologists and SLPs can play an essential role in communicating complex information to persons with limited health literacy, for example, those with cognitive

and/or language deficits. It is important that healthcare professionals and partners in public health work together to ensure that PEMs and patient-reported outcome measures (PROMs) are written at a level that can be easily read by their intended audience (ASHA, 2010). As such, improving health literacy is a major objective of U.S. Healthy People 2030 (https://health.gov/healthypeople) and the National Institute of Health's Clear Communication and Plain Language initiative (https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/plain-language). According to the Plain Writing Act of 2010, plain language is "communication your audience can understand the first time they read or hear it" (http://plainlanguage.gov/).

Recommended Reading Levels for Health-Related Materials

Despite the vast information available about CIs, the average English-speaking adult making decisions about cochlear implantation may not be able to fully comprehend CI PEMs because of their complexity and reading demands, which exceed reading ability (Institute of Medicine, 2004; Seymour et al., 2015). The average adult in the United States reads at the seventh- to eighth-grade level (Doak, Doak, & Root, 1996). The 2003 National Assessment of Adult Literacy (NAAL) survey of 19,000 English-speaking adults in the United States revealed that 14% have *below average* health literacy skills. (Kutner, Greenburg, Jin, & Paulsen, 2006). The Joint Commission (2010) describes below average literacy skills as "possessing no more than the most simple and concrete literacy skills". An individual's level of reading comprehension is often two or more grades below the estimated reading level calculated by readability formulae that calculate a grade level (Center for Disease Control and Prevention [CDC], 2009). The CDC (2009) also notes that the reader's perceived stress about reading can reduce comprehension levels. Therefore, to meet health literacy needs and benefit the average

English-speaking adult in the United States, The Joint Commission (2010) recommends that health-related materials be written in a manner equivalent to a fifth-grade education level.

Health Literacy Challenges

Individuals with limited health literacy may have less productive communication exchanges with healthcare professionals (Koh, Berwick, Clancy, Baur, Brach, Harris, & Zerhusen, 2012). They may not advocate for their health nor actively participate in the shared decision-making process - for example, they may refrain from using medical jargon/terminology, or may hesitate to ask questions or may use very few words (e.g., Katz, Jacobson, Veledar, & Kripalani, 2007; Koh et al., 2012; Manchaiah et al., 2020; Wells, Rush, Nickels, Wu, Bhattarai, & Yeh, 2020). Furthermore, individuals may ask healthcare professionals to repeat themselves, indicating that something was perhaps misunderstood. It is in everyone's best interest for healthcare professionals to use plain language to provide relevant and straightforward information to patients and their families (Aarthun et al., 2018).

Printed and Internet-Based Information

The internet has become a more convenient and commonplace resource for people to obtain health information, regardless of the quality or accuracy of the content (Chen, Li, Liang, & Tsai, 2018). Survey data from over 33,000 adults who participated in the 2011 National Health Interview Survey (NHIS) revealed that more than 50 percent of adults 18-60 years of age were likely to search for health information on the internet (Amante, Hogan, Pagoto, English, & Lapane, 2015). Social variables such as limited education (Edward, Morris, Mataoui, Granberry, Williams, & Torres, 2018), and low socio-economic status correlates with limited health literacy and contributes to a digital divide (Pick, Sarkar, & Parrish, 2018; Yoon, Jang, Vaughan, &

Garcia, 2020). According to the Institute of Medicine (2004), nearly half of the adults in the United States have limited health literacy, which includes internet literacy skills, but it is possible that anyone can misunderstand health information when the information is too complex (U.S. Department of Health and Human Services, 2021). It is increasingly important that the authors of both printed, and internet-based health information, consider the health disparities and negative health outcomes of readers with limited health literacy.

