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A survey of cochlear implant clinical protocols in India

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A Survey of Cochlear Implant Clinical Protocols in India

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Abstract

The most recent data published in December 2019 records that approximately 736,900 registered cochlear implantation devices have been received since their approval in the 1980s. While 183,100 of these devices belong to U.S. Citizens, the large majority of cochlear implant recipients live in other countries (U.S. Department of Health and Human Services, 2016). While a lack of standardized practices exists in relation to audiologic care and management of cochlear implant devices and patients, Browning et al. (2020) attempts to assess and analyze common practices amongst audiologists practicing within the United States of America. This survey uses a modified questionnaire based on Browning et al. (2020) as well as an international survey of clinical cochlear implantation practices by Vaerenberg et al., (2014) to further track similarities and differences among cochlear implant professionals in India to better understand the clinical practice of cochlear implantation worldwide.

Cochlear implant audiologists or other trained professionals involved in the cochlear implant fitting process may benefit from this research as it expands the knowledge of common cochlear implant fitting and follow-up practices in India and compares this data with what is known about similar clinical cochlear implant processes in the United States from a similar study by Browning et al. (2020).

Introduction

Cochlear implant devices are known to be the most cost-effective solution to significant hearing loss (World Health Organization, 2017). In 2018, the World Health Organization estimated that approximately 466 million people were living with a significant hearing loss. This organization projects that by 2050, over 900 million people around the world will be affected by debilitating hearing loss, with a disproportionately high amount of those affected living in lower income countries (World Health Organization, 2017). Despite this fact, most of the published research to date following the clinical protocols for cochlear implantation are focused on higher income countries like the United States and other western European countries, like the surveys by Browning et al. (2020), Vaerenberg et al. (2014), and Scherf et al. (2014).

The present survey intends to begin to fill in the gaps of knowledge currently surrounding the cochlear implant clinical protocols in one of the largest emerging cochlear implant markets: India. The country of India is of particular interest as it has been influencing the development of government-assisted programs in surrounding nations such as Nepal, Sri Lanka, and Bangladesh (Kumar & Kameswaran, 2017). The Cochlear Implant Group of India is a professional organization that has formed to give guidance to practicing cochlear implant professionals in the country; however, their recommendations are non-binding and mostly focus on cochlear implant candidacy rather than device programming and follow up care (The Cochlear Implant Group of India, 2018).

Browning et al. (2020) found a similar circumstance in the United States and sent out a survey to fill in the gap of knowledge surrounding these clinical programming and follow up practices in the country. The present survey is an extension of the Browning et al. (2020) survey after being modified for clarity and cultural considerations. Although the Cochlear Implant Group of India (2018) does not provide programming, otherwise known as MAPping recommendations, each cochlear implant manufacturer provides default programming choices that can be changed by the clinician during a MAPping appointment. Do clinicians in India prefer the default parameters like Browning et al. found in their survey? Is a preference for default parameters correlated with cochlear implant experience? These questions will be explored in the present study.

Methods

Participants

22 audiologists who self-identified as specializing in cochlear implants working in India fully completed this survey. Potential candidates for this survey were selected by personal contacts and membership through Indian-based audiology organizations. Survey candidates provided their email addresses and were sent a link to the survey, which was available via QuestionPro using a JMU license. The respondents were met with a statement explaining the creators of the survey, the purpose of the survey, the estimated completion time, and definitions for the subjects of certain questions in the survey such as adults, pediatrics, and mapping. See Appendix II for the introductory statement. Responses to the survey were anonymous. This survey was approved by the Institutional Review Board at James Madison University and is listed as Protocol ID 22-2901. Seventy four total unique Indian IP addresses attempted this survey, while 22 fully completed the full questionnaire and 52 dropped out (30% completion rate).

Questionnaire

Before creating the survey through QuestionPro, the questionnaire was developed to evaluate cochlear implant programming practices, objective measurements, subjective measurements, bimodal fitting practices, and habilitation/ rehabilitation practices for Indian cochlear implant audiologists and other professionals working in India who may perform these tasks. This questionnaire is a modified version of Browning et al. 2020's

questionnaire used to assess these same parameters in the cochlear implant audiologists of the United States. In the Browning et al. development of the questionnaire, the authors carefully created questions, undergoing twelve different versions that were critiqued by cochlear implant manufacturer representatives and cochlear implant clinical audiologists in the U.S. until the final version was approved for distribution. Similar to the development of the Browning et al. (2020) survey, The questionnaire from Vaerenberg et al. (2014) was considered as well as the questionnaire by Jeyaraman (2013), as this survey was specifically focused on the general cochlear implant practice and programs in India. With these two publications in mind, the current survey strives to build on the existing published knowledge of international, namely Indian, data.

The changes in the questionnaire for the present survey were reviewed and approved by the authors of this paper and their personal contacts who are working professionals in both the United States and India for clarity and cultural considerations. For instance, questions concerning the financial responsibility of the surgery and services were added since according to the author's personal contacts in India as well as Jeyaraman (2013), many government-assisted programs are well known and available in India for children who are cochlear implant candidates. Participants could choose to complete the survey in one sitting, or the survey had the option to save the participant's progress so that they could return to the survey to complete it at their convenience.

Once the survey was initiated, the first questions inquired about the participant's current clinical setting including their role in the clinical team, how many cochlear

implants they have personally activated, the general clinical setting in which they work, relevant services provided, and financial coverage of the device and services. Next questions related to clinical decision making such as who decides the manufacturer used, how many manufacturers the participant actively works with, pre-operative counseling, and frequency of off-label implantation. Next, participants were asked about mapping procedures for each of the manufacturers. If a participant did not work with a select manufacturer, they were prompted to not answer those specific questions. The next section inquired about objective measurements for pediatric patients and adult patients. Following this section, the participants were asked about their bimodal fitting preferences. Finally, questions concerning the recommendation of habilitation/ rehabilitation in cochlear implant patients appeared. At the conclusion of the survey, a free response box was available for any further comments the participant would like to add.

Results

Clinical Setting

All of the respondents self-identified as audiologists in the cochlear implant team. Of these audiologists, all were clearly knowledgeable in the fitting and follow up practices of cochlear implants based on their responses to the next two questions. The first question inquired about the approximate number of adult devices that the respondent personally activated, while the second question inquired the same about pediatric devices. While the responses for adults were few, ranging from 0 to 230, the pediatric activations were significantly higher, ranging from 0 to 1,600, with many of the respondents estimating their experience to be within hundreds and over a thousand pediatric activations.

Although all of the respondents were audiologists, their clinical settings were more diverse. The spread of clinical settings found that the majority of the participants worked in a privately owned audiology clinic (33%). This was closely followed by a tie of 26% working in a medical college hospital and the same number working in an institution clinic. Audiologists working in an otolaryngologist's practice made up 11% of the respondents and 4% of the participants indicated they worked in a non-listed setting. See Figure 1.

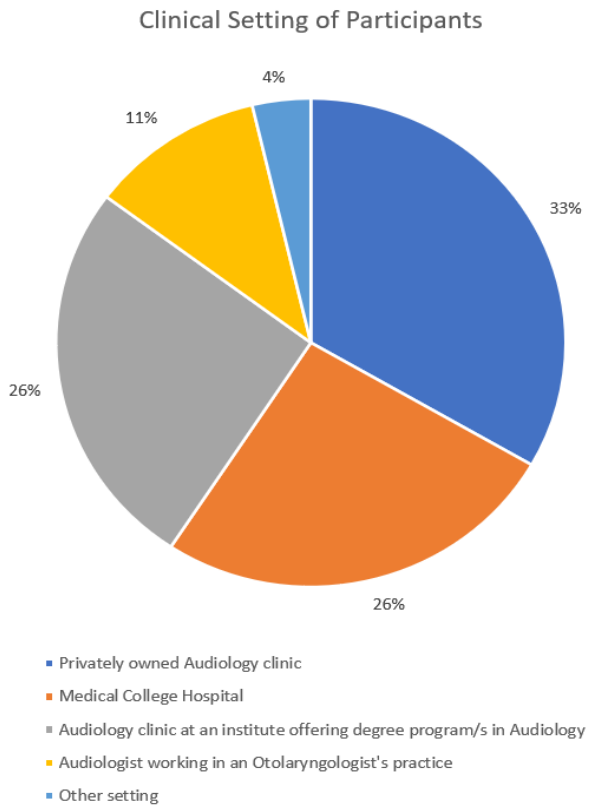

Figure 1. Clinical settings in which cochlear implant mapping is performed in India

Clear trends emerged for services offered at these differing settings. Medical or ENT services were offered at 71% of these clinical settings. The actual cochlear implant surgery was available at 48% of the workplaces. Auditory rehabilitation/ habilitation was offered at all of the settings. Services for fitting hearing aids was available at 91% of the practices. This may be an important factor for bimodal recommendations in future research. Vestibular assessment was available at 77% of the settings, and 64% of the practices offered psychological evaluations. In the free response section, other relevant

services that were offered at some settings that the respondents felt were relevant to this line of questioning included radiological evaluation, genetic counseling, and social services. See Figure 2.

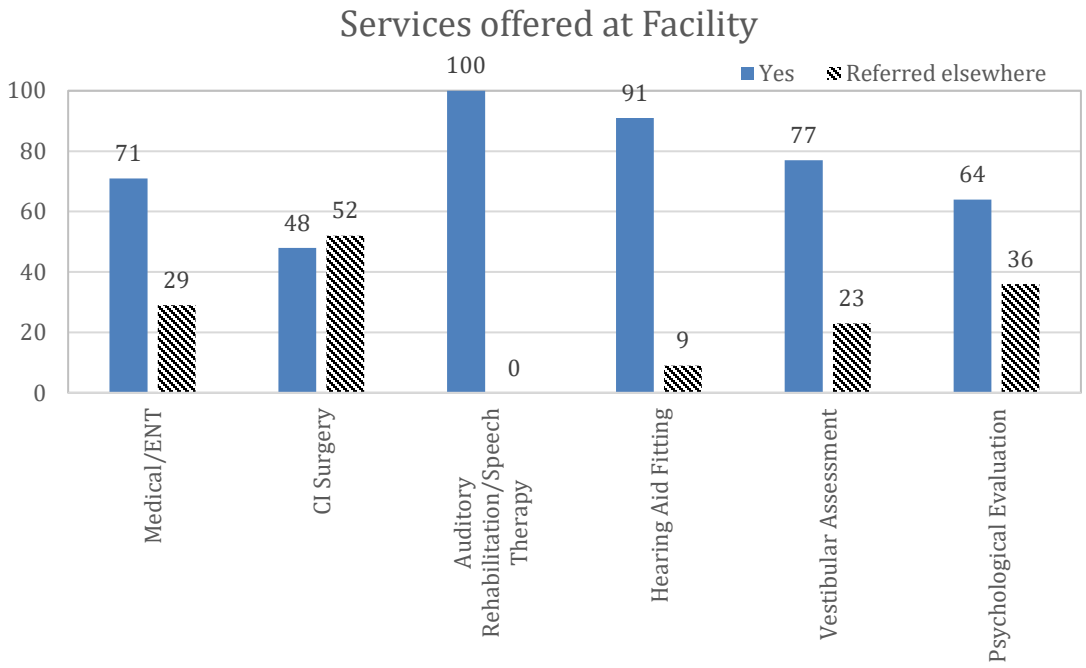

Figure 2. Different clinical services offered at the cochlear implant audiologist's work setting in India. Solid filled bars indicate the proportion of audiologists indicating the availability of a particular service. Hatched bars represent patient referral to other clinics.

Financial Considerations

The respondents were asked a question to identify various avenues for payment of cochlear implantation. Options included subsidized payment under a government scheme, total out of pocket payment, private insurance, other means (e.g. international aid groups)

and unknown. The respondents could select multiple options since the patient population in any clinic can vary in terms of paying for healthcare. Out of the 22 audiologists, 18 reported that some patients in their clinic are covered by the government schemes for reduced cost/free cochlear implantation (82%). Out of pocket payment for implantation was also identified as another common method of paying for services (also 18 out of the 22 audiologists). Upon an inspection of the individual responses it was confirmed that the 18 audiologists selecting the two responses did not overlap. There were 15 audiologists who selected both options as a mode of payment in their clinics. A smaller group of audiologists (4 out of the 22) responded that private insurance pays for the cochlear implantation in their clinics. The results obtained from this question provides a reflection of the various types of payment accepted at a clinic.

For those settings that participated in government assisted programs, approximately one-third (37%) indicated that between 76%-100% of patients participated in these offerings. Another 37% answered that approximately 51%-75% of patients at their facility received this assistance. Another 10% audiologists in this survey responded that every patient received help from these government services. A smaller group (5%) responded that only 25%-50% received government assisted services. Also, 11% indicated that less than 25% of their patients qualified. These findings provide additional information about government funded CI programs in the country. There are two audiologists whose work setting primarily caters to low income patients by providing cochlear implants are free or subsidized costs.

