

# Long-term cost implications for cochlear implant recipients

by  
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## **Declaration**

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## ABSTRACT

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Cochlear implantation is an expensive but cost-effective intervention which must be used for life. It can provide individuals with severe-to-profound hearing loss improved sound perception in comparison to that obtained using hearing aids. In South Africa implants are not state subsidised, and related costs need to be covered by implant recipients. Cochlear implant teams thus need to ensure that individuals, who are selected, will benefit from the device and will be able to use it for their lifetime. Implantees should know the immediate and potential future costs involved, to be able to decide on its affordability.

The primary aim of this study was to determine the immediate and long-term costs of cochlear implantation. One hundred and fifty four implant recipients from the Tygerberg Hospital-University of Stellenbosch Cochlear Implant Unit in Cape Town, South Africa were surveyed. Costs were categorized according to the time period post implantation and were converted to Constant Rands (June 2010) using the Consumer Price Index to allow for comparison in real terms over time.

In the first 10 years of implantation the average estimated costs incurred by adult implantees totalled R379 626, and children R455 225. The findings showed that the initial purchase of the implant system was the most substantial cost involved (currently R221 000). Upgrading the speech processor, which on the average took place every 7 years, was the second highest cost subjects encountered (currently R85 000). The cost of spares (on average R276 per year) and repairs (R3000 per repair) increased with duration of use. Battery costs ranged between R1200 and R3372 per year and insurance costs averaged R4040 per year.

Most appointments took place in the first two years following implantation. Average travel costs during the first two years were R1024 for those within 50km of the implant unit and R8645 for those living more than 1000km away. Accommodation costs for non-local recipients, peaked during this period (on average R3390). Additional rehabilitation services for paediatric implantees cost an estimated R37 159 in the first five years after implantation. Subjects advised potential implantees to save, budget and plan for the high costs involved in implantation, as well as to join a medical aid which could assist with the costs involved.

The findings of the study hold great relevance for both implantees and cochlear implant professionals. Careful consideration of the financial implications of cochlear implantation is critically important in the South African context to ensure that recipients are successful long-term cochlear implant users. Although the actual costs in the study were related to the one implant system used at Tygerberg Hospital-University of Stellenbosch Cochlear Implant Unit, it is believed that the types and amounts of costs involved hold relevance for all individuals implanted in South Africa.

## OPSOMMING

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Kogeleëre inplantering is 'n duur maar koste-effektiewe prosedure wat lewenslank gebruik moet word. Dit verskaf aan individue met erge-tot-uitermatige gehoorverlies verbeterde klankpersepsie in vergelyking met dié wat gehoorapparate gebruik. In Suid Afrika word kogeleëre inplantings nie deur die staat gesubsidieer nie en koste moet deur die inplantgebruiker verhaal word. Kogeleëre inplantingspanne moet gevolglik verseker dat individue wat geselekteer word daarby baat sal vind en lewenslank sal kan gebruik. Inplantgebruikers moet bewus wees van die onmiddelijke, sowel as langtermyn onkoste.

Die primêre doel van hierdie studie was om die onmiddelijke en langtermyn onkoste van inplanterings te bepaal. Een honderd vier en vyftig inplantgebruikers van die Tygerberg Hospitaal-Universiteit Stellenbosch Kogeleëre Inplantingseenheid in Kaapstad, Suid Afrika is gebruik vir die studie. Onkoste was gekategoriseer ten opsigte van die periode van tyd post-inplantering en dit is omgeskakel na konstante Randwaarde (Junie 2010) deur die Gebruikers Prys Indeks te gebruik sodat vergelykings gemaak kon word in reële terme oor tyd.

Gedurende die eerste 10 jaar na inplantering was die geskatte onkoste by volwasse inplantgebruikers R379 626 en by die pediatriese groep was dit R455 225. Bevindings het aangedui dat die aanvanklike aankoop van die inplantsisteem die grootste onkoste behels het (huidig R221 000). Opgradering van die prosesseerder, gemiddeld elke 7 jaar, was die tweede hoogste onkoste, naamlik R85 000. Die gemiddelde koste van spaaronderdele was R276 per jaar. Herstelkoste het R3000 per herstelling beloop. Koste van spaaronderdele en herstelkoste het met duur van gebruik vermeerder. Batteryonkoste het gewissel tussen R1200 en R3372 per jaar. Onkoste van jaarlikse versekering was gemiddeld R4040.

Meeste afsprake het gedurende die eerste twee jaar plaasgevind. Vervoerontkoste gedurende hierdie periode was R1024 vir die wat binne 50km woon en R8645 vir dié meer as 'n 1000km ver. Akkommodasie koste het 'n piek gedurende hierdie periode bereik (gemiddeld R3390). Addisionele rehabilitasie dienste vir pediatriese inplantgebruikers was gemiddeld R37159 gedurende die eerste vyf jaar. Die proefpersone het aanbeveel dat potensiële inplantgebruikers moet spaar, begroot en beplan vir die hoë onkoste en is aanbeveel om aan te sluit by 'n mediese fonds.

Die bevindinge van die studie is van belang vir beide ontvangers sowel as inplantingspanne. Bewusmaking van die finansiële implikasies van kogleêre inplantering is van kritiese belang om suksesvolle langtermyn gebruik te verseker. Alhoewel die werklike onkoste in die studie van toepassing is op een inplanting sisteem wat by Tygerberg Hospitaal-Universiteit Stellenbosch Kogleêre Inplantingseenheid gebruik word, kan dit aangeneem word dat die tipes en hoeveelheid onkoste van toepassing is op alle individue in Suid Afrika wat kogleêre inplantings ontvang.

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## INTRODUCTION

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Surgical rehabilitation via cochlear implantation has become almost a routine procedure in cases of severe-to-profound hearing loss where acoustic stimulation provided by hearing aids is not effective (Tange, Grolman & Dreschler, 2008). As a result of the improved sound perception, which cochlear implants can provide individuals, the expected hearing and speech outcomes for adults and children with severe-to-profound hearing loss have changed radically since their inception in the late 1980's (Niparko, 2009). Cochlear implants have become the treatment of choice for many individuals with severe or profound sensorineural hearing loss (Carpenter, 2009).

Cochlear implantation is an expensive intervention. While proven to be cost effective (O'Neill, 2002; Sach, 2002) and routinely made available in some countries to all, who meet the audiological, radiological and medical selection criteria, it is not easily available to patients in developing countries. To date 125 000 individuals have received cochlear implants worldwide, while potentially millions could benefit from such a device. The devices are sophisticated and provide good results for many patients, but they are also expensive retailing in the \$30 000 range. There are also the added costs of hospital admission, surgical fees and post-implant rehabilitation. These expenses keep cochlear implants out of reach for millions of individuals with profound hearing loss in poor and emerging countries (Glasscock, 2011). Financial constraints influence the accessibility of cochlear implants to severe-to-profoundly deaf individuals in developing countries of which South Africa is one.

In an attempt to better understand the economic constraints of cochlear implantation in South Africa, the present study investigated the costs of cochlear implantation, i.e. overall and specific costs, which implantees themselves, or the families of implantees, encountered as a result of receiving a cochlear implant. The study considered costs incurred over the duration of an individual's use of their implant, in an attempt to increase the knowledge of the long-term costs involved in implantation of children and adults.

The following presentation includes a glossary of terms used, a review of the literature and previous relevant research (Chapter 1), a summary of the methodology used in the study (Chapter 2), presentation and discussion of the findings (Chapter 3), a summary of the results, a critique of the study, clinical applications and suggestions for future research

(Chapter 4). References for all material cited in the text, as well as appendices providing supplementary information relevant to the study, are included at the end.

## **GLOSSARY OF TERMS**

**Bilateral cochlear implantation:** The use of two cochlear implants, one in each ear. The ears may be implanted in a one-stage (simultaneous) or a two-stage (sequential) surgical procedure (Tange et al., 2008).

**Bimodal stimulation:** The use of a conventional hearing aid in the non-implanted ear (Tange et al., 2008).

**Cost-effectiveness:** A method of evaluating the outcomes and costs of a medical technology designed to improve health, by considering the added value acquired in return for the added expense incurred (Palmer, Niparko, Wyatt, Rothman & De Lissovoy, 1997).

**Cost per QALY:** The incremental cost per quality adjusted life-year; an expression of the cost-utility relationship (Palmer et al., 1997).

**Cost-utility:** A form of cost-effectiveness analysis that quantifies outcome in terms of generic changes in life expectancy and health related quality of life. The unit of outcome is quality-adjusted life years (QALYs) (Lin, Niparko & Francis, 2009).

**Health utility:** A method of quantifying health related quality of life wherein health utility scores represent a valuation of one's health status expressed on a scale from 0.00 (death) to 1.00 (perfect health) (Lin et al., 2009). Health utility is a concept based on economic theory (Palmer et al., 1997).

**Localization:** The ability to determine the direction where a sound is coming from (Sammeth, 2007).

**MAPping:** The process of determining customised psychophysical data which translates acoustic information into electrical stimulation. The resulting MAP is stored in a program in the recipient's speech processor (Nucleus® Technical Manual, 2002).

**Open-set speech recognition:** The amount of speech an individual can identify, when assessed using meaningful speech material without providing a list of alternatives, contextual cues or other information to help identify the material (Dowell, & Cowan, 1997).

**Quality adjusted life-years (QALYs):** The number of years affected by a health technology, adjusted for the health-related quality of life experienced during those years using health utility (Palmer et al., 1997).

## 1. LITERATURE REVIEW

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### 1.1. A COCHLEAR IMPLANT

A cochlear implant is an electronic prosthetic device which is surgically placed in the inner ear and under the skin behind the ear in order to provide useful sound perception via electrical stimulation of the auditory nerve (American Academy of Audiology, 1995). The device is intended to provide some hearing sensation to severe-to-profoundly deaf adults and children. Since the introduction of multi-channel cochlear implants in 1984 (Eisen, 2009), these devices have revolutionised the potential hearing and speech outcomes of individuals with a severe-to-profound hearing loss. Virtually every aspect of auditory rehabilitation has been reinvented as a result (Niparko, 2009).

Over the past three decades there has been significant progress in both the design and performance of cochlear implants. They are now widely regarded as one of the greatest advances of modern medicine (Wilson & Dorman, 2009). In the early 1980's, when cochlear implants were introduced, individuals were not considered candidates for such intervention unless they had total or near total sensorineural hearing loss (Niparko, Lingua & Carpenter, 2009). Over time improved technology, improved surgical techniques and proven safety and efficacy of the intervention have brought about a relaxation in the selection criteria for candidates. Individuals with more residual hearing are now eligible for consideration for cochlear implantation. Cochlear implants have changed from being a last resort to being the treatment of choice for many individuals with severe or profound sensorineural hearing loss (Carpenter, 2009).