Readability Analysis

A common method of assessing the readability of PEMs and PROMs is by using a readability formula that estimates the ease of reading or the reading grade level (Freda, 2005). The readability of health-related materials is just one attribute of health literacy and is a key component identified in the Health Communication section of Healthy People 2030 (https://health.gov/healthypeople). Readability is defined as "the ease with which a person can read and understand written materials" (Freda, 2005) and is an important element of effective communication (Doak, Doak, & Root, 1996). Readability is a complex concept that encompasses the objective and clarity of documents, the complexity of syllables and words, writing style, sentence length and structure, and context. In addition, an individual's medical vocabulary, their ability to read and understand the healthcare materials, and basic knowledge of the subject matter, are necessary components to increase their ability to benefit from these materials (Gray, Zraick, & Atcherson, 2019).

PEMs Continue to Exceed Recommended Reading Levels

Printed materials are often provided to patients to communicate concepts related to a diagnosis and interventions. When analyzed, the readability of PROMs often exceeds the

appropriate reading level for its intended audience (Gray et al., 2019). It has been reported that internet-based health information provided by commercial organizations were much more difficult to read and comprehend than the content provided by nonprofit organizations (Bellon-Harn, Manchaiah, & Kunda, 2020). In the past decade, research in the field of audiology reveals that health-related materials and internet-based information are often written at a level higher than what the average adult in the United States can easily read and comprehend (Atcherson et al., 2014; Coco, Colina, Atcherson, & Marrone, 2017; Douglas & Kelly-Campbell, 2018; Klyn, Shaikh, & Dhar, 2019; Laplante-Lévesque, et al., 2012; Manchaiah, et al., 2019; Manchaiah et al., 2020; Nicholson, Atcherson, Martin, Spragins, Schlagenhauf, and Zraick, 2016; Seymour et al., 2015).

Internet Information: Convenient, but Complex

Parents may easily find information about CIs on the internet; however, research has shown that websites may be too complex to understand. Seymour et al. (2015) found that the CI information found on 40 websites have a mean reading grade level of 13.1, equivalent to that of a college freshman, and a Flesch Reading Ease score of "Difficult". The results of the Seymour et al. (2015) conclude that the average CI information on the internet exceeds the recommended reading grade level. In addition, Seymour et al. (2015) concluded that regardless of the vast range of very poor to good quality CI information found on the top 40 websites, the readability was too difficult for the average patient.

Cochlear implant (CI) brochures must be written at the least challenging reading level to help parents make an informed decision. Given the results of numerous studies analyzing the readability of PEMs in communication disorders, it seems likely that CI brochures will also be difficult to read and understand.

Purpose of the Study

The purpose of this study was to examine the ease of reading CI brochures that are provided to parents who are making informed decisions about the management of their child's hearing loss.

Research Question and Hypothesis

This research seeks to identify the reading level of CI brochures from three FDA-approved CI manufacturers in the United States: Advanced Bionics, Cochlear Americas, and MED-EL. The study hypothesis is that the CI brochures will exceed the recommended fifth-sixth grade reading level for PEMs (The Joint Commission, 2010).

CHAPTER TWO: METHODOLOGY

Institutional Review Board

This study did not involve human participants; therefore, Institutional Review Board approval was not required (See Appendix B).

Materials

PDF versions of the printed PEMs were requested from three major CI manufacturers. The following brochures were received and used to analyze their readability and grade level:

1. Advanced Bionics: Consumer Master Brochure
2. Cochlear Americas: The Cochlear Nucleus® Implant System Candidate Brochure
3. MED-EL: Candidate Booklet, North America

Readability Analysis

The CI brochures were converted from a PDF document into a Microsoft Word document. The files were uploaded for analysis into the Readability Studio, Professional Edition, Version 2020 software package (Oleander Software, 2020). This readability software allows users to choose from preset bundles of readability formulas based on the type of document or by selecting the desired formulae. The word counts for each CI brochure was verified by manually counting the words on 3 random pages and copying the text into the Readability Studio which provided a word count. That count was compared to manual count as well as the word count provided by Microsoft Word to ensure that there were no differences. After the entire document

was uploaded into the Readability Studio, the word counts for each corresponding document were compared to the word counts provided by Microsoft Word to ensure there were no differences.

Description of Readability Formulae

The three CI brochures were analyzed using six readability formulae recommended by the software company. These are recommended because they are the most widely used formulae to analyze the readability of various PEMs (Nicholson et al., 2016), and specifically for communication sciences and disorders.