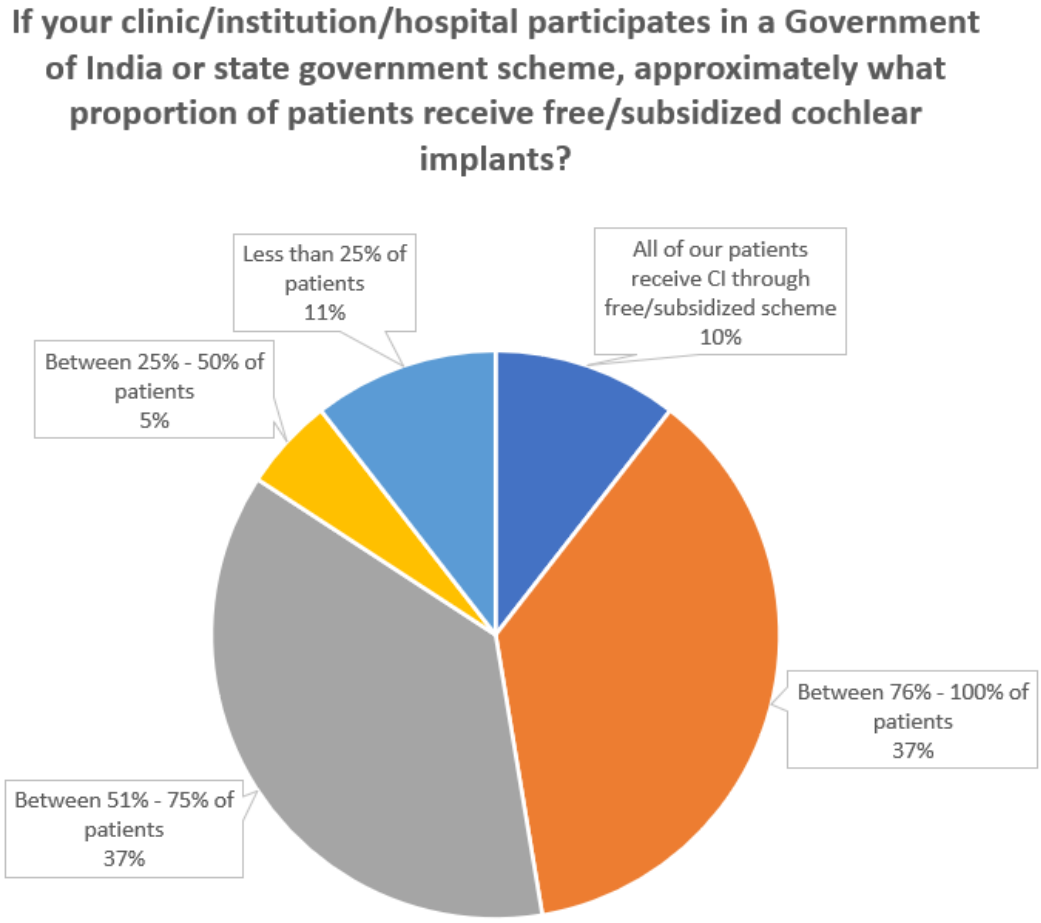

Figure 3. Proportion of audiologists reporting the share of their cochlear implant caseload funded by the government free/subsidized payment schemes.

Clinical Decision Making

It was of interest to survey the audiologists about the nature of decision making while selecting a cochlear implant manufacturer. The respondents were asked to select a

category from always, most of the time, about half of the time, sometimes, or never. When asked about the importance of the surgeon's preference for the CI model, 40% selected "most of the time". The rest of the categories are shown in figure 4 below.

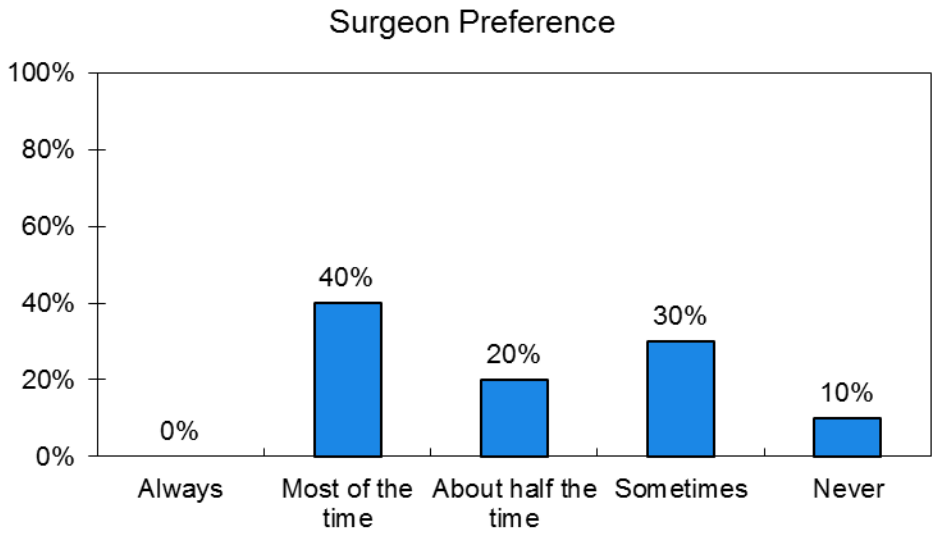

Figure 4. Surgeon's preference as a deciding factor in the selection of cochlear implant manufacturer.

Similarly, the audiologist's recommendation and the patient's preference were also examined as deciding factors in the final selection of the cochlear implant. Figures 5 and 6 summarize the results below. Another limiting factor in selecting a particular manufacturer of cochlear implant depends on the variety of manufacturers' products available at a particular clinic. Some clinics exclusively work with one cochlear implant manufacturer. In such a case, surgeon preference, audiologist recommendation or patient preference do not matter. Figure 7 shows the frequency this is a deciding factor.

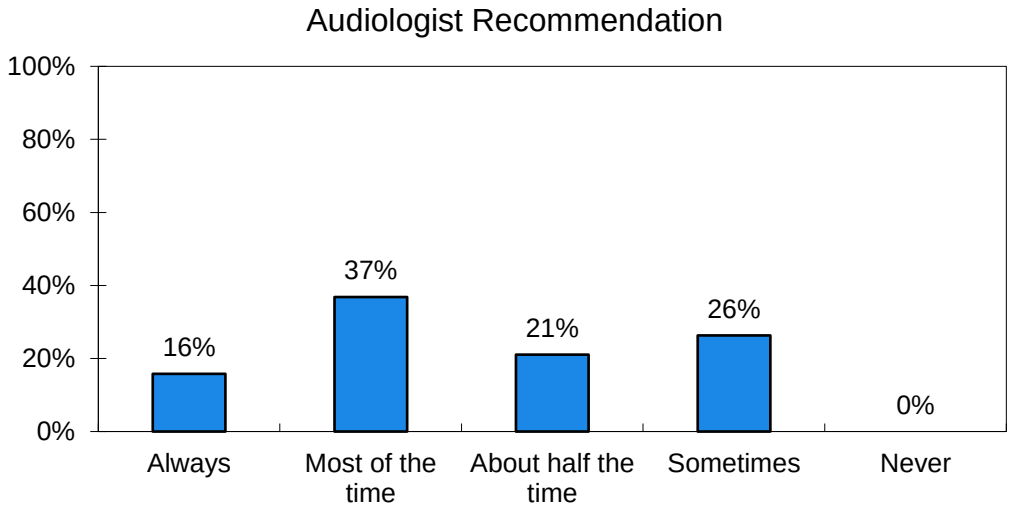

Figure 5. Importance of the audiologist's recommendation in the final selection of cochlear implant manufacturer.

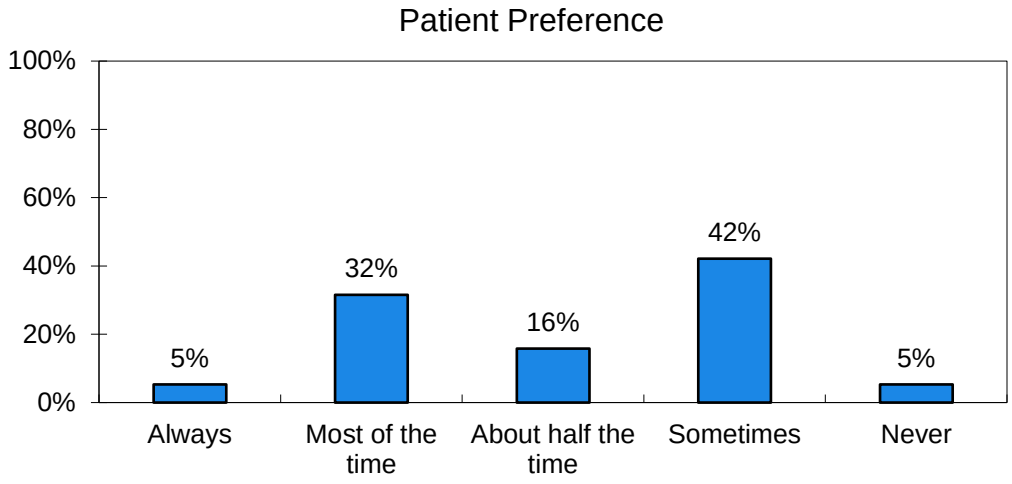

Figure 6. Importance of the patient's preference in the final selection of cochlear implant manufacturer.

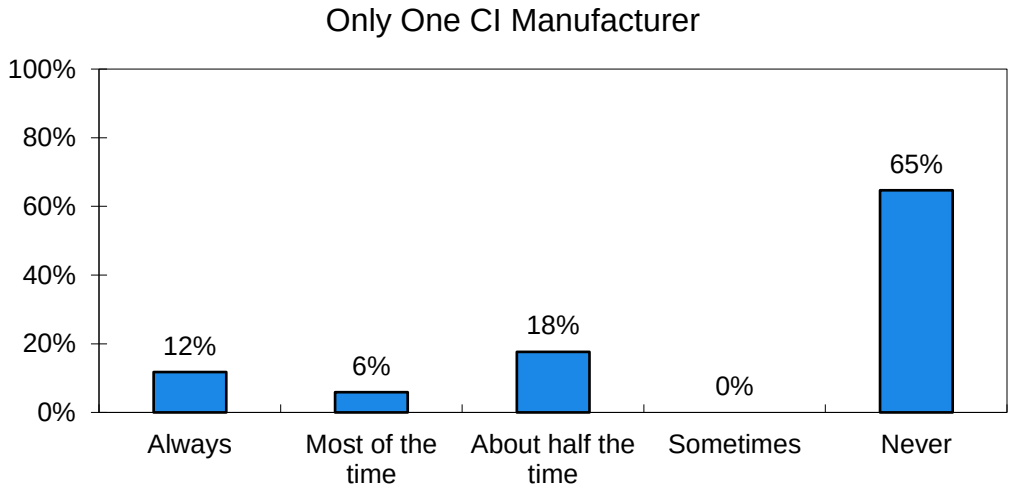

Figure 7. Proportion of clinical settings where only one cochlear manufacturer is offered to the patient.

Cochlear Implant Manufactures

The next section of the survey explored which cochlear implant manufacturers are most commonly used by the audiologists in India. All 22 participants (100%) responded that they work with implants manufactured by Cochlear Corporation. MED-EL (77.27%) and Advanced Bionics (68.18%) were also selected as CI manufacturers who they work with. Oticon Medical's Digisonic cochlear implants are a new entrant in India. Only 32% audiologists indicated that they work with Digisonic implants. One participant reported that they work with Digisonic implants if the patient receives a government grant to pay for the cochlear implants.

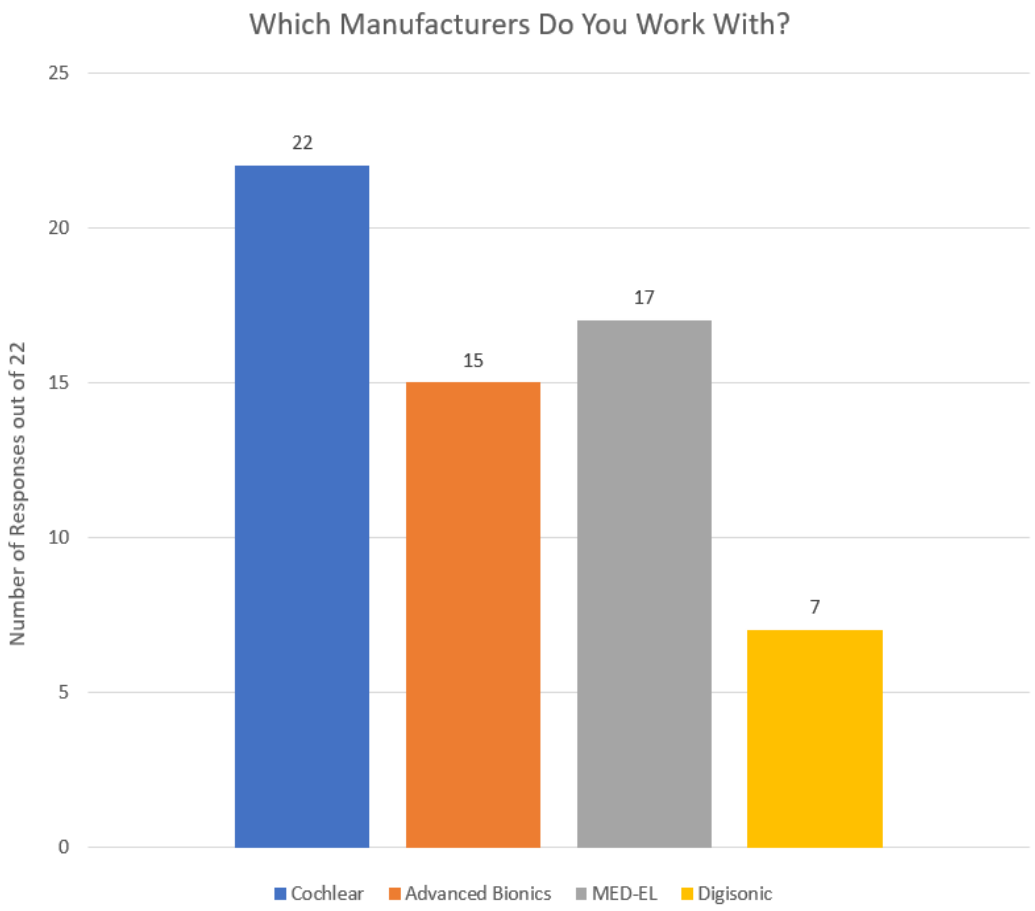

Figure 8. Number of audiologists (out of 22 participants) identifying the cochlear implant manufacturers they work with. As can be seen from this figure, most audiologists work with multiple cochlear implant manufacturers.