Cochlear implantation has been strongly associated with improved auditory performance and speech perception for adults and children. Its benefits range from awareness of sound to open set speech recognition, from telephone use to music appreciation and, for many recipients, improved speech perception even in background noise. The benefits extend further to improvements in education, occupation and quality of life (Carpenter, 2009). Studies have shown that children with implants have greatly improved access to auditory information



and can acquire spoken language skills (Fitzpatrick, Duriex-Smith, Angus, Olds, Schramm & Whittingham, 2006).

## **1.2. COST EFFECTIVENESS OF COCHLEAR IMPLANTATION**

Cochlear implantation is considered an expensive intervention. However, a systematic review of the economic evaluations and cost analyses of cochlear implantation published during the period 1995-2001, which included 21 studies of a possible 48, concluded that, in comparison to other health interventions, cochlear implantation is cost-effective regardless of age at implantation (Sach, 2002). Although the studies were conducted in different countries, by different researchers, using a variety of assumptions, all these studies, which considered unilateral cochlear implantation, found cochlear implantation to be a cost effective intervention for profoundly deaf children and adults (O'Neill, 2002).

Cost-effectiveness is a way of evaluating the outcomes and costs of a medical technology designed to improve health (Palmer et al., 1997). The effectiveness of cochlear implants can be measured in terms of health-related quality of life. Cost-utility, a variant of cost-effectiveness evaluation, is the analysis of choice when considering cochlear implantation. It allows for a wide range of benefits attributable to the cochlear implant to be added into the calculation, especially taking into account health-related quality of life. By considering the number of years, which are affected by a health technology, and adjusting this for health-related quality of life, which is experienced during those years using health utility (the value an individual attributes to a state of health), quality adjusted life years (QALYs) result as the measure of effectiveness (Palmer et al., 1997). Cost per QALY can then be determined for different interventions, which allows the comparison of the cost-effectiveness of different health technologies.

As early as 1995 cochlear implants were shown to rate very favourably within the cost-effectiveness range accepted by the American medical system (Wyatt, Niparko, Rothman, De Lissovoy, 1995). In a comparison of fourteen health technologies, cochlear implantation rated fourth most cost-effective, following neonatal intensive care (for babies 1-1.5kg), coronary artery bypass grafting and coronary angioplasty. Interventions, which had a higher cost per QALY, but which were still considered within acceptable ranges, included cardiac transplants,

knee replacements and haemodialysis. The available studies of the cost-utility of cochlear implants consistently indicate that the multi-channel cochlear implant occupies a highly favourable position in terms of its cost effectiveness relative to other surgical and medical interventions employed within the United States (Lin et al., 2009). In an Australian study conducted in 1995 (Health Economics Unit, 1995) cochlear implantation was again shown to be an effective technology. It offered good value for money when compared to a range of other medical procedures, which resources were being committed to. Neonatal intensive care for babies (1-1.5 kg) was again the most cost effective and hospital dialysis had the greatest cost per QALY. A study conducted in the United States in 1997 (Palmer et al., 1997) showed even more favourable cost per QALY results for cochlear implants than those previously reported for adults in Australia, the United Kingdom and the United States of America. The authors indicated that both their study, and previously published studies on multi-channel cochlear implants, demonstrated cost-utility ratios well within the accepted range of cost-utility for health technologies in each country. Paediatric cochlear implantation has been associated with cost savings in education, which offset some of the increased costs in the health sector (Barton, Stacey, Fortnum, & Summerfield, 2006a).

While unilateral cochlear implantation has shown to be cost effective, studies concerning the cost effectiveness of bilateral implantation are currently also taking place. In a study, which investigated bilateral cochlear implantation, Summerfield, Marshall, Barton and Bloor (2002) concluded that, although a second implant is likely to be less cost effective than the first, it could still be cost competitive compared with some other interventions routinely provided in the United States of America. More recently Bichey and Miyamoto (2008) showed that, in addition to the improvement noted in quality of life, there was a favourable cost-utility ratio after bilateral cochlear implantation in patients with profound hearing loss.

### **1.3. COST IMPLICATIONS OF COCHLEAR IMPLANTATION**

Cochlear implantation is a highly specialised area of life-long intervention. Summerfield (2002) indicated that the expectation is that the recipients will continue to benefit from an implant for twenty to thirty years with many recipients, especially children, being committed to using an implant for substantially longer than this. Obtaining a cochlear implant commits an

individual to a life time use of such a device in order to hear. For the person to be able to continue accessing the technology for the rest of his or her life many long term costs must be borne. While it is relatively easy to cost the immediate implementation of the technology, calculating the long-term costs can prove more challenging. The long term costs of cochlear implantation only became the focus of interest some time after its implementation as the long-term requirements for technical support and its funding, started emerging only as implant programmes came to maturity (Archbold, 2002).

There are many costs, over and above that of the implant system itself, involved in the process of cochlear implantation. For the purposes of economic evaluation the implementation process is customarily divided into four phases: assessment, implantation, rehabilitation and maintenance (Hutton & Politi, 1995). Each phase has its associated costs. Before the process can begin, individuals need to access a specialist facility where cochlear implantation is performed. As the service is highly specialised, it is only available in certain centres, and potential implantees may have to travel considerable distances in order to access an appropriate facility. This is especially true in developing countries.

The candidacy process starts with audiologic and medical assessment. The latter includes an otologic and radiologic assessment (high resolution computerised tomography (CT) of the temporal bones combined with magnetic resonance (MR) scans of the internal auditory canal and labyrinth). The assessment process stops at the audiologic or medical evaluations, if the findings contraindicate implantation (Niparko et al., 2009).

The implantation phase covers the operation to surgically insert the electrode array, and the post-operative care required. The operation requires hospitalisation, which may be extended by major or minor complications of surgery (Tucci & Pilkington, 2009). The timing of the device activation varies between clinics, from 10 days to 6 weeks after surgery (Rance & Dowell, 1997). Generally it occurs 2-3 weeks post-operatively, once the scalp has healed (Clark, Pyman & Webb, 1997).

Following the activation of the device, the rehabilitation phase begins with the programming of the device, followed by regular visits for aural rehabilitation and, for children, speech and language therapy and other therapies, which may be indicated. Despite advances in technology and improved outcomes, rehabilitation remains a critical and integral component

of successful cochlear implantation. Although cochlear implants have become more sophisticated, they cannot produce auditory sensations that are identical to those which occur in a normal auditory system. Individuals using cochlear implants experience a unique auditory signal that they need to learn to interpret, and aural rehabilitation is thus an integral component of the total rehabilitation process (Ross, 2009). Rehabilitation continues until the optimal potential of an implantee has been reached. While rehabilitation post implantation is important for all those, who receive a cochlear implant, children necessitate additional considerations. They require ongoing support throughout their schooling and later studying. Thus the social environment of the family and available education support are critical factors in ensuring that the implanted child derives maximum benefit (Hutton & Politi, 1995).

The maintenance phase, with its associated everyday running costs of the device and regular maintenance of it, will continue throughout the implantee's lifetime. Improvements in technology continue to be made and the maintenance phase will also involve a degree of replacement and upgrading of processors over time (Hutton & Politi, 1995). Upgrading the externally worn speech processor allows implantees access to improved technology and also ensures that they are able to continue using their implant even after older speech processors become obsolete. The rehabilitation and maintenance phases are of particular importance, when considering long-term use and benefit from cochlear implantation.

#### **1.4. CANDIDATE SELECTION**

As implantation is a highly invasive and permanent intervention, the potential for good long-term hearing and speech outcomes, and for long-term benefit and use, must be considered during assessment. The multi-disciplinary team making candidate selection must consider the current audiological, radiological and medical criteria for cochlear implant candidacy (Niparko et al., 2009). In addition they need to consider factors, which influence long-term use and thus outcomes such as maintenance, necessary upgrading of the external speech processor, access to appropriate rehabilitation and educational facilities and family support. Researchers in Pakistan (Khan, Mukhtar, Safeed & Ramsden, 2007) emphasised that selection criteria in developing countries need to be much more stringent and in some respects different to those in developed countries, as financial factors also need to be considered, when implants are

self funded. In their programme the professionals determine right at the outset of the pre-implant assessment phase whether a candidate has sufficient resources to afford the cost of implantation and the subsequent rehabilitation. Doing so means that many suitable candidates, who could have benefitted from cochlear implantation are declined due to lack of financial resources

Stringent evaluation, and careful selection by well trained clinicians, is needed to prevent later device non-use (i.e. recipients who stop using their cochlear implant), which is a serious outcome in terms of squandering both human and material resources (Raine, Summerfield, Strachan, Martin & Totten, 2008; Summerfield & Marshall (1995) cited in Niparko et al., 2009).

A retrospective audit of implantees, who stopped using their devices, by an established cochlear implant unit in Yorkshire in the United Kingdom, (Raine et al., 2008), concluded that non-use in that centre added 7% to the average cost. From a total of 340 individuals implanted at that centre, 11 of 155 children and 2 of 185 adults became non-users over an 11 year period. The investigators emphasized that it was crucial for a multi-disciplinary team to make patient selection in order to reduce non-use. In the initial 4 years of their programme, 37% of the children and 4.5 % of the adults became eventual non-users. After the initiation of improved patient selection criteria in 1994, a significant reduction in non-use was noted. The children's rate reduced to 2.9% and the adult to 0.6%.

In the Yorkshire study (Raine et al., 2008), the 2 adults, who stopped using their devices, did so because of psychological issues, and because they were unable to adapt to the type of stimulation provided by the implant. Of the 11 children, who stopped using their implants, 8 were congenitally deaf and implanted over the age of 3 years (the oldest was 11.6 years). The other 3 children, who had lost their hearing as a result of meningitis before the age of 1 year, were older than 4.6 years when they were implanted (the oldest was 6.3 years). Inadequate or inappropriate educational placement, which did not meet the needs of the child, and a lack of family support were also identified as issues related to subsequent non-use.