Table 1 lists and describes the six readability formulae selected to analyze the CI brochures. These include the Flesch-Kincaid (F-K) (Kincaid, Fishburne, Rogers, & Chissom, 1975), Flesch Reading Ease (FRE) (Flesch, 1948), FORCAST (Caylor, Sticht, Fox, & Ford, 1973), Fry Readability Graph (FRY) (Fry, 1968), Gunning FOG Index (FOG) (Gunning, 1952), and Simple Measure of Gobbledygook (SMOG) (McLaughlin, 1969).

In 2016, Nicholson et al. utilized five of the six formulae to assess the readability of newborn hearing screening brochures, F-K, FRE, FOG, FORCAST, and SMOG. The sixth formula, FRY, has been utilized to analyze PEMs related to hearing health (Manchaiah et al., 2020; Looi et al., 2021). The Flesch Reading Ease (FRE) calculates a score on a scale from 0 to 100 and identifies the difficulty (lower scores) or ease (higher scores) of reading the documents. The remaining five formulae, (F-K, FORCAST, FRY, FOG, and SMOG calculates the reading grade level for the documents.

Table 1. Readability Formulae: F-K, FRE, FORCAST, Fry, FOG, and SMOG

Measure	Algorithm	Scoring Output	Interpretation
F-K	F-K = (0.39 x ASW) + (11.8 x ASW) - 15.59 ASL = average sentence length ASW = average number of syllables per word	Calculates grade level based on sentence length and syllable count	Grade level indicates level of difficulty of reading material, e.g., 5.6 = fifth grade
FRE	FRE = 206.835 − (1.015 x ASL) − (84.6 x ASW) ASL = average sentence length ASW = average number of syllables per word	Calculates index score based on sentence length	Index score indicates difficulty of reading material Scores between: • 80.0 and 100.0 = fifth and sixth grade • 60.0 and 70.0 = eighth and ninth grade • 30.0 and 40.0 = college • 0.0 and 30.0 = college graduates
FORCAST	FORCAST = $20 - \frac{N}{10}$ N = number of single-syllable words per 150 words	Calculates grade level based on number of monosyllabic words	Grade level indicates level of difficulty of reading material, e.g., 5.6 = fifth grade
Fry	Fry = Plot AS1 on the y-axis of Fry Graph, and plot AS2 on the x-axis of Fry Graph AS1 = average number of sentences per 100 words of 3 random samples AS2 = average number of syllables per 100 words of 3 random samples	Calculates grade level based on sentence count, and syllable count	Grade level (1-17+) indicates level of difficulty of reading material, e.g., 5 = fifth grade
FOG	FOG = 0.4 x [(total words/total sentences) + 100 (complex words/total words)] Complex words = three or more syllables	Calculates grade level based on word count, sentence count, and word complexity	Grade level indicates level of difficulty of reading material, e.g., 5.6 = fifth grade
SMOG	SMOG = $3 + \sqrt{polysyllabic\ words}$ Polysyllable count = words with three or more syllables	Calculates grade level based on word complexity	Grade level indicates level of difficulty of reading material, e.g., 5.6 = fifth grade

Note: Adapted from The Principles of Readability, DuBay, (2004). http://www.impact-information.com/impactinfo/readability02.pdf

CHAPTER THREE: RESULTS

Table 2 illustrates the F-K, FORCAST, Fry, Gunning Fog, and SMOG reading grade levels, average reading grade level, and FRE readability index scores for the CI brochures. All five reading grade level formulae determined that 100% (n=3) of the CI brochure exceeded the recommended fifth- to sixth-grade reading level (minimum = 10.9, maximum = 17), with at least three formulae revealing one the CI brochures were written at the college level.

