Factors that Influence Device Selection by Parents of Pediatric Cochlear Implant Candidates

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FACTORS THAT INFLUENCE DEVICE SELECTION BY PARENTS OF PEDIATRIC COCHLEAR IMPLANT CANDIDATES

by
Zachary William Moore

An Independent Study Thesis
Presented in Partial Fulfillment of the Course Requirements for Senior Independent Study: The Department of Communication

March 28, 2016

Advisor: Donald M. Goldberg, Ph.D.
ABSTRACT

The purpose of this study was to investigate factors/variables and the importance of those factors during cochlear implant (CI) device selection by parents of recent pediatric CI recipients in the United States. The researcher created an electronic survey and asked audiologists and hearing-related professionals at various hospitals and CI centers across the United States to distribute the survey link to the parents of any of their pediatric CI patients who received CI surgery within the past two years under the age of five years. The survey included both Likert-type and open-ended questions regarding the importance of various factors/variables to the parents during their child’s CI device selection. Results of the study found that the participants ranked reported reliability and speech perception performance of the respective manufacturer’s CI device as the most important factor. Individually, the parents of Cochlear, Ltd. recipients found recommendations from others and the popular brand of the company to be most important; based on a limited sample, parents of Advanced Bionics recipients found the CI device’s waterproof capabilities to be most important; and, also based on a limited sample, parents of MED-EL recipients found the reported speech perception performance to be most important.

Keywords: cochlear implants, cochlear implant device selection, pediatric cochlear implant recipients
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In Loving Memory of

John William Guappone

My Friend, my Mentor, my Brother
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CHAPTER I

INTRODUCTION

Parents typically go through a tremendous amount of stress and have significant anxiety when they find out their child has a profound hearing loss. For many of those parents, the decision regarding selection of a cochlear implant (CI) device can only add to that stress and anxiety. There are numerous factors that come into play during the process of CI device selection that requires careful consideration by the parents of these children. The manufacturers of CIs all try to assist parents through the ways they market their devices and via the services they provide. It is important for both the parents and the professionals working with them to understand how each manufacturer addresses the varied decision-making factors. This introductory chapter will present the purpose of this study, several rationales to justify this research project, definitions of key terms, and the method by which data will be collected.

Purpose Statement

The purpose of this study was to investigate factors/variables and the importance of those factors during cochlear implant (CI) device selection by parents of recent pediatric CI recipients in the United States. These factors will include the marketing of the CIs, experiences and outcomes from other recipients, and the potential influences on the family by audiologists and other CI team members on the family. The three manufacturers currently approved by the United States’ Food and Drug Administration that were compared included Advanced Bionics, Cochlear Americas, and MED-EL. Centers with options of two or three CI manufacturers were studied in order to ensure a comparative decision-making process. The products developed by these three manufacturers will be examined along with the perceived performance outcomes of the CI devices in pediatric patients. This study focused on the factors considered most important to the
families and evaluated how these three companies address those factors when providing information to families who often have no prior experience with cochlear implant technology.

**Rationales**

Exploring the factors that affect device selection is considered important due to several reasons. First, the amount of literature or research studies relating to the decision-making between all three CI manufacturers in the United States is extremely limited. Most of the literature that does exist compares only two companies or studies only one aspect of decision-making such as device reliability. There have not been many clear, comprehensive analyses of current literature and comparison of all three CI manufacturers within the United States. The reports that do exist are limited to blogs and independent case studies sponsored by the individual manufacturers themselves (Hochmair, Nopp, Jolly, Schmidt, Schösser, Garnham, & Anderson, 2006; Spahr, Dorman, Loiselle, 2007). The informational brochures and pamphlets created and distributed by each of the CI manufacturers all contain abbreviated reference lists on the backs of the documents relating to studies completed “in-house” to promote their own device (Advanced Bionics, 2015a; “The Cochlear Nucleus System,” 2015; MED-EL, 2015). Withers, Gibson, Greenberg, and Bray (2011) argued that the constantly expanding sample population of CI candidates will require further research of different CI manufacturers. They stated that “information from [new] patients should be collated to further assist comparisons between [these] companies” (p. 126). This is especially true in the case of MED-EL, an Austrian-based company, and Advanced Bionics, a California- and Switzerland-based company, whose products are not included in as many CI centers as Cochlear Americas but will be included in this study.

Similar studies were completed in the United Kingdom which looked at survey data from parents of pediatric CI recipients who received services through the West of England Cochlear
Implant Programme at the Royal National Throat, Nose and Ear Hospital in Bristol (Clamp, Rotchell, Maddocks, & Robinson, 2013; Geyer, Seymour, Stott, Lynch, Beukes, Aleksy, & Graham, 2006). The challenge with these studies, however, was that only MED-EL and Cochlear devices were offered at the clinic, essentially limiting the comparison to only two companies. These studies also only examined families in the United Kingdom whose attitudes about decision-making factors may differ from the attitudes of American families. Other studies have examined CI recipients in countries such as China, Israel, and Canada, among others, providing data that may be skewed by different cultural factors from those of American families (Davids, Ramsden, Gordon, James, & Papsin, 2009; Eskander, Gordon, Kadhim, Papaioannou, Cushing, James, & Papsin, 2011; Li, Qin, Zhang, Li, Qi, & Liu, 2014; Migirov, Dagan, & Kronenberg, 2009). Differing factors include varying government approval of CI devices, affordability for certain families from lower financial backgrounds, and candidacy criteria that were either more or less stringent than those in the United States, among other variables. These factors not only involve the different attitudes towards CI technology in general within each of those respective cultures, but also by the availability (or not) of all three manufacturers at each of the CI centers in those studies. A comprehensive comparison is needed that addresses the devices of all three manufacturers in the United States and would therefore be more relevant to CI teams working with American patients.

Aside from the lack of literature pertaining to all three manufacturers’ products within the context of the United States, the second rationale stems from the lack of independent research comparing all three manufacturers and how CI recipients and their families respond to certain comparative factors. Case studies performed at various CI centers around the world have provided descriptive details pertaining to surgical complications and the reliability of different CI
devices in regards to “hard” and “soft” failures. Other than the aforementioned study by Clamp and his colleagues (2013), however, there is no scholarly research expanding case studies to examine how those complications actually affect patients’ perceptions of each respective device. This study aims to provide a basis of how and what factors contribute to the development of patients’ and their families’ perceptions and ultimate selection of each manufacturer’s CI device, specifically for pediatric recipients.

The third rationale for this study is the demand for updated research that enables CI manufacturers to fine-tune their marketing strategies in order to maximize sales. According to Mackert and Harrison (2009), “new research into consumers’ attitudes toward surgically implanted devices, and the decision-making processes that lead to purchases… could help inform [the] discussion [of direct-to-consumer advertising]” (p. 5). One of the biggest issues that surrounds the process of cochlear implantation is a consideration of “direct-to-consumer” advertising for a surgical procedure. Marketing to families of pediatric candidates as young as 12 months who are most likely dealing with immense stress, requires ethical cautions in regards to what manufacturers do or say. Determining the current factors that influence CI device selection allows manufacturers to focus on what these families find important and can provide straightforward information in order to best assist them as consumers. This information can then be used to ultimately increase sales through “honest” advertising.

Lastly, in addition to expanding the scholarship in the area, this study will also assist professionals in the provision of guidance during the cochlear implant decision-making process. In his article exploring the integration of parents more into the CI process, Marriage (2013) stated, “audiologists need to take the lead from parents… for applying and maintaining the hearing technology,” arguing that parents need to have a more central role when it comes to their
child’s CI (p. 9). In order for families of pediatric patients to make the most educated decisions, however, it is up to the audiologist and each member of the cochlear implant team to have a more complete understanding of each manufacturer’s devices. Several studies have examined out-dated CI technology or device models, and have pointed out the presence of continuously-evolving CI technology, which requires professionals on cochlear implant teams to provide the patient’s family with all the information about the different devices they can, in order for the patient to ultimately succeed as a CI recipient (Balkany, Hodges, Eshraghi, Butts, Bricker, Lingvai, Polak, & King, 2002; Clamp et al., 2013; Hildrew & Molony, 2013). Geyer and his colleagues (2006) also pointed out that it is important for patients and families to be involved with the CI decision-making process. With the complexity of the technology, however, and how quickly the technology is advancing, CI team members must first have an understanding of all available technology in order to help the families involved in the complex decision-making process.

Definitions

To completely understand this study, several key words need to be defined. First, a cochlear implant is an “electronic device that bypasses the cochlea by means of an electrode array stimulating directly the cochlear nerve… now considered to be [the] standard of care in treatment of children with severe to profound [sensorineural hearing loss]” (Vincenti, Bacciu, Guida, Marra, Bertoldi, Bacciu, & Pasanisi, 2014, p. 2). Following a cochlear implant being implanted, audiologists conduct a process called MAPping, or “programming,” which “determines how the cochlear implant will provide electrical stimulation to the auditory nerve to represent speech and environmental sounds detected by the sound processor” (Wolfe, Schafer, & Neumann, 2015, p. 1). A cochlear implant team includes a group of medical and medically-
related professionals including “an otolaryngologist, audiologist, a rehabilitation and educational professional,” as well as the patient and the patient’s family that work together to establish the best possible experience for the patient (Balkany et al., 2002, p. 357). The American Academy of Audiology defined an audiologist as “an individual who… is uniquely qualified to provide a comprehensive array of professional services related to… the audiologic identification, assessment, diagnosis, and treatment of persons with impairment of auditory and vestibular function” (as cited in Martin & Clark, 2012, p. 4).

The sample population that will be investigated in this study involves parents of pediatric patients at United States cochlear implant centers. A pediatric candidate for this study will be a patient between birth and five years; 11 months of age that meets the criteria of severe to profound sensorineural hearing loss in both ears (O’Brien, Valim, Neault, Kammerer, Clark, Johnston, Culver, Zhou, Kenna, & Licameli, 2012, p. 77). In order to be implanted in patients, especially those within the pediatric age range, new cochlear implant technologies must be regulated for safety. Cochlear implants are medical devices approved by the United States Food and Drug Administration (FDA), the federal regulatory agency tasked with determining the “safety and effectiveness” of consumable or medical treatment-related products through clinical trials and “postmarket surveillance” (Sorenson & Drummond, 2014, pp. 116-117). The FDA was given this authority by the Federal Food, Drug, and Cosmetic Act of 1938 (Ciociola, Cohen, & Kulkarni, 2014, p. 620). Finally, marketing means “to create exchanges that satisfy individual and organizational goals… through customer relationships” (Sheth & Uslay, 2007, p. 302).

**Description of Method**

This study will involve the quantitative method of survey research to investigate the factors deemed most important to families. The surveys will be distributed electronically through
audiologists at CI centers using a link to a Qualtrics survey to families of pediatric patients who had their surgery completed at medical facilities throughout different regions of the United States between January 1, 2014 and December 31, 2015. These facilities include those that offer either two or all three of the CI manufacturers’ devices. Specific CI centers will be selected using the “Find a Clinic” search on each individual CI manufacturer’s website to find a range of CI centers across the United States who offer two or more of the manufacturers’ CI devices. Audiologists or surgeons at these specific hospitals or CI centers will be sent an electronic survey link via e-mail. The survey will include Likert-type scales, ordinal rankings, and open-ended questions pertaining to the families’ experience with the cochlear implant device selection process.

**Conclusion**

This study will attempt to determine the most important factors in cochlear implant device selection among families of pediatric patients in various programs across the United States. The study is important for several reasons. The first reason is the value of helping in the expansion of literature through a comprehensive comparison of all three manufacturers within the United States. A second reason is to magnify knowledge of not only how the CI devices from each manufacturer differ, but how CI patients and their families perceive these differences. The third reason is to provide up-to-date information for cochlear implant manufacturers to use in order to fine-tune how they market their devices. A final reason for completing this study is for professionals on cochlear implant teams to better understand what factors are most important to a family of a pediatric candidate so they can provide the best services possible. The research will be conducted through quantitative methods, making use of surveys distributed to families of pediatric cochlear implant recipients primarily through hospital-based CI centers. The next chapter will look at previous research pertaining to the three cochlear implant manufacturers and
the decision-making process for these impacted families.
CHAPTER II

LITERATURE REVIEW

The study of variables among the Cochlear Implant (CI) devices for the three CI manufacturers in the United States and their influence in the device selection process for families is a relatively novel expedition. The existing literature provides a current outlook on the manufacturers’ CI devices and the overall performance outcomes of those devices, as well as some the ideas behind their marketing. Reviewing the available research will provide a comprehensive look at what is already known about the subject of this study. As previously mentioned, a major goal of this investigation is to add to the existing literature on CI device selection factors. This chapter will therefore explore the available research studies to establish a clear understanding of CI technology and the market for that technology before moving on to the actual study in the following chapters and completion of this goal.

Anatomy and Physiology of the Ear

Anatomy of the Ear

To the naked eye, a person’s ears may not seem very complex beyond holding up glasses or earrings. The hearing mechanism, however, is an intricate pathway of bones and an organ leading to the brain that is essential for the perception of sound. Sound is made up of vibrating air particles traveling as both sinusoidal and complex waves (Denes & Pinson, 2007, p. 17). These waves are funneled and transferred through the anatomical structures of the outer, middle, and inner ear sections before reaching the auditory nerve that delivers them to the brain. The average human ear picks up sound waves between the frequencies of 20 Hz to 20,000 Hz (Beck & Bhatara, 2012, p. 10; Denes & Pinson, 2007, p. 29). Each of the sections of the ear contains unique components with various functions in the perception of sound.
**Outer ear.** The first and most external section of the hearing mechanism is the outer ear. The pinna, or auricle, is composed of cartilage and is the outermost anatomical structure, located anterior to the mastoid process of the temporal bone (Mansour, Magnan, Haidar, Nicolas, & Louryan, 2013, p. 10; Seikel, King, & Downright, 2005, p. 436). The pinna contains several important landmarks related to sound reception, including the helix, the “curled margin” making up the external border; the concha, a bowl-like groove near the center of the pinna leading to the external auditory meatus; and the tragus, a cartilaginous flap protruding next to the concha (Seikel et al., 2005, p. 436). Medial to the pinna, or closer to the body’s midline, is the external auditory meatus (EAM), or “ear canal.” The EAM is a slight “S” shape measuring about 2.5 cm in length and 0.6 to 0.7 cm in diameter (Möller, 2006, p. 5). It is made up of cartilage for the initial third closest to the pinna and then changes to a bony makeup as it moves medially (Seikel et al., 2005, p. 438). The tympanic membrane (TM) is “a three-layered sheet of tissue” located at the end of the EAM and represents the border between the outer ear and the middle ear (Möller, 2006, p. 6; Seikel et al., 2005, p. 438).

**Middle ear.** The middle ear is an air-filled cavity located within the temporal bone of the skull (Mansour et al., 2013, p. 19; Martin & Clark, 2015, p. 17). There are six “walls” that surround the middle ear cavity: the lateral wall, the jugular (inferior) wall, the mastoid (posterior) wall, the tegmen (superior), the carotid (anterior) wall, and the cochlear (medial) wall (Mansour et al., 2013, p. 19; Martin & Clark, 2015, p. 239). The cochlear wall contains the oval window (superior) into the scala vestibuli of the cochlea and the round window (inferior) into the scala tympani of the cochlea, along with the promontory, a “bulge created by the basal turn of the cochlea” (Seikel et al., 2005, pp. 447-448). The Eustachian tube is another structure of the middle ear that connects the cavity to the nasopharynx located behind the nose and above the
throat (Möller, 2006, p. 8). The primary structures of the middle ear are the three “bones of the ear” or ossicles, which include the malleus, incus, and stapes (Seikel et al., 2005, p. 441). The malleus is the lateral-most ossicle and also the largest of the three. The manubrium of the malleus attaches to the TM and the head articulates, or connects, with the body of the incus. The lenticular process of the incus articulates with the head of the stapes. The footplate of the stapes rests in the oval window into the cochlea, essentially connecting the middle ear and inner ear (Martin & Clark, 2015, p. 241; Möller, 2006, p. 8; Seikel et al., 2005, pp. 441-444). The middle ear also contains two muscles, the tensor tympani and the stapedius, which are designed, in part, to protect the inner ear from excessively loud noises by stiffening the ossicular chain to reduce sound transmission in the presence of these noises (Denes & Pinson, 2007, p. 85).

**Inner ear.** The inner ear is the third and most medial part of the three ear sections. For the pediatric patients included in this study, this is the most relevant section of the ear because it involves the site of lesion for cochlear implant recipients. The structures of the inner ear are housed together in what is called the “labyrinth,” which is made up of an osseous part and a membranous part. The osseous or bony portion contains the vestibule or “entryway to the labyrinth,” the osseous semicircular canals, and the bony cochlear canal (Seikel et al., 2005, p. 452). The membranous portion is located within the osseous portion and includes the membranous, fluid-filled sac of the semicircular canals responsible for “equilibrium and balance,” and the cochlea (Denes & Pinson, 2007, p. 85). The auditory nerve, also referred to as the cochlear nerve or cranial nerve (c.n.) VIII, is also considered part of the inner ear. It is comprised of a bundle of individual nerve fibers that transfer electric energy signals from the outer hair cells of the cochlea to the central auditory nervous system of the brain (Martin & Clark, 2015, p. 280).
**Cochlea.** The cochlea is an extremely important anatomical structure of the hearing mechanism to understand in regards to cochlear implantation. As previously mentioned, this is the most relevant site within the auditory pathway for the pediatric CI recipients involved in this study. The cochlea is responsible for transforming the acoustic mechanical vibrations of the sound signal to electrical signals (Denes & Pinson, 2007, p. 85). There are three fluid-filled canals wrapped around a central core, the modiolus that make up the snail shell-shaped organ.

Anatomically, the scala vestibuli is the superior-most canal, found beyond the oval window. The scala tympani is the inferior-most canal, found beyond the entrance of the round window. The final canal is the scala media, also known as the “cochlear duct,” found between the other two scala, separated by two separate membranes (Martin & Clark, 2015, p. 278). Reissner’s membrane separates the scala vestibuli from the scala media, and the basilar membrane is the border or “floor,” between the scala media and the scala tympani (Seikel et al., 2005, p. 454). The scala vestibuli and the scala tympani are both filled with perilymph fluid and flow into each other at the point of the helicotrema, whereas the scala media is filled with the fluid called endolymph (Denes & Pinson, 2007, p. 86; Martin & Clark, 2015, p. 278).

The primary “organ of hearing” is the organ of Corti, located in the scala media along the basilar membrane (Seikel et al., 2005, p. 454). The organ of Corti contains the four rows of hair cells responsible for the transforming of sound energy to electrical signals. Essentially three of the four rows are outer hair cells (OHC) and the other row is more medial to the modiolus, separated by the tunnel of Corti and composed of inner hair cells (IHC). There are approximately 3,000 to 3,500 IHC and over 12,000 OHC within the cochlea, each with about 50 “hair-like projections” called stereocilia on top (Martin & Clark, 2015, p. 280; Möller, 2006, p. 11; Seikel et al., 2005, p. 455). The hair cells are the parts that connect the cochlea to the auditory nerve.
through neural synapses, which will be explained later (Seikel et al., 2005, p. 456). These sensory hair cells are physically supported by two individual sets of non-sensory cells, Hensen’s cells and Deiter’s cells (Möller, 2006, p. 12).

Different hair cells register or respond selectively to specific frequencies depending on location within the cochlea, known as a “tonotopic arrangement” (Seikel et al., 2005, p. 472). The basal end of the cochlea is located toward the oval and round windows and the apical end is located near the modiolus, the apex of the cochlea (Seikel et al., 2005, p. 452). According to Clark (2006), “high frequencies produce maximal vibrations at the basal end, and low frequencies at the apical end,” meaning higher-frequency sounds stimulate the hair cells closer to the vestibule and lower-frequency sounds stimulate the hair cells located farther within the cochlea (p. 791). For the vast majority of pediatric CI recipients included in this investigation, there is a deficiency in hair cells or malformation of the cochlea in some way that results in an inability of various degrees to transmit sound signals.

**Physiology of the Ear**

While the term “anatomy” refers to actual physical structures of the body, “physiology” addresses how those anatomical structures work to carry out a function (Martin & Clark, 2015, p. 16). The structures of the outer, middle, and inner ear work together as a “transducer” to convert sound waves from acoustical energy signals to mechanical signals to electrochemical energy signals that can be interpreted by the brain (Seikel et al., 2005, p. 435). The process starts out when sound waves are funneled by the unique shape of the pinna, especially by the concha, and set the EAM into vibration. The pinna and EAM act as an acoustic resonator and can increase the pressure of the sound waves with enhancement of the “signal intensity between 1500 Hz and 8000 Hz” (Seikel et al., 2005, p. 467) when it reaches the TM (Denes & Pinson, 2007, p. 80).
The resonant vibrations cause the TM to vibrate, setting in motion the ossicular chain.

The lever action of the ossicles results in the piston-like movement of the footplate of the stapes in and out of the oval window, stimulating wavelike movement of the fluid within the cochlea. This movement causes compression and rarefaction of both Reissner’s membrane and the basilar membrane based on the corresponding frequency of the sound signal. As the wave travels along the basilar membrane, it creates a “shearing action” of the outer hair cells, the location of which is determined by the signal’s frequency and the tonotopic arrangement of the hair cells (Seikel et al., 2005, p. 468, p. 471). Inner hair cells are stimulated by the movement of the endolymph within the scala media (Martin & Clark, 2015, p. 280). The stimulation of the hair cells causes chemical changes and activation of “electrical potentials” that in turn stimulate the corresponding nerve fibers of the auditory nerve (Seikel et al., 2005, p. 474). The brain is then able to perceive the electrical signals sent through the auditory nerve as sound.

**Physiological pathways.** The hearing mechanism is typically divided into two distinct pathways. The first is the “conductive portion,” which involves air conduction through the whole system, including the outer, middle, and inner ear (Martin & Clark, 2015, p. 17). The second pathway involves the “sensory/neural portion,” which is the cochlea and the auditory nerve. Sound traveling by bone conduction stimulates just the sensory/neural portion by bypassing the outer and middle ear and stimulating the cochlea directly (p. 17). There are three types of bone conduction. The first type is distortional, in which the bones of the skull are vibrated by the sound, causing “distortion of the structures of hearing within the cochlea” (p. 85). The second type is inertial, which involves the delayed movement of the stapes relative to the malleus and incus in and out of the oval window when the skull is vibrated, stimulating the cochlea. The third type is osseotympanic, in which vibrations of the skull have corresponding vibrations in the
EAM and ultimately the TM, resulting in stimulation similar to that via air conduction. (Martin & Clark, 2015, p. 85).