The Yorkshire team noted that the promotion of appropriate educational placement and support for cochlear implant recipients brought about the most noticeable changes in use of the device in their centre (Raine et al., 2008). Today, age at implantation, educational placement and family support are well recognized as issues affecting ongoing use of a

cochlear implant. Those providing the cochlear implant need to ensure that implantees have the necessary motivation, realistic expectations and support in order to be able to succeed with a cochlear implant (Niparko et al., 2009). In addition, in countries where cochlear implantation is not state funded, such as South Africa, it is critical that those providing the implant also consider the potential role that costs incurred by the implantee or their family play, in helping to ensure long-term use and access to appropriate intervention. Good long-term hearing and speech outcomes are highly dependent both on appropriate selection and on ongoing use of the device, as well as access to the support structures each recipient needs in order to benefit optimally from the implant.

### **1.5. RECIPIENT BORNE COSTS OF COCHLEAR IMPLANTATION**

Estimates of the costs involved in cochlear implantation can vary depending on whether the analysis takes the perspective of the implant recipient, a third party payer, such as the recipient's insurer or medical aid, or society at large (Palmer et al., 1997). Most economic studies to date concerned with costs related to cochlear implantation have taken the perspective of the third party payer, or society at large. Fewer studies have focussed on costs from the perspective of the implantee or their family. This information is of particular importance in countries, where recipient borne costs are significant and may in fact influence whether an individual is implanted or not.

Studies investigating the costs incurred by the implantees or their families in relation to cochlear implantation have mostly considered paediatric implantation. Barton, Fortnum, Stacey and Summerfield (2006b) compared the out-of-pocket expenditure incurred by families as well as lost productivity of parents for a group of families, whose child had received an implant, with those of a group of hearing impaired children who had not. Out-of-pocket expenditure was estimated to be significantly higher for families of implanted children, when the children were implanted before the age of five years, and had used their implant for less than two years. Lost productivity was significantly higher, when the children had used their implants less than two years. They concluded that families of implanted children incurred additional costs in the first two years after implantation in comparison to families where children were not implanted.

In a study aimed at estimating the cost effectiveness of paediatric cochlear implantation in the United States of America, Cheng, Rubin, Powe, Mellon, Francis and Niparko (2000) included changes associated with implantation regarding lost productivity of parents, travel and parking costs to attend appointments, and the cost of special equipment. They used informed assumptions about the resources used by the implanted children's families as the basis for the estimates in their study. From their cost utility analysis they concluded that cochlear implants were highly cost effective in children with a significant net expected financial saving to society over a child's lifetime. Cochlear implantation compared favourably with other medical interventions that used implants.

Sach, Whynes, Archbold and O'Donaghue (2005) estimated the time and out of pocket expenses incurred by families of children, who underwent cochlear implantation in the United Kingdom, using face-to-face interviews with parents of children implanted between 1 month and 13 years. The study was the first to obtain primary data on the time and out of pocket costs incurred by families at a cochlear implant programme in the United Kingdom. The time and out of pocket expenses were significantly higher for those, whose children had been implanted for less than two years. Travel costs were the greatest out of pocket expense incurred by families. Overall the findings showed that costs resulting from implantation declined over time.

When Fitzpatrick et al. (2006) developed a framework for the economic evaluation of cochlear implants for children in Canada they included identifying family related financial costs not covered by the health care or educational systems. The direct costs, which families reported, were primarily private cochlear implant insurance, extended warranties and charges for the maintenance and replacement of external equipment. The indirect costs included travel and time away from work.

Directly applying the study results of costs incurred by implantees or their families with respect to cochlear implantation from one country to another is difficult, given the differences in health care systems, costs of services, and health and educational service delivery methods (Fitzpatrick et al., 2006). The studies conducted to date have primarily been in countries, where a number of the direct costs involved are not carried by the implantees themselves. In the United Kingdom for example, the tax-funded National Health Service meets the costs of the entire cochlear implant service (Sach, Whynes, O'Neill, O'Donaghue &

Archbold, 2004). The implantees and their families thus carry no direct costs for the service, hence these studies concentrated on indirect expenses, such as time and out-of-pocket expenses. Findings from a study conducted in Pakistan (Khan et al., 2007) highlighted how critical it is to consider a patient's financial resources to fund both the implant device and the subsequent rehabilitation at the outset of pre-assessment in a developing country where implants are fully self funded. The study did not, however, list specific costs to patients. In South Africa most of the direct and indirect costs involved in the cochlear implant process, including obtaining the implant system itself, everyday use and long-term maintenance of it, have to be borne by the implantees or their families.

## **1.6. COCHLEAR IMPLANTATION IN SOUTH AFRICA**

South Africa has an estimated population of  $\pm$  40-45 million people ("South Africa.info", n.d.). Its health system consists of a large public or state sector and a smaller but fast-growing private sector. Eighty percent of the population is reliant on healthcare services provided by the state. The remaining 20% have access to private health care. Health care varies from the most basic primary health care offered free by the state, to highly specialised hi-tech services available in the private sector for those who can afford them . The public sector is under-resourced and over-used. The private sector, which is mostly run commercially, caters to middle- and high income earners, who tend to be members of medical aid schemes (18% of the population), as well as foreigners looking for top-quality surgical procedures at relatively affordable prices. The private sector also attracts most of the country's health professionals ("South Africa.info", 2011)

Most resources are concentrated in the private health sector which sees to the health needs of 20% of the population. Although the state contributes about 40% of all expenditure on health, the public health sector is under pressure to deliver services to about 80% of the population ("South Africa.info", 2011). The government is responsible for providing healthcare to the majority of its citizens, and is facing great challenges to do so. South Africa has one of the highest rates of HIV prevalence in the world with 11.8% of the population infected, and an estimated 1000 new infections each day. There is a marked rise in Tuberculosis and HIV co-infection adding to the mortality in the country. While South Africa has 0.7% of the world's



population, it has 17% of the global HIV epidemic and 28% of global HIV and Tuberculosis co-infected people (“U.S. Department of State”; June 2, 2011). Child mortality is also on the increase.

In the National Service Delivery Agreement negotiated between the health minister and the President, the government of South Africa identified 4 key outputs for the 2010-2014 health sector policy. These outputs are: to increase life expectancy, decrease maternal and child mortality, combat HIV and AIDs and the burden of disease from Tuberculosis and to strengthen the health systems. The government’s current vision for overhauling the health care system is aimed at re-engineering and prioritising primary health care, with its emphasis on health promotion and prevention of disease.

Against this backdrop of life threatening disease, vast numbers of individuals are dependent on the state for healthcare, with its limited resources and a prioritisation towards primary healthcare. Specialised rehabilitation such as cochlear implantation, which is essentially a quaternary level of care, is not currently seen as a priority for government spending. It is also unlikely that it will become so in the foreseeable future. Thus, unlike in many other countries, cochlear implants are not state sponsored in South Africa. The costs of the entire procedure have to be met by the implant recipients and their families. In the context where implantation occurs in the country understanding the financial implications of implantation is thus highly relevant for recipients. Although cochlear implants are proven to be cost effective and offer unparalleled speech and hearing outcomes for severe-profoundly hearing impaired individuals, they are used in low volumes and are a high cost medical intervention (Khan et al., 2007). Due to the substantial cost of the implant system itself, this expense frequently takes the primary focus. Less consideration is given to the ongoing financial costs of using and maintaining the implant system, and the necessary rehabilitation which needs to accompany the procedure. Without plans for these factors also being in place implantation will not succeed.

Wagenfeld and Müller (1994), who pioneered the work in the field of cochlear implantation in South Africa, cautioned that it is the financial implications of lifetime maintenance of an implant, rather than the supply of the implant hardware itself, which represent the major financial obstacle for implant recipients to overcome. Long-term support must be in place before embarking on cochlear implantation, if the rehabilitation measure is to succeed. Based

on their experience in South Africa, with the challenges of its developing healthcare and support infrastructure, the authors emphasized the critical need for a guarantee that the device would be maintained, and that sociological and educational factors were in place before giving consideration to implanting such a highly technical device as a cochlear implant. In the presence of a social system, which is insufficient to support an implantee's needs, adequate family support structures are critical, especially in the case of paediatric patients. Implantees need to be able to access the rehabilitation programmes and, for those being helped with the initial financial outlay of acquiring a cochlear implant, access to long-term support needs to be considered. In the absence of a national healthcare system that can support an implant recipient long-term, they cautioned that individuals must be financially capable of affording lifelong maintenance of the device and regular visits to the implant unit. Candidate selection must be strict enough to ensure that only those with a realistic probability of being successfully rehabilitated are implanted so that precious national resources are not squandered (Wagenfeld & Müller, 1994).

Seventeen years later in 2011 comments made by Wagenfeld and Müller in 1994 are still relevant to the reality of cochlear implantation in South Africa. Cochlear implants must be used for life. As implant programs mature and as more recipients use implants for longer the cost implications of this becomes a reality. The first individual to receive a multi-channel cochlear implant in South Africa was implanted 24 years ago in November 1986 at Tygerberg Hospital. By June 2010, when this study was conducted, almost 1000 individuals had been implanted in the country (J. Wiegman, personal communication, August 10, 2010). Initially, there was only one implanting unit in South Africa, based at Tygerberg Hospital in Cape Town. Over the years 7 more units have been established and currently there are eight implanting programmes in the country. The total recipient base keeps growing.

Despite an intuitive link between the impact of recipient borne costs on obtaining and using a cochlear implant, no previous studies have been conducted to examine the costs borne by individuals undergoing cochlear implantation in South Africa. As more individuals continue to be implanted, and existing implantees continue to need lifetime support, it becomes highly important to be able to detail these costs as well as examine and anticipate their course over time, guided by the experience gained from twenty four years of implantation in the country.

It is critical to establish what costs are involved for implantees, or their families in the process of cochlear implantation in South Africa. This can provide realistic information and clinical guidance to potential implant recipients to assist them in their choice of implantation for themselves or their children. The information will also help potential, as well as existing implantees, to be financially better prepared for the ongoing use of the implant over their lifetime. Information regarding the recipient borne costs of cochlear implantation is also needed to assist clinicians in choosing appropriate candidates, from the large pool of potential implant recipients requiring financial assistance. Hospital subsidies or donated funds are usually made available only to assist individuals with the initial cost of obtaining a cochlear implant system. In a country where the clinical need is great and resources are severely limited, there is an ethical obligation to try to ensure the optimal use of highly specialized life changing and expensive technology, such as a cochlear implant.