Pre-implantation counseling and off-label implantation

Pre-implantation counseling is an important step in the cochlear implantation process. The respondents reported that audiologists (100%) and otolaryngologists (86%) are involved in counseling patients and their families prior to the implantation. The

patients also benefit from meetings with other professionals such as psychologists (32%) and speech language pathologists (68%). Pre-implantation counseling data is displayed in figure 9. Off label cochlear implantation refers to cases where surgery is performed without strict adherence to approved candidacy criteria. Such instances may be warranted in cases of congenital malformations or ossification of the cochlea. The audiologists participating in this survey reported that off-label cochlear implantation is uncommon at their clinical sites ranging from 0% - 20%.

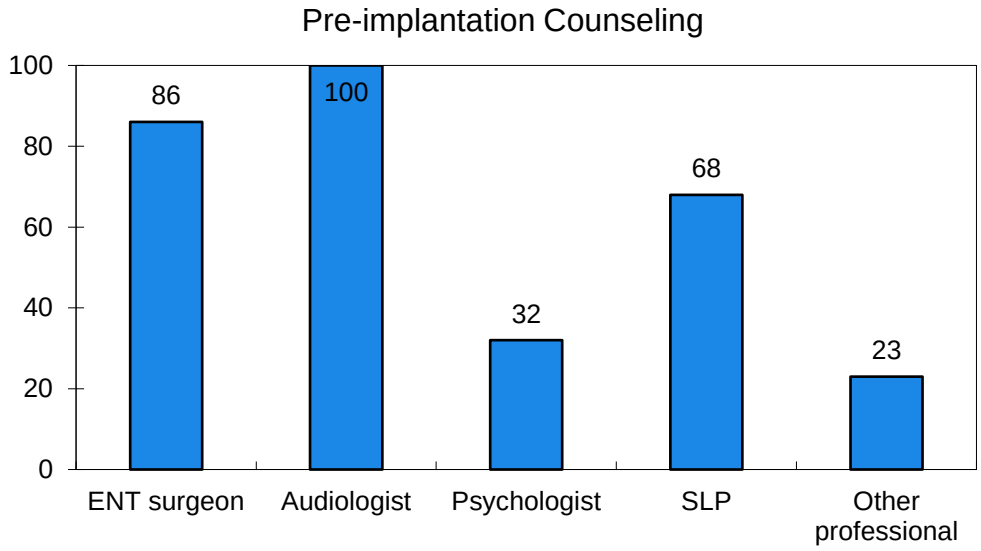

Figure 9.. Pre-implantation counseling by different members of the cochlear implant team. While the otolaryngologist and the audiologist spend time counseling prior to the implantation, other professionals are also involved in the process.

Preferences for Default MAPping Parameters

When MAPping Cochlear devices, data trends revealed at least 80% or more of the respondents indicated that they always or almost always prefer the default settings for all of the parameters which were evaluated in the survey. See Figure 10 for a visual representation of the preference for Cochlear default parameters. Please see Appendix II for the specific parameters. For MED-EL, at least 80% of the responses indicated always or almost always as the preference was found for all the parameters. See Figure 11 for the visual representation of the data and Appendix II for the specific parameters. For Advanced Bionics cochlear implants, the responses indicated the preference of always or almost always in at least half of the responses for the following parameters: number of active channels or electrodes, processing strategy (HiRes-P), pulse width, T Level, gain, volume max, volume min, sensitivity, IDR, audio mixing, mic mode omnidirectional, filter, and AGC. In Clearvoice off, a trend for deviating from the default settings was found in the data. See Figures 12 and 13 for the visual representation of the preference for Advanced Bionics default parameters and the preference for the Clearvoice default setting respectively. Specific data for MAPping preferences was not collected for Digisonic devices.

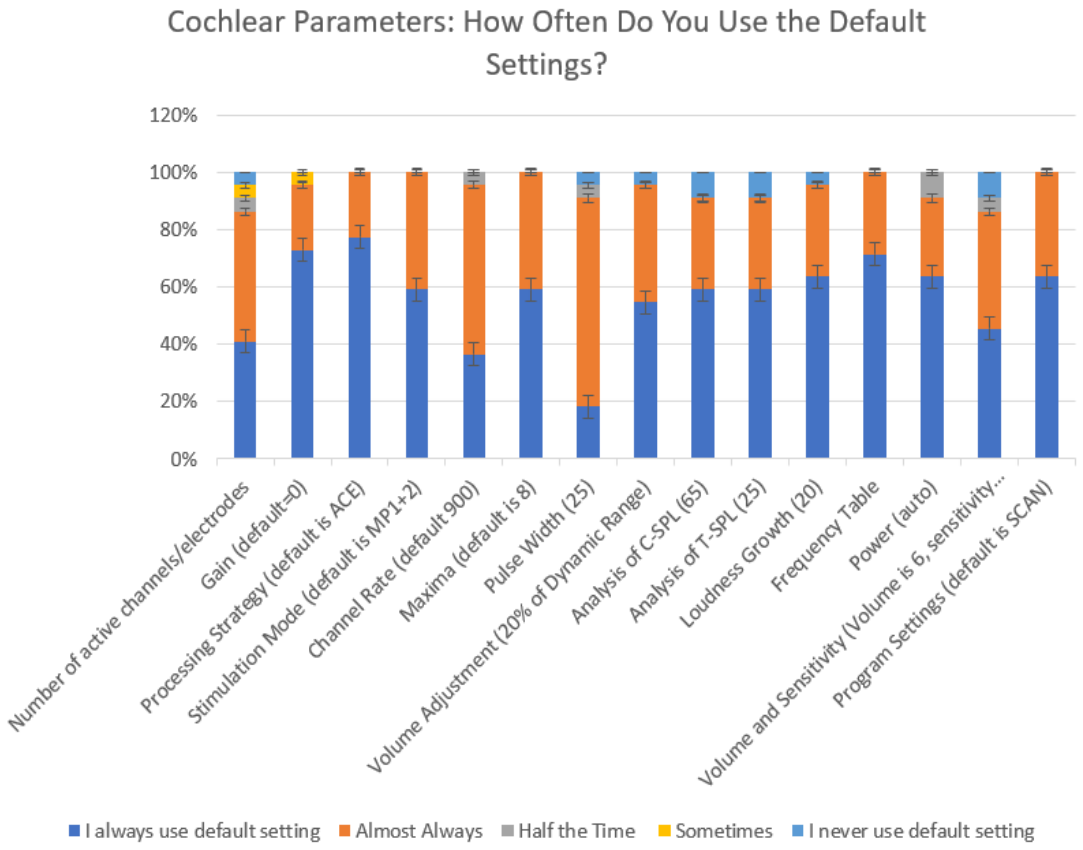

Figure 10. Proportion of times the audiologists select the default parameters in implants manufactured by Cochlear Corporation.

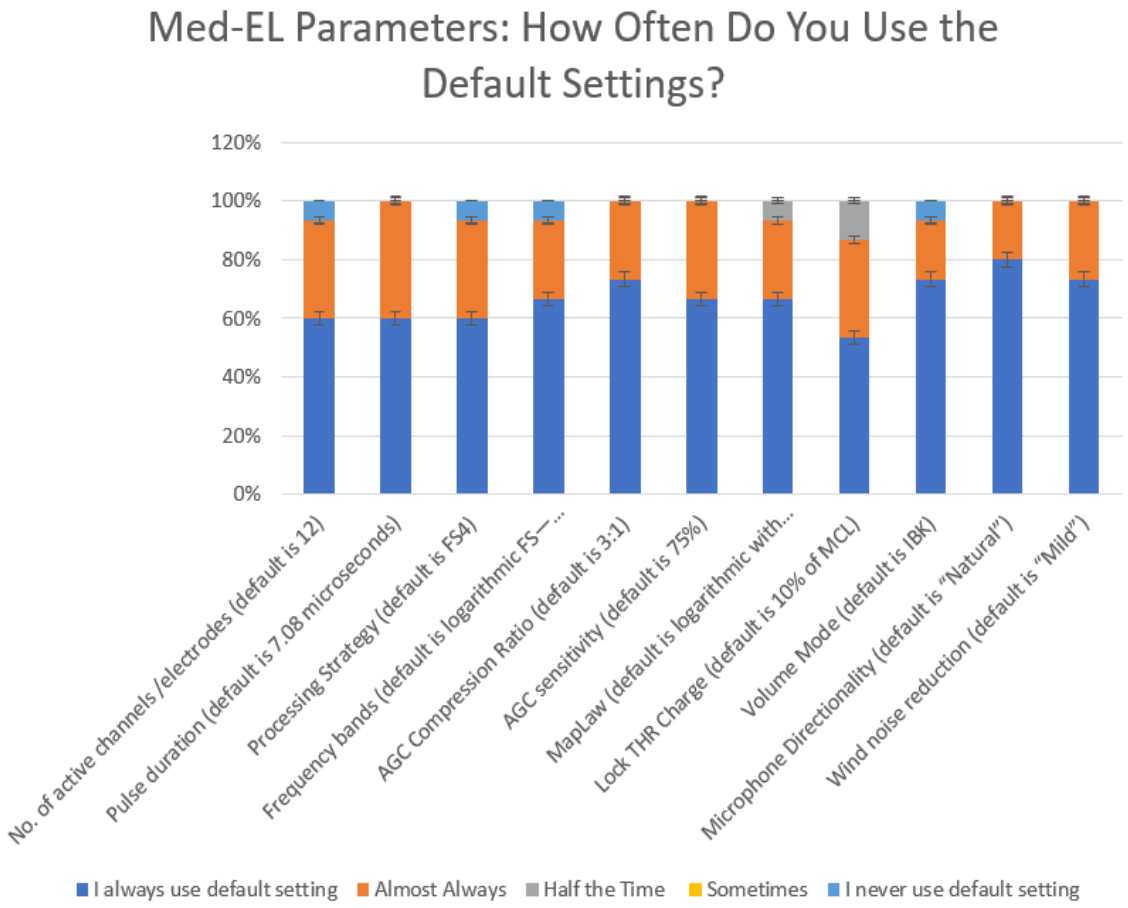

Figure 11. Proportion of times the audiologists select the default parameters in implants manufactured by MED-EL.

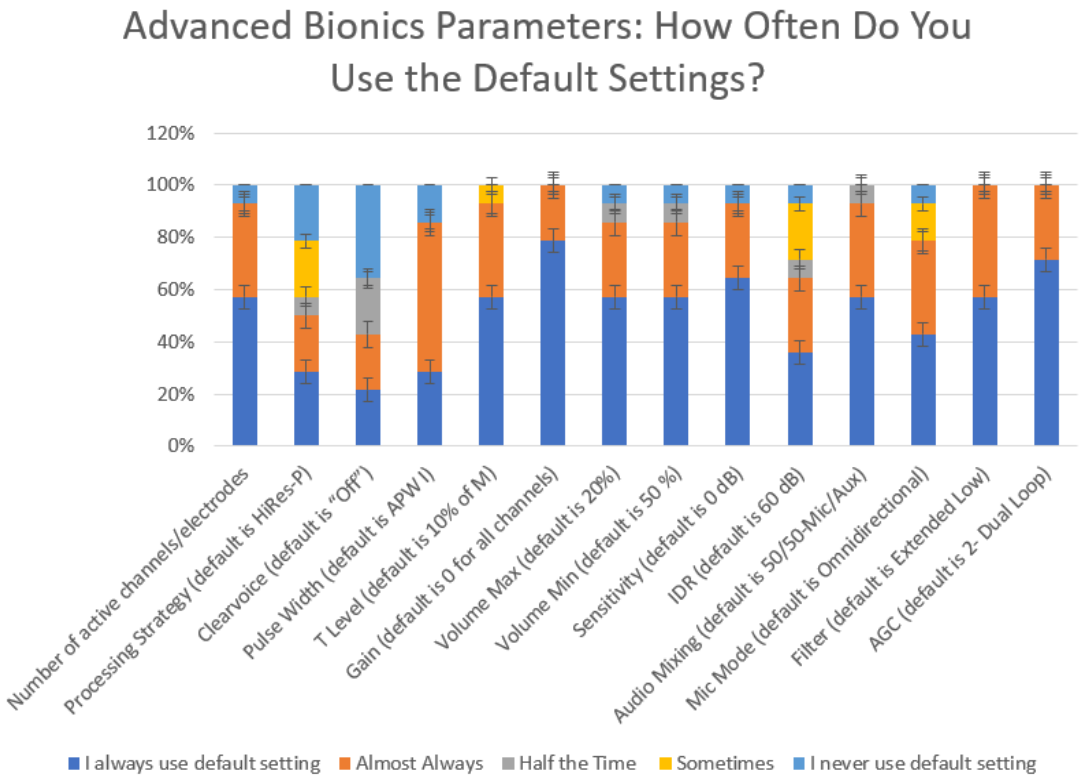

Figure 12. Proportion of times the audiologists select the default parameters in implants manufactured by Advanced Bionics.