**Hearing Loss**

The aforementioned hearing process occurs when an individual has no issues or defects along the auditory pathway. When a defect or lesion is present along the auditory pathway, it results in a hearing loss. Hearing loss is the most frequent birth defect found in the United States and “the most prevalent sensorineural disorder in developed countries” (Hoppman, Aypar, Brodersen, Brown, Wilson, & Babovic-Vuksanovic, 2013, p. 1). It is found in about two to three out of every 1000 “live births” (Hoppman et al., 2013, p. 1; Vincenti, Bacciu, Guida, Marra, Bertoldi, Bacciu, & Pasanisi, 2014, p. 2). The National Institute on Deafness and Other Communication Disorders (NIDCD) (2015) reported that bilateral hearing loss can be found among one in every eight United States citizen above the age of 12 years (para. 5). There are also about 37.5 million adults over the age of 18 years in the United States that report trouble hearing (National Institute on Deafness and Other Communication Disorders, 2015, para. 3). Hearing loss is not all the same, however, as different areas of the auditory pathway can be affected.

**Types of Hearing Loss**

There are three primary types of hearing loss. The first type is a conductive hearing loss. A conductive hearing loss involves a site of lesion in the outer and/or middle ear that attenuates, or “decrease[s] the strength of sound,” traveling to the cochlea (Martin & Clark, 2015, p. 18). In a conductive hearing loss, air conduction is abnormal while bone conduction is within normal limits because the cochlea and auditory nerve function normally when the sound bypasses the outer and middle ear (Johnson, 2012, p. 12; Martin & Clark, 2015, pp. 18-19). Possible pathologies within the conductive mechanism include “impacted cerumen (ear wax), growths, or
infections” in the outer ear and a “perforation in the tympanic membrane, the presence of fluid or otitis media, [and] a cholesteatoma” are all possibilities for the middle ear, among others (Johnson, 2012, p. 12). The vast majority of conductive hearing losses are medically treatable because the lesion is typically just blocking the air conduction of sound and can be treated through “drug therapy, external and/or middle ear surgery, and/or hearing aids” (Vincenti et al., 2014, p. 2).

The second type of hearing loss is a sensorineural hearing loss (SNHL). The site of lesion in a SNHL is the cochlea (sensory) and/or the auditory nerve (neural) (Johnson, 2012, p. 12; Martin & Clark, 2015, p. 19; Vincenti et al., 2014, p. 2). Over half of pediatric SNHL cases at the time of birth are results of genetic factors, whereas SNHL acquired after birth through infections or other factors make up anywhere from 15% to 40% of these pediatric cases (Vincenti et al., 2014, p. 2). The majority of SNHL is found within the cochlea as opposed to the nerve, meaning the sensory aspect is more often affected (Vincenti et al., 2014, p. 2). Sensory pathologies usually involve the destruction of hair cells due to a variety of causes such as “excessive noise exposure, ototoxic drugs, [and] aging” (Johnson, 2012, p. 12). Tumor growth is the more common pathology affecting the neural aspect of a SNHL (Martin & Clark, 2015, p. 19). The majority of SNHL cannot be treated medically and are considered permanent (Johnson, 2012, pp. 12-13).

Within the realm of SNHL there is a condition called auditory neuropathy spectrum disorder (ANSD) that has been recorded, with much variability, among anywhere from 2.4% to 15% of pediatric hearing loss diagnoses each year (Roush, Frymark, Venediktov, & Wang, 2011, p. 159). ANSD appears to involve normal outer hair cell function but abnormal functioning either within the synaptic connection between the inner hair cells and the auditory nerve, or in
the auditory nerve’s connection to the central auditory nervous system of the brain. Speech recognition in the presence of noise is exceptionally “poor” for ANSD patients, yet the hearing thresholds of persons with the condition range from normal limits to even hearing losses in the profound levels (Chandan & Prabhu, 2015, pp. 1801-1802; Roush et al., 2011, p. 159). This type of SNHL is difficult to diagnose and treat, especially when some ANSD patients, such as the 29% of patients in a study by Sininger and Oba (2001), experience “fluctuating” hearing loss (as cited in Chandan & Prabhu, 2015, p. 1802). Either hearing aids or cochlear implants are used to treat ANSD, though as Roush and her colleagues found in their 2011 study, the success of a patient with either of the respective hearing technologies vary from patient to patient (p. 167).

The third type of hearing loss is a mixed hearing loss. This is characterized by a site of lesion in any combination of both the conductive mechanism and the sensorineural mechanism (Johnson, 2012, p. 13; Martin & Clark, 2015, p. 19). Individuals with a mixed hearing loss have some type of pathology causing impedance of sound, such as impacted cerumen in the outer ear and/or middle ear fluid, along with a pathology in the inner ear affecting sound recognition, such as noise-induced hearing loss. Because both the conductive and the sensorineural mechanisms are affected, both air conduction and bone conduction are abnormal, with air conduction being more abnormal because it has to travel through all lesions (Martin & Clark, 2015, p. 19).

Outside of the three main types of hearing loss there are two more types that are less common. The first is a “central” hearing loss, which is characterized, according to Johnson (2012), by “congenital or acquired damage or disease (e.g., tumors) to the auditory nerve and its pathways, and reception and processing areas in the cortex [of the brain]” (p. 13). The pathologies relating to this type of hearing loss are considered “retrocochlear” (Johnson, 2012, p. 13), meaning they are located beyond the cochlea somewhere along the pathway from the
auditory nerve to the primary auditory cortex (Humes, Dubno, Gordon-Salant, Lister, Cacace, Cruikshanks, Gates, Wilson, & Wingfield, 2012, p. 637). Within this type of hearing loss is central auditory processing disorder, or (c)APD, which involves hearing thresholds that are within normal limits during testing, yet the individual has physical difficulty in sound comprehension (Martin & Clark, 2015, p. 329).

Central hearing losses are more difficult to diagnose than conductive and SNHL because they present similar loss of hearing sensitivity and poor understanding of speech in the presence of noise as well as asymmetric audiometric results that are consistent with tumors that could also be located beyond the cochlea (Johnson, 2012, p. 13; Martin & Clark, 2015, p. 319). Certain electrophysiological measures can, however, provide important clues in diagnosing hearing losses found in higher levels of the brain. Magnetic resonance imaging (MRI), which provides detailed looks at abnormalities within the central auditory pathway, and auditory brainstem response testing (ABR) are two measures that can be helpful in diagnosing central hearing losses (Johnson, 2012, p. 14; Vincenti et al., 2014, p. 4).

The second of the “rare” hearing losses is a “non-organic” or “psychogenic” hearing loss. This is a “tricky” hearing loss to diagnose for many audiologists or hearing-related professionals because there are no physical symptoms that reveal a hearing loss and oftentimes the individual’s audiometric testing results are within normal limits. The causes of this hearing loss, however, range from patients who are lying about having a hearing loss for personal gain to those who are under some sort of psychological stress that causes them to believe they struggle to hear (Martin & Clark, 2015, pp. 344-345).

**Degrees of Hearing Loss**

Regardless of the cause or type, it is important to discover the degree or severity of each
ear’s hearing levels in order to distinguish how much it affects the patient. The degrees of 
hearing loss may range from within normal limits to profound based on the individual’s hearing 
thresholds, measured in dB HL. Thresholds between -10 and 15 dB HL are considered within 
normal limits (WNL). Thresholds between 16 and 25 dB HL are considered slight or minimal, 
although for adults this range can also be considered within normal limits. Mild lies between 26 
and 40 dB HL; moderate is 41 to 55 dB HL; and moderately severe is 56 to 70 dB HL. The final 
two degrees are the most important in regards to cochlear implantation, including, in the case of 
hybrid implants, severe, 71 to 90 dB HL, and profound, which is any threshold greater than or 
equal to 91 dB HL (American Speech-Language-Hearing Association, 2015, chart; Johnson, 
2012, p. 11; Martin & Clark, 2015, p. 83). In order to determine the degree of hearing loss or to 
diagnose any of the aforementioned hearing losses, an individual must undergo various types of 
audiometric testing.

Assessment of Pediatric Hearing Loss

There are many different methods for assessing hearing loss among the pediatric 
population. Before detailing these methods, it is important to distinguish between testing and 
screening in the realm of audiology. Johnson (2012) defined “screening” as a “short testing 
process that serves to distinguish persons who may have a condition… that needs further 
evaluation from those who do not” (p. 9). Essentially, screenings discover which people are at 
risks for a condition. Audiometric testing expands upon pass/refer screenings with the goal of 
“making decisions regarding the type and extent of a patient’s hearing loss” (Martin & Clark, 
2015, p. 70). There are many different types of audioligic testing, each with a unique purpose.

Electrophysiological Testing

For over 97% of infants, the first measurement of hearing ability comes in the form of the
Universal Newborn Hearing Screenings (UNHS) (Krishnan & Van Hyfte, 2014, p. 283). In the United States, infants born in hospital settings within 43 states are required to undergo UNHS, which results in either a “pass” or a “referral” if failed (Armstrong, Maresh, Buxton, Craun, Wowrowski, Reilly, & Preciado, 2013, p. 1869). This screening is performed using electrophysiological measures, or those that measure “physiological responses to sound” (Johnson, 2012, p. 9), such as otoacoustic emissions (OAE) and, more recently, auditory brainstem response testing (ABR) (Martin & Clark, 2015, pp. 191-192; Porter, Neely, & Gorga, 2009, p. 457). Electrophysiological measures can be conducted regardless whether the patient is awake or asleep, but typically the patient has to be still (Kuki, Chadha, Dhandra, & Gulati, 2013, p. 245). Although not all hospital settings conduct both measures on every infant (Porter, Neely, & Gorga, 2009), in terms of benefit-to-cost, it is a “worthwhile investment” to conduct both ABR tests and OAE tests for every child (p. 58).

**Otoacoustic emissions.** During normal cochlea function, the outer hair cells of the cochlea actually produce sounds that can be picked up by a microphone within the external auditory canal. The first group of consistent, “soft” OAE sounds between -10 and +10 dB SPL (sound pressure level) are called *spontaneous otoacoustic emissions* (SOAE) and are produced without stimulation from outside sources (Martin & Clark, 2015, p. 165). The second group of OAEs that are measured are *evoked otoacoustic emissions* (EOAE), which are produced when an external acoustic stimuli is introduced through the external auditory canal (p. 166). Within the category of EOAEs there are two separate types: transient-evoked (TEOAE) and distortion product (DPOAE) (Martin & Clark, 2015 p. 166; Porter et al., 2009, p. 49).

TEOAEs are found when short “click” or “tone-pip” acoustic stimuli are presented. Testing for TEOAEs (as with all OAEs) involves the entire conductive pathway up to the
cochlea, but not the auditory nerve and beyond. Thus, while the presence of normal TEOAEs suggests no abnormalities in the outer and middle ear or cochlea, it cannot guarantee completely normal hearing. Conversely, absent TEOAEs do not concretely demonstrate the exact site of lesion (whether outer ear, middle ear, or cochlea) (Martin & Clark, 2015, p. 166).

In contrast, DPOAEs are produced when two tones of differing formant frequencies are presented into the ear, cochleae that function normally will respond with sounds at other frequencies (Martin & Clark, 2015, p. 166). The measurement of DPOAEs provides more “specificity” regarding outer hair cell function at certain frequencies of the cochlea as altering the stimuli frequencies changes the area of the cochlea that will respond (Porter et al., 2009, p. 449). Measurement of all OAEs is conducted using a probe tip with a microphone that is placed within the external auditory canal of the patient (Martin & Clark, 2015, p. 167). Because OAEs do not provide information regarding retrocochlear function, it is important to supplement OAE testing with testing that includes the neural pathway.

**Auditory-evoked potentials.** As previously discussed, the act of hearing involves electrical stimulation of the brain. Whenever sound stimulates the brain, electrical response signals are generated, called “auditory-evoked potentials” (AEP) (Martin & Clark, 2015, p. 169). Whereas OAEs measured the conductive pathway up to the cochlea, measurements of AEPs measure activity of the cochlea, auditory nerve, the central auditory pathway, and the temporal cortex (Chalak, 2015, p. 138). Tests of AEPs are advantageous for infants and “difficult-to-test” patients as they are “noninvasive, simple, [and] objective” and do not require active participation from the child (p. 138).

The most common form of AEP testing is through Auditory Brainstem Response (ABR) audiometry (Martin & Clark, 2015, p. 171). Electrodes are positioned on the mastoid process of
the side being tested (ipsi-lateral), on top of the skull, and on the mastoid process of the opposite (contra-lateral) side to measure responses. The audiologist presents either “click” (broad, rising stimuli) or “tone pip” (frequency-specific) stimuli to the patient and records the neural impulses through individual areas of the central auditory pathway, shown as separate “waves,” in response to the stimuli (Johnson, 2012, p. 330; Martin & Clark, 2015, p. 171).

The other, less-common form of AEP measurement is the Auditory Steady-State Response (ASSR). In ASSR testing, a continuous, ongoing stimuli is presented to evoke a continuous “steady-state neural response.” ASSRs that are considered within normal limits are able to match the changing amplitudes of the stimulus, revealing frequency-specific results (Martin & Clark, 2015, p. 178).

**Behavioral Testing**

In order to gain a complete picture of the child’s hearing function, audiologists compliment electrophysiological measures with behavioral audiometric testing. In contrast to electrophysiological measures, behavioral testing methods involve increased participation by the patient, meaning the patient must be conscious to complete testing. For pediatric patients younger than two years, the audiologist must be able to keep the child engaged by using variations of typical pure-tone and speech audiometric testing. The Alexander Graham Bell Association for the Deaf and Hard of Hearing recommends that all pediatric audiological evaluations should include an otoscopic inspection of the external auditory canal, case history of both the child and the family, electrophysiological testing, and behavioral audiometry testing (Flexer, Madell, & Hewitt, 2014, p. 3).

Behavioral testing for pediatric patients includes three different methods depending upon the age and social skills of the child. For children between birth and about seven to eight months
of age, behavioral observation audiometry (BOA) is commonly used (Johnson, 2012, p. 13; Martin & Clark, 2015, p. 196; Rose, 2011, p. 290). One clinician is positioned in front of the child, who is seated on his or her parent’s lap, to maintain the child’s focus between stimuli, while the other clinician is positioned either “behind [or] to the side” of the child (Martin & Clark, 2015, p. 196). The clinician that presents the stimuli to the child records the child’s response to certain sounds, such as toys or other noise-making objects, in an effort to determine the child’s ability to localize sound (Martin & Clark, 2015, p. 196; Rose, 2011, p. 290).

For children between the ages of eight months to approximately two years, visual reinforcement audiometry (VRA) is commonly used (Johnson, 2012, p. 10; Martin & Clark, 2015, p. 196; Rose, 2011, p. 290). This type of testing is set-up similar to the two-clinician system of BOA, but the stimuli is presented through one of two speakers in a “sound-field” on either side of the child (Martin & Clark, 2015, p. 196). A light or moving toy accompanies the signal delivered to a speaker to familiarize the child with a sound stimuli. The sound is gradually presented prior to the light or toy moving in an effort to get the child to move his or her head in the direction of the sound signal, with the light or toy as a “reward” for correctly hearing the sound signal (Martin & Clark, 2015, p. 196; Rose, 2011, p. 290).

For children between the ages of two years and five years, typical pure-tone and speech audiometry can be used, as well as conditioned-play audiometry (CPA) for children with attention difficulties (Johnson, 2012, p. 10; Martin & Clark, 2015, p. 202; Rose, 2011, p. 290). For pure-tone audiometry, the clinician attempts to find the patient’s hearing “thresholds,” or “softest” intensity at which the patient hears a sound stimuli at least 50% of the time at a given frequency (Johnson, 2012, p. 9; Rose, 2011, p. 291). The testing is completed via both air conduction, presented through headphones or ear inserts, and bone conduction, presented using a
bone oscillator. Using an audiometer, the air conduction measurements are tested and thresholds are recorded at the frequencies 250, 500, 1000, 2000, 4000, and 8000 Hz with an intensity range usually between -10 dB HL (hearing level) and 110 dB HL (Martin & Clark, 2015, p. 71). The child is instructed to either raise his or her hand or perform some other substitute such as pointing to the ear whenever he or she hears the stimulus sound (p. 201). The thresholds at 500, 1000, and 2000 Hz are averaged to find the “pure-tone average” (PTA), with the “best” two averaged to get the “two-frequency pure-tone average” or Fletcher average (Johnson, 2012, p. 14). Bone conduction tests by vibrating the skull at frequencies of 250, 500, 1000, 2000, and 4000 Hz, with an intensity range of only -10 dB HL to about 70 or 80 dB HL, effectively bypassing the outer and middle ear to directly stimulate the cochlea (Martin & Clark, 2015, p. 71).

Pediatric patients above the age of two years will also be administered speech audiometry, which essentially tests how well the patient hears and understands certain words (Rose, 2011, p. 291). The first step in speech audiometry is speech-recognition threshold (SRT) testing, which Martin and Clark (2015) defined as finding “the lowest hearing level at which speech can barely be understood” (p. 101). The stimuli for SRT are “spondee” words, which are “compound words consisting of two syllables that are of equal stress” (Johnson, 2012, p. 17). The SRT should be similar to the PTA for each respective ear, with emphasis on matching the air conduction threshold at 500 Hz (Martin & Clark, 2015, pp. 105-106). Following SRT testing, the child is tested for a “word recognition score” (WRS), which is the percent of words correctly repeated back when presented at a “most comfortable loudness” (MCL) level, usually 30 dB SL (sensation level, or “above threshold”), but not below 45 dB HL (Johnson, 2012, p. 17; Martin & Clark, 2015, pp. 106-108).
Conditioned play audiometry (CPA) may be used in addition to or in place of pure-tone and/or speech audiometry (Martin & Clark, 2015, p. 202). According to Johnson (2012), this method of testing involves “condition[ing a child] to complete a repetitive, motoric task… to indicate detection of an auditory stimulus” (p. 10). These tasks are usually simple, such as picking up a toy or dropping an object into a box or basket whenever the sound is heard. This usually enables more reliable testing data by keeping young children engaged and interested in responding (Martin & Clark, 2015, p. 202). For the patients that demonstrate a profound SNHL during any of these assessment procedures, such as the pediatric patients involved in this study, one possible option is to receive a cochlear implant.

**Cochlear Implants**

Before the specific CI manufacturers can be discussed, the CI technology, its parts and function, and candidacy criteria for recipients must first be defined. Cochlear implant technology affects the lives of a vast, ever-growing sample population of people. In 2008, a study estimated that there were 12,816 children within the age range of 12 months to six years who were potential candidates for cochlear implants (CIs), based on the prevalence of severe to profound hearing loss within that age group (Bradham & Jones, 2008, p. 1025). According to estimates by the National Institute on Deafness and Other Communication Disorders (NIDCD), there were around 25,500 pediatric CI recipients in the United States in 2009 and another approximately 41,500 adult CI recipients, based on surgeon reports at that time (as cited in Mauldin, 2012, p. 530). Adding to these estimates were the various reports ranging from one to six out of every 1000 newborns having a hearing loss of some degree for the past several years (Krishnan & Van Hyfte, 2014, p. 282; Vincenti et al., 2014, p. 2). These numbers all suggest a relatively large sample population of potential candidates for CIs. While many of the potential candidates chose
not to be implanted, those who did created a tremendous demand for CI technology and the related services required.

**History**

The lifespan of CI technology has been relatively short, yet the scientific discoveries and research that led to the development of CIs dates all the way back to the late 1700s. Electrical stimulation experiments began in 1790 when Alessandro Volta used electric currents from a battery connected to probes placed in each of his ear canals which were stimulated and there was recorded a “crackling, jerking, or bubbling” sound (as cited in Eshraghi, Nazarian, Telischi, Rajguru, Truy, & Gupta, 2012, p. 1968). Dr. Duchenne de Boulogne used alternating electric currents to stimulate the cochlea in 1855 and heard “similar” sounds as Volta; and Wever and Bray (1930) proposed through their studies with the cochlea that “if [electrical] potentials could be… replicated, then lost or absent hearing could be restored” (as cited in Eshraghi et al., 2012, p. 1968). Building off these experiments, André Djourno and Charles Eyriès tested electrical stimulation directly to the auditory nerve of a patient via a wire during a surgical procedure (American Speech-Language-Hearing Association [ASHA], 2004, para. 3). Djourno and Eyriès’ experiment was the first trial on the cochlea of a human patient, and resulted in the ability of that patient to discriminate between different intensities, or volume levels, but not necessarily between different sound frequencies (Eshraghi et al., 2012, p. 1968). While it did not completely “restore” the patient’s hearing, this finding did pave the way for the use of electrical stimulation as a “treatment” for a person with a profound hearing loss (ASHA, 2004, para. 3).

William F. House, M.D., an otologist, or “ear physician,” from Los Angeles, California is considered the “father of the cochlear implant” (Eshraghi et al., 2012, p. 1968). House worked with John Doyle, M.D., a neurosurgeon, to implant an early version of a CI into the scala
tympani of several patients for the first time in 1961. These CIs broke down physically inside the patients’ heads and the electrodes needed to be removed, but the patients were able to discriminate between different narrow-band frequencies to a limited extent. While Doyle did not have the funds to continue his work with CIs, House next joined with Jack Urban and developed the first CI that could be used by patients “outside of the laboratory” without the device becoming biodegraded (Eshraghi et al., 2012, p. 1968). In the mid-1960s, F. Blair Simmons, M.D. inserted an electrode directly into the modiolus of a “volunteer” patient who was both deaf and blind (ASHA, 2004, para. 3). This trial not only found an alternative mode of cochlear implantation, but when speech sounds, which are wide-band noises, stimulated electrodes in different areas of the cochlea, they evoked perception of speech up to the level of discrimination between different speech sounds; yet, the recognition and understanding of speech was still absent (Eshraghi et al., 2012, p. 1969).