Currently our knowledge of the costs involved in cochlear implantation in South Africa consists primarily of knowing the current prices of the implant system, surgery, repairs, spares and upgrades of the speech processor. The cost of an implant system is readily available from the distributors of the device. The cost of surgery can be determined by combining the costs of the surgeon, anaesthetist and hospital stay. An estimate of the surgery costs, together with the current system cost, has to be provided routinely to an individual's medical aid, when appealing on their behalf for a cochlear implant. These cost estimates also have to be provided to the individual so that they can secure funds to cover any system or surgery related costs themselves, if they do not have a medical aid, or to cover those outstanding costs, which are not covered by their medical aid, prior to implantation. While these costs are available from the distributor and from the surgeons, to date there are no documented reports of how these costs were funded or what the financial implications of these costs were for patients.

The current cost of repairing or upgrading a speech processor, as well as the cost of individual spare parts can also be obtained from the distributor of the device. Implant recipients can thus be informed of the relevant costs of parts or services needed at the time. However, while the current costs per event are known or readily available, knowledge of the actual long-term costs of South African implantees using an implant daily, replacing parts, and repairing and upgrading speech processors is lacking. Also lacking is the knowledge of the

cost implications of accessing a specialised unit to undergo implantation, programming of devices and rehabilitation, as they have not previously been documented for implant recipients in South Africa.

With the existing knowledge base, clinicians in South Africa are able to inform potential implant recipients of the initial costs involved in obtaining a cochlear implant. They are less able to inform and prepare them for ongoing costs over their lifetime, as much of the knowledge needed to do so is lacking or undocumented. Such knowledge is crucial, to guide implantees, to help guide professionals working in South African implant programmes in making suitable choices of candidates for implantation, and to inform funders.

The present study was designed to study the costs that have been incurred among the existing cochlear implant population at the Tygerberg Hospital-University of Stellenbosch Cochlear Implant Unit and to estimate future and life time costs of using a cochlear implant for this population.

## **2. METHODOLOGY**

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The present quantitative study employed a non-experimental ex post facto research design (Bailey, 1997; Hedge, 2003;). A survey of all available cochlear implant users, who had received a cochlear implant at the Cochlear Implant Unit based at Tygerberg Hospital in Cape Town, South Africa since the initiation of the programme in November 1986 up to March 2010, was undertaken. A survey was chosen in order to gather information from the large population of cochlear implantees. It was carefully designed to answer questions considered relevant and significant to the study's aims (Bailey, 1997). The subjects completed a questionnaire designed by the investigator, aimed at extracting information regarding direct costs (cochlear implant system, maintenance and supplies) and related costs (therapies, travelling, accommodation, hearing aids, assistive devices and insurance) incurred by implant recipients or their families as a result of obtaining and using a cochlear implant up to June 2010. Patient and distributor records were also examined regarding cost information. All data obtained was analysed and categorized into relevant cost areas.

### **2.1. AIMS OF THE STUDY**

#### **2.1.1. Primary aim of the study**

The main aim of the study was to investigate the long-term cost implications of cochlear implantation for implant recipients, who had received a cochlear implant at the Tygerberg Hospital-University of Stellenbosch Cochlear Implant Unit (hereafter referred to as the Tygerberg Hospital Cochlear Implant Unit).

#### **2.1.2. Specific aims of the study**

1. To establish the financial costs of the initial acquisition of the cochlear implant system incurred by implantees, or their families.

2. To investigate the costs of ongoing use of a cochlear implant incurred by implantees, or their families.
3. To investigate the related costs of travelling and accommodation during the process of acquisition and use of a cochlear implant.
4. To investigate the additional costs to implantees, or their families, of support services needed to ensure good hearing and speech outcomes (e.g. speech therapy, aural rehabilitation).
5. To investigate the manner in which implant recipients funded these various costs.
6. To monitor the development of these costs over time.
7. To provide a guide for implantees and clinicians with respect to long-term cost implications of cochlear implantation in South Africa.

## **2.2. RESEARCH SITE**

The study took place at the Tygerberg Hospital Cochlear Implant Unit in Cape Town, South Africa. The unit was the first to be established in South Africa (1986) and has the largest cochlear implant recipient base in the country, representing both state and private adult and paediatric users. At the time the study was conducted, 374 individuals had been implanted. The twenty-four year history of implanting adults and children allowed for access to long-term experience with cochlear implant recipients.

## **2.3. SUBJECTS**

### **2.3.1. Inclusion criteria**

The population consisted of all the accessible cochlear implant users, who had received their implants from the Tygerberg Hospital Cochlear Implant Unit.

The subjects were required to be cochlear implant users (adults and children) living in South Africa, who were actively using their implants. They were also required to have been using

their implant for a minimum period of three months at the time of the data collection in order for them to be able to contribute meaningful information regarding the use of an implant, in addition to the purchase of it.

### **2.3.2. Exclusion criteria**

Implantees implanted at other programmes, who had transferred to the Tygerberg Hospital Cochlear Implant Unit after their implantation, were excluded, as were implantees, who, at the time of the study, were living in other countries. Deceased implantees and those known to have stopped using their implants, were also excluded.

### **2.3.3. Description of subjects**

Out of the total 374 individuals implanted at the unit, 310 met the inclusion criteria and were sent the questionnaire. Such probability sampling, which includes the entire defined study population, is considered the ideal random method of participant selection (Drummond, 1996; Hedge, 2003,). All individuals had an equal chance of being included in the study. While there is a degree of volunteerism for all subjects because of the consent process in a study, allowing each individual in the population an equal chance to participate in the study reduced the potential effect of subject selection on the internal validity of the study (Bailey, 1997). In this study one hundred and sixty four individuals responded. Out of these 154 (50%) were willing to participate in the study. They consisted of 80 females and 74 males. Their age at implantation ranged from 6 months to 84 years with an average age at implantation of 22 years.

### **2.3.4. Investigator**

All the data collection was done by the investigator, who had been employed as a clinical audiologist at the Tygerberg Hospital Cochlear Implant Unit for nine years, and thus had extensive knowledge of cochlear implantation and the site.

## **2.4. ETHICAL CONSIDERATIONS**

### **2.4.1. Letters of consent**

Permission to conduct the study was granted by the Health Research Ethics Committee of the University of Stellenbosch and the Medical Superintendent of Tygerberg Hospital (Appendices A and B). Written consent was obtained from the cochlear implant recipients, or the parents of the recipients, who were willing to be included in the study. The information and consent letters (Appendix C) included all the ethical information as prescribed by the Health Research Ethics Committee of the University of Stellenbosch. The study was conducted according to the ethical guidelines and principles of the International Declaration of Helsinki (Bailey, 1997), South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research (South African Medical Research Council, 1993).

Subjects were fully informed about the nature of the project, the procedures, which would be used, and what the results would be used for. Participants were required to return a consent form in addition to giving tacit consent to participate by returning the survey. Participation was voluntary and the patients' autonomy was respected. It was clearly stated that there would be no negative consequences, regardless of the subject's willingness to participate. It was considered particularly important to ensure patients that non-participation would not compromise their care, especially since some of the subjects were being treated by the investigator. It was also made clear to subjects that they could withdraw from the study at any stage without fear of reprisal. Subjects were assured that their privacy would be guarded and that their information would be treated as confidential. They were informed that materials would be kept in a safe place throughout the study. Subjects were assured that their anonymity would be guaranteed in any publications resulting from the study (Bailey, 1997; Heaney & Dougherty, 1988; Hedge, 2003; South African Medical Research Council, 1993).

### **2.4.2. Risk/benefit ratio**

As the research activity consisted of filling in a questionnaire, the physical or emotional risks associated with subjects participating in the study were considered to be negligible or less than minimal risk (Hedge, 2003; South African Medical Research Council, 1993). Potential



benefits of the study for both the professionals involved in cochlear implantation and for future and even present implant recipients were considered significant. Accurate information on the long-term financial implications of cochlear implantation is expected to assist professionals in their choice of candidates and financial guidance of implantees. It will give individuals, considering implantation, a reliable basis on which to base their decisions regarding affordability of a cochlear implant. Recipients already implanted can also benefit, as the results can be used to provide long-term guidance to assist with financial planning.

#### **2.4.3. Confidentiality of records and information obtained**

Professional ethical guidelines were followed to ensure that all the information obtained remained confidential (Bailey, 1997). All data and records of the study were kept in the unit in a locked facility. All the subjects were coded by number, and only the investigator could link data to any individual subject.

### **2.5. DATA COLLECTION**

#### **2.5.1. Questionnaire**

Information was collected indirectly via the questionnaire (Bailey, 1997) and from patient records. Previous studies investigating costs incurred by implant recipients as a result of cochlear implantation have been conducted in other countries, including the United Kingdom (Barton et al., 2006b; Sach et al., 2005), the United States of America (Cheng et al., 2000) and Canada (Fitzpatrick et al., 2006). To date no such study has been conducted in South Africa. As the costs necessary for implantees to cover during the process of cochlear implantation vary greatly across countries, using existing questionnaires from studies conducted outside of South Africa was not felt to be appropriate. Consequently, a questionnaire, relevant for South Africa and the context in which cochlear implants take place in this country needed to be developed. The questionnaire utilised in this study was developed by the investigator in consultation with the founding Co-ordinator of the Tygerberg Hospital Cochlear Implant Unit. The content and phrasing of the questions was carefully considered to ensure that only questions relevant to the study were asked, in a way which did not lead the subject (Drummond, 1996). Feedback from colleagues working in the field of

cochlear implants was sought in order to help assess the content validity of the questionnaire, as well as the ease of understanding the questions. The questions did not include any cultural, racial, intelligence or language bias which could have influenced the results. Care taken in the design of the questionnaire helped to ensure the internal validity of the study (Bailey, 1997).

Throughout the study the cost information was only collected for the costs associated with one cochlear implant per recipient. In the case of bilateral cochlear implant users, the implantees were asked to only consider costs associated with the first cochlear implant they had received. This was stipulated in the questionnaire, and was also accounted for, when information was collected from patient records. The age of implantation and duration of use were dated from the time of the first implant received for recipients using two implants, or, from the time of the recipient's only implant, in the case of those who had one cochlear implant.

The questionnaire was originally developed in English and translated into Afrikaans. The accuracy of the translation was assessed by a bilingual English-Afrikaans speaking Speech-Language Therapist and Audiologist employed in an academic post at the Department of Speech-Language and Hearing Therapy, University of Stellenbosch. The questionnaire was made available to subjects in English or Afrikaans depending on their known preference.

### **2.5.1.1. Structure of the questionnaire**

#### **2.5.1.1.1. Topics**

The questionnaire (Appendix D) was designed to elicit the following information:

- Demographic information
- Costs of visits to the unit
- Repairs of speech processor
- Rehabilitation costs
- Insurance costs
- Use and cost of a personal Frequency Modulated (FM) system
- Use and costs of a hearing aid in the non-implanted ear

- Advice, which subjects would offer, to potential implantees regarding costs involved in cochlear implantation.