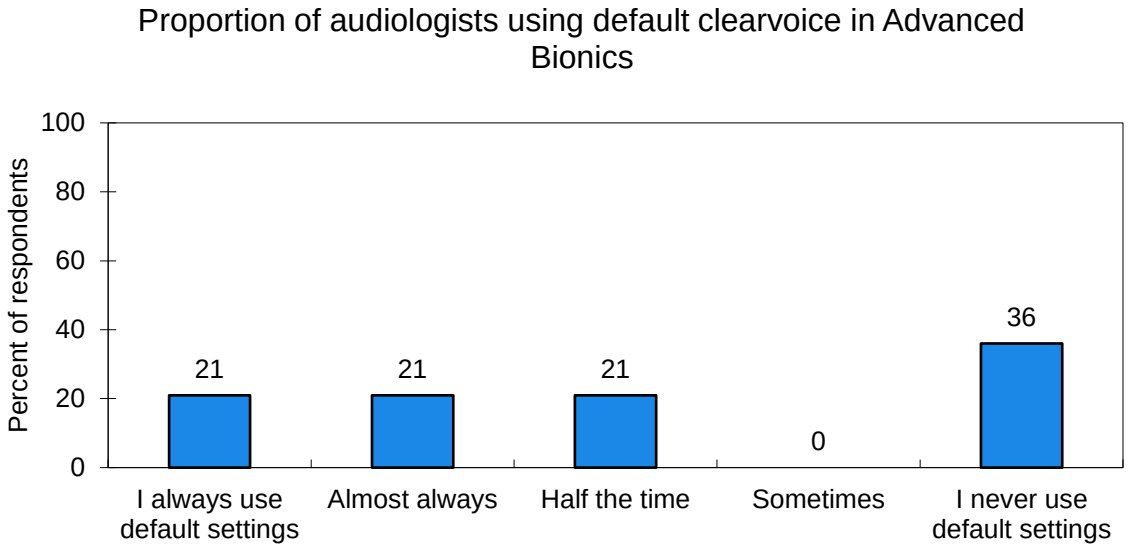

Figure 13. Proportion of audiologists selecting the default setting for Advanced Bionic's clear voice algorithm.

Pediatric Follow-Up Clinical Measurements

At initial and follow-up MAPping visits for pediatric patients, 95% of the respondents reported that they always measure electrode impedance. The remaining 5% indicated that they almost always measure the electrode impedance. For measuring ECAP (including NRT, NRI, and ART) in pediatric patients, 50% reported always taking these measurements, 14% almost always measure ECAP, 27% estimated that they measure ECAP approximately half of the time, and 9% reported sometimes measuring ECAP. Measuring e-ABR was more divided, with 50% reporting sometimes taking these measurements while 41% reported never measuring e-ABR. 5% reported measuring e-

ABR about half of the time and an equal 5% reported almost always obtaining e-ABR in their pediatric patients.

Pediatric ESRT (stapedial reflex) measurements were reportedly measured always by 5% of the audiologists. The respondents reported that they measured ESRT almost always (18%), half of the time (18%), and sometimes (27%). 32% of the audiologists reported never measuring ESRT. Vestibular testing in pediatrics like ENG or VNG is not as popular. 73% of the audiologists reported never obtaining this measurement in their pediatric population. 5% reported almost always obtaining vestibular data and 23% reported sometimes recording this information. See Figure 14 for the pediatric objective measurements data.

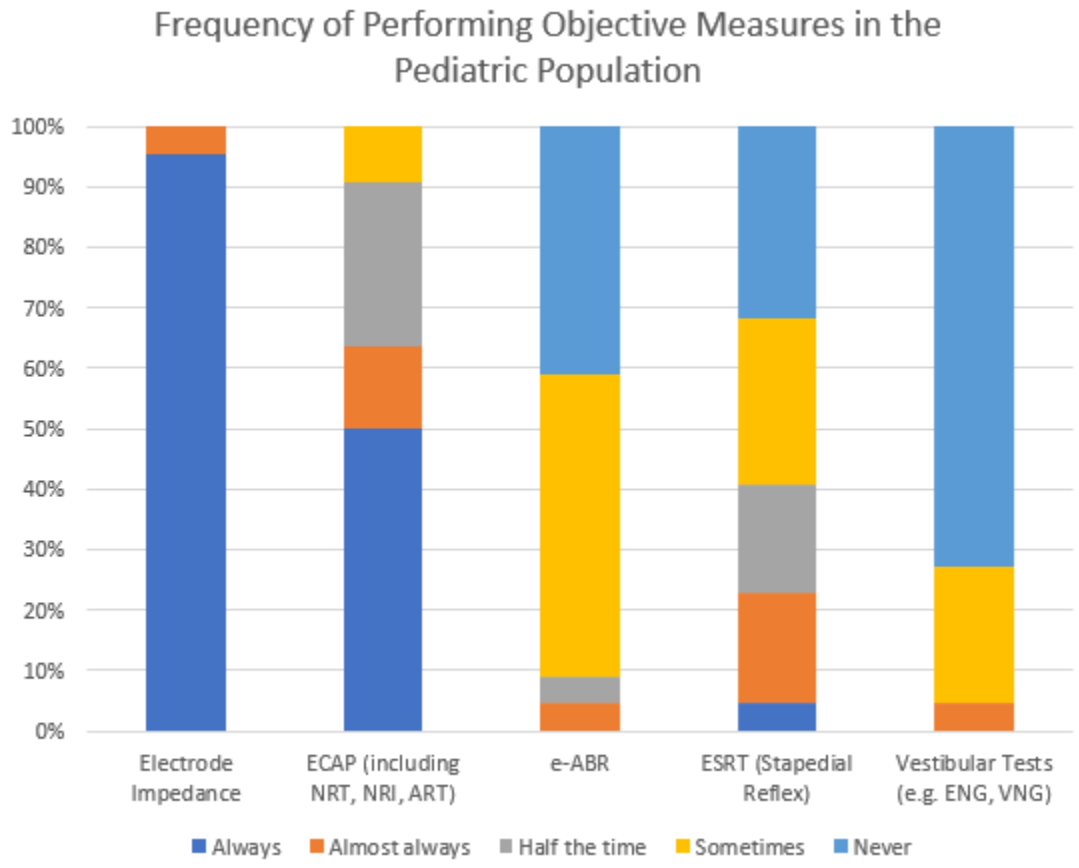

Figure 14. Frequency of performing objective measurements while programming cochlear implants in pediatric population.

Adult Follow-Up Clinical Measurements

For the adult population, 95% of the audiologists reported always measuring electrode impedance and 5% reported almost always obtaining this data. For ECAP measurements, 32% reported always, 21% reported almost always, 11% half of the time, 32% sometimes, and 5% reported never taking these measurements in their adult patients.

Similar to the pediatric data, e-ABR measurement was more split with 61% reporting never obtaining this data, while 33% reported sometimes measuring e-ABR and 6% reporting almost always running this test.

ESRT again reveals inconsistency in clinical practice with 5% reporting always, 11% almost always, 16% half of the time, 37% sometimes, and finally 32% reporting never running ESRT in their adult cochlear implant recipients. Vestibular data was reported as never being obtained by 74% of the responding audiologists. The remaining 21% reported sometimes collecting VNG or ENG data and 5% reported almost always collecting this vestibular information. See Figure 15 for the adult objective measurement frequencies.

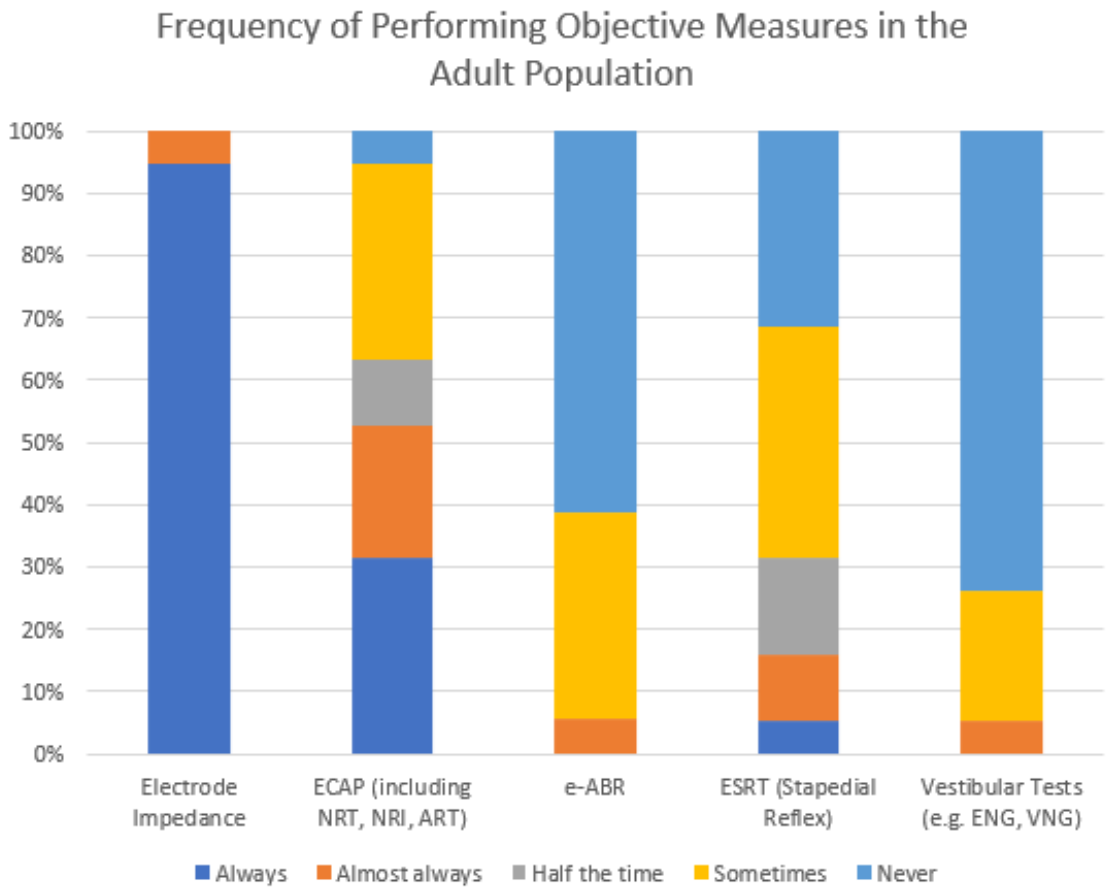

Figure 15. Frequency of performing objective measurements while programming cochlear implants in adult population.

Bimodal Fitting Practices

Most Indian cochlear implant audiologists are recommending bimodal fitting for their cochlear implant patients. 59% reported always recommending a hearing aid for the

non-implanted ear in adult recipients. 32% recommended a contralateral hearing aid most of the time and 9% recommended a hearing aid some of the time. For pediatrics, this trend continues with 91% of audiologists always recommending a bimodal fitting, 5% recommending a hearing aid in most cases, and 5% recommending a hearing aid about half of the time (figure 16).

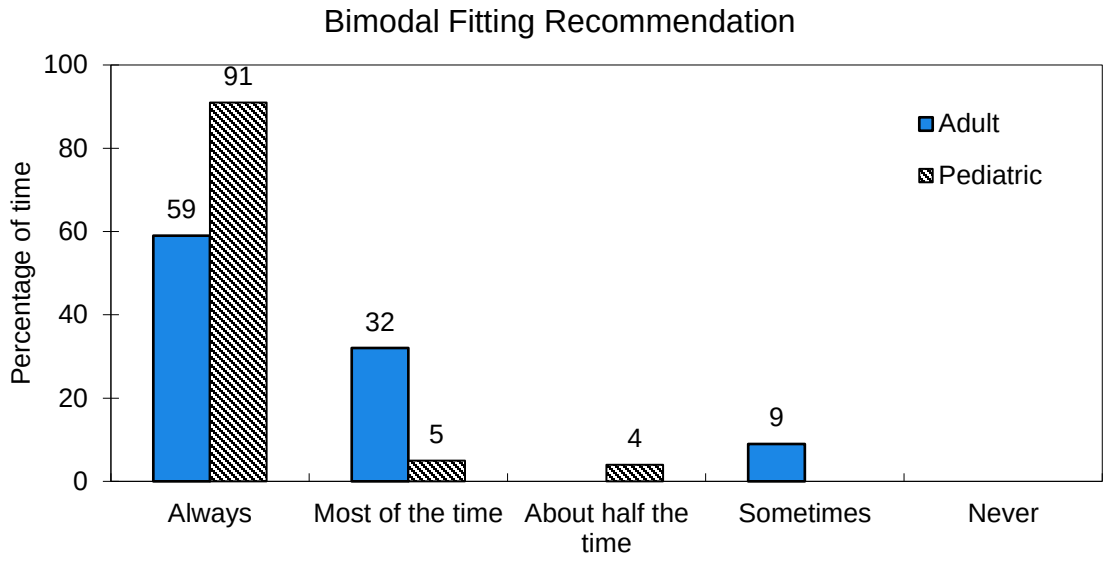

Figure 16. Bimodal fitting recommendation by cochlear implant audiologists in India. Solid bars represent adult population and the hatched bars indicate pediatric population.

When choosing the prescriptive formula for a bimodal fitting regardless of the age of the patient, 36% responded that they prefer the hearing aid manufacturer's proprietary formula, 29% recommended a NAL prescription, 29% use DSL, and 6% of the

audiologists use their own gain prescription. Please note that this question did not ask for preference in prescriptive formula for adults versus pediatrics. See Figure 17.