Looking to improve upon those findings, a group at the University of California at San Francisco (UCSF) worked to develop a functional CI with a single electrode that could result in efficient speech recognition in the 1970s (Eshraghi et al., 2012, p. 1969). This group included otologist Robin Michelson and neurophysiologist Michael Merzenich, among others, and, just like House’s early CI devices, their single-electrode CIs did not enable perception of speech sounds at the level of recognition. After further research using the auditory systems of animals, however, the UCSF team found that stimulating different sound frequencies with a single electrode was ineffective, requiring development of a CI with multiple electrodes to cover the tonotopic arrangement of the cochlea (p. 1970). Tonotopic arrangement refers to the “spatial representation of the frequency layout,” from the high-frequency basal region to the low-frequency apical region (Martin & Clark, 2012, p. 326).
In 1972, the technology company 3M bought the rights to market House and Urban’s single-channel CI, making it the first single-channel CI to be publically introduced (ASHA, 2004, para. 4; Eshraghi et al., 2012, p. 1970). The “House/3M” CI still did not enable speech recognition, but it did give recipients the ability to detect speech sounds that were helpful cues for speech reading (Chute & Nevins, 2006, p. 3). The FDA officially approved these devices for adults who were deafened postlingually only in 1982 (p. 3).

As the team at UCSF and 3M developed their respective CI devices in the United States, Graeme Clark, M.D. and his team at the University of Melbourne in Australia began development of a CI with multiple channels (Eshraghi et al., 2012, p. 1970). Clark saw that the past research with the single-channel CIs could not replicate and stimulate the high, second formant frequencies of speech that are instrumental to speech recognition (Clark, 2006, p. 792). The multi-channel device was therefore created and successfully implanted for the first time in 1978 and used a speech coding strategy that stimulated these high frequencies of speech in correct tonotopicity, resulting in the recipient’s ability to recognize “conversational speech” (Clark, 2006, p. 792). Clark’s CI, known as the Nucleus-22, was presented to the United States Food and Drug Administration (FDA). FDA testing led to the approval of CIs for use in adults with postlingual deafness in 1985, making it the first multi-channel CI approved in the United States. This new CI device became the main source of competition with the House/3M single-channel CI; however, the performance of the Nucleus-22 in speech recognition and understanding could not be matched by the House/3M device (Eshraghi et al., 2012, p. 1973). The Nucleus-22 was eventually approved as the first CI to be “safe and effective” for use in children as young as two years of age in June 1990 (Clark, 2006, p. 805). The other CI manufacturers followed Clark’s multi-channel model, setting up the current CI market through
years of competitive technological improvement.

**Components of a Cochlear Implant**

The modern CI is comprised of several different parts, which are commonly separated into external and internal positions, although some modern CI devices are being designed to be entirely internal. The external component of most CIs includes a microphone, speech (or sound) processor, and some type of transmitting coil, also referred to as an “external antenna” or a “telecoil” if wireless (Martin & Clark, 2012, p. 268; Vincenti et al., 2014, p. 3). The speech processor is worn either clipped to the user’s clothing or as a behind-the-ear (BTE) unit (Martin & Clark, 2012, p. 391).

The internal component consists of a receiver-stimulator embedded in the mastoid bone above the pinna to receive the coded sound signal and an electrode array that is inserted into the scala tympani of the cochlea (Vincenti et al., 2014, p. 3). The external components are connected to the internal components via magnets placed on the external coil and connected to the internal receiver-stimulator (p. 3). Most CI models in the past had switches on the external processor to adjust the settings or channels of the CI, but modern CI technology has moved to the use of remote units to adjust the settings in lieu of these switches, as well as display data-logs from the CI device usage (MED-EL, n.d.a, p. 20; “Let There Be Sound,” 2013, p. 21).

**Functions of a Cochlear Implant**

It may seem like a lot of parts for just one device, but each component is crucial in the function of a CI. For a device that has such a vast impact on individuals who are profoundly deaf and took so long to develop, the function of a CI is relatively simple. The ultimate goal of a CI is to bypass hair-cells that are ineffective and stimulate the auditory nerve directly (Martin & Clark, 2012, p. 391). Incoming acoustic speech signals are picked up by the microphone and converted
to an electrical signal (Johnson, 2012, p. 266). The electric signal is then transferred to the external speech processor and further converted into a digital code. Each manufacturer’s CI device is designed with a different speech coding strategy that distinguish how “loudness, pitch, and timing” of the sound signal is digitally coded. The transmitting coil then sends the digital signal to the internal receiver-stimulator through the skin as an FM radio-frequency link (Johnson, 2012, p. 266; Vincenti et al., 2014, p. 3). The receiver-stimulator converts this digital signal back to an electrical signal that is passed down the electrode array to the individual electrode terminals placed at specific points along the basilar membrane of the cochlea (Johnson, 2012, p. 266). These terminals act similar to hair cells, by stimulating the neurons in the spiral ganglion that relay to the auditory nerve and ultimately to the “auditory cortex” of the brain (Dorman & Wilson, 2004, pp. 437-438).

In what is referred to as “mapping” (or MAPping; switch-on; activation), an audiologist adjusts the settings of the speech processor to transmit the frequency, intensity, and timing characteristics of the sound signal to the electrode array (Martin & Clark, 2012, p. 393). This allows the electrode array to use this transmitted information in a way that “most effectively” matches the “natural” hearing of the CI recipient and provides maximum benefit (p. 393). Mapping also sets the “dynamic range” of the CI to limit the electrical current in each electrode to inputs between the “electrical threshold level” where the patient is first able to detect a sound and the “maximum comfort level” which is the “highest current level at which a patient can tolerate a sensation for an extended period of time” (Johnson, 2012, p. 281).

**Candidacy Criteria**

The embedding of the internal receiver-stimulator and the insertion of the electrode array makes cochlear implantation an invasive procedure. CIs are regulated as “Class III medical
devices” by the FDA, leading to strict regulation along with suggested guidelines from the CI manufacturers as well for the selection of candidates (Johnson, 2012, p. 269). The FDA-set age limit has changed several times over the lifespan of CIs from strictly adults above the age of 18 years who acquired a profound hearing loss after forming “language concepts” (Martin & Clark, 2012, p. 433); to 24 months of age in the 1980s; and finally down to the current lower limit of 12 months in 1998 (ASHA, 2004, para. 63; Johnson, 2012, p. 269). The cause for the lowering of the age limit can be pinpointed to the increase in research studies such as that of Waltzman and Cohen (1998) that demonstrated increased speech recognition and/or other health-related quality of life (HRQoL) benefits among children implanted prior to the age of two years (as cited in Balkany, Hodges, Eshraghi, Butts, Bricker, Lingvai, Polak, & King, 2002, p. 122).

The lower age limit in the United States may lower again in the near future due to models from Australia, which has moved towards implanting children at the age of only six months (Leigh, Dettman, Dowell, & Briggs, 2013, p. 444). Leigh and her colleagues at the University of Melbourne (2013) have conducted a “longitudinal evaluation” of a large sample of children that revealed “language growth rates comparable to that of their normal hearing peers” for children implanted before 24 months; however, there was no significant benefit from being implanted prior to 12 months as opposed to being implanted later (p. 447). This means that while children younger than 12 months may be able to physically undergo the surgical procedure, it is not necessarily beneficial from a developmental standpoint to implant children that young, barring any early complications such as meningitis.

Along with meeting age requirements, there are also guidelines from each of the manufacturers for type and degree of hearing loss that vary depending on the patient’s age. A thorough audiologic evaluation is completed to determine this information. All candidates must
have a sensorineural hearing loss bilaterally, that is, within the auditory system of both ears (Johnson, 2012, p. 270; Vincenti et al., 2014, p. 3). Children between 12 and 23 months of age must have a bilateral, profound sensorineural hearing loss with thresholds greater than 90 dB HL (ASHA, 2004, para. 63; Johnson, 2012, p. 270). The allowable degree of hearing loss increases for children 24 months or older to include bilateral severe-to-profound sensorineural hearing loss with thresholds greater than 70 dB HL. In adults that are 18 years or older the allowable degree of hearing loss includes bilateral moderate sensorineural with thresholds as low as 41 dB HL for recipients of a Cochlear Americas device up to severe-to-profound sensorineural only for the devices of the other two manufacturers (Johnson, 2012, p. 271). Adults must also score less than 50% on “open-set sentence recognition” testing, which involves listening to and repeating back sentences without the use of visual aids (Johnson, 2012, p. 270).

Before a candidate can be implanted, he or she must complete a hearing aid trial for a period of time to determine if they can achieve effective auditory function from amplification alone (Johnson, 2012, p. 272). If the candidate cannot achieve appropriate “communication benefit” from the hearing aid, they may choose to pursue a CI (ASHA, 2004, para. 63). Prior to being approved to undergo cochlear implantation surgery, the patient’s CI team members should complete a comprehensive medical evaluation of the patient to determine if there are any complications that may put the patient at risk during surgery. Vincenti and his colleagues (2014) pointed out that a critical factor to examine is whether or not the patient can physically tolerate the anesthesia that is used during surgery (p. 4). Imaging techniques such as computed-tomography (CT) scans and magnetic resonance imaging (MRI) are conducted on the recipient’s head to determine if there are any abnormalities or defects throughout the auditory system (Balkany et al., 2002, p. 357). These abnormalities include such phenomena as ossification.
(buildup of bone) of the cochlea resulting from otosclerosis or, more commonly in children, meningitis; malformation of the cochlea; and, possibly the most important, the absence of an auditory nerve with no connection to the cochlea (Balkany et al., 2002, p. 357; Johnson, 2012, p. 275). Patients that meet the aforementioned criteria with no abnormalities affecting cochlear implantation and how the motivational drive to make effective use of CI technology both by themselves and their families are ideally approved to undergo the surgical procedure. Before they go to surgery, however, there is one last process: the selection of a CI device from one of the manufacturers.

**Cochlear Implant Manufacturers**

After defining the specifics of CIs, the next step is to discuss the manufacturing of these medical devices. With such a significant population of people in America seeking CI services, it is important to examine CI manufacturing as a “business.” This means understanding that the companies that manufacture and distribute CI devices do so with the ultimate goal of making a profit. This requires a tremendous amount of focus on marketing along with science and research in order to be competitive in the market. While there are several more CI manufacturers around the world, such as the French company, Neurelec, and the Chinese company, Nurotron (“Brief Introduction,” 2014), there are currently only three main CI manufacturers that compete for sales within the United States market. These three CI companies competing for market share include Cochlear Americas, Ltd.; Advanced Bionics; and MED-EL.

**Cochlear Americas**

Australian-born Graeme Clark, M.D., and his research team at the University of Melbourne found that a multi-channel CI would better stimulate different parts of the cochlea than a single-channel CI device (Eshraghi et al., 2012, p. 1973). Thus, in 1973 Clark, along with
physicist David Dewhurst, began developing the world’s first multi-channel CI, and implanted the new device in August 1978 (p. 1973). Clark’s CI device differed from the multi-channel electrode designed by Ingeborg Hochmair in the way it coded speech frequencies (Clark, 2012, p. 73). Financial problems beset Clark with his CI and he was required to seek funding from the Australian government along with businesses in the private sector (Eshraghi et al., 2012, p. 1973).

In 1979, after noting the success of this new technology, Nucleus, a group that manufactured medical devices, such as heart pacemakers, looked to join with Clark to begin manufacturing the developing technology of multichannel CI (“History,” 2015, para. 8). Paul Trainor, the owner of Nucleus, took $4 million in Australian dollars from Nucleus to establish Cochlear, Ltd., and in 1981 the company built its first headquarters in Sydney, Australia. In 1984, the company expanded to the United States under the division name Cochlear Americas, with its current United States headquarters in Centennial, Colorado, just south of Denver (“History,” 2015, para. 13). The United States Food and Drug Administration (FDA) eventually approved the multi-channel implant as “safe and effective” in May of 1986, becoming the original version of the Nucleus CI used today (Clark, 2012, p. 79). It was not until 1990, however, that the United States FDA approved the implanting of this device in children between the ages of 2 and 17 years of age (“History,” 2015).

**Cochlear Americas models and devices.** Cochlear Americas’ cochlear implant processing system is known as the Nucleus. The current Nucleus system makes use of two separate microphones on the external processor that are “synchronized” to distinguish sounds for localization; which means they can pick up which direction the different sounds come from (“The Cochlear Nucleus System,” 2015, p. 19). The Nucleus system pairs with the current
CI24RE internal components, which use “SmartSound IQ” technology to make use of Advanced Combination Encoders (ACE) that use “place-coding” of different frequency formants of speech sounds (Clark, 2012, p. 79; “The Cochlear Nucleus System,” 2015, p. 18). With the ACE strategy, only the electrodes that match the frequencies of the incoming sound waves are stimulated, which can eliminate the stimulus from the ambient background noise (Battmer, Dillier, Wai Kong, Begall, Leypon, González, Manrique, Morera, Müller-Deile, Wesarg, Zarowski, Killian, Von Wallenberg, Smoorenburg, 2010, p. 658). This coding strategy reportedly allows for increased speech perception in noisy environments as well as enhanced perception of music. “SmartSound IQ” is also designed to adjust the user’s environment automatically by scanning for one of six environmental noise “scenes:” “Speech in Noise, Speech, Noise, Wind, Quiet, or Music” (“The Cochlear Nucleus System,” 2015, p. 18). The Nucleus CI24RE internal component is also reportedly approved for use within an MRI scan up to 1.5 Tesla when the internal magnet is removed (p. 33).

The newest speech processor model for Cochlear, Ltd. is the Nucleus 6. This processor is designed to be thin and lightweight, available in five colors with twelve color pattern cover options, and comes with a five-year warranty (“The Cochlear Nucleus System,” 2015, pp. 29). The microchip in the Nucleus 6 enables data logging capabilities that allow the user’s audiologist to track information about the device such as the amount of time the device is on, the use of accessories such as the telecoil, and the distribution of types of noise presented during an average day (p. 23). The Nucleus 6 also comes with a wireless “remote assistant” that monitors the functions of the speech processor and allows the recipient to adjust the settings of the processor, be alerted if the processor is not working, and to know when the batteries are running low (p. 25). Cochlear recently added a multi-color light alert system on the sound processor itself to
allow parents, teachers, and other caregivers to know when there is a problem with the telecoil or batteries (p. 25). There is also a wireless Bluetooth option for this processor that allows it to be connected to a TV, cellular telephone, or MP3 player (p. 13-15). Cochlear also sells a new “Mini Microphone” device that can be clipped to a partner/speaker’s collar, or even hooked up to a music player or computer, and transmit sound wirelessly to the CI device, working similar to an FM system to assist in listening in noisy backgrounds (p. 15).

The Nucleus 6 sound processor is covered with a “nano-coating” that allows it to be water-resistant to light rain, sweat, and humidity in the surrounding climate (“The Cochlear Nucleus System,” 2015, p. 27). In keeping up with the waterproof CI market, Cochlear recently received approval for the Nucleus Aqua+ waterproof casing for the Nucleus 6 sound processor that allows the user to swim, snorkel, and surf while still using the CI device (p. 27). The Aqua+ is only approved, however, for the Nucleus 6 with the rechargeable battery option (p. 27).

Cochlear Ltd. recently developed the new Nucleus Hybrid L24 implant that combines the speech perception of a CI (electrical stimulation) with the amplification of a hearing aid (acoustic stimulation) for patients with a mild-to-moderately-severe hearing loss (“Introducing Hybrid Hearing,” 2014, p. 3). The Hybrid L24 is the first and only one of its kind to be approved by the FDA (p. 3).

In order to fully provide an outlook on the full range of products offered by Cochlear Americas, it should be noted that they also offer an osseo-integrated implant system called the Baha™ (now in its fourth version). This device is designed for patients with single-sided deafness, where one cochlea is functional while the other is not; or a conductive or mixed hearing loss in which physical abnormalities of the ear make it impossible for a conventional hearing aid to provide any significant benefit (McLarnon, Johnson, Davison, Hill, Henderson,
Leese, & Marley, 2014, p. 641). This hearing implant is surgically inserted in the mastoid bone and converts sound signals to vibrations sent through the skull to stimulate the cochlea (“Bone Conduction Implants,” 2014). In the case of single-sided deafness, these vibrations are sent interaurally to the opposite cochlea (the functional one) (McLarnon et al., 2014, p. 641). The Cochlear Baha 4™ comes in two different versions—the “Attract” system and the “Connect” system. The Attract system uses magnets to connect the external processor to the internal abutment (“Bone Conduction Implants,” 2014). The Connect system protrudes from the skin so the processor can physically attach and detach to the abutment. The lifestyle of the patient is the ultimate deciding factor as to which system to choose. Like the Nucleus 6, the Cochlear Baha 4™ also has the option of wireless Bluetooth connectivity to devices such as televisions and cellular telephones.

**Advanced Bionics**

The second company to address is Advanced Bionics which was founded in 1993 and is now located in Valencia, California. This manufacturer’s CI technology began in the 1970s with research from a CI team from the University of California at San Francisco (UCSF) including Francis Sooy, Robin Michelson, and Michael Merzenich (Eshraghi et al., 2012, pp. 1973-1974). This team successfully developed their own multi-channel CI, but lacked the necessary funds to market their product. Renowned inventor Alfred E. Mann, who had previously completed work with a variety of different technologies from pacemakers to pharmaceuticals, eventually partnered with the UCSF CI team and established Advanced Bionics using their technology (“History of Innovation,” 2015, para. 2). The team’s external processor was paired with the original internal Clarion CI model, which was approved by the FDA in 1996 for use by adults and in 1997 for use in pediatric patients (Eshraghi et al., 2012, p. 1974).
Mann saw the CI market in the United States as “underserved” since it only included two manufacturers as competition and sought to improve on current technology to provide a “better product” (Coye, 2006, p. 104). Advanced Bionics owned about 18% of the CI market around the world with businesses in over 30 countries before being bought for $489 million by Sonova Holding in 2009 (Hsu, 2009). Sonova is a Swiss company with businesses in over 90 countries that specializes in hearing aids and includes the Phonak hearing aid company. Today Advanced Bionics prides itself on its partnership with Sonova and Phonak and the resulting ability to develop the most “innovative” CI technology to ultimately provide the best assistance to individuals who are deaf (“History of Innovation,” 2015).

**Advanced Bionics models.** The business partnership with Phonak has allowed Advanced Bionics to develop several speech coding strategies that could be paired with technology developed by Phonak, such as the UltraZoom microphone that is designed to pick up speech sounds from a speaker at zero degrees azimuth, or directly in front of the listener (Advanced Bionics, 2013a, pp. 12-13). The Phonak partnership also introduced DuoPhone technology to Advanced Bionics’ CIs, with the ability to transfer speech signals from a telephone to both CI devices in a bilateral recipient even though the telephone is held at just one ear (p. 18). The sound-processing strategies used in Advanced Bionics’ CI devices reportedly focus on better understanding of speech in the presence of background noise. Each of those strategies is built off their basic HiResolution Bionic Ear technology. The premise of this software is the timing of the stimulation of the electrodes within the cochlea. Advanced Bionics’ CIs are designed to send more stimulus pulses per second, nearly 83,000, through the electrodes than the other CI models in order to create more accurate timing of sound signals with auditory nerve firings (Advance Bionics, 2014, pp. 15-16).
The first and most commonly used sound-processing strategy is HiRes Fidelity 120, which is designed to “deliver five times more sound resolution” compared to other CI models (Advanced Bionics, 2014, p. 29). It does this by using up to 120 spectral bands of sound to enhance detail of sounds. The second strategy available is AutoSound technology which automatically adjusts the settings of the processor to match the “noise” of the user’s environment by “capturing the widest input dynamic range” of sound frequencies (Advanced Bionics, 2015b, p. 29; Advanced Bionics, 2013a, p. 27). The third sound-processing strategy is the ClearVoice technology, which is designed to pick up speech sounds while ignoring background noise by separating the two signals, improving speech understanding in noise, reportedly by 25% (Advanced Bionics, 2015b, p. 29; “Hear Your World,” 2013a, p. 12). ClearVoice also automatically adjusts the processor settings to adapt to the sounds of the environment (Advanced Bionics, 2013a, p. 28). The final strategy is HiRes Optima, which functions similar to HiRes Fidelity 120, but with a focus on conserving battery life (Advanced Bionics, 2015b, p. 29). The current technologies for the ClearVoice, HiRes Fidelity 120, and the HiRes Optima still have yet to be approved for pediatric use by the FDA as of 2015, but they are undergoing testing and are expected to be approved in the near future (Advanced Bionics, 2015b, p. 29).

The current internal component for the Advanced Bionics device used in the United States is the HiRes 90K™, which uses 16 separate current sources that enable currents to be “steered” in different proportions to each of the electrode contacts, resulting in increased perception of different pitches of sound (Saoji, Litvak, & Boyle, 2010, p. 465). There are three electrode options for this internal device built off the HiFocus™ technology: the curved “Mid-Scala” electrode designed to place the contacts in the center of the scala tympani; the straight “1j” electrode; and the thick-case “Helix” (Advanced Bionics, 2013a, p. 35). The HiRes 90K is
reportedly able to withstand MRI testing at 0.3 Tesla and 1.5 Tesla when the internal magnet is
removed (Advanced Bionics, 2015b, p. 26). The first CI device model offered by Advanced
Bionics was the Clarion sound processor (“History of Innovation,” 2015, para. 7). This model
has been upgraded and built upon several times, with the most up-to-date models, Naida CI Q30
and Q90 behind-the-ear processors, which received FDA approval in August 2015. The device
has the trademarked “featherlite instyle design” meant to be lightweight and available in 12
different colors (Garma, 2015, para. 1).

The Naida CI sound processor series and the new Harmony sound processor are rather
similar as behind-the-ear processors with compatibility with most of Advanced Bionic’s sound-
processing strategies and accessories. Both make use of T-Mic 2 microphone technology, which
is located at the entrance to the external auditory canal to reflect more typical sound reception
device offered by Advanced Bionics is the NEPTUNE, which has been promoted as being the
first waterproof processor in the industry (Advanced Bionics, 2013a, p. 22). NEPTUNE has what
is called a “freestyle” design, meaning instead of being solely a behind-the-ear processor, the
processor can clip to any article of clothing or apparel, such as shirts, goggles, and hats (p. 24).
Each of these sound processor choices are compatible with all the Advanced Bionics sound
coding software as well as a variety of accessories. Advanced Bionics stresses the wireless
connectivity that the Naida CI Q70, NEPTUNE, and Harmony all possess, allowing their CI
devices to connect to any sound-producing technological device that contains Bluetooth—
namely mobile phones, televisions, and laptop computers (p.15).