Table 2. Readability Results for CI Brochures

	CI Brochures		
Readability Formulae	*Advanced Bionics*	*Cochlear Americas*	*MED-EL*
F-K	11	12.3	13
FRE	48	46	38
FORCAST	11.4	11.2	11.9
Fry	15	14	17
FOG	10.9	11.8	12.7
SMOG	12.7	14.1	14.4
Average Grade Level	12.2	12.7	13.8

Note: The readability formulas used to calculate the average grade level include the F-K, FORCAST, Fry, FOG, and SMOG.

The FRE analysis (see Figure 1) showed that 100% (n=3) of the CI brochures were written at a comprehension level that is difficult for the average person to understand (minimum = 38 maximum = 48).

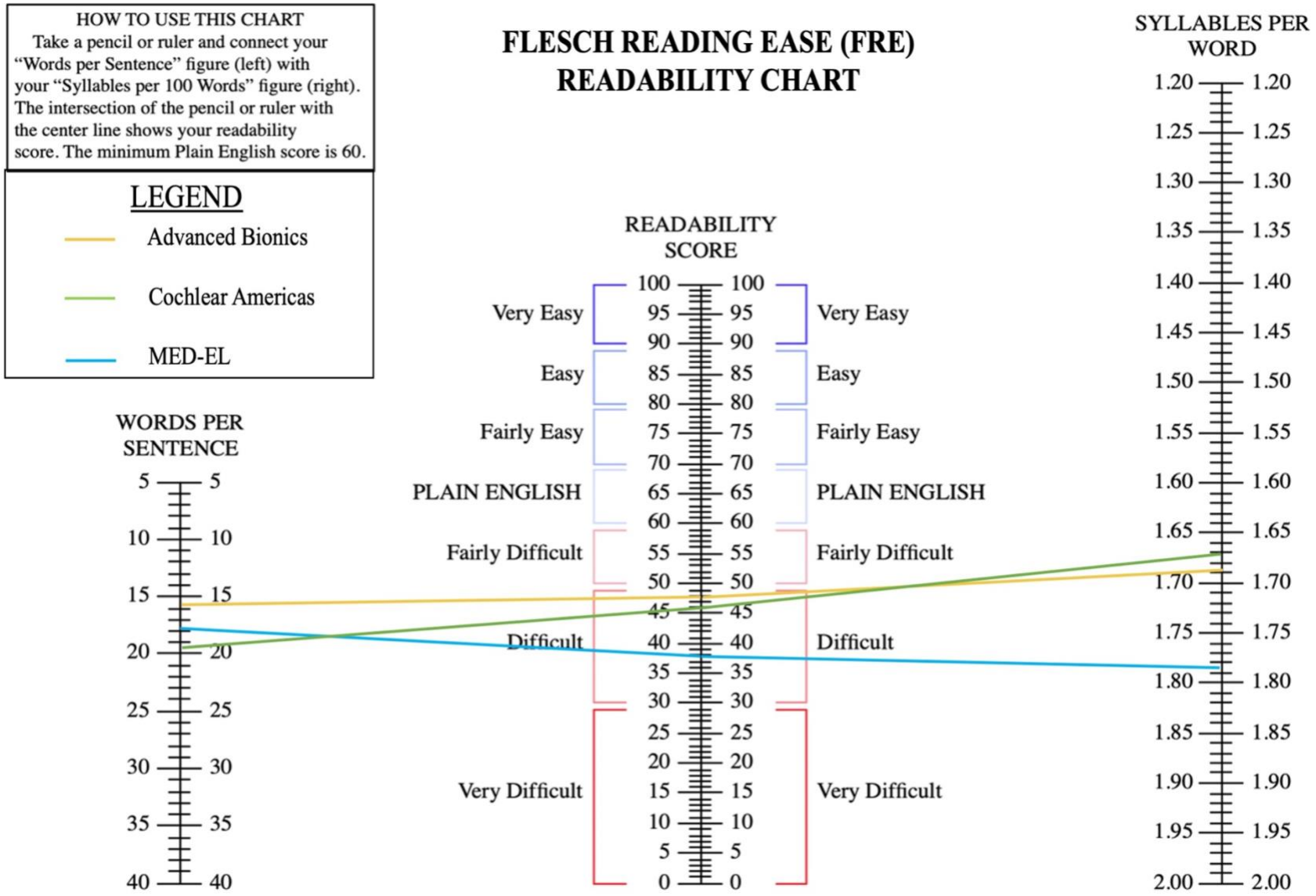

Figure 1. FRE Readability graph illustrating the ease of reading of the CI brochures.