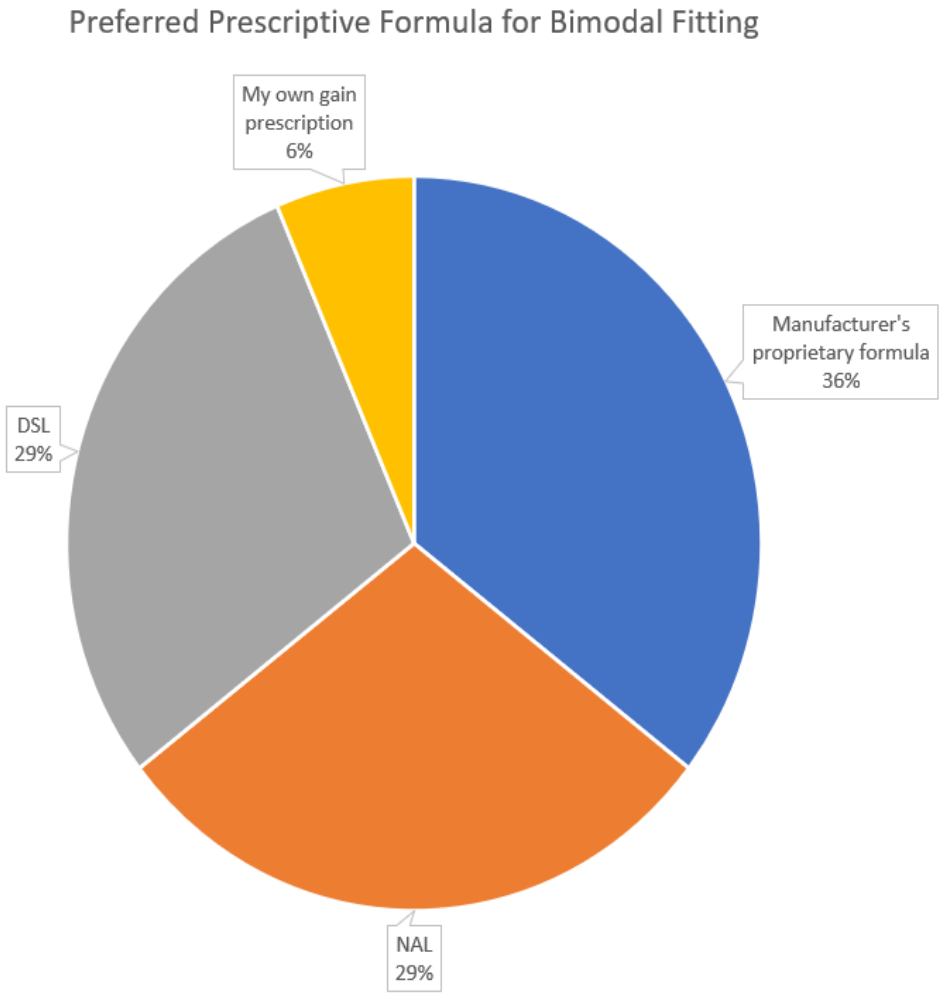

Figure 17. Audiologists' preferred hearing aid prescription formula in bimodal fittings.

Rehabilitation/ Habilitation Recommendations

For pediatric patients, 95% of the cochlear implant audiologists reported that they always recommend speech therapy. The remaining 5% stated that they recommended speech therapy most of the time for their pediatric population. Recommending computerized auditory training yielded more divided results with 57% of the audiologists never recommending this method of rehabilitation/ habilitation training. 10% always recommend computerized audiologist training and the remaining 33% recommended it once in a while for their pediatric patients.

Adult recommendations for rehabilitation / habilitation training differ greatly from the pediatric recommendations. 57% of the respondents always recommended speech therapy for their adult cochlear implant patients, and 5% recommended speech therapy most of the time. 5% recommended adult speech therapy about half of the time, 19% reported making this recommendation once in a while, and 14% never recommended speech therapy for their adult patients. Recommending computerized auditory training in the adult population was again, split. Of the respondents, 42% reported never recommending adult computerized auditory training, 11% reported always recommending this training, another 11% recommended this most of the time, 16% reported recommending computerized training about half of the time, and 21% reported once in a while making this recommendation. See Figure 18 below for habilitation/ rehabilitation recommendations in the adult and pediatric populations.

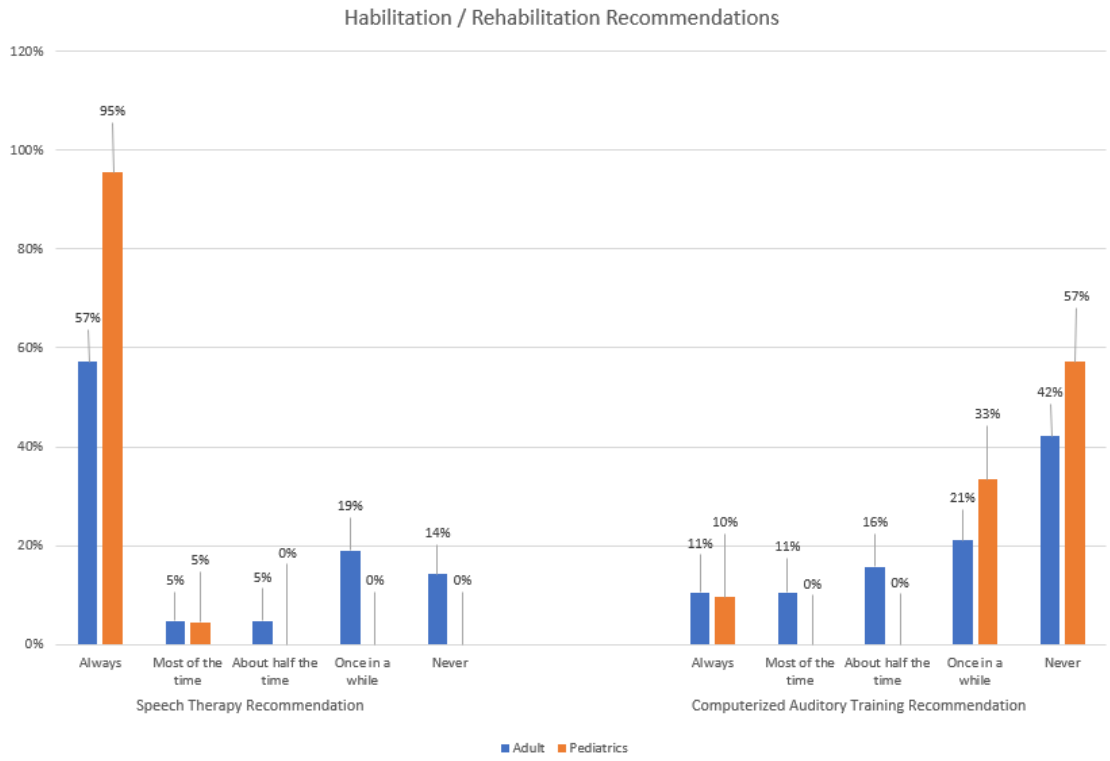

Figure 18. Frequency of speech therapy and computerized auditory training recommendation by audiologists.

Discussion

Jeyaraman (2013) surveyed pediatric cochlear implant centers and collected data concerning how patients paid for their cochlear implants. The Jeyaraman (2013) survey found that 52% of the patients were self-funded, 32% were funded by a government assisted program, 11% were funding by a non-profit organization, and 5% were funded by other charity organizations. Similarly, the present survey found that 40% of the respondents indicated that their patients paid out of pocket. Another 40% indicated government assistance programs aided their patients. 9% indicated that a private third party health insurance funded the procedure and follow up. This option was not included in the Jeyaraman (2013) survey. In the present survey, another 9% indicated that non-profit or charity organizations helped their patients to cover the cost. 2% responded that costs associated with the survey and follow up were unknown to them.

Preference for Default Parameters

Indian clinicians appear to follow the same patterns as was seen in the data following clinical preferences in the U.S. by Browning et al. 2020. When MAPping Cochlear and Med-El devices, there is a clear preference for the default parameters established by the respective manufacturers. In most parameters of an Advanced Bionics device, the same rings true; however, there is much more variety in the clinical MAPping decisions of the processing strategy, which is currently HiRes-P, and the preference for Clearvoice off.

In the free response section, no respondents chose to elaborate why they choose to change these two parameters when working with Advanced Bionics cochlear implants. An interesting fact to note is that although HiRes-P is the default parameter in the MAPping software for Advanced Bionics, the company recommends in its trainings to switch the processing strategy to HiRes Optima P to significantly improve the battery life of the processor. The company has not changed its default processing strategy since HiRes P is the processing strategy used in the U.S. to gain FDA approval, not HiRes Optima P.

Advanced Bionics is the only cochlear implant manufacturer out of the three that does not recommend measuring T levels. In the initial FDA approval process, Clearvoice was not an option in the software, so the default remains off. Since this process, this parameter, when turned on has received a superior ranking, showing significant improvements in speech clarity. As many findings in this data collection in India follows the same observations as Browning et al. 2020, it may also be assumed that the thought processes are the same between these two groups of professionals. In the Browning et al. 2020 paper, they also noted that clinicians mentioned changing these parameters based on patient preference and issues with sound quality, which matches up with the information showing Clearvoice on may alleviate these common complaints from patients.

Follow-Up Clinical Measurements

Vestibular symptoms post cochlear implant operation can be as prevalent as 20% according to a study conducted by Bittar, Sato, Ribeiro, & Tsuji in 2017. Despite the high risk of dizziness in patients, 73% of the Indian audiologists surveyed in the present study indicated that they never evaluate the vestibular system in their pediatric patients and 74% reported never assessing their adult patients.

While it was reportedly used more often than vestibular assessment, ESRT still revealed a large variance in frequency amongst Indian clinicians. For the pediatric population, the respondents indicated that they always (5%), almost always (18%), or measured ESRT half of the time (18%) for their pediatric patients. This totals up to clinicians regularly measuring ESRT in their pediatric population 41% of the time. For adults, the Indian audiologists indicated always (5%), almost always (11%), and measuring ESRT half of the time (16%). This adds up to 32% regularly utilizing this objective measurement. These data are similar to the finding from Vaerenberg et al. (2014) where they found that 39% of cochlear implant centers reported using eSRT as an objective measurement in MAPping visits.

Vaerenberg et al. 2014 reported that 59% of their surveyed cochlear implant centers used eCAP measurements when MAPping devices. In the present survey, 64% of the Indian audiologists reported always or almost always measuring eCAP in their pediatric population. For the adult population, 53% of the clinicians reported always or almost always measuring eCAP. eCAP is clearly the more popular measurement; however, the current data available comparing the two tests reveals that eSRT may be a

better predictor of MCL (Walkowiak et al. 2011). Additionally, time is valuable to any working professional and Kosaner, Spitzer, Bayguzina, Gultekin, & Behar (2018) found that measuring eCAP takes four times longer than measuring eSRT in cochlear implant patients. Similar to the data from Browning et al. (2020), the current data reveals a potential lag in implementing strategies in the modern research.

Bimodal Fitting Practices

Browning et al. 2020 hypothesized that if more pediatric cochlear implant audiologists were surveyed in the U.S., there would be a higher preference for the DSL prescriptive formula. In the current study, the question concerning the preference for bimodal fitting formulae did not specify adult or pediatric patients. In the current study, there was a much higher number of cochlear implants activated by the respondents for the pediatric population, so it can be assumed that the respondents were answering in general or leaning towards their clinical decisions for their pediatric patients. The results yielded a fairly even preference between the manufacturer's proprietary formula (36%), an NAL prescription (29%), and DSL (29%). Only a small 6% answered that they use their own gain prescription.

Regardless of prescriptive formula preference, most audiologists recommended a bimodal fitting for their patients. 91% of the respondents stated that they recommended bimodal fittings always or most of the time for their adult patients and 96% for the same

in their pediatric patients. In the future, further clarification in this question could be warranted to include asking if they would recommend a bimodal fitting if the patient was a candidate. The current question did not specify this candidacy so there could have been an unintended interpretation of this question.

Rehabilitation / Habilitation Recommendations

Jeyaraman (2013) mentions the large rural population of cochlear implant recipients and candidates in India. This information coupled with the idea that India is not considered to be a higher income country compared to the U.S. may help to interpret the data revealing a lowered rate of computerized training for rehabilitation or habilitation therapy in India. 57% of the respondents reported never recommending this method of therapy for the pediatric population and 42% never recommended it for the adult population.

57% of the audiologists always recommended speech therapy for their adult recipients compared to 95% always recommended it for their pediatric patients. The difference in frequency of this recommendation between the two populations could be due to the fact that for most adult cases, it is assumed that rehabilitation would be the case due to the fact that the adult would have likely acquired their hearing loss post language acquisition. Since the adult patient likely already acquired speech before their hearing loss progressed to the significance warranting a cochlear implant intervention, they likely would not require speech therapy.

When referencing the pediatric population and the modern recommendations for early intervention, the cochlear implant is likely received prior or in conjunction with speech and language acquisition; therefore, speech therapy would be integral for more rapid success. Additionally, the Cochlear Group of India (2018) has set forth a “mandatory” post-operative recommendation that the cochlear implant team must provide weekly habilitation or rehabilitation plans for cochlear implant patients. Seeing as this recommendation was set as a “mandatory” recommendation by this group, it is interesting that not all practicing audiologists are recommending habilitation or rehabilitation interventions.

Conclusion

In conclusion, the results of the present survey indicate that audiologists in India have a clear preference for the default parameters as set for by the cochlear implant manufacturers; however, there are exceptions where individual professionals may deviate from these default settings. The audiologists responding to this survey clearly have varied methods for working with their cochlear implant patients and these methods may not follow the recommendations set forth by the Cochlear Implant Group of India (2018). Similar to the findings by Browning et al. 2020, many audiologists in India do not always use objective measurements in cochlear implant MAPping appointments. This could be due to lack or access or lack of experience in their settings. In general, it does appear that

these audiologists generally follow the same clinical practices and general recommendations as one another. These generalized clinical practices that have some variation backs the idea that clinicians adapt to each patient that comes through the door. Future research should adapt to cultural considerations for each region analyzed and should encourage more free response sections so that the clinical decision-making process may be better understood when a deviation from the default is found. Information collected in the present survey is not intended to be used to create standardized best practices in India or elsewhere. The information collected is intended to be used to create a better understanding of current clinical practices to improve future cochlear implant clinical outcomes for our patients.

Appendix I: Literature Review

Hearing loss is a medical condition that affects millions of people around the globe. The most recent data published by the World Health Organization (WHO) in 2018 estimates that approximately 466 million people are currently living with significant hearing loss, enough to interfere with these people's quality of life and daily living. In 2018, this equated to approximately 6.1% of the global population and is only expected to grow as the advances in healthcare expands the expected lifespan. In fact, WHO estimates that by 2050, over 900 million people will be living with disabling hearing loss (World Health Organization, 2018).