**MED-EL**

The third manufacturer, Medical Electronics, commonly referred to as MED-EL, was
started in Innsbruck, Austria by Ingeborg Hochmair, Ph.D., and Professor Erwin Hochmair (”About MED-EL,” 2013). The Hochmairs began their work with CIs as part of a team involving Professor Kurt Burian at the Technical University of Vienna, applying for a research grant in 1975 and implanting their first device in December 1977 (Eshraghi et al., 2012, p. 1972). The 3M Company that marketed the first CIs signed a deal with the Hochmairs in 1981 that gave the company the rights to sell their CIs; however, the Hochmairs eventually split from 3M and established their independent company, MED-EL, in 1990 (p. 1973). MED-EL spread to the United States in 1997, joining Cochlear Americas and Advanced Bionics in the competitive American market (Chute & Nevins, 2006, p. 4).

MED-EL’s main corporate headquarters and primary research and development activities are still located in Innsbruck, Austria, with branches in over 26 countries around the world. In the United States, MED-EL’s headquarters are located in Durham, North Carolina (”About MED-EL,” 2013). The Hochmairs created their first hybrid multi-channel intracochlear electrode prior to starting MED-EL in 1977. This electrode could stimulate different positions of the cochlea at the same time, resulting in more frequencies being heard and better perception of pitch (Hochmair, 2013, p. 1). In 1991, MED-EL created the first behind-the-ear (BTE) processor, moving away from large processors that had been typically clipped to the user’s belt or other item of clothing. From their beginnings, MED-EL has experienced much development and improvements of their CI technologies as well as further industry-firsts; namely the use of their devices in the first bilateral (both ears) implantation in 1996 (Hochmair et al., 2006, p. 207).

**MED-EL models.** MED-EL’s most up-to-date CI is the SYNCHRONY. The device’s internal components are built within a titanium housing and is designed to be small and thin in order to require less intrusive “drilling” of the temporal bone (MED-EL, 2015, p. 28). The
SYNCHRONY contains two titanium pins for stability and includes a choice of five different electrode arrays, each differing in length and the spacing of the electrode terminals (p. 29). The choices, from longest to shortest, are Standard, FLEX28, FLEX24, Medium, and Compressed. These electrodes are designed to be extremely flexible, substituting wavy wires for straight, in order to minimize injury during surgery (MED-EL, 2015, p. 31). The SYNCHRONY makes use of what MED-EL calls “triformance” technology, including “Complete Cochlear Coverage, FineHearing, and Structure Preservation” (p. 36). Complete Cochlear Coverage means the electrodes are long enough to cover all points of tonotopic arrangement of the cochlea (p. 43). FineHearing uses the “Fine Structure Processing (FSP)” sound-coding strategy that uses coding by place and coding by rate to cover all ranges of sound frequencies during speech perception (MED-EL, 2015, pp. 20-21). MED-EL’s CI was reportedly designed to resemble normal hearing in most sound frequencies better than other sound coding technologies, especially for music and speech in the presence of noise; by “covering” more of the cochlea than other implant devices (MED-EL, n.d.b, p. 15).

The most recent external audio processor models that MED-EL offers are the SONNET, which is a recent upgrade of the OPUS 2, and the RONDO. Both of these devices are compatible with the SYNCHRONY internal device and were integrated with MED-EL’s MAESTRO 6.0 software system, which refers to the operating system that converts sound waves into electrical pulses and uses the “FineHearing” technology (Tibbitt, 2014, p. 2). MED-EL’s electrode array is frequently reported as the longest of any CI on the market and results in “better speech perception… with stimulation of the apical region of the cochlea” (Hochmair, Arnold, Nopp, Jolly, Roland, & Müller, 2003, p. 617; MED-EL, 2015, p. 32). The RONDO was created in 2013 as the world’s first all-in-one processor with the magnet telecoil and the sound processor in
one external unit (MED-EL, 2015, p. 20). Using three 675 zinc-air batteries, the RONDO is reported to last up to 75 hours, with rechargeable options as well (p. 20). MED-EL also offers a “WaterWear Accessory” cover for the RONDO for water-resistance (p. 21). The SONNET was approved by the FDA in January 2015 and included an external processor and separate telecoil. It was designed to be lightweight and compatible with three different battery options including a rechargeable option. The SONNET weighs less than 11 grams with zinc-air batteries (MED-EL, 2015, p. 18). These products have been designed to be as light and thin as possible in order to be more appealing than other manufacturers’ models.

Each of the companies has their own unique products and strategies for the perception of sound. They offer such a wide range of products that any possible ranking of the manufacturers simply based on the amount of options would be extremely difficult. Thus, it is important to establish an understanding of the performance outcomes for each of the manufacturers’ devices. The next section will examine a sampling of clinical studies involving the testing of the manufacturers’ varied CI technology and the recorded patient preferences for certain CIs over others.

**Patient/Device Outcomes**

After understanding the historical backgrounds and available CI products from each of the three manufacturers, next in the process of decision-making is to pay attention to the outcomes of those CI devices, in view of both patient performance and patient perception. Each of the manufacturers includes several research-based studies in their print advertising, arguably to demonstrate the clinical effectiveness of their respective products compared to the other two. While these varied studies suggest superior performance relative to the other companies, it is important to understand that there have been both positive and negative outcomes for each
company and all three have their challenges.

Recalls of the CI devices (voluntary pulling of the device off-market), for example, have occurred for two of the three manufacturers. Cochlear imposed a recall on their Nucleus N5 CI500 device in September 2011, citing manufacturing errors that allowed for water to get into the electrodes and cause device failure (Hildrew & Molony, 2013, p. 2829). Advanced Bionics has also had moisture buildup in their HiRes 90K internal CI devices since the early 2000s, forcing them to recall these specific devices several times; most notably in September 2004, March 2006, and November 2010 (Kosnar & Myers, 2014; “Sonova Announces,” 2011, para. 2). Only two out of over 28,000 HiRes 90K devices presented “technical issues” during the 2010 recall, however, resulting in a return to the market in 2011 after upgrades to the “manufacturing process” were made (“Sonova Announces,” 2011, para. 5).

For CIs in general, the average recipient experiences comparable health-related quality of life (HRQoL) as compared to people with hearing within normal limits (WNL), notably after six years of CI device use (Meserole, Carson, Riley, Wang, Quittner, Eisenberg, Tobey, Francis, & Niparko, 2014, p. 730). These findings suggest that regardless of the choice of the three manufacturers’ CI devices, consistent and proactive use of the technology has been associated with a positive patient outlook on their physical and emotional health as well as “social functioning” (p. 722). With the appropriate level of determination, motivation, and having a strong support group surrounding the pediatric recipient, development of listening and spoken language can successfully be obtained with CI devices. The differences that are present, however, deal with speech perception, individual patient issues post-surgery, and parents’ perceptions of a variety of CI variables (Migirov, Dagan, & Kronenberg, 2009, p. 741; Withers, Gibson, Greenberg, & Bray, 2011).
Speech Perception Outcomes

The second area of complications involves the performance of each CI device in regards to perception of speech. As previously mentioned, all modern CIs are designed with multiple channels that enable the recipient to pick up second formant frequencies in speech sounds and increase speech recognition (Clark, 2006, p. 792). CI candidates have speech recognition scores that are typically below 50% prior to cochlear implantation, meaning there is a large room for improvement in that area (Johnson, 2012, p. 270).

Fulcher and her colleagues (2012) conducted a study of children with profound sensorineural hearing loss that were implanted early and found that 90% of the children demonstrated receptive speech perception skills within normal limits (WNL) after three years, and 100% demonstrated WNL after four and five years (p. 1789). For pediatric CI recipients with partial deafness, speech perception rates have been shown to increase dramatically, improving specifically from 34% pre-surgery to 67% post-surgery with no background noise and from 7% to 47% in the presence of background noise in one sample of 15 recipients (Cosetti & Waltzman, 2012, p. 158).

MED-EL’s claims have been the increased performance of speech perception up to 30% compared to Advanced Bionics and Cochlear, Ltd. (MED-EL, n.d.a, p. 58). One experiment tested 18 patients administered the “Hearing in Noise Test” (HINT) and the “Consonant-Nucleus-Consonant” (CNC) test, both with and without the use of a MED-EL CI device (in this case the older internal PulsarCI100), in the presence of a +10 signal-to-noise ratio (SNR) (Prentiss, Sykes, & Staecker, 2010, p. 198). There was an increase of speech perception from an average of 25.7% words correct on the HINT without use of the CI to around 65% with the use of the CI; and an increase from 16.7% correct without to 38% correct with the CI using the CNC.
stimuli (p. 200). This reflected the reported effectiveness of MED-EL CI devices in performing in noise. Likewise, Yathiraj and Rao (2013) studied 17 pediatric CI recipients using pre-processing strategies with three different Cochlear Americas sound processors (CP810, Freedom, and Sprint) and found that with a +10 dB SNR the speech recognition scores only dropped by 4% (p. 57). This stands as one testament to the ability to perceive speech in the presence of noise for Cochlear Americas’ CI devices.

A case study completed by Withers and his colleagues (2011) involved a single patient who received surgery at the Royal Prince Alfred Hospital in Australia. This patient was implanted with bilateral, sequential CIs. One included a MED-EL SONATA TI 100 (an older internal device) coupled with an Opus 2 external processor [CI 1] and for the second ear, a Nucleus 24k CI24R from the Cochlear Corporation [CI 2] (p. 124). Based on the patient interview and quantitative outcome data, the patient scored poorer on all trials of the CNC in presence of noise as well as the City University of New York (CUNY) test via the MED-EL device than with the Cochlear device (p. 125). Despite the positive statistical outcomes, however, that same patient described the MED-EL device as having a more “natural” sound compared to a “microphone[-]like” sound of the Nucleus processor (p. 125). Although the study involves only one patient, results suggested that although one CI device may perform better in speech perception than another statistically, patients may qualitatively feel more comfortable with the statistically “inferior” device. This leads to the next area for discussion—actual perceptions of a variety of CI variables by patients and their families.

One study examined the Harmony CI from Advanced Bionics and the Nucleus 5 CI from Cochlear Americas based on performance of their respective frequency modulation (FM) systems in noise (Wolfe, Morais, Schafer, Mills, Mülder, Goldbeck, Marquis, John, Hudson,
Peters, & Lianos, 2013). FM systems involve a receiver that picks up a sound signal and sends it as an amplified electrical signal via radio waves to the CI device of the user (Johnson, 2012, p. 244). These devices help to increase or improve the signal-to-noise ratio (SNR) presented to the listener, effectively improving speech recognition in the presence of environmental noise (Wolfe et al., 2013, p. 715). After testing 17 Harmony recipients and 20 Nucleus 5 recipients with a controlled FM system, Wolfe and his colleagues found “no difference in speech recognition in quiet” between the two CI devices (p. 721). The researchers in this specific study were cautious to extend or generalize these results to all sound processing models for Advanced Bionics and Cochlear Americas, citing limitations such as differing input dynamic range within the CI devices and no control for patient demographics (p. 723).

**Surgical Complications**

One area of monitoring and study relates to the surgical complications or surgical outcomes from the surgical procedure of cochlear implantation. A study at the Sheba Medical Center in Israel found issues in individual patients implanted between 2001 and 2007 stemming from all three manufacturers’ CI devices (Migirov et al., 2009). Foreign body and allergic reactions to the silicone housing were found in two patients fitted with Cochlear America’s Nucleus CI, both requiring re-implantation of the CI with the latter being re-implanted allergy-free with an unspecified MED-EL device (p. 743). Vestibular problems such as disequilibrium and vertigo were frequently mentioned as the most common surgical complication throughout many case reviews and were associated with all three manufacturers’ devices (Farinetti, Gharbia, Mancini, Roman, Nicollas, & Triglia, 2014, p. 179; Li, Qin, Zhang, Li, Qi, & Liu, 2014, p. 1041; Migirov, Muchnik, Kaplan-Neeman, & Kronenberg, 2006, p. 198; Migirov et al., 2009, p. 743). These problems most likely resulted from the “surgical trauma” of inserting of electrodes into the
cochlea, which is connected to the vestibular labyrinth responsible for balance coordination (Li et al., 2014, p. 1044). Overall, however, this issue appeared to be more of a generally CI issue rather than a device-specific problem.

Infections of the area surrounding the implanted component have also been found in patients using each of the CI devices. Among CI recipients in the study by Migirov and her colleagues (2009), the Nucleus was the only device to be associated with infection around the wound (p. 742). While “device-related infection” was found in less than 1% of patients, the Cochlear Nucleus N5 internal component was associated with infection surrounding the wound in 1.6% of patients in a fairly large study of 122 patients implanted at the Ochsner Clinic Foundation in New Orleans, Louisiana between 2005 and 2012 (Hildrew & Molony, 2013, p. 2832). A similar study at the Hospital of Marseille in France included MED-EL devices as well as Nucleus devices implanted in 37 and 194 children, respectively, between 1993 and 2013, and found infection in 20 pediatric patients with the devices affected unspecified (Farinetti et al., 2014, p. 178). Seromas, or cyst-like swelling of the skin filled with non-bacterial “serous fluid” associated with surgical operations (Nemade & Naik, 2014, p. 749), were found in 15 patients and were associated with all three manufacturers’ devices (Migirov et al., 2009, p. 742). Because of the associated infection complications with all devices, it has been suggested that infection was more of a result of surgical techniques, with smaller rates of infection related to smaller incisions during surgery (Li et al., 2014, p. 1044).

CI Device Reliability

The third area of complications involves the reliability of each respective CI device and the parents’ perceptions of those devices. Cochlear implantation is such a life-changing procedure for young children and their families, so those families are going to want a CI device
that is reliable and will not easily break down or quit functioning. While advances in CI technology have decreased device failures drastically, failures of these electronic devices do happen. When this occurs, patients often require surgery for removal (explantation) and re-implantation, which can be quite a challenge (Cosetti & Waltzman, 2012, p. 159; Hildrew & Molony, 2013, p. 2829). Some studies have estimated the rate of re-implantation among pediatric CI recipients between 6% and 13% (Eskander, Gordon, Kadhim, Papaioannaou, Cushing, James, & Papsin, 2011, p. 1190). These numbers may not be large, but they do show evidence that CI devices are not perfect by any means as far as reliability goes. It is important to note, however, that research has found that re-implantation does not negatively impact speech perception in the majority of patients (Eskander et al., 2011, p. 1194).

Failure of CI devices can be broken down into either “soft” or “hard” failures. A soft failure is defined as “declining performance, aversive auditory and nonauditory symptoms, or intermittent function” (Eskander et al., 2011, p. 1190). This means the CI still maintains a connection between each of the parts both externally and internally, but the overall performance is decreased. A hard failure is defective hardware in the CI that “provides immediate, insufficient auditory input to the patient” (p. 1190). The biggest difference between the two is that a hard failure renders the CI device useless and essentially broken while a CI with a soft failure will still function. Research studies related to soft and hard failures are fairly common.

One patient review study from the Hospital for Sick Children in Toronto, Canada found that 16 CIs out of a total of 462 implanted between January 2002 and December 2007 were re-implanted due to hard and soft failures of the original devices (Davids, Ramsden, Gordon, James, & Papsin, 2009, p. 981). Eskander and his colleagues (2011) also examined patients at the Hospital for Sick Children, but they used a much larger sample of 971 CIs among 738 pediatric
recipients between 1990 and 2010. Cochlear Americas’ CI22M and CI24 series CI devices were used in all but one of the recipients, who had two unspecified Advanced Bionics CI models. In this study, the researchers recorded 13 hard failures and 12 soft failures, two of which were the only Advanced Bionics devices in the sample (p. 1192). Cullen and his colleagues (2008) reported 61% of their 107 reviewed cases of cochlear implantation revision surgeries were due to hard or soft failure (as cited in Li et al., 2014, p. 1040).

The largest sample of the reviewed studies examined 2,827 CI devices in 2,311 patients over a 30-year span between January 1982 and June 2011 at the Sydney Cochlear Implant Center in Sydney, Australia (Wang, Wang, Psarros, & Da Cruz, 2014, p. 2393). The CIs included in the study were 97.7% Cochlear Americas Nucleus models, 2.2% MED-EL models, and one Advanced Bionics Clarion II (p. 2394). The researchers narrowed the sample down to the 235 patients requiring revision surgery for a device failure using Cochlear Americas Nucleus CIs. They found the failures included “damaged electrode arrays; missing hermetic seals; damage to the receiver-stimulators; circuit abnormality; and electronic malfunction[s],” with a failure rate in the pediatric population of 7.6% (p. 2394, p. 2398). The hermetic seal failures came from two Nucleus CI512 devices during the period of voluntary recall for moisture buildup by Cochlear Americas. While there were no recorded failures or revision surgeries for the MED-EL or Advanced Bionics devices in this study, the researchers did point out that each successive Nucleus model created demonstrated a lower failure rate than the previous model (p. 2398).

Thorough, comprehensive comparisons of the CI devices from the three manufacturers regarding reliability were nearly impossible to identity due to vast differences in the numbers of each manufacturer’s devices implanted at the individual CI centers. The reliability rates were also completely variable from study to study, never revealing a concrete reliability comparison.
Reports from Johns Hopkins suggested that 68% of their re-implantation surgeries were for Advanced Bionics CIs compared to only 26% and 2% for MED-EL and Cochlear Americas, respectively (as cited in Eskander et al., 2011, p. 1194). However, half of the cochlear implantations at their facilities used Advanced Bionics devices. Meanwhile, Gosepath and her associates (2009) reported a “revision rate” of 16.2% for MED-EL CIs and only 4.2% for Cochlear CIs (as cited in Eskander et al., 2011, p. 1194). A cumulative failure percentage (CFP) of 9.8% was calculated for a sample of 122 Cochlear Nucleus N5 CIs between 2005 and 2012 to determine the prevalence of Nucleus devices that ended up with a hard failure over that time period (Hildrew & Molony, 2013, p. 2829).

All three of these examples point to a different “winner” in the “game” of reliability. These findings clearly make decision-making based on reliability outcomes, along with surgical complications and speech perception for that matter, all very difficult. With no clear “front-runner” arising from patient/device outcomes, another perspective to examine is the marketing strategies of each of the CI manufacturers. The next section will examine whether the content of messaging as well as the way information is shared to families as consumers is effective in influencing or altering CI device selection.

**Marketing**

Before proceeding to the analysis of how each CI manufacturer markets their respective devices, a review of marketing and marketing strategies, specifically with the use of media and advertising, must first be presented. The United States of America’s overall economic institution has been described as a “market economy,” which, according to Colander (2013), is “an economic system based on private property and the market in which… individuals decide how, what, and for whom to produce” (p. 52). Direct decisions pertaining to the production and sale of
goods (e.g., price, location, amount produced) are made by individuals within the economy, not by the government. Thus, individuals looking to conduct a successful business and make a profit must conduct their own research on their respective product market and fine-tune strategies to appeal to the desires of a maximum number of consumers.

It is important for private businesses to employ modern marketing strategies that focus on building lasting connections and relations with clients and consumers in addition to simply focusing on their products and sales (Porcu, del Barrio-García, & Kitchen, 2012, p. 315). The method of reaching consumers in the contemporary United States of America is advertising through many popular forms of media such as printed periodicals (e.g., magazines and newspapers), television, and, within the past two decades, Internet platforms including websites and social media sites (Berger, 2012, pp. 61-63).

Marketing and Media

The key components of marketing, according to Cheon, Cho, and Sutherland (2007), deal with the product’s appeal (e.g., quality, packaging, accessories); the price of the product; distribution of the product; and, most pertinent to this component of this chapter, the promotion of the product to potential consumers (pp. 112-114). In an effort to increase sales of their products, businesses typically need to promote the product by reaching out to the desires of consumers through various advertising strategies. After all, consumers are less likely to seek out and purchase a product of which they have no prior knowledge. Although a study by Rideout and his colleagues (2010) was limited to children and adolescents between the ages of 8 and 18 years, the researchers reported that 7 hours and 38 minutes of daily “entertainment media” use was logged, such as “smart phones,” television, and magazines, suggesting an enormous platform to tap into for advertising for all age groups (as cited in Comstock & Scharrer, 2012, p.
Interestingly, the medium that reaches the largest audience of consumers is television, especially with United States census data from 2010 revealing over 61 million basic cable subscribers in this country alone (Berger, 2012, p. 23; United States Census Bureau, 2012). Television advertisements come overwhelmingly in the form of commercials, of which Berger (2012) stated that the average American spends a sum equivalent to one year over the course of their lives watching (p. 61).

Certain factors play into what media consumers lean toward and how they use media. One theory that explains media usage is the “Uses and Gratifications theory,” which posits that individuals will choose a specific medium that is most favorable to lead them to a desired outcome (Eastin, Cicchirillo, & Mabry, 2015, p. 420). For example, if a teenager wants to find out about a new pair of Michael Jordan-brand sneakers, they may choose to look up the page for Jordan products using the Twitter social medium on their mobile smartphone. Reasons for choosing this medium may be because it is much quicker than waiting for a television commercial about the sneakers or flipping through magazines trying to find one specific print advertisement. Consumers will select media that they are comfortable with and that provide the greatest expectancy of results (Eastin et al., 2015, p. 420). It is thus wise for businesses to research which medium or media will meet the expectations of consumers relative to the product and then focus advertising efforts through the most “effective” medium.

When companies advertise using media such as television and printed publications, a large amount of time is devoted to “media aesthetics” (Berger, 2012, p. 35). This involves using creative methods like brightly colored scenes and celebrity endorsements to make advertisements, and subsequently the product itself, more visually appealing to audiences.
(Berger, 2012, p. 35). The “aesthetic context” is designed to generate predictable patterns of positive consumer responses to the perceptual aspects of the marketing message (Zettl, 2014, p. 9). Berman (2015) stated that a positive mood “decreases the extent to which [consumers] will critically review an advertisement’s claims, thus increasing its persuasiveness” (p. 520). The use of humor, images of people smiling and laughing, and popular contemporary songs in the background, among others, are commonly-used tactics to achieve a subconscious positive mood within media advertisements (Berman, 2015, p. 520).