The overall mean reading grade level for the F-K, FORCAST, Fry, Gunning Fog, and SMOG tests were 12th grade (readability score 12.1, SD 0.828), 11th grade (readability score 11.5, SD 0.086), 15th grade (readability score 15, SD 1.247), 11th grade (readability score 11.8, SD 0.734), and 13th grade (readability score 13.7, SD 0.74), respectively (as illustrated in Figure 2).

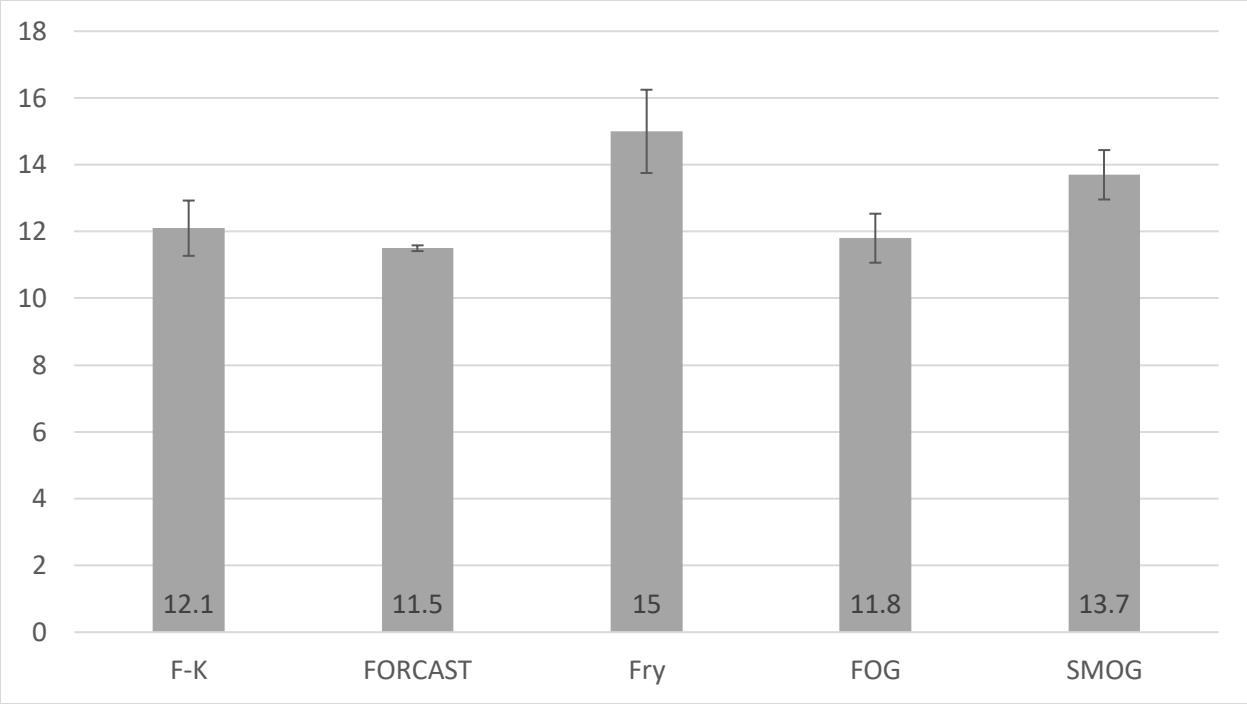

Figure 2. Columnar chart illustrating the reading grade levels and corresponding standard error of mean for the F-K, FORCAST, Fry, Gunning Fog, and SMOG.

Table 3 illustrates relative text-based features that were examined in the analysis of the three CI brochures.