The demographic information requested on the questionnaire included implantee name and date of birth. These details were needed to cross reference information obtained with patient records.

#### **2.5.1.1.2. Questionnaire format**

The questionnaire consisted of nine question areas. Eight asked for estimates of various costs and provided the subjects with option ranges to choose from. The questions included: forced alternatives (yes/no type questions) and, where possible, presented closed set options for subjects' responses (Drummond, 1996). The questions were structured in this manner to aid the speed and ease of completion for subjects. One of the questions (Question 1.8) requested comment, in addition to the closed set options response, in order to gain further information from the subjects. One question (Question 8) was open-ended. This question probed advice which subjects would give others regarding costs. The open-ended structure afforded the subjects an opportunity to respond more freely, and to include information, which they felt was relevant to the question (Drummond, 1996).

The subjects were instructed to fill in as much information as possible. If they could not remember or did not have access to exact amounts they were asked to give estimated costs. Provision was also made for subjects, who did not remember a particular cost to indicate this on the questionnaire. In order to gain an idea of the different costs incurred at different time periods in the implantation process, the questionnaire requested the information according to time periods. These included: initial evaluation, 1-2 years, 3-5 years, 6-10 years, 11-15 years, 15-20 years and more than 20 years after receiving a cochlear implant. As the length of time the implantees had been using their cochlear implants varied, they completed only those time periods relevant to them.

### 2.5.1.1.3. Description of questions and rationale for their inclusion

**Questions 1, 2 and 3** collected data related to **visits** to the cochlear implant unit. Costs involved in visits to the unit are important, as they affect an implant recipient's ability to access the services necessary for successful use of their implant. Being able to access a specialised unit, where assessment, programming, aural rehabilitation, troubleshooting of devices and long-term management is conducted, is critical for cochlear implant users. Despite an increase in the number of cochlear implant programmes in South Africa in recent years, the number of specialised units and services is still limited and an individual's ability to access the unit needs to be considered.

**Question 1** gathered information about the **distance** subjects lived from the cochlear implant unit. Sub-question 1.8 requested information regarding any relocation made in order to be closer to the unit. Sub-question 1.9 asked subjects, if they had transferred to a closer cochlear implant unit due to costs.

**Question 2** requested information on the **travel arrangements** to and from the unit, including type of transport used, as well as cost. Previous studies conducted by Cheng et al. (2000) and Sach et al. (2005) also considered travel costs.

**Question 3** probed the need for **accommodation** for non-local implant recipients, when attending appointments, type of accommodation (friends/family or paid), where applicable, and cost. As cochlear implantation involves a series of ongoing appointments, whose frequency depends on the interval post implantation, implantees ideally need to be close to the unit during the assessment and initial programming periods, as well as follow-up visits. These activities require a series of visits in close succession, and accommodation costs need to be factored in for those implantees, who live out of easy access to the implant unit. The questionnaire distinguished between those, who stayed with relatives or friends, and those, who had to pay for accommodation. The questionnaire gave subjects a range of options to choose from for costs of accommodation, to enhance the ease of completion of the question.

**Question 4** probed information regarding the number of post warranty **repairs** needed for the speech processor. Repair costs form part of the maintenance costs involved in cochlear implantation. The externally worn speech processor has a three year warranty period from the time of fitting, after which implantees are responsible for any repair costs. Without being able

to cover the repair costs, implant recipients would be unable to continue using their cochlear implants. The subjects were asked for the number of times their processor had been repaired following the expiry of the warranty period. The details concerning, the times the processor/s were repaired and the costs involved, were obtained from the patient records in order to improve the accuracy of the information obtained.

**Question 5** gathered information about the **insurance** of the speech processor. Those, who were insured, were requested to provide information about the length of time they had been insured, as well as their current monthly premium. Insuring the speech processor is an optional cost, which some implantees choose to undertake to help with the cost of repairs to the speech processor, or the cost of replacement, should the processor become damaged beyond repair, lost or stolen. Insurance often represents a significant monthly cost to implant recipients and is thus an important cost to take into account.

**Question 6** investigated the purchase of a **personal FM system** and the costs involved. A personal FM system is an assistive listening device comprising a receiver, which couples to the cochlear implant speech processor, and a transmitter worn by the person speaking to the cochlear implant user. Numerous studies have shown substantial benefits in speech recognition in noise when using a personal FM system (Anderson, Goldstein, Colodzin, & Iglehart, 2005; Schafer & Thibodeau, 2004; Wolfe, Schafer, Heldner, Mulder, Ward & Vincent, 2009). Improvements by up to 50 percentage points for speech understanding in noise were noted for cochlear implant recipients using an FM system in comparison to not using a system (Wolfe et al., 2009). An FM system can assist school-aged children in the classroom with hearing in background noise and at a distance from a speaker. As these remain two areas of ongoing difficulty for hearing impaired children, despite the use of a cochlear implant, Madell (2003) indicated that every child with a cochlear implant would need an FM system in class and in other difficult listening situations. In a mainstream schooling environment, which is the ultimate aim for the majority of children receiving cochlear implants, an FM system is essential for optimal use of the cochlear implant. In South Africa especially, where mainstream classes are large ( $\pm$  30-50 children in a class) and where there is no extra educational support provided, FM systems become critically important for hearing impaired learners. Students in tertiary academic environments who use a cochlear implant can also benefit from an FM system (Madell, 2003).

**Question 7** extracted information about the **use of a hearing aid** in the contra-lateral ear (the ear not implanted), i.e., the purchase of the aid and monthly battery cost. The use of a hearing aid, in addition to a cochlear implant, would have contributed to additional costs for the subjects, and it was thus considered important to elicit this information. The ongoing use of a hearing aid in the contra-lateral ear by individuals, who receive a unilateral cochlear implant, has been an increasing trend in more recent years, as patients with increasing amounts of residual hearing have been implanted. Using a hearing aid in the non-implanted ear offers the advantages of improved speech discrimination in quiet and in noise, and improvements in sound localization (Tange et al., 2008).

**Question 8** was an open-ended one, designed to give subjects an opportunity to **advise potential implantees about costs** and planning for costs, involved in obtaining and maintaining a cochlear implant based on their own experience. The implantees, or parents of implantees, were considered to be in a unique position to give insight from their own point of view into obtaining a cochlear implant and long-term use thereof. Using an open-ended format gave subjects an opportunity to make comments, which they felt were important.

**Question 9** examined **rehabilitation costs for children** (those, who were implanted below the age of thirteen years). While a cochlear implant provides greater access to sound and better sound perception for severe-profoundly deaf individuals, its success is largely dependent on the long-term rehabilitation that accompanies it. The rehabilitation provided after cochlear implant surgery is a powerful beneficial factor, which has been shown to have strong influence on outcome (Robbins, 2009). The first year is especially critical for rehabilitation, and for this reason this year was probed separately in the questionnaire. Provision was made in the questionnaire for indicating multiple therapies for up to ten years post implantation. The years post implantation were grouped into 1 year, 2 years, 3-5 years and 5-10 years post implantation. Types of therapy, as well as the costs involved, were requested for each time period. The frequency of therapy during the first year was also probed. Due to the long term nature of the information sought, provision was made for those, who could not remember the costs involved to indicate this on the questionnaire.

#### **2.5.1.1.4. Pilot study of the questionnaire**

Prior to being used in the study the questionnaire was piloted on three cochlear implant recipients, who were not included in the study itself. This small preliminary study was conducted to ensure that subjects would understand the questionnaire, as it had never been used before and to help plan the procedures which would be used in the data collection (Doehring, 2003). In survey research the composition of questions is particularly important. A pilot study is necessary to determine, if the respondents understand the questions, if the questions are eliciting the desired information and to evaluate, if the survey is too long or too short (Bailey, 1997).

In addition to completing the questionnaire, these implant recipients were asked to provide feedback on the time needed to complete the questionnaire, the ease of understanding the questions, the layout of the questionnaire and possible changes to the questions. This was done to ensure that subjects would be able to understand and complete the questionnaire correctly, and to change any areas, which were noted to be problematic (Bailey, 1997).

All the implant recipients in the pilot study indicated that they could follow all the instructions easily and that they understood all the questions as asked. Minor modifications to the reply format were made on the basis of their responses and suggestions.

#### **2.5.1.1.5. Distribution of the questionnaires**

The questionnaire together with an information sheet and consent form was distributed to subjects in one of three ways: via email, post or in person, when the implantees attended their follow up appointments at the implant unit. Questionnaires were returned via email, fax, post (using a pre-paid envelope provided) or by hand directly to the cochlear implant unit. E-mail and telephone reminders were used to help improve the return rate of the questionnaires.

#### **2.5.2. Patient records**

The questionnaire was used in conjunction with examination of patient and distributor records, to collect data regarding costs involved in implantation, maintenance and rehabilitation. In

order to reduce the length of the questionnaire, as well as to increase the accuracy of information for questions, where the long-term nature of the information sought might have been influenced by subjects' recall, information, which was readily available in patient records was obtained from these sources rather than from the subjects themselves. As a considerable amount of the information required details from many years ago, the investigator attempted to minimise the possible effect of inaccurate recall by checking and supplementing the information supplied by the questionnaire against information from patient records. All the data collected from the questionnaires and patient records was recorded and entered on a database, to which only the investigator had access.

Information from patient records was extracted from databases at the Tygerberg Hospital Cochlear Implant Unit and Southern ENT Pty (Ltd), the Tygerberg Hospital Income Classification System (Appendix E) and the Tygerberg Hospital Cochlear Implant Unit Follow-up Protocol (Appendix F). The following information was obtained:

- Date of implantation
- Age at implantation
- Duration of use of cochlear implant
- Income status
- Details of initial system costs
- Number of visits
- Maintenance costs
- Speech processor upgrades

Age at implantation and duration of use were noted as trends affecting costs in a previous study conducted by Barton et al. (2006b).

The Tygerberg Hospital's Income Classification System was used to extract information regarding the **income status** of subjects. In this system, patients' financial status is classified, according to their monthly income, into one of five categories viz. H0, H1, H2, H3 or P, ranging from those with no income (H0) (e.g. on a disability grant or under 6 years old), to those who are classified as private patients (P) (on medical aid or earning above a certain



amount). The cost of hospital appointments is based on a sliding scale and is determined by the patient's income category.