To achieve a positive mood among consumers, modern marketers employ the strategy of “neuromarketing,” which involves the subconscious influence of “lighting... logos, colors, displays, and the look of the product” on the consumer’s purchasing decision, (Berman, 2015, p. 500). Vecchiato (2013) and his research team conducted electroencephalography (EEG), a type of neurological test, and found high activation of limbic system responses, responsible for subconscious activity (e.g., emotion), in the left-frontal hemisphere of the brain during viewing of favorable television commercials along with responses of the cognition-based pre-frontal cortex (p. 66). For pictorial art, Zaidel (2015) examined several neurological studies and found common activation of the cingulate gyrus, involved with emotional sensory information, as well as cognitive areas of the brain, such as the pre-frontal and orbitofrontal cortexes during the observation of “beauty” paintings (p. 379). Emotional sensory information (e.g., pleasure versus pain) is “labeled” before cognitive analysis of the stimulant occurs, meaning the emotional responses affect how the brain’s cognitive functions respond (Mora, 2015, p. 12). These neurological findings point to the use of a combination of strong emotional appeals and use of cognitive function techniques in advertising to balance activation of the appropriate areas of the brain. By adjusting media aesthetics to better appeal to the emotions of the limbic system,
marketers attempt to create a positive mood among consumers.

Corporate marketing divisions invest copious amounts of time and money, some spending up to $21 billion a year, trying to find what characteristics are the most aesthetically appealing to the public at a given time (Berman, 2015, p. 517). These funds result in large pools of revenue for the media platforms that display the advertisements. In 2007, newspaper companies averaged 60-70% of total revenue through advertising revenue alone (Manduchi & Picard, 2009, p. 211). Revenues have grown as different media platforms have expanded, with advertising on Internet platforms bringing in $36.5 billion in 2012 (Liu & Viswanathan, 2014, p. 609). Such immense financial numbers require developing a sound company image, known as “branding” (Bisschoff, Van Staaden, & Buys, 2013, p. 84). Marconi (1996) stated that consumers develop a perception of a product based on their current knowledge of the manufacturer behind the product (as cited in Bisschoff et al., 2013, p. 84). It is extremely common for consumers to enter grocery stores and recognize many products by the name or logo of the manufacturer or producer. Therefore, it is vital that businesses work to create a positive image, or brand, in order to influence consumers to purchase their products.

**Medical Device Marketing**

Marketing strategies, including the use of media, extend to all aspects of business. In the area of medicine, advancements have been made to assist patients with health complications that might have been life-threatening just a few years ago. Within these advancements, the development of many implantable medical devices has generated wide attention and major benefits for humanity. In order for these products to positively affect the lives of patients, however, manufacturers must engage in effective marketing strategies for spreading awareness of the benefits of their products.
Marketing within the medical field, namely with pharmaceuticals, differs from other product areas. The commonly implied goal for medical products is to provide treatments to patients with the most effective benefits possible. Many scholars, however, view medical marketing in a different light. Sah and Fugh-Berman (2013) have claimed that both pharmaceutical companies and medical device manufacturers focus marketing efforts on “targeting the right doctors with the right message at the right frequency through the right channel” (p. 670). Light, Lexchin, and Darrow (2013) condemned medical marketing techniques as “undermining” the advising and benefiting role of physicians by simply trying to sell “innovative” drugs (p. 590). Thus, medical companies must approach marketing their products with extreme caution and attention to the needs of both physicians and consumers.

Estimates place the expected value of the market of medical devices around the world to exceed $228 billion in 2015 (Zheng & Redberg, 2014, p. 798). The monies dedicated to marketing goes toward strategies that make effective use of the medical device manufacturers’ understanding of “social psychology” to play to the consumers, which include both the recipients of the devices and the medical facilities that distribute the product (Sah & Fugh-Berman, 2013, p. 665). This psychology has reportedly involved factors that establish an effective relationship with the patient as a consumer in a way that promotes the patient’s Health Related Quality of Life (Brand & Stiggelbout, 2013, p. 225). The medical devices ultimately need to be designed to benefit the patient, not just to make a profit off the consumer. This benefit is best established when the marketing strategies have the goal of “patient-centered care” to make sure “patients have the education and support they need to make decisions and participate in their own care” (Apker, 2012, p. 196). Before medical devices can be marketed and distributed to patients, however, they must go through an extensive approval process through the federal government’s
Food and Drug Administration (FDA).

**FDA and premarket approval for medical devices.** The FDA was first given authority to “ensure that drugs and devices are safe and effective” (Ciociola, Cohen, & Kulkarni, 2014, p. 620) in 1938, with primary authority to regulate medical devices being granted in 1976 with the Medical Device Amendments in an effort to “substantiate ‘reasonable assurance of safety and effectiveness’ before allowing manufacturers to market their products” (Sorenson & Drummond, 2014, p. 116). The most common submission for new devices is the “510(k)-premarket notification,” which enables a device to be approved immediately if it is deemed “substantially equivalent” to similar existing “predicate” devices already approved (Ciociola et al., 2014, p. 623; Committee on the Public Health, 2011, pp. 85-86; Sorenson & Drummond, 2014, p. 117). In the United States, medical devices are categorized into three different classes based on “intended use, whether the device is invasive or implantable, and the risk posed by the device to the user” (Sorenson & Drummond, 2014, p. 117).

Devices rated as “Class I” are typically considered “low-risk” and are usually simply constructed, such as “tongue depressors, crutches, and scalpels” (Sorenson & Drummond, 2014, p. 118). These devices do not require premarket notification other than regulations regarding labeling and generally pose no significant health risks. Devices in the “Class II” category are considered “medium-risk” and are often subjected to the 510(k) submission process prior to being initially placed on the market along with FDA monitoring while on the market (p. 117). These devices include endoscopes, infusion pumps, and condoms, for example (p. 119). Approximately 90% of medical devices are in these two categories and are approved by the FDA to begin marketing, which generally takes less than a year (Committee on the Public Health, 2011, p. 86).
“Class III” medical devices are subject to a more critical approval process, however, which usually takes much longer than Class I and Class II devices. These devices are considered “high-risk” and are defined as “those that support or sustain human life, help prevent the impairment of human health, or might present an unreasonable risk of illness or injury,” as well as any new product with no “predicate,” or similar device that was previously approved (Zinn, Allen, & Hacker, 2012, p. 2305). Medical devices submitted for approval under this category require “premarket approval (PMA),” in which extensive clinical trials must be performed with the outcomes showing full “safety and effectiveness” of the device before the device can be sold (Sorenson & Drummond, 2014, p. 117; Zheng & Redberg, 2014, p. 798). Class III medical devices may have strict regulations, but it is important that manufacturers of these devices be explicit in labeling and marketing their products to ensure the safety of patients by FDA guidelines.

**Cochlear implant device marketing.** Cochlear implants (CIs) fall under the category of Class III medical devices due to the major risk of being surgically implanted. During the FDA approval process, CIs undergo PMA regulations that require extensive clinical trials before any innovative device changes can be marketed (Zheng & Redberg, 2014, p. 798). There have been numerous CI device “innovations” over the years, however, resulting in a vast number of predicate PMAs. Thus, CI manufacturers are able to submit minor changes or upgrades to devices as a “PMA supplement,” which requires less clinical testing data and is, therefore, quicker (Zheng & Redberg, 2014, p. 798). The efficiency of this submission supplement encourages manufacturers to make one device change submission at a time, as opposed to multiple changes in one application. While this is effective in cutting down on time, Zheng and Redberg (2014) have claimed that this puts clinicians in a bind because it allows for multiple
variations in device products on the market at a given time (p. 798). Thus, when clinicians attempt to read about “up-to-date” CI products in “recent” articles, the chances are high that the CI technology has already been upgraded. Therefore, the marketing strategies of CI manufacturers are aimed at constantly providing updated awareness to CI teams along with introductory information to patients and families.

Unlike many pharmaceutical drugs or lower-class medical devices, CIs do not use direct-to-consumer marketing strategies. One possible reason behind this is the need for “specialized expertise” in both surgically implanting and MAPping the device (Mackert & Harrison, 2009, p. 4). Of course, most patients and their families do not undergo the education and training that audiologists and other professionals on a CI team do in order to fully understand the CI technology. It is difficult, therefore, for a direct-to-consumer approach, leaving CI manufacturers to direct potential recipients to consult their audiologist and/or physician. Sorkin (2013), currently the Executive Director of the American Cochlear Implant Alliance (ACIA), wrote that many medical professionals working in hearing loss-related fields, however, are hesitant or uncomfortable with discussing the option of cochlear implantation or making referrals for further CI evaluation for potential CI candidates (p. S6). A lack of CI competency also affects overall professional expertise, as a study by Sorkin (2010) of 150 early intervention (EI) specialists in the United States revealed only 67% knew even the minimum age requirement of 12 months for children to receive a CI (as cited in Sorkin, 2013, p. S7). Another study by Sorkin and Zwolan (2008) found only 31% of families of pediatric CI candidates received information from their EI specialists about CIs (as cited in Sorkin, 2013, p. S7). If many “knowledgeable” professionals are unable to thoroughly discuss CI information, it is reasonable to suspect that CI candidates and/or their families, especially those with no prior CI experience, would struggle to fully comprehend
the benefits and risks of direct-to-consumer advertising of CIs.

A second possible reason for the lack of direct-to-consumer advertising of CIs is the ongoing debate over the ethics of cochlear implantation. The Deaf community involves persons who use American Sign Language as their primary mode of communication and view deafness with high self-esteem along with a strong sense of identity, not as a handicap or disability (Sorkin, 2013, p. S7). Members of this community believe cochlear implantation is a near “genocidal” process that treats deafness as a disability to be “fixed” and not as an identity or minority culture. Opposition to CIs also reflects the belief that if children who were implanted did not reach the listening and spoken language expectations associated with CIs, it would be severely detrimental to their self-esteem and emotional psyche for the rest of their lives (Most, Wiesel, & Blitzer, 2007, pp. 69-70). Mackert and Harrison (2009) claimed that the informational brochures the CI manufacturers give to CI candidates and their families “do not provide the full picture… of the potential cultural risks and implications” of cochlear implantation from the perspective of the Deaf community (p. 5). Adapting their advertising messages or simply involving cultural perspectives breaks away from the manufacturers’ business goal of simply pushing a product to sell, but can “gain the trust of healthcare consumers… and win the business that comes with that trust” (Mackert & Harrison, 2009, p. 5).

The third possible reason for the lack of direct-to-consumer marketing tactics is that the vast majority of CIs are not directly paid for by the recipient or the family like most other marketed products. Most CI devices and the required surgery are covered by the patient’s insurance, meaning the only cost to patients or their families may only be the co-pay or deductible on the insurance claim. Patients can be covered by one of three types of insurance plans: private, governmental (Medicare or Medicaid), or federal employee plans (e.g., military).
Most private insurance plans now cover both unilateral and bilateral cochlear implantation along with some of the diagnostic and auditory (re)habilitation services (p. S8). Retroactive to April 4, 2005, Medicare was reformed to cover cochlear implantation for adults in addition to children ages 2 to 17 years, provided they meet the criteria of a bilateral, moderate-to-profound, sensorineural hearing loss (Department of Health & Human Services & Centers for Medicare & Medicaid Services, 2005, p. 3). This indirect method of payment affects the marketing strategy of CI manufacturers both positively and negatively. On the positive side, manufacturers are able to market to potential CI candidates and their families that CIs will more than likely not cost them a dime, but on the negative side they do not see a direct return on investment when marketing directly to patients.

In lieu of direct-to-consumer advertising, CI manufacturers use a variety of marketing strategies aimed toward medical clinics and professionals working in CI- and hearing loss-related fields. Sah and Fugh-Berman (2013) claimed that medical device manufacturers, including CI manufacturers, determine which marketing messages are most effective based on “uplifts in… medical device sales from sales rep visits, gifts, meetings, continuing medical education seminars, and so on” (p. 670). Light, Lexchin, and Darrow (2013) discussed the strategy of reciprocation between manufacturers and physicians using the term “gift economy” due to the common practice of giving packages to clinicians who prescribe or refer their products to patients (p. 591). Thus, to avoid negative connotations and perceptions, CI manufacturers avoid bringing attention to gifting tactics in their consumer-directed marketing.

**Cochlear Americas marketing.** With a thorough understanding of the basics of marketing, with medical devices specifically, the principles can now be applied to the three CI manufacturers being investigated. The first manufacturer, Cochlear Ltd. and Cochlear Americas
[“Cochlear”] brand their CI devices under the slogan “Hear now. And Always” and can be identified in the CI market by their yellow color scheme (“The Cochlear Nucleus System,” 2015, p. 1). As of 2013, Cochlear held two-thirds of the market share for the billion-dollar global cochlear implant market (Kirkwood, 2013, para. 20), with sales revenue of around $820.8 million ($320.8 million in the United States) between June 2013 and June 2014 (Cochlear Ltd., 2015, p. 75). Overall sales revenue increased to over $925.6 million ($402.9 million in the United States) between June 2014 and June 2015, with $826.8 million of that total brought in from their cochlear implant sales (Cochlear Ltd., 2015, p. 75). While “achieving annual revenue and [Executive Board] targets and personal objectives” are a significant motive behind marketing efforts (Cochlear Ltd., 2015, p. 49), the annual Director’s Report (2015) stated “Cochlear’s strong relationship with its customers and professionals will continue to underpin demand and sales growth for the business” (p. 37). All of this suggests a patient-centered approach, as defined by Apker (2012, p. 196), for the Cochlear Ltd. marketing strategy.

In order to develop and maintain customer relationships, it is necessary for Cochlear to communicate directly to patients and professionals. While they do not air television commercials in the promotion of their products, Cochlear does provide many print documents, along with an extensive website. They publish updated informational brochures and pamphlets at least yearly, with their multi-page booklets published apparently every other year (“Let There be Sound,” 2013; “The Cochlear Nucleus System,” 2015). Potential CI recipients and/or their families can request these informational documents to be mailed to them through Cochlear’s website. The collection of Cochlear documents for this study involved the use of a quick, convenient process, in which the documents were mailed via FedEx overnight shipping and received by the researcher within two business days.
To gain a clearer understanding of the media aesthetics used by Cochlear, a brief qualitative analysis of their current, main CI informational booklet was conducted. The color scheme of yellow and white used in Cochlear’s main logo immediately jumps out as both colors are found on every page in this 42-page booklet—“The Cochlear Nucleus System: Hear the Sounds of Life.” The document is structured with colored pictures including quotes and phrases, such as “hear what you’ve been missing” (p. 6) and “sometimes the biggest miracles are also the smallest” (p. 10), on the left-hand side and clinical data about their products on the right-hand side. Out of 22 pictures involving human subjects, 19 involve people who are smiling or laughing. This combination of positive emotion-provoking pictures and logical data falls in line with what Vecchiato (2013) and Zaidel (2015) refer to as “effective” neuromarketing strategies. Offering data and information about how CIs work, and specifically how Cochlear’s CI technologies work, aims to create a more knowledgeable consumer, enabling them to participate more in the decision-making process through patient-centered care (“The Cochlear Nucleus System,” 2015).

Cochlear engages in marketing techniques aside from printed informational brochures as well. All three CI manufacturers advertise their brand and products at conferences around the world. For large conferences, such as the 2015 AG Bell Listening and Spoken Language Symposium and AG Bell Biennial Conventions, Cochlear sponsors a booth to promote their CI products to conference attendees (AG Bell, 2015, chart). The company also financially sponsors several smaller conventions each year, including the 2015 Northeast Cochlear Implant Convention in Massachusetts and donating $500 as a “Silver” sponsor to the “HEAR Indiana” Listening and Spoken Language Conference in Indianapolis (“Sponsors,” 2015; HEAR Indiana, 2015, chart). Sponsoring or donating to these conferences is inexpensive relative to the millions
of dollars of revenue generated, yet it allows Cochlear to expose its brand to consumers and hearing-related professionals in a positive and interactive manner.

**Advanced Bionics marketing.** The second CI manufacturer to analyze is Advanced Bionics (AB), which currently operates under the patient-centered slogan, “Your life. Our commitment” (Advanced Bionics, 2015b, p. 4). AB’s holding company, Sonova, partners four individual company brands (Phonak, Unitron, AB, and Connect Hearing) together to provide extensive services for a wide range of hearing-related services, including hearing aids [Phonak and Unitron] and both hearing-assistive technology and professional networking (Sonova Holdings AG, 2015, p. 7). The ability to collaborate from several different hearing loss-related fields, especially between AB and Phonak, is a major benefit that is focused on in their marketing messages (Advanced Bionics, 2013b, p. 2; “Bring on the Sound,” 2015, p. 6). AB also made the waterproof capabilities of their NEPTUNE device and waterproof accessories for the Naida series a major marketing focal point (Advanced Bionics, 2015b, p. 30).

Sonova, and subsequently AB, emphasize “innovation” as the main marketing focal point, investing 7-8% of sales revenue back into research and development annually among the different brands to continue upgrading hearing technology (Sonova Holdings AG, 2015, p. 6). AB generated roughly over $196 million in CI sales worldwide between 2014 and 2015 while trying to recover from 2013 Naida CI Q70 recalls (p. 69). These sales numbers are significantly lower than those of Cochlear, a reflection of the difference in market share between the two manufacturers. Similar to Cochlear, however, AB goes beyond financial motives, placing emphasis on patient-centered marketing to create “strong productive relationships between employees, customers, and other stakeholders” (p. 7). Thus, while AB’s CI sales are much smaller than Cochlear’s, they benefit from the partnership with Sonova, a leader in hearing-
assistive technology worldwide, and their ability to integrate technologies from the consolidation of brands.

The most common method of direct-to-consumer advertising used by AB is the distribution of informational brochures. Like Cochlear, these documents can be requested for free through AB’s main website or through the CI center from which the family is receiving services. The majority of these pamphlets involve the blue color scheme that AB identifies with along with pictures coupled with typed information and statistics about AB and/or its products, consistent in general layout or format to that of the other two manufacturer’s documents. One of AB’s biggest booklets, the 30-page “Bring on the Sound” (2015), is structured with a picture of a CI recipient including a unique buzz-word phrase (e.g., “Bring on the dream,” p. 7) on the left page and information relating to each respective phrase on the right page. Almost all of the pictures involving human subjects (12 out of 13) include people that are smiling or laughing. This, too, follows the “neuromarketing” suggestions of Vecchiato (2013) and Zaidel (2015) by appealing to both positive emotion and logic simultaneously. (Advanced Bionics, 2015b).

Sonova reported sales and marketing costs of over $619,000 during the 2014-2015 fiscal year (Sonova Holdings AG, 2015, p. 72). This cost included AB’s considerable involvement in hearing loss-related conferences to promote their brand, specifically those involving CIs and other assistive listening devices. They were regularly involved, albeit to differing degrees, in the same conferences as the other CI manufacturers. For the 2015 AG Bell Listening and Spoken Language Symposium AB out-spent Cochlear, exhibiting a booth as a “Gold Level Sponsor” along with buying advertising spaces on materials and “give-aways” such as banners, lanyards, and even pens distributed to conference attendees (AG Bell, 2015, chart). AB was a “Gold” level sponsor with a $1,000 donation to the 2015 “HEAR Indiana” Listening and Spoken Language
Conference (HEAR Indiana, 2015, chart). While they did not sponsor the 2015 Northeast Cochlear Implant Convention in Massachusetts, their corporate partner, Phonak, was a sponsor (“Sponsors,” 2015, chart). Donations and sponsorships by AB are not limited to these conferences, however, as they appear to have attempted to promote their brand publicly around the world at numerous events.

**MED-EL marketing.** The third manufacturer, MED-EL, used the slogan “Hear Life,” moving to a new slogan, “It’s your Moment” in 2015 (MED-EL, 2015, p. 1). Their primary focal points for marketing appear to include their “FineHearing” technology; the longer lengths of their electrode arrays; as well as the MRI compatibility of their SYNCHRONY implant (up to 3.0 Tesla) (MED-EL, 2015, pp. 14-21, 27-29, 34). Unlike the other two CI manufacturers, MED-EL’s shares run through the Austrian stock exchange market and annual financial reports could not be located. MED-EL reported on their website, however, that between June 2012 and June 2013 they sold 14,027 CI devices, which they claimed was 18% of the *global* CI market share (“Cochlear Implants: Facts,” 2015, para. 3). In order to market to consumers and reach those sales numbers, MED-EL has conducted similar tactics as have the other manufacturers, using printed informational brochures and sponsorship of various conferences.

MED-EL generates one large 152-page booklet combining all their current product information, background on anatomy and physiology of the ear, and scientific measures of their implants (MED-EL, 2015); along with many one- to three-page pamphlets specific to one CI device model or therapy service. Aesthetically, the booklet and pamphlets, as well as MED-EL’s website, use their red color scheme with numerous pictures. The most recent booklet follows suit; alongside the other two manufacturers, by utilizing combined emotional and arguably logical neuromarketing strategies (Vecchiato, 2013; Zaidel, 2015). Of the 35 human subject
pictures, 33 involved people smiling and/or activities associated with positive emotions, such as walking along the beach on the cover or mountain biking (MED-EL, 2015, p. 4). Interestingly, while the pictures in the booklet are designed to evoke positive moods among the reader, MED-EL did not structure every page with a picture on one side and typed information on the other.

As noted earlier, each of the three CI manufacturers tend to sponsor conferences and events in which the others are involved. MED-EL was a “Gold Level Sponsor” of the 2015 AG Bell Listening and Spoken Language Symposium (AG Bell, 2015, chart). They were also sponsors of the 2015 Northeast CI Convention, but were not involved in the 2015 “HEAR Indiana” Listening and Spoken Language Conference, an example of one event that not all three sponsored (“HEAR Indiana,” 2015; “Sponsors,” 2015, chart).

While the three CI manufacturers differ in the characteristics/accessories of their respective CI devices to focus on, they are quite similar in the way they convey information to consumers. The actual media platforms for marketing are not seemingly significant in affecting parental decision-making due to lack of variation, yet the distinct product accessories and capabilities highlighted may very well be significant from a marketing perspective.

**Conclusion**

Cochlear implants are a “medical miracle” in the eyes of many parents of children who are deaf. They have come such a long way in advancement in a relatively short amount of time. The three major cochlear implant manufacturers spend millions of dollars to continue that technological development as well as marketing their product to the public. For what seems to be such a small device, the manufacturers of CIs provide an incredibly large array of options for not only CI models but accessories and processing strategies as well. Although there is such a variety of CI technologies and products, the current research does not point toward a specific
manufacturer’s device as superior over the others.