Table 3. Text-based Quantitative Features of the PROMs

	Features						
CI Brochures	Words	Syllables	Sentences	Monosyllabic Words	Complex Words	Difficult Sentences	Average Sentence Length
Advanced Bionics	4572	7710	294	2634	790	71	15.6
Cochlear Americas	13545	22614	696	795	2383	204	19.5
MED-EL	18979	33823	1066	10186	3960	252	17.8

CHAPTER FOUR: DISCUSSION

When PEMs are difficult to read, they may leave parents overwhelmed and lacking the confidence to ask questions to make an informed decision. Parents must understand all the treatment and post-therapy steps to be taken for their child to achieve the best outcome. In a study, conducted by Hardonk, Daniels, Desnerck, and Loots (2011), families of six deaf children with at least one deaf parent were interviewed to identify factors in deciding between (CI) and traditional hearing aids. One family in the Hardonk et al. (2011) study reported that they felt as though they were not provided with enough information and guidance to make an informed decision. Readable CI PEMs empower parents with the knowledge about their child's hearing loss and available CI technology and features. Parents and the interdisciplinary team members can make shared decisions and work to resolve questions and concerns to ensure that parents can truly make an informed decision (Brewer, Pollock, & Wright, 2014).

The results of all six readability formulae in this study indicated that the CI brochures were written at a level that may be too difficult for most English-speaking adults to read and understand (Doak et al., 1996) (see Table 1 and Figure 1). The three CI brochures examined were written between a reading grade level range of 10.7 to 17, with a mean readability score of a U.S. college freshman reading level. Comparably, Looi et al. (2021) examined seven CI brochures from the four CI manufacturers available in Australia and found those were written between an 8.2 to 16.0 reading grade level, with a mean readability score of a 12th grade reading level. The mean FRE rating in this study was "Difficult" implying that the CI brochures would be difficult to understand by someone in ninth grade (Flesch 1948). Likewise, the Looi et al. (2021) study resulted in a mean FRE rating of the CI brochures that is "Difficult". The results of

this study are consistent with those of Looi et al. (2021) and support the previous research that CI brochures are difficult to read and written at grade levels exceeding the recommended reading levels. Given the research results, CI brochures may not be helpful for patients seeking more information to make more informed decisions.

The CI brochures from this study and the 2021 Looi et al. study are written at levels higher than other non-CI related audiology PEMs and PROMs (see Table 4). In Table 4, a comparison of readability studies of audiology PEMs and PROMs indicates that at least 338 non-CI PEMs and PROMs are written with a mean reading grade level between sixth- and twelfth-grade level. In addition, Table 4 indicates two newly developed PEMs were written at a second- and seventh-grade level and two revised PEMs were written at a fourth- and fifth-grade level (Caposecco, Hickson, & Meyer, 2011; Caposecco, Hickson, Meyer, & Khan, 2016; McMullan, Kelly-Campbell, & Wise, 2018; Pryce, Durand, Hall, Shaw, Culhane, Swift, Straus, Marks, Ward, & Chilvers, 2018). Another study, conducted by Nicholson et al. (2016), examined 48 U.S. newborn hearing screening brochures of which most were written at or near the sixth-grade reading level. The mean readability of newborn hearing screening brochures (Nicholson et al., 2016) and the mean readability of the CI brochures examined in this study have a difference of six reading grade levels. In addition, hearing aid PEMs are reported as having an average ninth-grade reading level (Caposecco et al., 2016), and 10th-11th grade reading level (Joseph, Svider, Shaigany, Eloy, McDonald, Folbe, and Hong, 2016). This trend of increasingly difficult readability could indicate that more complex medical and technical language is being used in hearing healthcare brochures that convey information to parents about hearing loss, diagnostic testing, and the features and benefits of amplification technology.