As the number of people with hearing loss rises, it increases disproportionally around the world. For example, by 2050, WHO estimates that approximately 72 million citizens from high income areas like the United States, Western Europe, and Australia will have significant hearing loss compared to 267 million citizens in South Asia. With such substantial projections like these, it is imperative that research is conducted on the current practices to combat this condition in all emerging markets, not only those in higher income countries.

The World Health Organization (2017) also published a report addressing the economic impact of unaddressed hearing loss. This economic impact is not limited to the cost of an amplification device and related services; this impact also addresses other life consequences of significant hearing loss. When hearing loss is unaddressed, it can have

negative impacts on communication with others (Ciorba, Bianchini, Pelucchi, & Pastore, 2012), language acquisition (Yoshinaga, Sedey., Coulter, & Mehl, 1998), academic achievement (Tharpe, 2008), and job opportunities (Jung & Bhattacharyya, 2012). All of these potential negative impacts can also lead to feelings of isolation, depression, and cognitive decline (Arlinger, 2003).

This economic report focuses on the impacts of a significant hearing loss defined as at least a moderate degree of hearing loss. Globally, it is estimated that in 2015, the economic impact of significant hearing loss to the healthcare sector was approximately $67-107 billion dollars, $3.9 billion dollars for the educational sector, $105 billion loss in the job market, and $573 billion lost in societal costs as a result of social isolation, communication problems, and social stigma. Altogether, this is an estimated $750-790 billion-dollar annual loss globally. An estimated 63% to 73% of this loss in the healthcare and educational sectors come from low- and middle-income countries. This may be because the larger availability of medical and healthcare solutions tends occurs in higher income countries, so there are higher rates of interventions that may decrease this loss. Furthermore, this report continues on to state that cochlear implants are undoubtedly the most cost-effective solution for addressing the economic impact that hearing loss has globally. In fact, the cost of the cochlear implant and associated services are significantly less than letting the hearing loss go untreated (World Health Organization, 2017).

Patients of any age can have significant hearing loss. In fact, of those who are affected by disabling hearing loss, WHO estimates that 93% are adults and 7% are

children (World Health Organization, 2018). Even though more adults are potential cochlear implant candidates than the pediatric population, many financial assistance programs may focus on the pediatric population as the consequences of auditory deprivation for this population may be more costly than the financial impact of the un-aided adults (World Health Organization, 2017).

Although many factors may increase the risk of hearing loss such as age, occupation, genetics, overall health, etc., hearing loss can affect anyone. In the last centennial, nearly all markets have seen a surge in technological advances, especially in healthcare. The field of audiology is no different and has been attempting to discover innovative solutions to address hearing loss. One of the solutions for the most significant of hearing losses is the cochlear implant device.

A cochlear implant is a medical device which transforms soundwaves into electrical signals that directly stimulate the auditory nerve for the brain to interpret (Waltzman & Roland, 2014). These devices must be custom programmed to the individual with regular follow up visits with a cochlear implant professional for best outcomes (Vaerenberg et al., 2014). Regular follow up programming visits are integral to the success of the patient as Hughes et al. (2001) points out that the minimum current levels increase over the first year following implantation for the pediatric population and the maximum current levels increase over the same time period for both the adult and pediatric cochlear implant population. By carefully programming these devices, the patient may see large improvement in their speech understanding. Traditionally, prior to

implantation, these patients yield poor word understanding and the intention of receiving a cochlear implant is to replace the low or non-functioning auditory abilities with a new way of interpreting auditory stimulus (Waltzman & Roland, 2014).

A normal auditory system transfers sound energy into mechanical energy which is lastly transferred into electrical energy that the auditory nerve sends to the brain to interpret. To understand how the cochlear implant works, it is important to first understand an intact system and how it transfers this sound energy. Following the transfer of energy, soundwaves which travel through the air make their way into the s-shaped outer ear canal, hit the tympanic membrane, otherwise known as the eardrum. When the tympanic membrane moves due to the vibration of the soundwaves, this initiates the ossicles, the three tiny bones in the middle ear which are attached to the tympanic membrane to move in tandem. The final of the three ossicles, the stapes, is attached to the oval window of the cochlea, otherwise known as the hearing organ (Wilson & Dorman, 2008). The cochlea is innervated by the VIIIth cranial nerve, otherwise known as the auditory nerve.

The cochlea is the most complex of all the sensory organs in the human body and is vital for auditory input and processing. Located in the petrous portion of the temporal bone, the cochlea is often discussed in one of two perspectives. The first perspective views the cochlea as it sits in the skull, wrapped up like a snail shell around a bony axis called the modiolus. In the second perspective, the cochlea is discussed uncoiled. In humans, the cochlea has around 2.5 turns as it spirals around the 5mm tall modiolus.

When unrolled, the cochlea is around 30-40mm long. The cochlea is made up of two labyrinths: the osseous (bony) labyrinth and the membranous labyrinth (Nie, 2018).

The osseous labyrinth is composed of bony structures, while most of the cochlear contents reside in the membranous labyrinth. The membranous labyrinth contains three fluid filled compartments: the scala vestibuli, the scala tympani, and the scala media. The scala vestibuli and the scala tympani are connected at an area of the osseous labyrinth called the helicotrema (Moller, 2006). The scala media, also known as the cochlear duct, is separated by Reissner's membrane superiorly and the basilar membrane inferiorly (Seikel, Konstantopoulos, & Drumright, 2018).

The organ of Corti resides on the basilar membrane and contains the inner and outer sensory hair cells of the cochlea (Seikel et al., 2018). The basilar membrane is the widest and thickest at its base and becomes narrower and thinner as it continues to the end of the apex. The basilar membrane is arranged in a log-linear pattern tonotopically. In other words, each frequency within the normal human hearing range has a specific place on the basilar membrane where the membrane reaches its maximum displacement, also referred to as the resonant frequency. As sound enters the cochlear system via the vibration of the oval window, the fluid displaces the basilar membrane and triggers the hair cells to release neurotransmitters, which triggers the electrical impulses for the auditory nerve (Nie, 2018).

The cochlear implant is one of the most successful medical inventions of all time. The cochlear implant device is made up of an internal component and an external component. The internal component consists of an internal receiver with an electrode array which is inserted into the scala tympani in the cochlea (Zwolan, 2008). When different electrodes are activated by varying degrees of electrical current, they stimulate tonotopic neurons of the auditory nerve. This stimulation creates a signal for the brain to interpret as an auditory signal, and in the optimal situation, the patient perceives and understands this signal similarly to how most people interpret natural soundwaves (Wilson & Dorman, 2008). The idea behind the electrode array is to match up as much as possible with the tonotopic organization of the basilar membrane. The multiple electrode stimulation should improve the place-frequency information that the brain was previously lacking to adequately separate (Saleh et al., 2013).

Following the surgery where the internal component is implanted into the patient, the external cochlear implant device is fit, otherwise known as programmed, to the patient's specific needs. This external component is what picks up natural soundwaves, processes this signal, and sends this signal to the internal component to be transformed into electrical impulses for the internal component to receive and continue the signal transfer to the auditory neurons (Wilson & Dorman, 2008). The fitting process begins approximately one month after the surgery to ensure that the incision area and surgical area have healed, and the swelling has reduced as to not interfere with patient comfort or the connectivity of the two device components (Vaerenberg et al., 2014). Vaerenberg et

al. (2014) international survey results confirm that on average, cochlear implant centers wait the average one-month period after surgery to begin the audiologic care.

At first fit, the cochlear implant manufacturers recommend that impedance measures are taken to ensure the integrity of the electrodes in the internal component's electrode array. If any of the electrodes are flagged as having a problem, those electrodes, and typically the adjacent electrodes are deactivated in the software (Vaerenberg et al., 2014). After the impedance measures are complete, most programming professionals move on to measuring the minimum (referred to as T Levels or THR) and maximum current levels (referred to as C Levels, M Levels, or MCL) for the electrical signals from the cochlear implant. The process to setting these levels differs amongst cochlear implant manufacturers (Wolfe & Schafer, 2014).

Obtaining the minimum and maximum current levels can be done with objective, subjective, or both types of measures. Sound booth testing is not typically performed at the cochlear implant fitting appointment according to Vaerenberg et al. (2014). Follow up programming appointments generally consist of programming the minimum and maximum current levels until they become stable for the patient as well as booth testing to document patient progression with the cochlear implant in terms of auditory perception and understanding. Any cochlear implant programming is saved as a MAP. A MAP simply refers to a saved cochlear implant program or parameters (Wolfe & Schafer, 2014).

According to Kumar & Kameswaran (2017), an estimated 63 million Indian citizens live with severe to profound hearing loss. This means that approximately 63 million Indians are potentially eligible for a cochlear implant according to the guidelines set forth by The Cochlear Implant Group of India (2018). With ever growing numbers, India is growing with the trend. As of 2017, the country contained approximately 200 cochlear implant centers and had developed The Cochlear Implant Group of India, which provides guidance for cochlear implantation practices in the country. Additionally, by 2017, the country had seen over 25,000 cochlear implantations (Kumar & Kameswaran, 2017).

The emerging market in India is not isolated. In fact, upon such successful program implementation, surrounding countries such as Nepal, Sri Lanka, and Bangladesh have collaborated with the Indian government to employ similar government programs within their borders (Kumar & Kameswaran, 2017). High success and heavy influence on the world market make India a great area of interest in modern cochlear implant device fit and follow up methodology.

As the popularity of cochlear implants increases, as does the need for standardized care. The Cochlear Implant Group of India has published their recommended guidelines for clinical practice; however, these are guidelines rather than true, binding requirements for professionals who work with these devices (The Cochlear Implant Group of India, 2018). While this is a great starting point, to the knowledge of

the authors of this paper, there is no published data exhibiting if Indian professionals are following these recommendations in their practices.

Vaerenberg et al. (2014) published some of the first information about international cochlear implant trends. This study sent a survey to 47 international cochlear implant centers to find out about the current clinical trends in the fit and follow up of cochlear implant patients. These centers spanned a total of 17 different countries. Amazingly, all of these cochlear implant centers participated in this survey. The study also invited the participants to provide further, more specific information where the researchers followed the fitting process for five actual patients at each center. A total of 34 of the centers participated in the follow up cochlear implant fitting data collection. The survey focused on five main areas: number of patients and the projected patient growth, cochlear implant brands used, MAP parameters used, assessments used for performance and programming, and targets used.

While Vaerenberg et al. (2014) collected some of the first international data about clinical cochlear implant strategies, this research was skewed towards the European practices and may be lacking in the larger global perspective. This is especially imperative to understand as the WHO data has identified other emerging global giants in terms of growing markets and regions with high numbers of significant deafness that could be described as more of the developing world rather than higher income countries (World Health Organization, 2018).

The Vaerenberg et al. (2014) study also found that certain countries tended to be outliers in terms of their methods and protocols compared to the rest of the survey respondents. For example, the Mumbai cochlear implant center, which is located in India, reported that they tend to see their patients for follow up appointments after the first year only at the patient's request while the common trend for the majority of the other centers surveyed revealed that their standard protocol was to see their cochlear implant recipients on a minimum of an annual basis following the first year. As the current study is evaluating the clinical practices in India, this was a particularly interesting finding within the Vaerenberg et al. (2014) survey.

Similar to Vaerenberg et al. (2014) survey, Jeyaraman (2013) also sent out a survey specifically looking at general cochlear implant practices and habilitation programs, but this survey focused solely on cochlear implant centers within India. The survey was sent to 35 Indian cochlear implant centers and had a 63% response rate. Since the focus was more on habilitation services, the questions mostly implied the practices used for pediatric patients. This survey found that nearly half of the programs advised a program lasting longer than a year while the other half advised a year of habilitation services.

Prior to the implementation of governmental assistance programs for cochlear implant recipients, including the pediatric population, most Indians had to cover the cost of the cochlear implant and the subsequent care. This made cost a major concern and possible deterrent for treatment for significant hearing loss in the country. This may be

one of the main contributing factors as to why the public was slow to adopt cochlear implantation as a common practice in India when looking at the growth since the first availability of these devices in the country (Jeyaraman, 2013). Another known factor was social constraints as many communities were not quick to adapt to the new technology (Kumar & Kameswaran, 2017).

Jeyaraman (2013) reports that one such government assistance program in India covers the funding for the cochlear implant surgery and habilitation program for pediatric patients 12 years of age and younger. Other programs may cover partial cost or have a limit to what services or costs are covered. In the Jeyaraman (2013) survey, they found that the pediatric cochlear implant centers were reporting approximately 52% of the patients were self-funded, 32% were funded by a government assistance program, 11% were funded by nonprofit organizations, and 5% were funded by other charities.

The term habilitation is in reference to the pediatric population where these patients will be acquiring oral-aural language with their cochlear implant. The term rehabilitation is in reference to the adult or at the very least, the post-lingual population where these patients will be aiming to have greater benefit in the already acquired oral-aural cues from an earlier time in the patients' lives. Since the first cochlear implant approval in 1985, candidacy requirements in the U.S. and around the world have expanded to include both the pre and post lingual patients, which in turn also expands the potential habilitation and rehabilitation strategies used in the follow up care of cochlear implant patients (Carlson et al. 2018).