When it comes to decision-making for the parents of pediatric candidates, there is a plethora of data from research studies reviewing previous implantations that provide vital information into outcomes as well as cautions or even dangers of choosing a specific CI device. There are also many professionals whose jobs include assisting in giving comprehensive knowledge to the families about all three or fewer of the CI devices. As Brand and Stiggelbout (2013) stated “the process of discussing available options… should come to a point where a certain [option] appears as the best possible strategy, weighing in both the medical evidence and the patient’s perspective” (p. 227). This statement supports the notion that the final decision is arguably and ultimately up to the families to research and understand. The factors they decide on, however, are most important. The decision-making process these families embark on can contribute to the research data and help professionals create a more fine-tuned strategy for providing information and assistance to future families in the same position.
CHAPTER III

METHOD

The previous chapter examined current information pertaining to cochlear implants (CI) and the three CI manufacturers in the United States. After exploring CIs in this broad sense, this chapter will lay out the process by which the specific purpose of this study was carried out. The purpose of this study was to investigate factors/variables and ranking of those factors on cochlear implant device selection among CI manufacturers within the United States by parents of pediatric CI recipients. This chapter will describe the justification of this study’s method, the participant demographics, the survey instrument, and the procedures that followed.

Justification of Method

To investigate the factors affecting parent decision-making, the study was conducted using quantitative survey research methods. Survey research aims to generalize patterns found among a smaller sample population’s responses to the larger population as a whole in an attempt to predict how the overall population will act or behave in a certain situation (Wrench, Thomas-Maddox, Richmond, & McCroskey, 2016, p. 219). The use of survey research was justified in this study because it allowed for a broader sample size and quantitative data from multiple families to be combined to reveal patterns among the decision-making factors affecting parents of pediatric cochlear implant recipients. The type of survey used was an “analytical survey,” which “explain[s] why people think or act as they do by identifying likely causal influences on their attitudes and behavior” (Wrench et al., 2016, p. 217). In this analysis, the survey was designed to examine why the participants chose a specific manufacturer’s CI device over others based on various factors and considerations.

Online survey research has strengths and weaknesses affecting any study. According to
Babbie (2011), online survey research is a relatively inexpensive technique because there are no mailing or material costs (p. 302). Online surveys are also effective in quickly reaching large sample populations and allowing parents within that sample population to complete and submit the survey at their convenience (p. 302). In the realm of weaknesses, online survey research is ineffective when parents who may be potential participants are not able to access the Internet or be able to ask potential clarifying questions in an efficient manner (p. 301). Also, because the surveys were distributed via a third-party (the cochlear implant center professionals), there was an issue with having potential families’ email contacts with which to distribute the survey link. All-in-all, however, the ease of use and quickness of online survey research were believed to outweigh the disadvantages.

Participants

The population was limited to parents or guardians over the age of 18 years who had a child who underwent CI surgery before the age of six years and between January 1, 2014 and December 31, 2015. The link to the survey was distributed to 33 major hospitals and cochlear implant centers across the United States that offered two or three manufacturers’ devices to patients. The link was also distributed to Cochlear, Ltd.’s regional managers, whose clients included numerous cochlear implant centers across the United States, in the hopes they would pass along the link to parents whose children fit the above criteria.

Instrument

As noted above, this study was administered using an electronic, online survey (see Appendix A). The survey began with a brief paragraph explaining the survey and the consent process was included at the beginning of the survey. The paragraph detailed the rights of the participant to choose not to answer any specific question or questions and to withdraw at any
point during their response. Participants were asked to confirm they were over the age of 18 years and that their child fit the study’s inclusion criteria for cochlear implant surgery age and selection. The parents/guardians were also given the contact information for both the researcher and the advisor and instructed to ask any questions that they had about the survey or the study as a whole, in addition to requesting results of the study.

The survey was composed of 48 items. These items involved 31 Likert-type scales, 30 of which asked parents to rate their response on a 7-point scale from “Not at all Important” to “Extremely Important” (Items 13-42). There were also 13 nominal questions, 3 open-ended questions, and 1 ranking item. An example of one of these questions was “Who made the final decision regarding which manufacturer’s device to choose,” in which the participant is asked to select one of either “Parent(s), Child, Audiologist, Surgeon/ENT/Otologist, or Other” (Item 10). The items in the survey were designed to address four distinct categories: demographic information (n=6), cochlear implant selection (n=6), satisfaction with the cochlear implant device (n=3), and decision-making factors (n=33). The 33 decision-making factor items were split into three subcategories: aesthetics, performance-related information, and manufacturer-specific information. Certain factor-related items were adapted from the survey used in a similar study by Clamp, Rotchell, Maddocks, and Robinson (2013) in an attempt to cover as many potential cochlear implant decision-making factors as possible.

Procedure

As the study involved human subjects, an application to the College of Wooster’s Human Subjects Review Committee (an Institutional Review Board) was submitted including a description of the study’s research method and the electronic survey on December 2, 2015. The study was approved through an expedited review process on December 11, 2015. In order to
distribute the approved survey to parents whose children fit the population description, a procedure for locating those parents was developed. The survey was created and administered electronically using Qualtrics software (see Appendix A). The selection of participants for the study involved a combination of “network” and “purposive” sampling techniques (Wrench et al., 2016, p. 317, p. 319). Network sampling involved the referral of certain individuals that meet the research criteria by a third party (p. 319). Purposive sampling involved selecting participants that “meet some predetermined criteria” (p. 318), which, in the case of this study, was the pediatric patients’ CI criteria that was outlined above.

The CI centers to which the survey link was sent were found using the three CI manufacturers’ “Find a Clinic” search bars located on their respective websites, along with further investigation through the individual CI centers’ websites to determine which CI centers supplied either two or more of the manufacturers’ CI devices. Contact emails for many of the matching CI centers were located using the organizational member search on the American Cochlear Implant Alliance’s (ACIA) website. The initial participation request email (see Appendix B) was sent out to the contacts at the selected centers with a link to the survey as well as a recruitment flyer (see Appendix E) on December 22, 2015. The contacts were asked to distribute the link to the families that fit the study’s inclusion criteria via email or social media posts. The survey link was also sent out to Listening and Spoken Language Specialists (LSLS) and a total of approximately 12,000 Alexander Graham Bell Association for the Deaf and Hard of Hearing’s “E-Blast” on January 7, 2015 (See Appendix C).

Both audiologists and therapists from several CI centers replied to the researcher regarding the initial request email on December 22 and December 23, 2015. Those that replied received a “thank-you” email that included an invitation to view the results of the study in late
Spring 2016 (see Appendix D). On January 26, 2015 a follow-up email was sent to all CI centers that were included in the original December 22, 2015 email (see Appendix F). Upon closing the survey on February 5, 2016, the data from the responses were inputted into SPSS for analysis. Findings and their interpretation will be further discussed in Chapter IV.

**Conclusion**

This chapter discussed the justification for the use of survey research, the participant sample, the instrumentation used to collect data, and the procedure for obtaining participant responses. While there was difficulty reaching out to parents whose children fit the sample criteria, the help of audiologists and therapists at various cochlear implant centers was instrumental in obtaining participants for this study. The next chapter will analyze and discuss findings from those families who were able to access the survey.
CHAPTER IV
RESULTS AND DISCUSSION

The purpose of this study was to investigate a range of factors/variables and the influence of those factors on cochlear implant (CI) device selection among the three CI manufacturers in the United States, by parents of recent pediatric CI recipients. A total of 33 CI centers from across the United States were contacted and asked to distribute a survey link to the families of all patients who fit the inclusion criteria for this study. This chapter will first analyze the data from the participating families and then discuss the patterns that emerge from the results.

Presentation of Findings

While the number of families to whom the survey link may have been distributed to may range in the hundreds to thousands, a total of 30 families participated in the survey. Of those 30, however, only 21 families or 70% completed the survey and met the inclusion criteria for the study, and were subsequently used for data analysis.

In order to understand the backgrounds of participating families and their children, the researcher asked six demographic questions — the child’s age at CI implantation; child’s current age; the number of CIs the child received (including whether the surgery was simultaneous, sequential, or unilateral); the responding parent’s relation to the child; whether the child was the only member of the immediate family to receive a CI; and the parent’s prior knowledge of CIs.

Child’s Age at Implantation

The first question participants were asked was the age of their child at the time they received his or her CI. Participants were given seven age range choices: Less than 12 months; 12 months to 1 year, 11 months; 2 years to 2 years, 11 months; 3 years to 3 years, 11 months; 4 years to 4 years; 11 months; 5 years to 5 years, 11 months; and “Older.” Of the 21 total
participants, 25% (n=5) were less than 12 months at the time of implantation; 40% (n=8) were 12 months to 1 year, 11 months; 15% (n=3) were 2 years to 2 years, 11 months; 10% (n=2) were 3 years to 3 years, 11 months; 5% (n=1) were 4 years to 4 years, 11 months; and 5% (n=1) were 5 years to 5 years, 11 months (see Figure 1). Note: 5% (n=1) did not respond to this question.

Multiple parents outside the 21 participants involved in this analysis completed the survey, but responded with “Older.” Their responses were thus excluded from the study data due to their child being outside the study criteria for participation.

\[ \text{Figure 1. Age of child at time of implantation} \]

The participants were then asked to provide their child’s current age. The age range choices were the same as those used in the previous question. Of the 21 participants, 23.8%
(n=5) were 12 months to 1 year, 11 months; 33.3% (n=7) were 2 years to 2 years, 11 months; 9.5% (n=2) were 3 years to 3 years, 11 months; 9.5% (n=2) were 4 years to 4 years, 11 months; and 23.8% (n=5) chose “Older” (see Figure 2) (see Appendix A). Those who selected “Older” were included in the analysis, unlike the previous question, because their respective children still met the inclusion criteria for the study.

**Figure 2.** Current age of the pediatric CI recipient

**Child’s CI Demographics**

Participants were next asked the number of CIs their child received. The options were “One (unilateral),” “Two (simultaneous bilateral—one surgery),” and “Two (sequential bilateral—two surgeries).” Of the 21 participants, 33% (n=7) received one CI; 29% (n=6) received simultaneous bilateral CIs; and 38% (n=8) received sequential bilateral CIs.
In a separate question, participants were asked if the child in question was the only member of the immediate family to receive CIs, to which 81% (n=17) replied “Yes,” and 19% (n=4) replied “No.”

**Parent Demographics**

The demographic information pertaining to the 21 responding parents indicated that 90.5% (n=19) were mothers of the child; 4.8% (n=1) included the father; and 4.8% (n=1) responded with “Other.” The participant who responded “Other” indicated that she was the “adoptive mother” of the child.

In a separate question, participants were asked about their experiences with CI technology prior to their child’s implantation. The options were—“I had never heard of cochlear implants”; “I had only generally heard about them”; “I have cochlear implants”; “I work with cochlear implants”; and “Other”—which included a line for specifying “Other” experiences. Of the 21 participants, 23.8% (n=5) chose “I had never heard of cochlear implants;” 61.9% (n=13) chose “I had only generally heard of them;” 4.8% (n=1) chose “I have cochlear implants;” and 9.5% (n=2) chose “Other.” The two participants that responded “Other” specified their experiences as “I researched them for a year prior” and “her [the child] oldest brother has bilateral cochlear implants.”

**Manufacturer’s Devices Available/Selected**

A major factor in this study’s inclusion criteria was that the families had to have had a choice between either two or three of the CI manufacturers’ devices. When the participants were asked how many different CI manufacturer’s devices were available to them at the time of selection, 5% (n=1) had a choice between two companies and 95% (n=20) had a choice between all three. The option for “One” manufacturer’s device was available on the survey, but any
respondents who selected this option would have been removed from analysis.

Expanding upon the previous question, participants were asked which specific CI manufacturer’s devices were offered to them at the time of selection. The options included Cochlear Americas, Advanced Bionics, MED-EL, “Other,” or “I don’t know.” Cochlear Americas’ devices were available to 95% (n=19) of the 20 participants who answered the question; Advanced Bionics’ devices were available to 95% (n=19); and MED-EL’s devices were available to 90% (n=18) of participants. One participant (5%) answered “I don’t know” and another survey participant did not answer this question.

The final question pertaining to which specific manufacturer’s device was selected asked participants which manufacturer’s device they chose for their child. The options were the same as the previous question regarding devices offered. Of the 21 participants, 57% (n=12) selected Cochlear Americas; 24% (n=5) selected Advanced Bionics; 14% (n=3) selected MED-EL; and 5% (n=1) were not sure which manufacturer’s device they chose (see Figure 3).

![Figure 3. Distribution of manufacturer’s device(s) participants selected.](image)

- Cochlear Americas (n=12)
- Advanced Bionics (n=5)
- MED-EL (n=3)
- Not Sure (n=1)

(N=21)
CI Device Selection Process

In addition to which specific manufacturer’s devices were available and selected, participants were also asked several questions regarding who made the final selection and what information they used to make that decision. When asked who made the final decision, 95% (n=20) of the 21 participants responded that the “parent(s)” made the final selection while the other 5% (n=1) responded “Other.” In the case of the “Other” response, this participant noted that the final decision was made by “the state of Alaska.”

Participants were then asked about the pre-selection information resources that were available to them at the hospital or CI center. The participants were asked to select ALL answers that applied to their situation, thus meaning that each option’s percentage represents how many participants out of the 21 included that option in their response. There were a total of 65 resources used across all 21 participants. Of the 21 participants, 85.7% (n=18) received “information from cochlear implant team”; 38.1% (n=8) received “scholarly research articles”; 76.2% (n=16) received “promotional brochures/pamphlets from [the] manufacturers”; 33.3% (n=7) received “cochlear implant support group information”; 23.8% (n=5) received “advice/experience [from] a family member”; and 52.4% (n=11) received “recommendations from other parents.”

The next question regarding resources during the CI selection process asked participants about the types of marketing media they used to make their decision. Similar to the previous question, this item asked participants to select ALL options that applied to their situation. A total of 55 responses were recorded. Of the 6 options, “print ads” were used by 57.1% (n=12) of the 21 participants; “social media/online blogs” were used by 61.9% (n=13) of participants; “videos” were used by 28.6% (n=6) of the participants; “DVDs/CDs” were used by 14.3% (n=3) of the
participants; “manufacturer websites” were used by 76% (n=16) of participants; and “conference presentations” were used by 5% (n=1) of participants (see Figure 4). A total of 14% (n=3) of the 21 participants said they did not use any marketing media for their decision (“None”), and 4.8% (n=1) selected “Other,” specifying that they used “one on one with the Audiologist” for help with their decision.

![Figure 4. Types of marketing media used during CI device selection.](image)

**CI Device Selection Factors**

Arguably, the most important segment of the survey revolved around a vast number of device selection factors and their individual importance to the families that participated in the study. Overall, there were 30 factors listed on the survey, grouped into three categories—aesthetics; performance-related; and manufacturer-specific. Participants were asked to rank the
importance of each factor on their device selection using a Likert-type scale of 1 through 7; with 1 representing “Not At All Important” and 7 representing “Extremely Important.” Additionally, 2 represented “Very Unimportant”; 3 represented “Somewhat Unimportant”; 4 represented “Neither Important nor Unimportant”; 5 represented “Somewhat Important”; and 6 represented “Very Important.” Options 1-3 were grouped together during analysis and reported as “Unimportant”; Option 4 was analyzed and reported as “Neutral;” and options 5-7 were grouped together during some analyses and reported as “Important.” Thus, factors scored 3 or below (1, 2, and 3) were considered unimportant; scores of 4 were considered neutral; and scores of 5 and above (5, 6, and 7) were considered important.

Aesthetic Factors

Participants were given a list of 5 CI device selection factors related to the aesthetics of CI devices. These questions explored the physical appearance of the device and accessories. The item numbers were Questions 13-17 (see Appendix A). See Table 1 for a summary overview of all the results. Note: one participant did not respond to these questions.
Table 1

*How Important Certain Aesthetic Factors Were to Parents of Pediatric CI Recipients during CI Device Selection*

<table>
<thead>
<tr>
<th>Factor (n=20)</th>
<th>Unimportant 1-3</th>
<th>Neutral 4</th>
<th>Important 5-7</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size of external processor</td>
<td>15% (n=3)</td>
<td>5% (n=1)</td>
<td>80% (n=16)</td>
<td>5.45</td>
<td>1.64</td>
</tr>
<tr>
<td>Design/appearance of external component(s)</td>
<td>15% (n=3)</td>
<td>5% (n=1)</td>
<td>80% (n=16)</td>
<td>5.30</td>
<td>1.59</td>
</tr>
<tr>
<td>Color options available</td>
<td>40% (n=8)</td>
<td>20% (n=4)</td>
<td>40% (n=8)</td>
<td>3.80</td>
<td>1.79</td>
</tr>
<tr>
<td>Accessories available</td>
<td>35% (n=7)</td>
<td>15% (n=3)</td>
<td>50% (n=10)</td>
<td>4.45</td>
<td>2.14</td>
</tr>
<tr>
<td>Weight of the device</td>
<td>20% (n=4)</td>
<td>0% (n=0)</td>
<td>80% (n=16)</td>
<td>5.25</td>
<td>1.74</td>
</tr>
</tbody>
</table>

**Performance-Related Factors**

The second section of CI device factors included a list of 16 items related to the reported performance and function outcomes of the CI devices. The items under this category were Questions 18-33 (see Appendix A). Table 2 shows an overview of the results from the 19 participants who responded to these items. Two participants did not respond to these items.
Table 2

<table>
<thead>
<tr>
<th>Factor (n=19)</th>
<th>Unimportant (1-3)</th>
<th>Neutral (4)</th>
<th>Important (5-7)</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported reliability of internal components</td>
<td>5.3% (n=1)</td>
<td>0% (n=0)</td>
<td>94.7% (n=18)</td>
<td>6.58</td>
<td>1.39</td>
</tr>
<tr>
<td>Reported reliability of external processor</td>
<td>5.3% (n=1)</td>
<td>0% (n=0)</td>
<td>94.7% (n=18)</td>
<td>6.42</td>
<td>1.43</td>
</tr>
<tr>
<td>Placement of microphone on external processor</td>
<td>5.3% (n=1)</td>
<td>10.5% (n=2)</td>
<td>84.2% (n=16)</td>
<td>5.47</td>
<td>1.39</td>
</tr>
<tr>
<td>Length of warranty</td>
<td>5.3% (n=1)</td>
<td>5.3% (n=1)</td>
<td>89.5% (n=17)</td>
<td>5.79</td>
<td>1.47</td>
</tr>
<tr>
<td>Battery life</td>
<td>5.3% (n=1)</td>
<td>0% (n=0)</td>
<td>94.7% (n=18)</td>
<td>5.68</td>
<td>1.45</td>
</tr>
<tr>
<td>Battery options for external processor</td>
<td>5.3% (n=1)</td>
<td>5.3% (n=1)</td>
<td>89.5% (n=17)</td>
<td>5.68</td>
<td>1.49</td>
</tr>
<tr>
<td>Compatibility with Bluetooth devices</td>
<td>10.5% (n=2)</td>
<td>5.3% (n=1)</td>
<td>84.2% (n=16)</td>
<td>5.47</td>
<td>1.58</td>
</tr>
<tr>
<td>Compatibility with hearing aid technology</td>
<td>50% (n=9)</td>
<td>16.7% (n=3)</td>
<td>33.3% (n=6)</td>
<td>3.33</td>
<td>2.40</td>
</tr>
</tbody>
</table>

*NOTE: n=18

- Waterproof external processors | 10.5% (n=2) | 0% (n=0) | 89.5% (n=17) | 5.95 | 1.65 |
- Child-friendly controls | 10.5% (n=2) | 5.3% (n=1) | 84.2% (n=16) | 5.84 | 1.68 |
- Physical ease of use of controls on external | 15.8% (n=3) | 0% (n=0) | 84.2% (n=16) | 5.58 | 1.64 |
- Ease of use for “remote” | 26.3% (n=5) | 5.3% (n=1) | 68.4% (n=13) | 4.79 | 1.99 |
- Reported performance of device in noise | 5.3% (n=1) | 0% (n=0) | 94.7% (n=18) | 6.16 | 1.38 |
<table>
<thead>
<tr>
<th>Factor (n=19)</th>
<th>Unimportant 1-3</th>
<th>Neutral 4</th>
<th>Important 5-7</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported performance of device for music</td>
<td>10.5% (n=2)</td>
<td>10.5% (n=2)</td>
<td>79.0% (n=15)</td>
<td>5.74</td>
<td>1.69</td>
</tr>
<tr>
<td>History of voluntary recalls for the device</td>
<td>10.5% (n=2)</td>
<td>10.5% (n=2)</td>
<td>79.0% (n=15)</td>
<td>5.84</td>
<td>1.71</td>
</tr>
<tr>
<td>History of surgical complications for device</td>
<td>5.3% (n=1)</td>
<td>10.5% (n=2)</td>
<td>84.2% (n=16)</td>
<td>6.16</td>
<td>1.61</td>
</tr>
</tbody>
</table>

**Manufacturer-Specific Factors**

The third Likert-type scale category of device selection factors dealt with elements pertaining specifically to each individual manufacturer. This category looked beyond the devices of the manufacturers and sought information regarding actions by the manufacturers such as marketing and business partnerships. These 9 factors included items 34-42 (see Appendix A). Table 3 shows an overview of the responses to these factors. Three participants did not respond to these items.
Table 3

*How Important Certain Manufacturer-Specific Factors Were to Parents of Pediatric CI Recipients during CI Device Selection*

<table>
<thead>
<tr>
<th>Factor (n=18)</th>
<th>Unimportant 1-3</th>
<th>Neutral 4</th>
<th>Important 5-7</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of lawsuits Against the manufacturer</td>
<td>0% (n=0)</td>
<td>33.3% (n=6)</td>
<td>66.7% (n=12)</td>
<td>5.39</td>
<td>1.29</td>
</tr>
<tr>
<td>“Market share” of the device’s manufacturer</td>
<td>38.9% (n=7)</td>
<td>33.3% (n=6)</td>
<td>27.8% (n=5)</td>
<td>3.39</td>
<td>2.03</td>
</tr>
<tr>
<td>Manufacturer’s business partnerships</td>
<td>27.8% (n=5)</td>
<td>33.3% (n=6)</td>
<td>38.9% (n=7)</td>
<td>3.78</td>
<td>1.96</td>
</tr>
<tr>
<td>Manufacturer’s country of origin</td>
<td>33.3% (n=6)</td>
<td>27.8% (n=5)</td>
<td>38.9% (n=7)</td>
<td>3.83</td>
<td>2.09</td>
</tr>
<tr>
<td>Manufacturer’s customer service/support</td>
<td>5.6% (n=1)</td>
<td>5.6% (n=1)</td>
<td>88.9% (n=16)</td>
<td>6.00</td>
<td>1.19</td>
</tr>
<tr>
<td>Recommendation from other users</td>
<td>0% (n=0)</td>
<td>5.6% (n=1)</td>
<td>94.4% (n=17)</td>
<td>6.11</td>
<td>0.90</td>
</tr>
<tr>
<td>Audiologist’s familiarity with the specific device</td>
<td>0% (n=0)</td>
<td>16.7% (n=3)</td>
<td>83.3% (n=15)</td>
<td>5.83</td>
<td>1.10</td>
</tr>
<tr>
<td>Surgeon’s familiarity with the specific device</td>
<td>0% (n=0)</td>
<td>16.7% (n=3)</td>
<td>83.3% (n=15)</td>
<td>6.06</td>
<td>1.16</td>
</tr>
<tr>
<td>Aesthetics of the manufacturer’s marketing media</td>
<td>33.3% (n=6)</td>
<td>33.3% (n=6)</td>
<td>33.3% (n=6)</td>
<td>3.83</td>
<td>1.72</td>
</tr>
</tbody>
</table>

“Most Important” Factor

Along with rating device selection factors on a Likert-type scale, participants were also asked to name the “MOST important factor that influenced which manufacturer’s device [their] family chose.” This item was presented as an open-ended question. Common themes found in the
majority of the participants’ descriptions included but were not limited to: manufacturer’s innovation (n=4); waterproof capabilities (n=4); reported speech/word recognition with the device (n=3); and audiologist/parent recommendations (n=3). To see a full summary of verbatim responses, see Appendix G.