Table 4. Mean reading grade level from audiology PEM and PROM readability studies

Author (Year)	Scope (Language)	PEMs / PROMs	Mean Reading Grade Level
Atcherson et al. (2011)	Tinnitus (English)	PROMs (n = 15)	Ninth grade +
Atcherson, Richburg, et al. (2013)	Auditory processing disorders (English)	PROMs (n = 8)	Eighth grade +
Atcherson et al. (2014)	Audiology consumer info (English)	PEMs: articles in ASHA website after 2011 (n = 74)	Tenth grade +
Caposecco et al. (2011)	Hearing aids (English)	PEMs: newly developed user guide (n = 1)	Second grade +
Caposecco et al. (2014)	Hearing aids (English)	PEMs: user guides (n = 36)	Ninth grade +
Caposecco et al. (2016)	Hearing aids (English)	PEMs: user guide (n = 1) original and revised	*Original:* Tenth grade + *Revised:* Fourth grade +
Coco et al. (2017)	Audiology and otolaryngology (Spanish)	PROMs (n = 5)	Sixth grade +
Douglas & Kelly-Campbell (2018)	Audiologic rehabilitation (English)	PROMs (n = 10)	Seventh grade +
Joseph et al. (2016)	Hearing aids (English)	PEMs: user guides (n = 6)	Tenth grade +
Kelly (1996)	Hearing aids (English)	PEMs: user guides (n = 109)	Tenth grade +
Kelly-Campbell et al. (2012)	Audiology (English)	PROMs (n = 4)	Seventh grade +
Looi, et al. (2021)	Cochlear Implants (English)	PEMs: brochures (n = 7)	Twelfth grade +
Manchaiah, et al. (2019)	Hearing disability (English)	PROMs (n = 14)	Ninth grade +
McMullan et al. (2018)	Hearing aids (English)	PEMs: user guide (n = 1) original and revised	*Original:* Twelfth grade + *Revised:* Fifth grade +
Nair & Cienkowski (2010)	Hearing aids (English)	PEMs: user guides (n = not reported)	Eighth grade +
Nicholson et al. (2016)	Newborn hearing screening (English)	PEMs: brochures (n = 48)	Seventh grade +
Pryce et al. (2018)	Tinnitus (English)	PEMs: newly developed decision aid (n = 1)	Seventh grade +

To better understand the differences in readability scores, one needs to review the common features presented in Table 3. The different counts of words, syllables, and sentences provide a quantitative analysis of different features used in creating the readability formulae to estimate the reading grade level or reading ease (see Table 1). The readability software has limitations in recognizing electronic documents and formatting, for example, text boxes and punctuation may alter counts and spacing that create the appearance that a new idea or utterance has begun. Other limitations include the ability to calculate design features including the font type and size, and the use the negative space on the page.

Counseling patients is an important element of clinical practice. To afford professionals the opportunity to develop and implement clinical counseling skills, undergraduate and graduate programs should consider coursework that aligns with patient-centered interactions, and informational counseling. Student development activities could include how to explain diagnostic test results and content of PEMs as well as implement assignments that prepare the student for having knowledge/understanding of health literacy reading levels. Pre-professional training may include students breaking down the PEMs to identify difficult to comprehend content, then recreate sentences and paragraphs to present material in role playing exercises to facilitate understanding PEMs from a patient's point of view. Another exercise that could help students further develop counseling skills is to have students create summaries and quick reference guides using plain language to supplement the PEMs. In supervised clinical practice, supervisors can provide evidence-based clinical standards, additional coaching/modeling, and feedback, so students can identify opportunities to further develop their skills learned through academic and clinical experiences.

Professionals should consider the average reading level needed to understand and act upon PEMs when presenting information and resources to the patient or the parents for informed and shared decision-making. Professionals can anticipate the elevated reading levels of PEMs and overcome some challenges by taking into consideration the PEMs readability. Professionals can explain complex medical terminology and jargon to patients and their families using common, everyday words. Some best practices may include using pronouns such as “you”, “she”, and “he”, making interactions patient-centered, and use plain language when presenting information.

Authors of PEMs should consider the health literacy skills of the reader to facilitate effectiveness in the decision-making process. One consideration is to review the readability of the PEMs and include definitions of complex medical terminology and incorporate plain language into their PEMs. Additionally, they should consider spacing, headings, sentence structure, bullets and visual organization of the materials and use relevant images. Another consideration would be to create a quick reference guide with easy-to-read headings and simple designs to summarize key points.