Jeyaraman (2013) also found that in Indian habilitation programs, the professionals involved on the habilitation cochlear implant teams were as follows: audiologists and speech pathologists (43%), special educators (25%), trained non-professionals (19%), specialists with diplomas/ certifications in hearing instruments (9%), social workers (2%), and otolaryngologists (2%). The study also found that 68.2% of the surveyed centers required the pediatric patients to try amplification for 3-6 months before implantation, which is particularly interesting as the recommendations from The Cochlear Implant Group of India were published at this time which suggested that amplification with auditory based intervention had to be implemented for at least 3 months before the decision for surgery (Jeyaraman, 2013; The Cochlear Implant Group of India, 2018). Additionally, many of the centers were developed under the guidance of this group. It is unclear if the remaining 31.8% of the centers required more or less time with alternative amplification prior to cochlear implantation (Jeyaraman, 2013). This survey summarized its findings by emphasizing the need for a standardized service delivery model that would best fit the needs of India. As this does not currently exist, a good starting place may be finding out the common clinical trends currently in practice.

As mentioned above, India is not the only country who lacks true, evidence-based binding requirements for the standardized care of cochlear implants. Virtually all countries regularly fitting cochlear implants have developed groups who make recommendations towards the goal of a standardized care but based on the trends reported in surveys like the Vaerenberg et al. (2014) survey and the Jeyaraman (2013)

survey, these recommendations have not necessarily been implemented in widespread practice. Browning et al. (2020) completed a comprehensive survey to track these trends in the United States. Their study and its questionnaire were based off of the Vaerenberg et al. (2014) survey and also included data collection for areas like clinical setting, bimodal fitting, and specific evaluations used to drive programming and document performance.

Bimodal fitting refers to patients who wear a cochlear implant on one ear and a hearing aid on the opposite ear. Some hearing aids are specifically designed to operate with cochlear implants in terms of inter-ear communications. For example, if a patient wears a ReSound brand hearing aid on one ear and a Cochlear brand cochlear implant on the opposite ear, these devices can be paired and work together for sound processing and streaming. If a patient has a hearing aid not designed for their cochlear implant device, the two devices can still be worn. In this case, the devices must be treated and cared for as two completely independent devices (Wolfe & Schafer, 2014).

Scherf et al. (2014) published an international survey where they collected international fitting data specifically evaluating bimodal fitting practices. They emphasize that bimodal fittings should be considered standard practice since the binaural benefits provided by this type of fitting are well documented in the modern literature. These benefits include but are not limited to improvements in speech perception in noise, improved localization, and improved sound and music quality. In the earlier days of cochlear implantation, a common worry was that having the mismatched technology in a

bimodal fitting could lower overall performance and the performance of the cochlear implant (Scherf et al. 2014). Messersmith, Jorgensen, & Hagg, (2015) quote research suggesting that lowered performance with a bimodal fitting versus the cochlear implant alone is more suggestive of an inappropriate bimodal candidate. This result is more indicative that the patient is a bilateral cochlear implant candidate.

Ching, Incerti, & Hill (2004) disputed this theory when they found significant binaural benefits in their experiments namely in the realms of speech understanding, horizontal localization, and real-life functional performance in patients who were fit bimodally. These benefits were discovered in users who had been wearing both their cochlear implant and hearing aid for more than five years and in new users who had only had their hearing aid for eight weeks prior to testing. Based on the results of this study, they also suggested that bimodal fittings become the standard in situations of unilateral cochlear implantation (Ching et al., 2004).

In the situation where a patient has lower speech perception performance when fit bimodally and a second cochlear implant is not an option, Messersmith et al. (2015) offer some potential solutions for hearing aid programming where the patient may see an improvement. Factors where a patient may not be a bilateral cochlear implant candidate even if their speech perception scores suggest otherwise include but are not limited to health status of the patient, surgical considerations, and cost of a second implant and related services. Rather than forego the hearing aid right away, Messersmith et al. (2015) suggests modified the frequency response of the hearing aid by 1) manipulating gains

across all frequencies, usually the high frequencies or 2) through the use of frequency lowering algorithms provided by the hearing aid manufacturer's software. Caution should be taken on these approaches as research conducted on the outcomes associated with these programming changes have been mixed.

Ultimately, the results in the Messersmith et al. (2015) study found that their bimodal fitting procedure was not a one size fit all solution and called for more complex research on this subject that takes into consideration bilateral cochlear implant candidacy, cochlear dead regions, and neural atrophy following auditory deprivation. Another conflicting finding in the research surrounding bimodal fitting practices is that of the recommended fitting formula. Messersmith et al. (2015) and Yehudai et al. (2013) suggest more emphasis in the low frequencies may improve speech performance for the bimodal patient; however, Siburt and Holmes (2015) surveyed 93 cochlear implant centers and the majority reported using NAL formulas, which instead, increases high frequency gain.

The Scherf et al. (2014) survey investigated common trends in modern bimodal fitting practices internationally. This survey sought answers for seven areas: profile, general information, bimodal counseling, patient feedback, the bimodal fitting process, bimodal evaluation, and the projected bimodal future. 65 clinicians responded to the survey from 12 countries. The results indicated that in the adult unilateral cochlear implant population, 32% were bimodal users compared to 26% in the unilaterally implanted pediatric population. All respondents indicated that they would recommend a

bimodal fitting if the patient was a candidate. For 65% of respondents, the bimodal services were performed at the same facility rather than have the patient have different service providers. There was no general consensus for the bimodal candidacy criteria besides the patient having aidable hearing in the contralateral ear. One common factor that was reported for patients choosing to not go down the bimodal route was the cost of the hearing aid.

The recommendations for when to begin the hearing aid fitting varied amongst the clinicians with 58% recommending fitting the hearing aid at the cochlear implant activation while another 25% recommended that the hearing aid be fitted at least a month after the cochlear implant activation. Another trend included that 77% of clinicians recommended part-time use of the hearing aid compared to 13% who recommended full time use. During the hearing aid fitting appointment, 86% of respondents reported that they would turn off the cochlear implant device. Common hearing aid fitting methods included no gain for the high frequencies, subjective hearing aid balancing, fitting the hearing aid and the cochlear implant independently of one another, and trial and error type approaches. Many clinicians reported that they would leave the hearing aid programming as is before the cochlear implant activation. One important note about this survey is that the data may be skewed since 35% of the respondents were from Belgium (Scherf et al., 2014).

Shapiro and Bradham (2012) credit the success of the cochlear implant user largely to the audiologist MAPping the device. This makes evaluating the practices of

these clinicians even more imperative to the ultimate goal of creating national or even global standardized fitting and follow up practices. The Browning et al. (2020) survey had a 70% response rate after sending their survey to self-identified cochlear implant audiologists across the United States. This study also addressed how national organizations like the American Speech Language Hearing Association and the American Academy of Audiology provide cochlear implant clinical practice recommendations, similar to those provided by The Cochlear Group of India, but again, these are non-binding recommendations and may possibly be lacking true researched evidence to support all of the recommendations (Sorkin et al. 2013).

The Browning et al. (2020) survey collected data for the following areas: work setting, number of pediatric and adult cochlear implants activated by the survey respondent, additional cochlear implant related services offered, which manufacturer is used, the frequency of use of default manufacturer settings for each manufacturer, use of objective measures during programming, use of subjective measures during programming, bimodal fitting practices, and habilitation/ rehabilitation practices. Overall, this survey did not find a correlation between experience and practical application of techniques. This study did find that preference for default manufacturer settings was largely dependent on the manufacturer of the cochlear implant device, similar to the findings in the international survey completed by Vaerenberg et al. (2014).

The Browning et al. (2020) survey also found that in the United States, objective programming practices were practically the same regardless of the age of the patient.

There was a difference in what objective measurers were used: most measured impedances, 42% for adult patients and 62% for pediatric patients regularly measured electrically evoked compound action potentials (eCAP), and less than 20% measured electrically evoked auditory brainstem response (eABR), electrically-evoked stapedial reflex threshold (eSRT), or vestibular assessments. The pros and cons of the different objective tests may influence why some are used over others. For example, Kosaner, Spitzer, Bayguzina, Gultekin, & Behar (2018) found that eSRT takes four times as long to measure in the appointment than eCAP; however, Walkowiak et al. (2011) reports that for predicting MCL, eSRT outperforms eCAP. For most clinicians time is extremely valuable and must be considered along with best patient practices, which may account for the disparity in clinical practices found in the Browning et al. (2020) survey results.

As far as subjective measurements, this survey found that practices may be dependent on the selected manufacturer. T levels were almost always measured for Cochlear devices but decreased in usage for Med-El and Advanced Bionics as the software for these two manufacturers have the capability of predicting these values based on other measurements. Other subjective measure findings included that 56% of respondents reported regularly using loudness balancing techniques and only 16% regularly measured pitch ranking between electrodes. It is interesting to note that Saleh et al. (2013) reports that the method of pitch ranking electrodes is known to improve speech perception scores, yet this is a measure infrequently evaluated by the clinicians responding to this survey.

The large majority, specifically 75% of the respondents, tend to recommend bimodal fitting for their cochlear implant patients. An interesting finding is that many participants are more likely to recommend a bimodal fitting after the patient has worn only the cochlear implant for a period of time. This differs from the research done by (Scherf et al. 2014), who encourages minimizing the risk of auditory deprivation for both ears. This again emphasizes the point that although trends and recommendations exist, they may not align with the modern research for true evidence-based practice. The respondents also clarified the situations where they would likely not recommend a bimodal fitting. These included if the patient was a binaural cochlear implant candidate, if the patient was not motivated for contralateral amplification, and if auditory performance decreased with auditory stimulation on the contralateral side (Browning et al., 2020).

For fitting a hearing aid for bimodal listening, the fitting formula typically used varied amongst participants. 40% reported that they preferred the National Acoustic Laboratories (NAL) fitting formulas, 25% reported preference for Desired Sensation Level (DSL) or the manufacturer proprietary fitting formula. Please note that similar to research (Ching et al. 2010) suggesting DSL fitting formula usage for the pediatric hearing aid population, United States cochlear implant audiologists tend to prefer this fitting formula for their pediatric cochlear implant patients as well. As far as preferred hearing aid manufacturer for a bimodal fitting, 81% of audiologists prefer recommending

the hearing aid manufacturer that has partnered with the cochlear implant manufacturer for inter-device communication possibilities (Browning et al., 2020).

One of the only findings where practices differed between the adult cochlear implant population and the pediatric population was in terms of habilitation/ rehabilitation recommendations. 100% of respondents recommend speech therapy for pediatric patients compared to the mere 26% who recommend speech therapy for adults (Browning et al., 2020). This may simply be due to the fact that it is assumed that most of the pediatric population receive a cochlear implant for language development while the majority of the adult population is assumed to have developed language prior to cochlear implantation. On the reverse, 52% of United States participating audiologists recommend computer based listening programs for their adult patients compared to only 30% making the same recommendation for their pediatric patients (Browning et al., 2020).

While discussing the results, Browning et al. (2020), makes an excellent observation that in the United States, manufacturer defaults must be approved prior to using them, especially for the pediatric population. This means that there may be different defaults and settings available in other countries, like India. Additionally, there are four cochlear implant manufacturers available in India compared to the United States, the fourth addition being Digisonic (Vaerenberg et al. 2014).

Another area where clinical practice in the Browning et al. (2020) study differs from the current research suggestions include the use of vestibular objective measures.

Bittar, Sato, Ribeiro, & Tsuji (2017) reports the incidence of dizziness following the cochlear implant surgery to be upwards of 20%. Despite this high incidence, United States audiologists are reporting infrequent vestibular assessments for these patients in everyday practice. It is also interesting to note the large number of clinicians who use any hearing aid formula besides an NAL fitting formula as Ching et al. (2004) is still to this day one of the only studies providing true evidence-based recommendations for bimodal fitting. This study specifically outlines the fitting protocols used during experimentation and gave direct measures of binaural benefits and increased speech perception performance while matching NAL targets.

The Cochlear Implant Group of India (2018) sets forth the following audiological testing and results recommendations that will be explored in this survey and discussion. This first section will explore the tests and results which the Cochlear Implant Group of India lists as being mandatory in their recommendations. In regard to both objective and behavioral testing, severity of hearing loss which would make a patient a candidate for cochlear implantation includes severe to profound hearing loss, moderately severe to profound hearing loss, bilateral moderately severe to profound hearing loss, and these hearing losses should be accompanied by a Type A or As tympanogram with absent reflexes. These hearing losses should present on one or more of the following behavioral tests: behavioral observation, visual reinforcement audiometry, sound field testing, pure tone audiometry, and immittance test battery for the tympanogram and reflexes. When behavioral testing is not an option or results are unreliable, an auditory brainstem

response (ABR) test using clicks with rarefaction and condensation as well as 500 Hz and 1000 Hz tone bursts should show absent bilateral wave V at 90 dB nHL. For otoacoustic emissions (OAEs), including screening and diagnostic OAEs, these OAEs should be absent and repeated after 15 days for infants. Finally, if the above criteria are met, the patient should receive little or no benefit when fitted with hearing aids on the aided audiogram, speech perception tests, and auditory/speech therapy progress reports after at least 3 months of wearing the hearing aids.

The next test is instead listed by The Cochlear Group of India as recommended instead of mandatory recommendations. Use of the auditory steady state response testing (ASSR) is indicated when no wave V is present on the ABR. Finally, the group lists the next set of tests as optional in their recommendations. Trans tympanic electrically evoked brainstem response test, cortical testing, late latency response (LLR) test, and the middle latency response (MLR) test may be used when there is indication that cochlear nerve hypoplasia or aplasia or auditory neuropathy spectrum disorder (ANSD). Speech and language evaluations are also optional in the group's recommendations for standard pre-operative cochlear implant practices.

For post-operative care as it relates to the relevant cochlear implant programming and habilitation/ rehabilitation to this study, for both pediatrics and adults, The Cochlear Implant Group has listed that it is mandatory to obtain a cochlear implant aided audiogram to ensure proper MAPping and that weekly habilitation/ rehabilitation plans must be enacted. For adults, the aided testing must also include speech perception testing.

Under recommended practices, the group lists that standardized speech perception tests must be developed for all regional languages, which implies that these tests do not currently exist (The Cochlear Implant Group of India, 2018).