**Ranking Factor Categories**

The final question pertaining to device selection factors asked participants to rank five factor categories based on how influential the categories were during their respective device selection. The five categories were “Device aesthetics”; “Speech perception performance”; “History of device complications”; “Manufacturer-specific marketing”; and “Rehabilitation services offered by each manufacturer.” Participants were asked to rank the categories in order from 1 to 5, with 1 representing “Most Influential,” and 5 representing “Least Influential.” Four participants did not respond to this question. Table 4 shows an overview of the 17 participants’ results. The mean scores represent the overall corresponding rank position.
Table 4

*Ranking of Certain CI Device Selection Factor Categories Based on Their Influence during CI Device Selection*

<table>
<thead>
<tr>
<th>Factor (n=17)</th>
<th>Most Influential</th>
<th>Least Influential</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Device aesthetics</td>
<td>5.9% (n=1)</td>
<td>17.6% (n=3)</td>
<td>29.4% (n=5)</td>
<td>35.3% (n=6)</td>
</tr>
<tr>
<td>Speech perception performance</td>
<td>82.4% (n=14)</td>
<td>11.8% (n=2)</td>
<td>5.9% (n=1)</td>
<td>0% (n=0)</td>
</tr>
<tr>
<td>History of device complications</td>
<td>11.8% (n=2)</td>
<td>47.1% (n=8)</td>
<td>17.6% (n=3)</td>
<td>17.6% (n=3)</td>
</tr>
<tr>
<td>Manufacturer-specific marketing</td>
<td>0% (n=0)</td>
<td>5.9% (n=1)</td>
<td>5.9% (n=1)</td>
<td>35.3% (n=6)</td>
</tr>
<tr>
<td>Rehab services offered</td>
<td>0% (n=0)</td>
<td>17.6% (n=3)</td>
<td>41.2% (n=7)</td>
<td>11.8% (n=2)</td>
</tr>
</tbody>
</table>

**Satisfaction with CI Device**

The final section of the survey involved three questions asking participants about their satisfaction with the CI device they chose. These questions included Items 45-47 (see Appendix A). The first item asked participants to rate their level of satisfaction with their selected CI device from 1 to 7 on a Likert-type scale, with 1 representing “Very Dissatisfied” and 7 representing “Very Satisfied.” Additionally, a rating of 2 represented “Dissatisfied”; 3 represented “Somewhat Dissatisfied”; 4 represented “Neutral”; 5 represented “Somewhat Satisfied”; and 6 represented “Satisfied.” Of the 18 participants who responded to this question, the minimum value selected was 5, indicating that ALL parents were satisfied with the device selected to some degree, with a mean value of 6.72 and a standard deviation of 0.57 (see Figure 5). Note: Three participants did not respond to this question.
The next question asked participants whether they would choose the same manufacturer’s device if they had to go through the CI device selection process over again. Of the 18 participants who responded, 88.9% (n=16) said they would choose the same manufacturer’s device; and 11.1% (n=2) answered “Not Sure.” Three participants did not respond to this question.

The final item related to device satisfaction was an open-ended question asking participants to explain why they would or would not choose the same manufacturer’s device. 15 participants responded to this question. Common themes found in the majority of participants’ responses included, but were not limited to: reliability and performance of the device (n=4); the manufacturer’s customer service (n=4); the ability for their child to engage in water-related activities with the device (n=3); and general happiness with the device (n=3). Regarding reliability and performance, one participant responded:
We cannot tell you how pleased we are with MedEl’s product. Our daughter’s speech and language was completely caught up with her peers after two years with the devices. She attends regular preschool and loves music and dancing. Her Rondo and Opus II processors have given her full access to the sound she needs to live her life.

An example of one participant’s response regarding the manufacturer’s customer service was:

They have great customer service. Whenever there has been an issue we have received replacement parts within 2 days and if the processor is the issue they contact the audiologist themselves and it still arrives rather quickly for the nature of the situation. Friendly and helpful customer service as well.

An example of one participant’s response regarding the CI device’s waterproof capabilities was:

Allowing our son to participate in swimming, fishing and other water-based recreational activities in the same manner as other children was extremely important to us – this will help him enjoy ‘normal’ activities like any other child. All 3 manufacturers offered reliable devices that performed well, but this was the differentiating factor. Our audiology and surgery team was equally familiar with all 3 manufacturers, leaving the decision to us as parents.

For a full summary of the 15 participants’ verbatim responses, see Appendix H.

Other Factors

The last item on the survey asked participants if there were any other important factors that influenced their decision during CI device selection that were not included in the survey. Eight of the participants responded to this open-ended question. Responses of note included, but were not limited to: assistance from CI clinic (n=2); misleading data printed by one manufacturer (n=1); and the quality of the sound their child would be hearing (n=1) (i.e., “chipmunk” sound versus “normal”). One of the participants whose response included assistance from the CI clinic said, “How the clinic prepared the family in making the selection. We were given four brochure bundles of all the Implants available at the time and shown the actual devices we would receive. The Audiologists demonstrated their use.” The participant’s response involving misleading data
from one manufacturer was:

One of the companies that we did not choose had misleading data on one of their charts in the promotional packet we received. We felt that if they were not to be completely trusted to compare their product directly with the other companies then they were not a company that we wanted to work with.

The participant who responded regarding the quality of the sound their child would be hearing stated, “How or what would the child hear with the device. Some people reported hearing things as if they were the chipmunks and other different experiences. Obviously I wanted my son to hear as close to ‘normal’ as possible.” To see a full summary of verbatim responses, see Appendix I.

**Discussion**

The overall results of this study demonstrated a wide range of importance placed on various CI device selection factors. Many of the results reflected what has been reported in the literature as well as suggested some important and intriguing themes. Again, overall, the device selection process and the specific manufacturer’s device selected were both regarded positively based on the survey findings.

The vast majority of participants that responded to the survey were the patient’s mother, a potential variable to examine in the future. Close to all the participants had little to no prior knowledge of CIs and most of the pediatric recipients were the first person in their respective families to receive a CI. Despite the large number of respondents having minimal experience with CIs, the final decision regarding which manufacturer’s device to select was made by the parents in the majority of responses. This was in agreement with Geyer and his colleagues’ (2006) recommendation for parent involvement in CI decision-making, as well as the effective approach of patient-centered care described by Brand and Stiggelbout (2013, p. 227).
CI Manufacturer Distribution

As was the scenario in many case studies and reviews, the distribution of recipients of each respective manufacturer’s device was uneven. In general, the distribution reflected the market share within the United States, with Cochlear Americas being selected by the most families (n=12); Advanced Bionics by the second-most (n=5); and MED-EL with the fewest (n=3). Due to this inequality of numbers between manufacturer’s devices selected, however, it was determined to be appropriate to avoid conducting certain cross-tabulation measures comparing families based on manufacturer chosen. That being said, sufficient data was obtained using frequency counts for the various CI device selection factors.

Information Resources Used

In preparation of making the selection of one CI manufacturer’s device, participants arguably made use of a large assortment of information resources. The most commonly available resource was information from the CI team (n=18), followed by promotional brochures from the manufacturers (n=16). The least common resource available was advice from family members (n=5), followed by information from CI support groups (n=7). Of the resources actually used to make the decision of a CI device, manufacturer websites were most commonly used (n=16), followed by social media and online blogs (n=13) and then print ads (n=12). The resources that were least commonly used were conference presentations (n=1) and DVDs and CDs (n=3). These results are reasonable, considering online resources are more accessible to families than traveling to conferences.

Discussion of Factors

Aesthetics. Among the aesthetic factors, the size of the device (M=5.45, SD= 1.64) and the design of the external processor (M=5.30, SD=1.59) were rated for importance as the highest
and second highest, respectively. The weight of the device was the third-highest rated important aesthetic factor (\(M=5.25, SD=1.74\)). While these factors were the top three aesthetic factors, their mean ratings were still rated lower than the top three factors in both the performance-related and manufacturer-specific categories.

**Performance-related.** The top “importance” factors in the performance-related category were the reported reliability of the internal component (\(M=6.58, SD=1.39\)); reported reliability for the external processor (\(M=6.52, SD=1.43\)); and history of surgical complications (\(M=6.16, SD=1.61\)) which was tied by performance in noisy environments (\(M=6.16, SD=1.38\)). This category had two statistical outliers. The means for compatibility with hearing aid technology (\(M=3.33, SD=2.40\)) and the remote’s ease of use (\(M=4.79, SD=1.99\)) were the lowest rated factors. This meant that while most factors appeared to have some level of importance to the participants, these two factors were of much less importance.

**Manufacturer-specific.** The top factors in the manufacturer-specific category were recommendations from other users (\(M=6.11, SD=0.90\)); the surgeon’s familiarity with the device (\(M=6.06, SD=1.16\)); and the manufacturer’s customer service (\(M=6.00, SD=1.19\)). The manufacturer-specific categories had more factors that were rated as less important than the aesthetic and performance-related categories. The factors that received the lowest average rating were market share (\(M=3.39, SD=2.03\)), business partnerships (\(M=3.78, SD=1.96\)), country of origin (\(M=3.83, SD=2.09\)), and aesthetic of manufacturer’s marketing media (\(M=3.83, SD=1.72\)). These factors centered more on the business and marketing aspects of the manufacturers than the actual CI products, and were not apparently impacting parental device selection.

**Factor Ratings Compared to Previous Study**

In the similar study conducted in the United Kingdom by Clamp, Rotchell, Maddocks,
and Robinson (2013), “robustness and reliability” were found to be the most important factors for participants during CI device selection, with “comfort” and “size and shape” coming in second and third, respectively (p. 133). This study found similar results, as “reported reliability for internal components” \( (M=6.58, \text{SD}=1.39) \) and “reported reliability for external processor” \( (M=6.52, \text{SD}=1.43) \) were rated with the highest and second-highest, respectively, for their degree of importance among the 30 rated factors. This makes sense given that so much goes into the implantation process that parents just want the CI device to work. These young pediatric recipients will also be using the CI for the rest of their lives, so reliability is extremely important, needing to last for potentially 70 plus years. It is also interesting to point out that in the study by Clamp and his colleagues (2013), “recommendations from other CI users” were rated second-lowest by the study’s participants (p. 133). In this study “recommendations from other CI users” was one of the highest-rated factors based on average \( (M=6.11, \text{SD}=0.90) \). While these are interesting similarities and differences, further research should be conducted to more thoroughly compare parents from the United States and parents from the United Kingdom during the CI device selection.

**Trends among “Most Important” Factors**

The responses to the open-ended questions provided a more defined glimpse into which factors were the “most” important to the parents who participated in the study. The most common factors mentioned were innovation and waterproof capabilities of the external processors, each mentioned by four individual participants. Of the responses by parents who selected Cochlear, the common trends were the popularity of the Cochlear brand \( (n=3) \) and recommendations by both the audiologist and other Cochlear users \( (n=3) \). One Cochlear user stated, “It was recommended by our audiologist whom we greatly trust. We researched and
talked to other parents. We felt that Cochlear was the most advanced in their technology and seemed to be on the cutting edge of technology.”

The waterproof capabilities of the CI device was discussed by the parents of three Advanced Bionics recipients and one Cochlear parent. With three of the five Advanced Bionics users expressing waterproof external processor as the most important factor, it was seemingly important and effective for Advanced Bionics to address the waterproof capabilities of the Neptune processor as frequently and as detailed as possible in their marketing messages. The three MED-EL recipients’ parents all expressed that MED-EL’s reported speech perception outcomes were the deciding factor. One MED-EL parent stated, “We believe that MED-EL’s technology provides the best sound for all listening situations (speech, music, etc.) and environments (quiet, noisy, etc.).” The responses for this question were especially intriguing because they characterized factors depending upon manufacturer.

**Factor Category Ranking**

The results from the ordinal ranking of five factor categories revealed interesting trends as well. Based upon means, speech perception performance was overwhelmingly ranked first as the “Most Influential” (\(M=1.24, SD=0.56\)). The remaining rank order went as follows: history of device complications as second most influential (\(M=2.59, SD=1.12\)); device aesthetics in third place (\(M=3.29, SD=1.10\)); rehabilitation services as fourth most influential (\(M=3.53, SD=1.12\)); and manufacturer-specific marketing in fifth as the least influential factor (\(M=4.35, SD=0.86\)).

Taken at face value, the lower scores for the manufacturer-specific factors, especially those related to marketing, demonstrated a lack of importance placed on how each manufacturer markets their respective brand. Berman (2015) stated, however, that marketing aesthetics and branding affected consumers by creating a “subconscious” positive mood while viewing the
marketing media (p. 520). Thus, the participants in this study may have been subconsciously influenced by certain marketing factors, but may not have consciously thought it held much individual importance in their decision when responding to the survey item. Additionally, Bisschoff, Van Staaden, and Buys (2013) stated consumers’ perceptions of a company’s brand were based on their knowledge of the company and its product (p. 84). The participants in this study demonstrated a lack of prior experience with CI technology, meaning for the majority of participants, the knowledge of the CI manufacturers prior to CI device selection was non-existent or minimal. Thus, branding techniques may not have had as much of an impact on many participants who were not familiar with the three manufacturers, leading to the lower ratings of importance on factors such as market share or marketing media.

**High Parent Satisfaction**

Regardless of which manufacturer’s device each participant selected or how they arrived at that selection, all participants were satisfied with their child’s CI device. The responses of satisfaction in this survey are similar to the 100% parent satisfaction in the study by Clamp and his colleagues (2013); although, as those authors pointed out, parent satisfaction supports “the final decision made… [but] does not address patient satisfaction with the choice process per se” (p. 133). Fortunately, almost all participants (n=16 out of 18 total responses) said they would choose the same manufacturer’s device if they had to go through the device selection process over again, shining a positive light on not only the manufacturer’s themselves, but the selection process as well. Further research should seek to discover more about patient satisfaction with the CI device selection process as a whole.

**Explanations for Choosing the CI Device Again**

Essentially all participants responded that, if given the opportunity to go through CI
device selection again, they would still select the same manufacturer’s device. The reason why, however, varied depending upon which manufacturer’s CI device was selected (see Appendix H). For the parents of pediatric Cochlear recipients, customer service (n=3) and accessories available (n=3) were most commonly discussed as positive aspects that led to their satisfaction with the manufacturer. One participant stated,

“We have two children that have the N6 through Cochlear. We could not be more pleased. Their customer service has been wonderful working with us when parts are damaged or broken, (which happens often with little children). Since our son was implanted at the age of 3, he has had 3 upgrades in the less than 6 years. Each device has had better sound, and the N6 offers blue tooth capabilities, a mini mic for small, noisy settings, and is waterproof – a MUST for active children!”

The reason parents of pediatric Advanced Bionics recipients said they would choose the manufacturer’s CI device again once again centered on their respective child’s ability to engage in activities in and around water (n=2). One participant stated,

“Allowing our son to participate in swimming, fishing and other water-based recreational activities in the same manner as other children was extremely important to us – this will help him enjoy “normal” activities like any other child. All 3 manufacturers offered reliable devices that performed well, but this was the differentiating factor. Our audiology and surgery team was equally familiar with all 3 manufacturers, leaving the decision to us as parents.”

Both parents of pediatric MED-EL recipients who responded to this survey item discussed their respective child’s rehabilitative success with the Opus II processor as the reason they would select the manufacturer’s CI device again.

**Conclusion**

This chapter provided the results of the participants’ survey responses. Many of the responses followed trends set in current literature, such as the high importance of how the CI devices performed in speech perception and how reliable the devices were reported to be. There were also some new findings, however, such as the low importance of manufacturer-specific
marketing, which should interest professionals working on pediatric CI teams. The final chapter will draw conclusions based on the results from the survey, point out limitations from this study, and provide recommendations for future research.
CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

This study has examined a range of factors/variables and the influence of those factors on cochlear implant (CI) device selection among the three CI manufacturers in the United States, by parents of recent pediatric CI recipients. In order to carry out this study, a survey was designed and distributed electronically to various CI centers across the United States via an email and survey link, and subsequently distributed to parents whose children met the inclusion criteria. The previous chapter discussed the results of the survey data/responses. This chapter will address the major conclusions found in this study, implications of the findings, limitations, recommendations for future research, and final thoughts regarding this investigation.

Major Conclusions

The conclusions drawn from this study cannot necessarily be expanded to represent the thoughts of entire population of parents of pediatric CI recipients in the United States. That being said, the results of this study demonstrated several conclusions of note. The first major conclusion was that there was very minimal experience with CI technology among parents prior to the CI device selection process. Many of the pediatric CI recipients were the first in their families to receive a CI. The parents who participated in this study were able to make use of many different resources to familiarize themselves with the different CIs during device selection. For most, the world of CIs and the complete details about CI technology was an unfamiliar world.

The second major conclusion was that the CI device selection process was generally a positive experience for parents. This conclusion was based on positive or high ratings for a range of device selection factors in general, high satisfaction ratings, and positive comments regarding
not only the device selected, but the help of the CI clinic as well. None of the parents expressed any major concerns or regrets regarding their CI device selection process. These positive responses point toward there being no “wrong” choice for their selection of a CI device.

The third major conclusion was that overall, parents primarily wanted the CI device to “work” for their child. This was demonstrated by the fact that the highest-rated factors were reliability, speech perception, history of surgical complications, and recommendations from other users. All of these factors were related to how well the device worked as opposed to outside features such as aesthetics or accessory compatibility options. Pediatric CI recipients were presumably going to have these CIs for the rest of their lives, so it appeared to be most important to these parents that those CI devices worked as safely and effectively as possible.

Implications of Research Findings

The results of this study brought about three major implications that can be applied to “real-world” scenarios. The first implication was the pivotal role the CI team needs to play in providing knowledge about CI devices and their manufacturers in order to help parents of pediatric CI recipients make the best informed decisions. The study indicated the limited experience with CIs parents had prior to their child receiving them, as well as the high importance placed on meetings with the CI team and the CI professionals’ familiarity with the CI devices. These aspects made it more and more obvious that professionals on CI teams, especially the surgeons, need to constantly update themselves on the knowledge of both current and forthcoming CI device technology and options. This was especially true since there are often frequent upgrades and changes to current CI device technology navigating through the Food and Drug Administration’s approval process.

The second implication was that there needs to be more research conducted that
compares the performance and functioning of each CI manufacturer’s newest external and internal devices side-by-side. Reliability and speech perception performance were rated as the most important factors to the parents involved in this study, meaning there needs to be a continued effort to provide reports of the performance of each subsequent CI device. It is especially important since upgrades and new CI devices are constantly submitted to the FDA for approval each year.

The third implication was that the CI manufacturers would be wise to review the findings of this other studies (for example Clamp, Rotchell, Maddocks, & Robinson, 2013), and fine-tune their marketing messages to more pointedly address the reliability and performance aspects of their respective CI devices. Seeing that these factors have now been shown in two separate studies to be the highest-rated in regards to importance, these factors need to be more carefully crafted and emphasized in comparison to all the other factors and characteristics marketed about CI devices. In contrast, the aesthetics of the marketing messages involving these and other factors appeared to be less important to the parents in this study, and may not need as much time and money to promote the aesthetics in the manufacturer’s media messages. It was also apparent that each individual CI manufacturer needs to make sure their respective websites were as patient-friendly and appealing as possible, due to the large number of families who used the websites when learning about CIs and ultimately making their CI-selection decision.

**Limitations**

While this study had some interesting findings and implications, several limitations affect the study’s generalizability to the whole population of pediatric CI recipients. It is important to note that due to various factors such as a small sample size and lack of being able to run certain analytical tests. The first limitation was the small sample size that participated in the survey.
While 21 participants was a reasonable number with which to run frequency counts, that number pales in comparison to the much larger number of pediatric CI recipients across the United States whose families have gone through a similar CI device selection process.

The second limitation was the lack of demographical information obtained from the subjects. The participants of this study lived in many different states from Alaska to Florida and in between. Thus, it would be wise to account for geographical differences as well as state-by-state legal variations. For example, one participant noted that the “state of Alaska” decided which CI manufacturer’s device to choose. Also missing from the demographic questions was the gender of the child who was the recipient of the CI. There may have been variations in the importance of certain factors such as color options and aesthetics of the CI device’s external components that may be explained by the gender of the child.