Recommendations for further research include analyzing CI brochures in other languages available, such as Spanish, to potentially identify discrepancies, complexity, and challenges with the translation. Secondly, creation of focus groups with monolingual and bilingual parents to determine if, and what components of the CI brochures influence their decision-making, and whether additional challenges are uncovered based on the content within the PEMs. And finally, collaborations with manufacturers, PEM authors and professionals to explore revisions of existing materials and/or development of future brochures for greater ease of reading for the intended audience.

Conclusions

Parents decisions about their child's healthcare and CI technology is an ongoing, multi-step process. Parents receive information from the audiologist, SLP, and other members of their child's interdisciplinary team. In addition, parents may seek second opinions, ask friends and family, and search the internet for convenience and accessibility. PEMs are only one component of data that parents might utilize to make decisions and can be a valuable resource for patients and their families.

Results from this study confirm that the current CI brochures available from all three CI manufacturers were too difficult for the average adult in the United States to read and comprehend. The elevated reading levels are attributed to the medical and technical terminology, industry jargon, complex sentence structure, long word and sentence lengths, and the use of passive voice. Due to their complexity, these CI brochures may not be helpful to parents in making decisions for their child. If parents cannot read the materials, they are less likely to use these CI brochures in the decision-making process.

Professionals may need to take extra time to determine whether the patient or their families understand the content. This can be accomplished by asking the parents if they have additional concerns or questions that are not addressed in the PEMs. Additionally, the developers of these materials should consider the health literacy skills of the reader and how CI brochures can be developed using language that is easy to read and useful for parents making important decisions about their child. Finally, audiologists and SLPs should work collaboratively with parents to support them in the shared decision-making process. Specifically, this collaboration ensures that the CI brochures and other PEMs provided to parents are understandable and useful as they navigate through what is best for their child.

APPENDIX A: ACRONYM KEY

ACRONYM	FULL NAME
AAA	American Academy of Audiology
ASHA	American Speech-Language Hearing Association
ASL	American Sign Language
CDC	Center for Disease Control and Prevention
CI	Cochlear Implant(s)
DHH	Deaf or Hard of Hearing
EHDI	Early Hearing Detection and Intervention
FDA	Food and Drug Administration
F-K	Flesch-Kincaid
FOG	Gunning FOG Index
FRE	Flesch Reading Ease
FRY	Fry Readability Graph
HAT	Hearing Assistive Technology
JCIH	Joint Committee on Infant Hearing
K-12	Kindergarten Through 12th Grade
LSL	Listening and Spoken Language
NAAL	National Assessment of Adult Literacy
NHIS	National Health Interview Survey
PE	Pressure Equalization
PEMs	Patient Education Materials
PROMs	Patient-Reported Outcome Measures

SLP	Speech-Language Pathologist
SMOG	Simple Measure of Gobbledygook
UNHS	Universal Newborn Hearing Screening

APPENDIX B: IRB DETERMINATION: NOT HUMAN RESEARCH

UNIVERSITY OF CENTRAL FLORIDA

Institutional Review Board
FWA00000351
IRB00001138, IRB00012110
Office of Research
12201 Research Parkway
Orlando, FL 32826-3246

NOT HUMAN RESEARCH DETERMINATION

September 23, 2020

Dear Janel Cosby:

On 9/23/2020, the IRB reviewed the following protocol:

Type of Review:	Initial Study
Title of Study:	Readability of Cochlear Implant Brochures: A Potential Factor in Parent Choice
Investigator:	Janel Cosby
IRB ID:	STUDY00002269
Funding:	None
Grant ID:	None
Documents Reviewed:	• IRB HRP-250 Form, Category: IRB Protocol

The IRB determined that the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations.

IRB review and approval by this organization is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are research involving human in which the organization is engaged, please submit a new request to the IRB for a determination. You can create a modification by clicking **Create Modification / CR** within the study.

If you have any questions, please contact the UCF IRB at 407-823-2901 or irb@ucf.edu. Please include your project title and IRB number in all correspondence with this office.

Sincerely,

Racine Jacques, Ph.D.
Designated Reviewer

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