Interestingly, the above information from the recommendations from The Cochlear Implant Group of India is as comprehensive as the recommendations are in relation to audiologic services that will be covered in the present survey. The recommendations do not list any more specifics about cochlear implant MAPping, amount of follow up adjustments and testing, or methods relating to the audiologic services during the follow up appointments. This continues to leave an absence in the knowledge of clinical application and methodology of cochlear implant fitting and follow up practices.

Appendix II: A Survey of Cochlear Implant Clinical Protocols

Hello: We appreciate your willingness to participate in this survey about cochlear implant clinical protocols in your clinic. This survey is being administered by researchers from James Madison University. Your participation in this survey is completely voluntary and your answers will be completely anonymous. The survey is expected to take approximately 30 minutes of your time. When considering the following questions, Please think of your cochlear implant programming practices in general and what testing and programming you usually perform.

Definitions: Adult: Patients age 18 years and older; Pediatric: Patients below 18 years of age; Mapping visits: Mapping visits refer to the visits when at least a new MAP is measured, and the sound processor is configured and programmed (with either an old or new MAP).

Please answer the following questions about your own clinical setting

Please identify your role in the cochlear implant team:

1. Audiologist

2. Otolaryngologist (ENT specialist)

3. Other professional

Since you began programming cochlear implants, about how many ADULT cochlear implants have you, personally, activated?

Since you began programming cochlear implants, about how many PEDIATRIC cochlear implants have you, personally, activated?

What best describes your clinical setting? (Select all that apply)

1. Privately owned Audiology clinic
2. Medical College Hospital
3. Audiology clinic at an institute offering degree program/s in Audiology
4. Audiologist working in an Otolaryngologist's practice
5. Other setting

Types of Services provided at your workplace: Please indicate which services are provided at the facility in which you work.

Medical/ENT

1. Yes
2. Referred elsewhere

Surgical (cochlear implantation)

1. Yes

2. Referred elsewhere

Auditory rehabilitation / Speech Language Therapy

1. Yes

2. Referred elsewhere

Hearing aid fitting

1. Yes

2. Referred elsewhere

Vestibular assessment

1. Yes

2. Referred elsewhere

Psychological evaluation

1. Yes

2. Referred elsewhere

Other (please explain)

How is the cost of cochlear implantation covered at your clinic/institution/hospital? (Select all that apply)

1. Patient pays the cost of device and surgery from their own pocket

2. A private third party (health insurance) pays majority of the cost

3. The patient receives the cochlear implant free (or subsidized) cost through a Government of India or State Government scheme.

4. Other means (e.g. international aid groups)

5. Unknown

If your clinic/institution/hospital participates in a Government of India or state government scheme, approximately what proportion of patients receive free/subsidized cochlear implants?

1. All of our patients receive CI through ADIP scheme
2. Between 76% - 100% of patients
3. Between 51% - 75% of patients
4. Between 25% - 50% of patients
5. Less than 25% of patients

Please answer the following questions about the process of selecting cochlear implants for your patients

How is the decision made about which Cochlear Implant manufacturer to use?

	Always	Most of the time	About half the time	Sometimes	Never	N/A
Surgeon preference	❑	❑	❑	❑	❑	❑
Audiologist recommendation	❑	❑	❑	❑	❑	❑
Patient preference	❑	❑	❑	❑	❑	❑
Only one CI manufacturer available at my clinic	❑	❑	❑	❑	❑	❑

Which Cochlear implant manufacturers do you work with in your clinic?

1. Cochlear

2. Advanced Bionics

3. MED-EL

4. Digisonic

5. Other indigenously developed cochlear implants (please elaborate in the text box below)

Please provide any additional information about other cochlear implant manufacturers used in your clinic (manufacturer name)

Pre-implantation counselling: which clinical professionals are involved in counselling the patient and their family prior to the cochlear implantation? (check all that apply)

1. ENT surgeon
2. Audiologist
3. Psychologist
4. Speech Language Pathologist
5. Other professional

How frequently are patients implanted off-label? (Off-label refers to a case where the patient does not satisfy all the CI candidacy criteria, but the surgeon feels a medical necessity to perform cochlear implantation) Please enter your answer in the text box below (e.g. less than xx% cases)

The following questions are about mapping Cochlear devices.

Do you work with Cochlear devices?

1. Yes

2. No

Which of the following services you provide for Cochlear patients?

1. Pre-implantation counseling

2. Mapping

3. Troubleshooting

4. Follow up mapping / fine tuning

5. Aural rehabilitation

6. Other _____

When mapping Cochlear devices how often do you select the default settings for the following parameters?

	I always use default setting	Almost Always	Half the Time	Sometimes	I never use default setting
Number of active channels/electrodes	❑	❑	❑	❑	❑
Gain (default=0)	❑	❑	❑	❑	❑

Processing Strategy (default is ACE)	❑	❑	❑	❑	❑
Stimulation Mode (default is MP1+2)	❑	❑	❑	❑	❑
Channel Rate (default 900)	❑	❑	❑	❑	❑
Maxima (default is 8)	❑	❑	❑	❑	❑
Pulse Width (25)	❑	❑	❑	❑	❑
Volume Adjustment (20% of Dynamic Range)	❑	❑	❑	❑	❑
Analysis of C-SPL (65)	❑	❑	❑	❑	❑

Analysis of T-SPL (25)	❑	❑	❑	❑	❑
Loudness Growth (20)	❑	❑	❑	❑	❑
Frequency Table	❑	❑	❑	❑	❑
Power (auto)	❑	❑	❑	❑	❑
Volume and Sensitivity (Volume is 6, sensitivity is 12)	❑	❑	❑	❑	❑
Program Settings (default is SCAN)	❑	❑	❑	❑	❑

If you do not use the default settings for any of the parameters, what value (or range of values) you typically use? Please enter in the text boxes below. If it is not applicable, leave the boxes empty and move to the next question.

	Enter alternate values in the boxes below.	What is your reason for using alternate values?
Number of active channels/electrodes	❑	❑
Gain (default=0)	❑	❑
Processing Strategy (default is ACE)	❑	❑
Stimulation Mode (default is MP1+2)	❑	❑
Channel Rate (default 900)	❑	❑

Maxima (default is 8)	❑	❑
Pulse Width (25)	❑	❑
Volume Adjustment (20% of Dynamic Range)	❑	❑
Analysis of C-SPL (65)	❑	❑
Analysis of T-SPL (25)	❑	❑
Loudness Growth (20)	❑	❑
Frequency Table	❑	❑
Power (auto)	❑	❑

Volume and Sensitivity (Volume is 6, sensitivity is 12)	❑	❑
Program Settings (default is SCAN)	❑	❑

The following questions are about mapping Advanced Bionics devices.

Do you map Advanced Bionics devices?

1. Yes
2. No

Which of the following services do you provide for Advanced Bionics patients?

1. Pre-implant counseling
2. Mapping
3. Troubleshooting
4. Follow up/fine tuning
5. Aural rehabilitation

6. Other

When mapping Advanced Bionics, what percentage of the time do you use HiRes Optima P vs. HiRes Optima S strategies?

	Enter your answer in % below. Both should add up to 100%.
HiRes Optima P	❑
HiRes Optima S	❑

When mapping Advanced Bionics devices how often do you select the default settings for the following parameters?

	I always use default settings	Almost always	Half the time	Sometimes	I never use default settings
Number of active channels/electrodes	❑	❑	❑	❑	❑
Processing Strategy (default is HiRes-P)	❑	❑	❑	❑	❑
Clearvoice (default is “Off”)	❑	❑	❑	❑	❑
Pulse Width (default is APW I)	❑	❑	❑	❑	❑
T Level (default is 10% of M)	❑	❑	❑	❑	❑
Gain (default is 0 for all channels)	❑	❑	❑	❑	❑

Volume Max (default is 20%)	❑	❑	❑	❑	❑
Volume Min (default is 50 %)	❑	❑	❑	❑	❑
Sensitivity (default is 0 dB)	❑	❑	❑	❑	❑
IDR (default is 60 dB)	❑	❑	❑	❑	❑
Audio Mixing (default is 50/50-Mic/Aux)	❑	❑	❑	❑	❑
Mic Mode (default is Omnidirectional)	❑	❑	❑	❑	❑
Filter (default is Extended Low)	❑	❑	❑	❑	❑
AGC (default is 2- Dual Loop)	❑	❑	❑	❑	❑

If you do not use the default settings for any of the parameters, what value (or range of values) you typically use? Please enter in the text boxes below. If it is not applicable, leave the boxes empty and move to the next question.

	Enter alternate values in the boxes below.	What is your reason for using alternate values?
Number of active channels/electrodes	❑	❑
Processing Strategy (default is HiRes-P)	❑	❑
Clearvoice (default is “Off”)	❑	❑

Pulse Width (default is APW I)	❑	❑
T Level (default is 10% of M)	❑	❑
Gain (default is 0 for all channels)	❑	❑
Volume Max (default is 20%)	❑	❑
Volume Min (default is 50 %)	❑	❑
Sensitivity (default is 0 dB)	❑	❑
IDR (default is 60 dB)	❑	❑
Audio Mixing (default is 50/50-Mic/Aux)	❑	❑

Mic Mode (default is Omnidirectional)	❑	❑
Filter (default is Extended Low)	❑	❑
AGC (default is 2- Dual Loop)	❑	❑

The following questions are about mapping Med-EL devices.

Do you work with Med-EL devices?

1. Yes

2. No

Which of the following services do you provide for Med-EL patients?

1. Pre-implantation counseling

2. Mapping

3. Troubleshooting

4. Follow up / fine tuning

5. Aural Rehabilitation

6. Other

When mapping Med-EL devices how often do you select the default settings for the following parameters?

	I always use default settings	Almost always	Half the time	Sometimes	I never use default settings
No. of active channels /electrodes (default is 12)	❑	❑	❑	❑	❑
Pulse duration (default is 7.08 microseconds)	❑	❑	❑	❑	❑

Processing Strategy (default is FS4)	❑	❑	❑	❑	❑
Frequency bands (default is logarithmic FS—100 to 8500 Hz)	❑	❑	❑	❑	❑
AGC Compression Ratio (default is 3:1)	❑	❑	❑	❑	❑
AGC sensitivity (default is 75%)	❑	❑	❑	❑	❑
MapLaw (default is logarithmic with compression=500)	❑	❑	❑	❑	❑
Lock THR Charge (default is 10% of MCL)	❑	❑	❑	❑	❑
Volume Mode (default is IBK)	❑	❑	❑	❑	❑

Microphone Directionality (default is “Natural”)	❑	❑	❑	❑	❑
Wind noise reduction (default is “Mild”)	❑	❑	❑	❑	❑

If you do not use the default settings for any of the parameters, what value (or range of values) you typically use? Please enter in the text boxes below. If it is not applicable, leave the boxes empty and move to the next question.

	Enter alternate values in the boxes below.	What is your reason for using alternate values?

No. of active channels /electrodes (default is 12)	❑	❑
Pulse duration (default is 7.08 microseconds)	❑	❑
Processing Strategy (default is FS4)	❑	❑
Frequency bands (default is logarithmic FS—100 to 8500 Hz)	❑	❑
AGC Compression Ratio (default is 3:1)	❑	❑
AGC sensitivity (default is 75%)	❑	❑
MapLaw (default is logarithmic with compression=500)	❑	❑
Lock THR Charge (default is 10% of MCL)	❑	❑

Volume Mode (default is IBK)	❑	❑
Microphone Directionality (default is “Natural”)	❑	❑
Wind noise reduction (default is “Mild”)	❑	❑

Regardless of the cochlear implant manufacturer, indicate how often you use the following objective measurements.

PEDIATRIC Patients

	Always	Almost always	Half the time	Sometimes	Never

At mapping visits I measure electrode impedance in pediatric patients	❑	❑	❑	❑	❑
ECAP (including NRT, NRI, ART) in pediatric patients	❑	❑	❑	❑	❑
e-ABR in pediatric patients	❑	❑	❑	❑	❑
ESRT (stapedial reflex) in pediatric patients	❑	❑	❑	❑	❑
Vestibular tests (e.g. ENG, VNG)	❑	❑	❑	❑	❑

ADULT Patients

	Always	Almost always	Half the time	Sometimes	Never
At mapping visits I measure electrode impedance in adult patients	❑	❑	❑	❑	❑
ECAP (including NRT, NRI, ART) in adult patients	❑	❑	❑	❑	❑
e-ABR in adult patients	❑	❑	❑	❑	❑
ESRT (stapedial reflex) in adult patients	❑	❑	❑	❑	❑
Vestibular tests (e.g. ENG, VNG)	❑	❑	❑	❑	❑

Bimodal fitting (Hearing aid in the non implanted ear)

How often do you recommend a hearing aid for the non-implanted ear in adult patients?

1. Always
2. Most of the time
3. About half the time
4. Sometimes
5. Never

How often do you recommend a hearing aid for the non-implanted ear in pediatric patients?

1. Always
2. Most of the time
3. About half the time
4. Sometimes

5. Never

When fitting hearing aid on the non-implanted side, which prescriptive formula/e do you use? (select all that apply)

1. Manufacturer's proprietary formula

2. NAL

3. DSL

4. My own gain prescription

Aural Rehabilitation

How often do you recommend the following for pediatric CI patients?

	Always	Most of the time	About half the time	Once in a while	Never
Speech Thearpy	❑	❑	❑	❑	❑

Computerized Auditory training	❑	❑	❑	❑	❑

How often do you recommend the following for adult CI patients?

	Always	Most of the time	About half the time	Once in a while	Never
Speech Thearpy	❑	❑	❑	❑	❑
Computerized Auditory training	❑	❑	❑	❑	❑

We are almost done! Would you like to provide any additional comments? Please use the box below. Thank you!

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