The third limitation was the design of the survey. There were more visits to the survey link than the 21 eventual participants who fully completed the survey. The surveys that were thrown out were either not stopped at certain points during the survey, usually at the start of the Likert-type scales for the CI device selection factors. This may have been caused by confusion in the wording of certain questions or the overall length of the survey. There were also typing errors found after distribution of the survey, such as Item 47 asking participants to explain their answers to “Question 16,” which was the correct item number on the survey draft, but not on the final survey. Also, the labeling for each number on the Likert-type scale items were not quite distinct and may have confused certain participants or made it more difficult to determine the correct level of importance for certain individuals.

A fourth limitation was the sampling technique used to recruit participants. The researcher was only able to send the survey link to CI centers whose contact information and
emails posted on the American Cochlear Implant Alliance’s website, or those centers who had direct connections to the research advisor. This left out a large number of potential CI center contacts to be asked to forward the survey link to their pediatric CI patients. It was also unknown if this sampling technique acquired truly random samples.

The fifth limitation was the challenge of using an electronic survey. While this was quite arguably the most efficient method based on time and expense, the survey may not have reached potential respondents who did not have access to or did not know how to use the Internet or a computer. The researcher was also not readily available to answer any questions or concerns any participants had about the survey directly since the survey was sent by email.

A sixth limitation was the time frame from when the participants and their children went through the CI device selection process to when they filled out the survey. There was the possibility that the participants may not have completely remembered all of their feelings and rationales for their selection decisions at a later date.

A final limitation was that the responses were heavily represented by families who chose the Cochlear Americas CI device. Since the number of Cochlear recipients was so high, “full” representation from the other two manufacturers was problematic.

**Recommendations for Future Research**

While this study had many limitations, the investigation has set the stage for several recommendations for future research related to pediatric CI device selection. Because the sample size for this survey was so small, the first recommendation for future research would be to increase the number of CI centers to which the survey link is distributed. Along with broadening the CI center base for participation of more parents, it would also be wise to make use of quota sampling when seeking participants. Using this sampling technique, a future study should
purposefully include a set number of participants for each CI manufacturer and thus be able to run statistical analyses among the recipients/groups using different CI devices. It may also be wise to expand the population from children who received CIs within the previous two years to within the previous four or more years. While the aim of this study was to maintain recent CI recipients, it may be beneficial to the sample size to pool from a larger population.

A second recommendation for future research would be to examine the importance of certain factors during CI device selection for adults and their families. Differences, if any, between adults and children may result as different factors are compared.

A third recommendation for a future study is to look specifically at CI recipients based on different scenarios. One example is to examine CI recipients who have been explanted and re-implanted to see any differences in whether the recipients or their families choose different CI manufacturer’s devices after complications had been identified. A second example is CI recipients who have two different manufacturers’ devices in their right versus left ears. These scenarios, and possibly others, may allow for additional comparisons on an individual basis.

A final recommendation for a future study is to examine either recipients’ or their families’ experiences, satisfaction, and/or comfort with the CI device selection process in general. This study includes satisfaction levels for the respective CI devices and their manufacturers, but it does not provide a full picture of the entire CI device selection process or the clinical setting. It may be beneficial in helping recipients and their families have the optimal experience in selecting a device if a future researcher looks into the actual procedures utilized by professionals on CI teams for device selection and how those procedures affect patient satisfaction.
Final Thoughts

This study was not the first to examine the importance of certain factors to families of pediatric CI recipients during CI device selection, and, hopefully, it will not be the last. The results of this study indicated the high importance being placed on the reliability and speech perception performance of the CI device. While it was strongly recommended that these areas be covered extensively by both the CI team and the CI manufacturer, there were still many other factors that were extremely important to parents. Not all pediatric CI recipients were exactly the same, and their families were certainly not the same either. It was important for any reader of this study to understand that the best strategy for CI device selection was to center the process on the individual needs of the families.

Throughout the process of conducting and writing this independent study, I learned a great deal about the wonderful world of CIs. This topic was an interesting blend of my Communication Science and Disorders and Communication Studies backgrounds, especially with the examination of the marketing aspect of CIs. The entire research process has taught me to pay close attention to detail. While the high importance placed on reliability and performance seemed like “common sense,” the “low” importance placed on marketing and device aesthetics was very intriguing.

My final hope as a researcher is that all families of pediatric CI recipients understand that there is no “wrong” choice for a CI device. All three CI manufacturers have developed products that are proven to be effective in providing the ability to hear to people of all ages. Regardless of the choice of which CI device to select, all pediatric CI recipients have the opportunity to obtain hearing and spoken language skills through practice that are at or above their “typical” hearing peers. During this time of understandable pressure and stress, it is my hope that parents
understand the marvelous technology that is found in CIs and feel comfortable knowing that their child can be successful and live a happy and productive life with any of the three CI manufacturers’ devices.
REFERENCES


Appendix A

Survey

Hello. My name is Zachary Moore and I am a Senior Communication Sciences and Disorders major at the College of Wooster in Wooster, Ohio. I am conducting a Senior Independent Study Thesis on the influence of various factors on the cochlear implant device selection process for families of pediatric cochlear implant recipients in the United States. This study has been approved by the College of Wooster’s Human Subjects Review Committee (HSRC) or “IRB.” Please do not put your name or your child’s name anywhere on this survey. All responses will remain confidential and deleted upon completion of the study. Please try to answer each question completely and to the best of your knowledge. You may skip any question, and if at any time you wish to discontinue your participation in this study, you may do so without any penalty or consequence. This survey will take approximately 10 minutes to complete. By completing this survey, you are indicating that you are a parent or guardian, age 18 years or older, of a pediatric cochlear implant recipient between the ages of birth to 5 years old who underwent cochlear implant surgery between the dates of January 1, 2014 and December 31, 2015; have read and understand the above information; and that you consent to allow the information you provide to be reported in aggregate form. Your participation is entirely voluntary and risk-free. This study is advised by Donald M. Goldberg, Ph.D. (dgoldberg@wooster.edu), a Professor at the College of Wooster and a Staff Consultant at the Cleveland Clinic (goldbed@ccf.org). If you have any questions regarding the research or your rights as a participant, please contact the researcher at zmoore16@wooster.edu or (330) 853-4027, or Dr. Goldberg. Thank you for your participation and support of this study.

Selecting "I Accept" below indicates that you have read and understand the above information and agree to allow your responses to be used by the researcher in this study:

- I Accept
- I Decline

If I Decline Is Selected, Then Skip To End of Survey

Q1 At what age did your child receive his/her cochlear Implant(s)?
- Less than 12 months
- 12 months to 1 year; 11 months
- 2 years to 2 years; 11 months
- 3 years to 3 years; 11 months
- 4 years to 4 years; 11 months
- 5 years to 5 years; 11 months
- Older (Please specify age) ____________________

Q2 What is your child's current age?
- Less than 12 months
- 12 months to 1 year; 11 months
- 2 years to 2 years; 11 months
- 3 years to 3 years; 11 months
- 4 years to 4 years; 11 months
Q3 How many cochlear implants did your child receive?
- One (unilateral)
- Two (simultaneous bilateral -- one surgery)
- Two (sequential bilateral -- two surgeries)

Q4 What is your relation to this child?
- Mother
- Father
- Other (Please specify) ____________________

Q5 Is this child the only member of the immediate family (mother, father, siblings, grandparents, aunts, uncles, and first cousins) to have a cochlear implant?
- Yes
- No

Q6 What were your experiences with cochlear implant technology prior to your child’s implantation?
- I had never heard of cochlear implants
- I had only generally heard about them
- I have cochlear implants
- I work with cochlear implant technology
- Other (Please specify) ____________________

Q7 How many different cochlear implant manufacturer's devices were available to you at the time of selection?
- One (1)
- Two (2)
- Three (3)

Q8 Which specific cochlear implant manufacturer's devices were available to you at the time of selection? Select ALL that apply.
- Cochlear Americas
- MED-EL
- Other (Please provide the name)
- Advanced Bionics
- I don't know
Q9 Which cochlear implant manufacturer's device did you select?
- Cochlear Americas
- MED-EL
- Other (Please provide the name) ____________________
- I don't know

Q10 Who made the final decision regarding which manufacturer's device to choose?
- Parent(s)
- Child
- Audiologist
- Surgeon/ENT/Otologist
- Other (Please specify) ____________________

Q11 What information resources were made available to you at the hospital/cochlear implant center at the time of device selection? Select ALL that apply.
- Information from cochlear implant team
- Scholarly research articles
- Promotional brochures/pamphlets from manufacturers
- Cochlear implant support group information
- Advice/Experience of a family member
- Recommendation from other parents
- Other (Please specify) ____________________

Q12 Which type(s) of media/marketing did you use to make your decision? Select ALL that apply.
- None
- Print ads
- Social media/Online blogs
- Videos
- DVDs/CDs
- Manufacturer websites
- Conference presentations
- Other (Please specify) ____________________
Please rate the following factors from 1-7 according to how important each specific factor was in your family's decision at the time of cochlear implant device selection. (Some of the selected questions were adapted from Clamp, Rotchell, Maddocks, & Robinson, 2013).

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<tr>
<th></th>
<th>Not at all Important (1)</th>
<th>Very Unimportant (2)</th>
<th>Somewhat Unimportant (3)</th>
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<td>Accessories available (e.g., headbands, stickers, etc.) (16)</td>
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<td>Reported reliability of the internal components (18)</td>
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<td>Placement of microphone on external processor (20)</td>
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<td>Length of warranty on the device (21)</td>
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<td>Battery options for the external processor (e.g., rechargeable, replaceable) (23)</td>
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<td>Compatibility with Bluetooth devices (phones, TV, etc.) (24)</td>
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<td>Compatibility with hearing aid technology (for bimodal recipients) (25)</td>
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<td>Child-friendly controls/protections (27)</td>
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<td>Physical ease of use of controls on the external processor(s) (28)</td>
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<td>Ease of use for the &quot;remote&quot; (29)</td>
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<td>Reported performance of the device in noisy environments (30)</td>
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<td>Reported performance of the device for music (31)</td>
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<td>History of voluntary recalls for the device (32)</td>
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<td>History of surgical complications for the device (33)</td>
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Please rate the following factors from 1-7 according to how important each specific factor was in your family's decision at the time of cochlear implant device selection. (Some of the selected questions were adapted from Clamp, Rotchell, Maddocks, & Robinson, 2013).

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<td>&quot;Market share&quot; of the device's manufacturer</td>
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<td>Manufacturer's business partnerships</td>
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<td>Manufacturer's country of origin (i.e., U.S. or other)</td>
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<td>Manufacturer's customer service/support</td>
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<td>Recommendation from other users</td>
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<td>Audiologist's familiarity with the specific device</td>
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<td>Surgeon's familiarity with the specific device</td>
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<td>Aesthetics of the manufacturer's marketing media (e.g., brochures, website, etc.)</td>
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**Q43** What was the MOST important factor that influenced which manufacturer's device your family chose?
Q44 How would you rank the following factor categories (1 = Most Influential, 5 = Least Influential) in regards to their influence on your personal cochlear implant device selection? Drag and drop the categories in order from 1-5.

_____ Device aesthetics
_____ Speech perception performance
_____ History of device complications
_____ Manufacturer-specific marketing
_____ Rehabilitation services offered by each manufacturer

Q45 How would you rate your "Level of Satisfaction" with the device you selected?

- Very Dissatisfied (1)
- Dissatisfied (2)
- Somewhat Dissatisfied (3)
- Neutral (4)
- Somewhat Satisfied (5)
- Satisfied (6)
- Very Satisfied (7)

Q46 If you had to go through the device selection process again, would you choose the same manufacturer's device?

- Yes
- No
- Not Sure

Q47 If you answered either "Yes" or "No" to Question 19, please explain why:

Q48 Are there any other factors important to your family's decision that were not asked about in this survey? If so, please explain below:

Thank you for taking the time to participate in this study. The results of this survey will be available in Spring 2016. If you would like to view the results, please contact the researcher using the email below. Again, all participants’ names and data will remain confidential throughout the entire research process. Once again, your participation is greatly appreciated.

Researcher's Contact: zmoore16@wooster.edu
Thesis Advisor’s Contact: dgoldberg@wooster.edu or goldbed@ccf.org
APPENDIX B:

E-mail Message to Cochlear Implant Audiologists:

Hello, my name is Zack Moore and I am a senior Communication Sciences and Disorders major at the College of Wooster in Wooster, Ohio. At the College of Wooster, all seniors are required to complete a Senior Independent Study Thesis. For my senior thesis, I have chosen to analyze how different factors affect the decision of parents of pediatric cochlear implant recipients regarding which cochlear implant manufacturer’s device to select. I am looking for parents or guardians who are 18 years or older and have a child that received cochlear implant surgery before the age of 6 years between January 1, 2014 and December 31, 2015 who are willing to fill out my survey. The survey addresses which cochlear implant manufacturer the family chose and what were the factors that were most important in influencing that decision.

Your cochlear implant center was selected because it provides either two or all three of the manufacturers’ devices to pediatric patients. I understand that you have a busy schedule, but it would be very much appreciated if you and/or your colleagues could find the time to distribute the attached “Recruitment Flyer” and survey link below to all of the parents of these patients who fit the criteria stated above.

Below is the link to my survey, which is completely voluntary for any of your patients. They may choose to decline participation at any time, even if they have already begun filling it out, without any consequences. No names will be recorded, and participation is completely anonymous. Additionally, my study has been approved by the College of Wooster’s Human Subjects Review Committee (HSRC) or “IRB.” The link will be open from mid-December 2015 and continue to early 2016.

Thank you very much for your time and consideration. If you are interested in the results of this study, they will be available in Spring 2016. Please feel free to email me or my advisor any questions or concerns. The results of this study will be available in April 2016 by emailing the researcher.

Link to the survey: https://wooster.co1.qualtrics.com/SE/?SID=SV_0P45dFypNssUmQR

I wish you all the best this holiday season!

Researcher: Zack Moore  
The College of Wooster, Class of 2016  
Department of Communication Sciences and Disorders  
zmoore16@wooster.edu

Advisor: Donald M. Goldberg, Ph.D.  
Professor, College of Wooster  
Staff Consultant at the Cleveland Clinic/Hearing Implant Program  
goldbed@ccf.org  
(216) 312-6804
Appendix C

E-mail Messages to Listening and Spoken Language Specialists:

Pediatric Cochlear Implant Manufacturer Decision Study

Zack Moore is studying the decision-making process families go through in selecting their child’s cochlear implant (CI) manufacturer. Parents who have worked with CI teams in the United States and had a choice in the selection of either two or all three of the CI manufacturer are being sought for this study. The children of the parents should be under 6 years old and their CI surgery should have taken place between January 1, 2014 and December 31, 2015. Parents who are willing to participate, or audiologists on CI teams in the United States, who are able to share the project’s recruitment flyer with parents who meet the study’s participation criteria, should email Zack for a recruitment flyer and/or go to his project’s survey link if they meet the study’s participation criteria.
Appendix D

Thank-You Response to Cochlear Implant Audiologists:

Thank you very much for helping me out with my study. I sincerely appreciate it. I will make sure to send along a copy of my findings to you when I finish in the Spring. Please let me know if you or any of the parents have any questions or concerns and I will do my best to provide clarification as soon as I can. I am really excited by the amount of positive responses I have already received!

Thank You,
Zack Moore
APPENDIX E:

Recruitment Flyer

Parents Needed!

Attention Parents or Guardians:
If your child had cochlear implant surgery for one or two ears...
✓ Prior to turning 6 years-old AND
✓ Between January 1, 2014 and December 31, 2015

Please consider participating in a College of Wooster Senior’s Research Project investigating cochlear implant device selection by following the link below!
https://wooster.co1.qualtrics.com/SE/?SID=SV_0P45dFypNssUmQR

Researcher: Zachary Moore, College of Wooster, Class of 2016
Advisor: Donald M. Goldberg Ph.D., CCC-SLP/A College of Wooster Consultant, Cleveland Clinic Foundation, Hearing Implant Program
Follow-up Email to Cochlear Implant Audiologists:

Hello,

I hope this email finds you well. I wanted to follow up with you regarding my Independent Study research project participation request a month ago. As a reminder, I am analyzing how different factors affect the decision of parents of pediatric cochlear implant recipients regarding which cochlear implant manufacturer’s device to select.

I am preparing to close the survey early next week. If you have already distributed the survey link, I want to thank you once again. If you have not, I would sincerely appreciate your help in distributing my survey to parents or guardians who are 18 years or older and have a child that received cochlear implant surgery at your center before the age of 6 years between January 1, 2014 and December 31, 2015. For any qualifying families, please either send them the link to the survey below or have them email me a request for the survey link at zmoore16@wooster.edu.

Link to the survey: [https://wooster.co1.qualtrics.com/SE/?SID=SV_0P45dFypNssUmQR](https://wooster.co1.qualtrics.com/SE/?SID=SV_0P45dFypNssUmQR)

Thank you once again for your time. I will contact you later in the Spring regarding the results of my study if you are still interested.

Researcher: Zack Moore  
The College of Wooster, Class of 2016  
Department of Communication Sciences and Disorders  
zmoore16@wooster.edu

Advisor: Donald M. Goldberg, Ph.D.  
Professor, College of Wooster  
Staff Consultant at the Cleveland Clinic/Hearing Implant Program  
goldbed@ccf.org  
(216) 312-6804
Appendix G

Verbatim Responses to Survey Item 43

Item 43: What was the MOST important factor that influenced which manufacturer’s device your family chose?

Verbatim Responses:

No Response (n=3)

Patients who Selected Cochlear Americas:

Reviews on how efficient it was, most popular brand, less complains [sic], and what I felt comfortable with, overall appearance.

The way the internal processor was going to be implanted.

Best looking device.

Accessories available to help extend and maximize our son’s ability to engage with his world.

Audiologist’s recommendations.

Product reliability.

It was recommended by our audiologist whom we greatly trust. We researched and talked to other parents. We felt that Cochlear was the most advanced in their technology and seemed to be on the cutting edge of technology.

Longevity of the manufacturing company. Special features. Water tight… sealed and my child can wear device in pool. My child was 18 months when she got cochlear [sic].

Customer service, electrode array, recommendations from others

To keep it the same brand that I (his mother) had because of the familiarity of the company and its assets.

Patients who Selected Advanced Bionics:

The engineering and precision of the technology – through our research, it seemed as though AB was most innovative.

The waterproof ability of the Advanced Bionics Neptune device.
Technological advancement and actual ability to hear well. Outcomes.

Waterproof of Neptunes, the technical literature suggested the capabilities of Naidas were most robust.

The water accessories, our son loves the water and we want him to be able to hear when he’s in it.

**Patients who Selected MED-EL:**

We believe that MedEl’s technology provides the best sound for all listening situations (speech, music, etc.) and environments (quiet, noisy, etc.).

Success rate for children with my daughter’s diagnosis.

Percentage of word recognition.
APPENDIX H: Verbatim Responses to Survey Item 47

Item 47: If you answered “Yes” or “No” to Item 46, please explain why:

Verbatim responses:

No Response (n=6)

Patients who Selected Cochlear Americas:

So far it’s been holding up to its performance.

I really like all of the extra things that the device has. Its [sic] super simple to use, and really light weight.

It’s been great.

Have utilized the Cochlear Hope Webinars and find them tremendously useful. All of our Audiologist’s expertise and knowledge in working with the Implant.

Ease of use of all equipment, reliability of product, knowledge of programming by audiologist, customer service for company.

We have two children that have the N6 through Cochlear. We could not be more pleased. Their customer service has been wonderful working with us when parts are damaged or broken, (which happens often with little children). Since our son was implanted at the age of 3, he has had 3 upgrades in the [sic] less than 6 years. Each device has had better sound, and the N6 offers blue tooth capabilities, a mini mic for small, noisy settings, and is waterproof – a MUST for active children!

I’m satisfied with the device!!!

Any issues we have had, Cochlear took care of us.

Patients who Selected Advanced Bionics:

We are very happy with AB. Our only gripe with them is that they came out with a new processor less than 2 months from when my son was activated and before his second implant 10 months later and wouldn’t consider upgrading his processor – so in less than one year of bilateral implants, he will have two different processors.

Allowing our son to participate in swimming, fishing and other water-based recreational activities in the same manner as other children was extremely important to us – this will help him enjoy “normal” activities like any other child. All 3 manufacturers offered reliable devices that performed well, but this was the differentiating factor. Our audiology and surgery team was
equally familiar with all 3 manufacturers, leaving the decision to us as parents.

AB has the most cutting edge technology.

Waterproof great in pool or lake. Get to enjoy being a kid. Takes away limitations of disability and hearing. She loves her neptunes [sic], her ears are too small still for Naidas.

They have great customer service. Whenever there has been an issue we have received replacement parts within 2 days and if the processor is the issue they contact the audiologist themselves and it still arrives rather quickly for the nature of the situation. Friendly and helpful customer service as well.

**Patients who Selected MED-EL:**

We cannot tell you how please [sic] we are with MedEl’s product. Our daughter’s speech and language was completely caught up with her peers after two years with the devices. She attends regular preschool and loves music and dancing. Her Rondo and Opus II processors have given her full access to the sound she needs to live her life.

We are very happy with our daughter’s Opus 2s. her [sic]rehabilitation so far has been wonderful. We would choose Med-El again.
APPENDIX I: Verbatim Responses to Survey Item 48

Item 48: Are there any other factors important to your family’s decision that were not asked about in this survey? If so, please share below.

Verbatim responses:

No Response (n=13)

Patients who Selected Cochlear Americas:

Yes the warranty needs to be life time on all parts since this is a life device that the person has to wear.

They have had fantastic customer service.

How the clinic prepared the family in making the selection. We were given four brochure bundles of all the Implants available at the time and shown the actual devices we would receive. The Audiologists demonstrated their use.

The audiologists helped to answer questions about the different companies based on experience.

Patients who Selected Advanced Bionics:

Likelihood of innovation and potentially for company to be around in 80 years. Liked that AB had Rogers and Phonak. Has large capital for innovation, research, support.

How or what would the child hear with the device. Some people reported hearing things as if they were the chipmunks and other different experiences. Obviously I wanted my son to hear as close to normal as possible.

Patients who Selected MED-EL:

One of the companies that we did not choose had misleading data on one of their charts in the promotional packet we received. We felt that if they were not to be completely trusted to compare their product directly with the other companies then they were not a company that we wanted to work with.

No