Patient records were also examined to obtain details of the **initial cost and the method of financing of the cochlear implant system**. Potential funding sources included contributions from medical aids, funding from donors or sponsors, private (e.g. self) funding or a combination of these sources.

The **number of visits** made by subjects to the implant unit post implantation was estimated, for the different time periods. The estimate was based on the predicted scheduling of appointments generally followed at the Tygerberg Hospital Cochlear Implant Unit in consultation with the co-ordinator of the unit (Appendix F). The duration of use of the cochlear implant determines the schedule of required appointments for programming of the speech processor, hearing testing and monitoring of progress. The implantee's age at implantation also influences the number of appointments needed. Although visits are most frequent in the first year after receiving a cochlear implant, follow-up visits are required for the rest of the implantee's lifetime, in order to monitor the function of their cochlear implant system.

**Maintenance costs** of the cochlear implant were also examined over time. These included: the purchase of replacement and spare parts, speech processor repair costs, cost of batteries and upgrading of processors. Due to the long-term nature of the information being sought in this study, records of the distributor of the product used at the Tygerberg Hospital Cochlear Implant Unit were examined to obtain the costs of spares, repairs and batteries to eliminate the effect of subject recall on the accuracy of the information sought. All the individuals implanted at the Tygerberg Hospital Cochlear Implant Unit use a Nucleus® cochlear implant system, manufactured by Cochlear Ltd. As there is only one distributor of Nucleus® products in South Africa (currently Southern ENT Pty (Ltd)), all individuals implanted at the unit purchased spares and replacements from this distributor, and all the repairs were also managed by them. The current distributor's records date back to 2001 and all spares and repair costs incurred by subjects from that time were recorded. Information from the distributor's records was also used to validate subjects' recollections and predictions of monthly battery cost and to obtain average battery costs per speech processor type.

Information regarding the details of the **upgrades of the speech processor**, which the implantees underwent over time, was extracted from the unit's records. This information, which included the dates of upgrades and the speech processor type, was available for all implant recipients in the study. Upgrades were assigned to the time period post implantation, when they occurred.

Costs involved in replacing parts, as well as battery usage, are influenced by the type of speech processor an implantee is using. This information was thus important to obtain, when examining costs involved. Technology does not stay static, and improvements and advances in technology continue to be made in the field of cochlear implantation. As a result, the maintenance phase involves a degree of replacement and upgrading of processors over time (Palmer et al., 1997). While the implantee's implanted electrode array continues to be used, upgrading of the externally worn speech processor is possible, as new speech processors become backwards compatible with older implant models. Over the past 24 years of implantation at the Tygerberg Hospital Cochlear Implant Unit a new speech processor has been introduced approximately every 5 years.

While some implant recipients choose to upgrade their speech processors, others may find themselves in a position, where they are obliged to do so due to the finite life span of a speech processor. Once the manufacturer's parts are no longer available for a particular type of speech processor, it is declared obsolete. Once their processor has been declared obsolete, implant recipients have to replace their speech processor with the later models available, to continue using their cochlear implant. Upgrading of a speech processor is expensive. Currently the cost involved is approximately 40% of the initial cost of the implant system.

Throughout the collection of data from patient records, the various costs incurred by subjects were assigned to the relevant time period, in which they occurred. These time periods mimicked those used in the questionnaire i.e. 1-2 years, 3-5 years, 6-10 years, 11-15 years, 15-20 years and more than 20 years post implantation.

In addition to the information obtained from the subjects in the study, the current financial status and needs of fifty implantees, whom Tygerberg Hospital has assisted with funds for implantation, was reviewed. This was considered an important additional contribution to the

study, as these state implantees are potentially most vulnerable to financial strain as a result of the long-term costs involved.

## **2.6. DATA ANALYSIS**

The investigator extracted the raw data from the questionnaires, patient and distributor records. In consultation with professors in the Departments of Statistics, Economics and Logistics of the University of Stellenbosch, the data was analysed to establish the relationships, trends and patterns of all the costs and related costs incurred by cochlear implant users, or their families, from the time of assessment through to the current time. Descriptive statistics were used. Means were used as a measure of central tendency and ranges as a measure of variability (Stein & Cutler, 1996).

In consultation with a Professor of Economics, all costs obtained were converted into South African Rand values as at June 2010, using the Consumer Price Index (CPI) (P0141) for 2010. The following conversion formula was used:  $(\text{Cost in year } x) \times (\text{Average CPI in year } x) \times (\text{CPI June 2010})$ . As a result, all costs were in Constant Rands and could thus be compared in real terms. Where ranges of costs were provided, the midpoint of the range was used in the calculations. Where the subject's responses fell into an open interval range, the investigator estimated the most likely value to be used in the calculations. Very few responses were noted in the open ended ranges, so this did not have a significant effect on the analysis.

In the analysis of accommodation costs, the midpoint of the range of values given was used and converted to 2010 amount. Year 1 was used for evaluation (or year before implantation in e.g. January). For years 1-2 year 1 CPI was used, since most visits took place in the first year. For other years the midyear's (i.e. midpoint) CPI was used to calculate 2010 equivalent.

A professor in the Department of Logistics at the University of Stellenbosch assisted in statistically analyzing the probability of occurrences of various costs in the different time periods following implantation, using contingency tables, based on the relative frequencies of occurrences for subjects in the study. These included the occurrences of spares purchases, repairs and upgrades. Frequency distribution tables were constructed to analyse this information (Stein & Cutler, 1996).

As Question 8 was an open ended question, the responses were subjected to a theme analysis (Aronson, 1994). Responses were coded by subject number and analysed independently by the investigator and by another senior audiologist with extensive clinical and academic experience in the field of cochlear implantation. The main themes were independently extracted from each subject's answer by the two analysers and compared. A 92% correlation between the two analysers' themes was obtained, indicating high inter rater reliability (Doehring, 2003; Hedge, 2003). The few discrepancies were discussed to reach a consensus. The main themes were then analysed for all subjects to extract the most frequently occurring themes in the group and trends were extracted.

### 3. RESULTS AND DISCUSSION

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The findings of the study will be presented and discussed in the following order: demographics of subjects (including age at implantation, duration of implant use, income status and hearing aid use), the costs involved in implantation and advice which cochlear implant recipients would offer future candidates regarding costs involved in cochlear implantation. The special case of state implantees, who have been financially assisted by Tygerberg Hospital, will be discussed next, then the probability of requiring various spares, repairs and upgrades over time will be considered followed by the estimated costs of the first 5 and 10 years post implantation based on results obtained in this study.

In the discussion of the costs involved in implantation, results pertaining to costs directly related to the cochlear implant device will be presented and discussed first i.e. the initial cost of the cochlear implant system, cost of batteries, spares, repairs and upgrades. Thereafter the results of costs applicable to some, but not all subjects, will be discussed. These include: costs related to additional devices used by some implantees, viz. hearing aids and FM systems, as well as costs related to insurance. Following this the results of costs involved in accessing the cochlear implant centre will be presented and discussed. These include: costs related to travel, accommodation and hospital visits. Finally costs associated with rehabilitation of children receiving a cochlear implant will be considered.

A total of 164 individuals responded to the survey. Of these a total of 154 completed questionnaires (50% response rate) were received and included in the study. The ten individuals, who responded but did not fill in the questionnaire, listed the following reasons for not taking part: 2 indicated that they were unable to participate due to medical reasons, 2 cited lack of time to complete the questionnaire, 4 indicated that they could not complete the questionnaire due to their lack of records and 2 indicated that they did not want to take part in the study. One hundred and forty six individuals did not respond. The response rate was in keeping with general findings of response rates to postal questionnaires which are usually between 40-60% even when people are interested in the subject (Oppenheim (1996) cited in Drummond (1996)).

### 3.1. Demographic characteristics of subjects

#### 3.1.1. Age at implantation

Table 1 summarises the age of subjects at the time they were implanted. The average age of subjects at implantation was 22 years. The youngest subject was implanted at 6 months and the oldest at 84 years of age. Eighty-two subjects (53%) were implanted as children (i.e. below the age of 13 years). A small number of subjects (8) were implanted as teenagers (13-18 years old at the time of implantation) and 64 (42%) were implanted as adults (older than 18 years at implantation). For those implanted as children, the average age at implantation was 4 years 5 months. For the teenagers the average age at implantation was 15 years 9 months and the average age at implantation for the adult subjects was 45 years 2 months.

Table 1. *Subjects' age at implantation(yrs=years; m=months)*

Age at implantation	Total (n=154)	Children(n=82)	Teenagers(n=8)	Adults (n=64)
Average	22yrs	4yrs 5m	15yrs 9m	45yrs 2m
Range	6m-84yrs 7m	6m-12yrs 8m	13yrs-18yrs	18yrs-84yrs 7m

#### 3.1.2. Duration of implant use

Table 2 shows the length of time the subjects had been implanted. On average the subjects had used their implants for 7 years 4 months. The shortest duration of use was 3 months, and the longest 22 years 7 months. Those implanted as children had, on average, used their implants for 8 years, with a range from 3 months to 21 years 2 months. The teenagers' average duration of use was 6 years 2 months, ranging from 1 year to 15 years 3 months. The adults had, on average, used their implants for 6 years 8 months. The most recently implanted adult subject had used his implant for 4 months. The longest implanted adult subject had used an implant for 22 years 7 months.

Table 2. *Duration of cochlear implant use (yrs=years; m=months)*

Duration of use	Total (n=154)	Children (n=82)	Teenagers (n=8)	Adults (n=64)
Average	7yrs 4m	8yrs	6yrs 2m	6yrs 8m
Range	3m-22yrs 7m	3m-21yrs 2m	1yr-15yrs 3m	4m-22yrs 7m

### 3.1.3. Income status

The Tygerberg Hospital's Income Classification System was used to determine the current income status of the subjects, classified as H0, H1, H2, H3 or P (see Appendix E). The patient's classification category is based on the patients' (or family's) monthly income, ranging from those classified as H0 (lowest income) to those classified as H3 (highest income). Those on a medical aid are classified as P (private). The classification category determines the amount patients are charged on a sliding scale per hospital appointment. Figure 1 shows the income classification of the subjects.

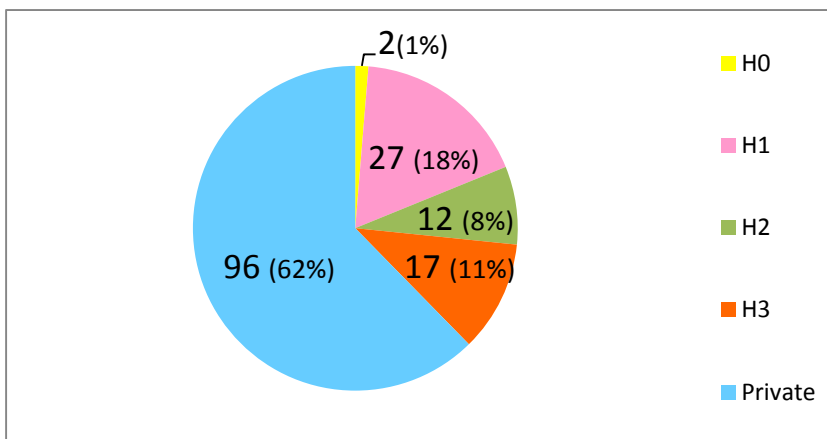


Figure 1. *Current income status of subjects*

As seen in Figure 1, 96 subjects (62%) were on medical aids (classified as Private). Seventeen subjects (11%) were single patients with a monthly income of more than R6000, or families with a monthly income of more than R8334 (classified as H3). Twelve subjects (8%) were single patients with a monthly income between R3000 and R5999 per month, or families with a monthly income between R4167 and R8333 (classified as H2). Twenty-seven subjects were single patients with a monthly income of less than R2999, or families with a monthly income less than R4166 (classified as H1). Two subjects were state patients under 6 years of age, who qualified for free hospital appointments (classified as H0).

### 3.1.4. Hearing aid use in the non-implanted ear

Fifty subjects (32%) were using a hearing aid in the non-implanted ear, in addition to their use of a speech processor in the implanted ear.

### 3.1.5. Types of implants

Table 3 shows the types of implants which subjects had received.

Table 3. *Types of implants used by subjects*

Type of implant	Number of implantees
Nucleus ® CI 22 series	25
Nucleus ® CI 24M	28
Nucleus ® CI 24K	1
Nucleus ® CI 24R (CS)	15
Nucleus ® CI 24 R (ST)	1
Nucleus ® CI 24 R (CA)	20
Nucleus ® CI 24M double array	1
Nucleus ® CI 24 RE	61
Nucleus ® CI 512	2



The type of implant the subject received depended on which implants were available when they were implanted. All those implanted before 1997 received a Nucleus® CI 22 series implant, as the Nucleus® 24 series of implants only became available after 1997. One subject received a double array due to a severely ossified cochlea. The largest group of subjects was using the Nucleus® Freedom® implant system (Nucleus® CI 24 RE).

### 3.2. Cost of the cochlear implant system

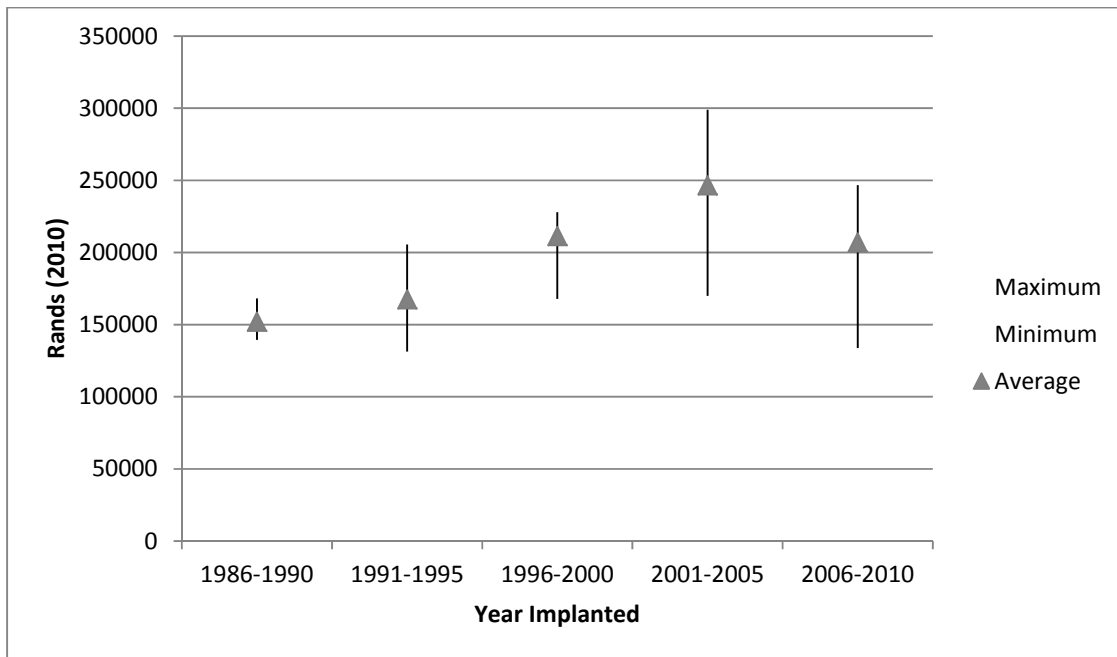
Table 4 shows the implant system cost per subject, grouped according to the year they were implanted. Inflation was accounted for by using the Consumer Price Index (P0141) and all prices are in Constant Rands as at June 2010.

Table 4. *Cochlear implant system costs grouped according to the year implanted*

Year implanted	Average system cost (2010 Rands)	Range (2010 Rands)
1986-1990	R152 026	R139 375-R168 184
1991-1995	R167 546	R131 348-R205 583
1996-2000	R211 413	R167 837-R227 971
2001-2005	R246 589	R169 987-R299 009
2006-2010	R206 976	R133 800-R247 722

As can be seen in Table 4 the highest and lowest average cost varied by almost R100 000. The average cost of implants increased steadily from the R152 026 in the earliest period to the R246 589 during the 2001-2005 period with a dip in the latest period. On average an implant system in the most recent time period (2006-2010) cost almost R55 000 (R54 950) more than in the earliest time period (1986-1990).

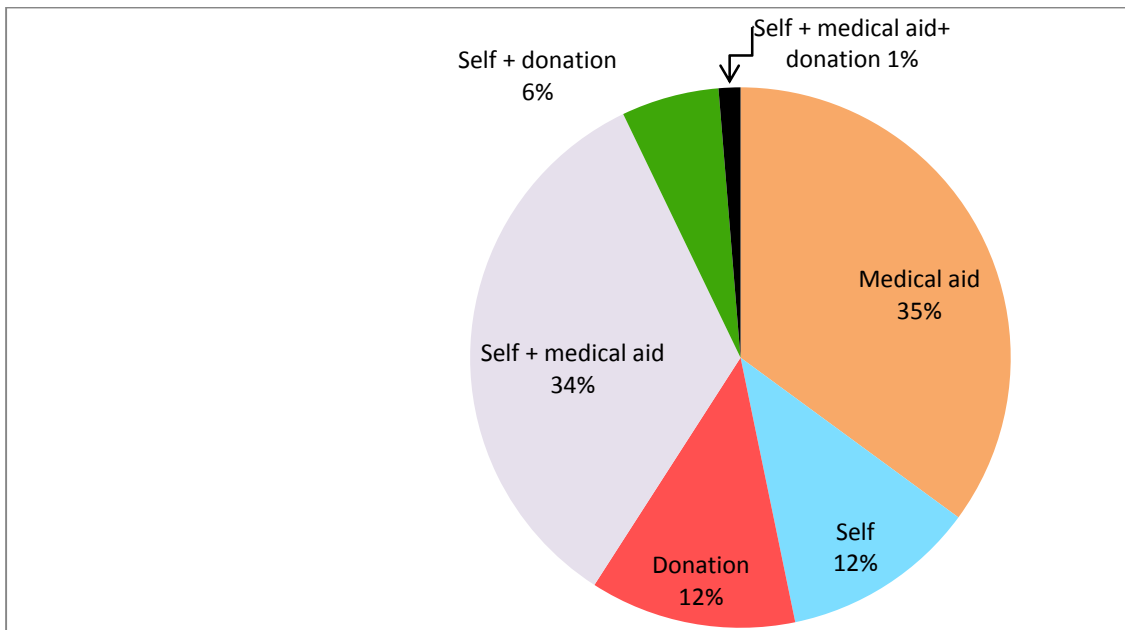
Figure 2 shows the rising trend for the average system cost over the twenty four year period, with a peak in average cost occurring between 2001-2005. As the implant systems are manufactured outside of South Africa and imported for use, a major reason for their cost fluctuations and increase may be due to the exchange rate changes.



**Figure 2. Cochlear implant system costs** grouped according to the year implanted

The system cost was by far the largest single cost involved in cochlear implantation. This result was similar to the findings in a recent French study which also reported the cost of the device as the main cost in implantation (Molinier, Bocquet, Bongard & Fraysse (2009)). In that study the cost of the device represented 64.4% and 68.8% of the total cost for children and adults respectively. Currently the system used at the Tygerberg Hospital Cochlear Implant Unit costs R221 000 (June 2010). The system cost is the same for both private and state individuals, as well as for paediatric and adult recipients.

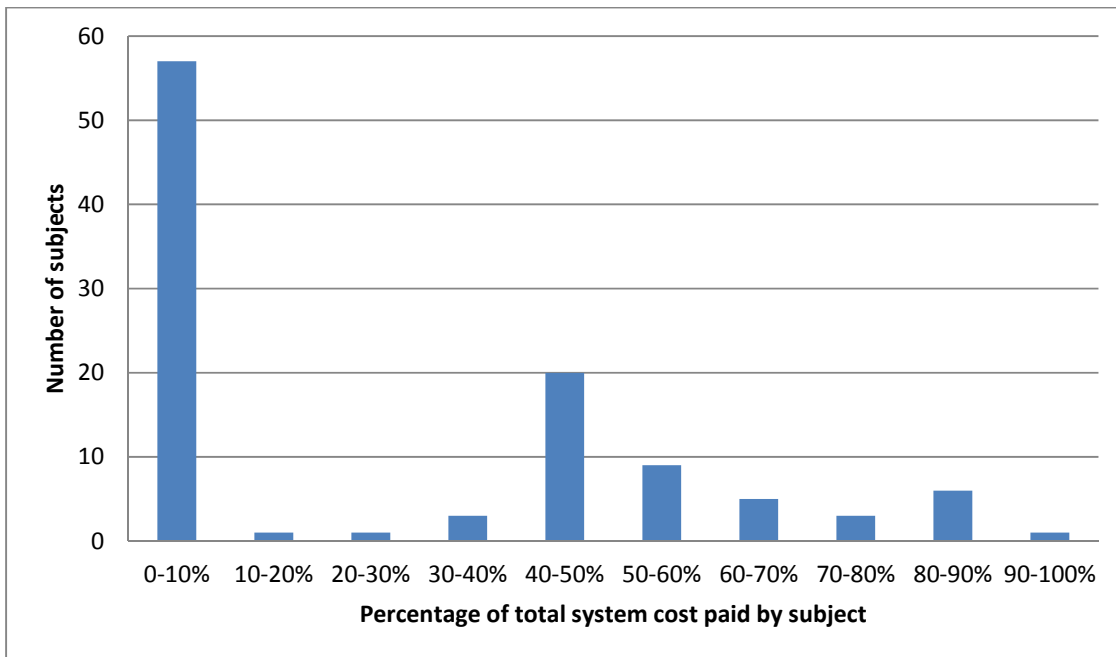
The amount that the subjects themselves paid towards the initial cost varied greatly. The individual's contribution to the system cost depended on whether they were on a medical aid or not, and, for those on a medical aid, on what proportion of the system cost the particular medical aid was willing to cover. Those not on a medical aid had to fund the entire cost of the system themselves. Figure 3 shows the different sources used by subjects to fund the cost of the cochlear implant system.



**Figure 3. Sources of funding for cochlear implant systems**

Figure 3 shows that 30% of the subjects (12%+12%+6%) were not on a medical aid when they were implanted. Twelve percent of these subjects had to fully fund the implant system themselves. Another 12% were fully assisted by donors. Six percent of the subjects funded their implant system using a combination of their own funds and those from a donor.

As seen in Figure 3 70% of the subjects (35%+ 34%+ 1%) were on a medical aid at the time they were implanted. There was considerable variation in the medical aids' contribution towards the cost of the implant system for these subjects. Half the subjects on a medical aid had the system fully funded by their medical aid. The other half of the subjects were on a medical aid, which only partially funded the system cost. These subjects had to pay in widely varying amounts of the system cost themselves, ranging from 5% to 95% of the cost. Figure 4 shows the percentage which these subjects had to pay towards the initial system cost.



**Figure 4. Own contribution to the cochlear implant system cost paid by subjects on a medical aid**

As shown in Figure 4, 57 subjects on medical aids (37%) paid less than 10% of the cochlear implant system cost themselves. This included the 54 subjects (35%) whose implant costs were fully sponsored by their medical aid. Most of the remaining 49 subjects had to pay more than half the initial cost of the system themselves, despite being on a medical aid. In present day terms this would mean paying more than R110 000. Two subjects used their own funds, combined with funding from their medical aid and additional funds from a donor to purchase the implant system.

**In summary:** The **cochlear implant system** was the most substantial single cost involved in implantation (R221 000 at June 2010). For a third of the subjects their medical aids had paid the amount in full. Some of the remaining two-thirds of the subjects received partial contribution from a medical aid (on average 50% of the cost); some had received, full or partial funding from a donor, while others had paid the total cost of the system themselves.

### 3.3. Batteries

The subjects' estimates of monthly battery cost were validated against the distributors' records of batteries purchased by them. These costs were analysed according to the type of

speech processor used. An average monthly battery cost per speech processor was determined. Table 5 details the monthly battery costs per speech processor type.

Table 5. *Monthly battery costs*

Speech processor type	Percentage of subjects' current speech processor	Body-worn or ear-level	Type of battery used	Average monthly battery cost (2010)	Range of monthly battery cost (2010)
Spectra/SPrint™	7%	Body worn	Penlight	R100	R50-R150
ESPr™/ESPr™22	1%	Ear-level	2 disposables (size 675)	R125	R100-R150
ESPr™ 3G (22/24)	24%	Ear-level	3 disposables (size 675)	R161	R126-R196
Freedom®	64%	Ear-level	3 disposables (size 675)  Or Lithium-ion (rechargeable), based on 2 years use (charger + 2 batteries included)	R180  R281	R110-R146
CP810	4%	Ear-level	Lithium-ion (rechargeable), based on 2 years use (charger + 2 batteries included)	R240	

As can be seen in Table 5, battery costs were strongly influenced by the type of speech processor. Ear-level speech processors were, on average, associated with greater monthly costs than body-worn processors. The greatest monthly costs were noted for the Freedom® processor.

On average, battery costs for the subjects varied from R100 to R281 per month (R1200-R3372 per year). Most subjects (93%) were currently using ear-level speech processors with only 7% of the subjects using body-worn speech processors. Nearly two thirds of the subjects were using the Freedom® speech processor. They were paying an average of R180 per month for disposable batteries, or R281 a month for rechargeable batteries (based on a 2 year lifespan of each battery, 2 batteries and charger included in price). Twenty four percent of the subjects were using an ESPrit™ 3G, paying an estimated average of R161 per month on batteries. At the time of the study, the latest Nucleus® speech processor, the CP810, had only been in use in South Africa for 6 months. Only 6 subjects were using this processor. All were using rechargeable batteries provided with the implant system, which cost an estimated R240 a month (based on a 2 year life span of each battery, 2 batteries and charger included in the price).

In addition to the type of processor, battery use, and thus cost, can also be influenced by individual implantee factors. These include programming parameters (such as coding strategy, maxima, rate of stimulation and pulse width), skin flap thickness, amount of hours of use of the device and noise level in the implantee's everyday listening environment. Individual recipient factors could account for the wide range of costs noted within a particular processor in Table 5. This was particularly noticeable for the ear-level processors. One particular subject at the high end of the range for the Freedom® battery costs had to spend almost 60% more on batteries per month than the average cost. This individual variation could have been caused by the subject's thick skin flap resulting in greater power requirements and greater battery drain. Such individual factors are difficult to predict prior to implantation.

Before the introduction of an ear-level speech processor in 1999, all implantees were using body-worn devices in South Africa. Body-worn speech processors use penlight batteries, which can be disposable, or rechargeable. The rechargeable batteries used in the body-worn devices are not product specific. They are the same as those used in other electrical appliances, are readily available and cost relatively little. In 1999 the introduction of ear-level

speech processors necessitated a move towards the use of disposable 675 batteries. Initially ear-level speech processors used 2 batteries at a time. In order to support faster stimulation rates, the later generation ESPrit™ 3G and Freedom® processors required the use of 3 batteries at a time. The latest ear-level Nucleus® speech processor, the CP810, once again uses 2 disposable batteries at a time, as the system uses power more efficiently than its predecessors. An ear-level speech processor typically requires 20-30 disposable batteries a month. This is significantly more than the requirement of a powerful hearing aid, which implantees would typically have been using prior to being implanted. Such hearing aids would generally use 2-3 batteries a month. The greater battery use in speech processors is due to the greater power demand of the processor in comparison to that of a hearing aid.

Rechargeable batteries for the Freedom® speech processor became an option for South African implantees from December 2006. Currently the latest two ear-level speech processors (Freedom® and CP810) can use either rechargeable or disposable batteries. The rechargeable batteries for the ear-level speech processors are specifically made for the processor and currently cost R2150-R2445 each. They have a one year warranty. The high cost of these batteries can result in greater expense to implant recipients than that of disposable batteries over a year's use. A possible cost saving to implantees of using rechargeable batteries with their ear-level speech processor can only be made, if the implant system or processor is fully funded by a medical aid or sponsor, and the batteries are included in the price. In this case implantees do not pay the cost of batteries until they themselves have to replace the rechargeable batteries after the one year warranty period. Due to the high cost of the rechargeable batteries for ear-level processors relative to the cost of disposable batteries in the South African market, many implantees, who are using rechargeable batteries for their ear-level processor choose to return to using disposable batteries once their rechargeable batteries can no longer be used. While rechargeable batteries for the current ear-level speech processors may be more convenient and more environmentally friendly, they are not currently a cost saving option in the South African context.

As can be seen batteries constitute a significant ongoing cost item to implant recipients. Most recipients need to cover the cost of the batteries themselves. Most medical aids do not cover the cost of batteries, and the few that do, tend to deduct the amount from the implantee's

savings account. While improvements in battery life, and thus battery cost, may be expected in the future, prospective implantees need to be aware that monthly battery costs for a speech processor will be relatively high and significantly greater than for a hearing aid. The significance of battery costs to subjects was noted in response to the open ended Question 8 of the questionnaire, where subjects were asked to advise potential implantees. Almost a quarter of the subjects warned about the high cost of batteries and advised users to make provision for this cost each month.

***In summary:*** The average **battery costs** for the subjects varied from R1200 to R3372 per year (R100 to R281 per month). The costs were influenced by the speech processor being used, and were generally lower for body-worn devices than for ear-level speech processors. Purchasing the currently available rechargeable batteries for the ear-level speech processors appeared to be less cost effective for subjects than purchasing disposable batteries.

### **3.4. Spares**

In the present study, spare parts for the cochlear implant device included all external hardware, which attach to the speech processor as well as items needed to maintain the device. External hardware included: cables, coils, magnets and, for the body-worn devices, microphones. Items initially provided with the device to maintain it (e.g. drying capsules and drying kits), which had to be replaced by subjects over time, were included. Implant recipients received one spare cable with their processor at the time of fitting. All external hardware was under a one year warranty from the time of fitting. Thereafter the cost of any replacements was borne by the implantees.

Complete records for spare parts purchased by subjects from the current sole supplier were available from 2001. In order to obtain data regarding spares used over the entire duration of a subject's use of their implant, only those subjects implanted from 2001 were included in the analysis of spare parts purchased. This equated to 103 subjects (67% of the sample). Subjects were grouped according to the duration of use of their implants. The overall cost of spare parts purchased by subjects will be presented first. Thereafter the purchase of cables and coils will be presented and commented on in greater detail.



### 3.4.1. Total spares costs

Table 6 provides the cost details of spares purchased per subject, grouped according to the year they were implanted.

Table 6. *Details of spares costs (N=number of subjects implanted)*

Year implanted	N	Number of subjects who bought spares	Total average spares cost per subject (2010 Rands)	Average spares cost per year per subject (2010 Rands)
2001-2002	9	7 (78%)	R2672 (Range:R0-R9164)	R268 (Range: R0-R196)
2003-2004	21	17 (81%)	R1867 (Range: R0-R7919)	R234 (Range: R0-R990)
2005-2006	20	17 (85%)	R2361 (Range: R0-R5215)	R394 (Range: R0-R869)
2007-2008	31	20 (65%)	R838 (Range: R0-R3183)	R210 (Range: R0-R796)
2009-2010	22	4 (18%)	R86 (Range:R0-R578)	R43 (Range: R0-R289)

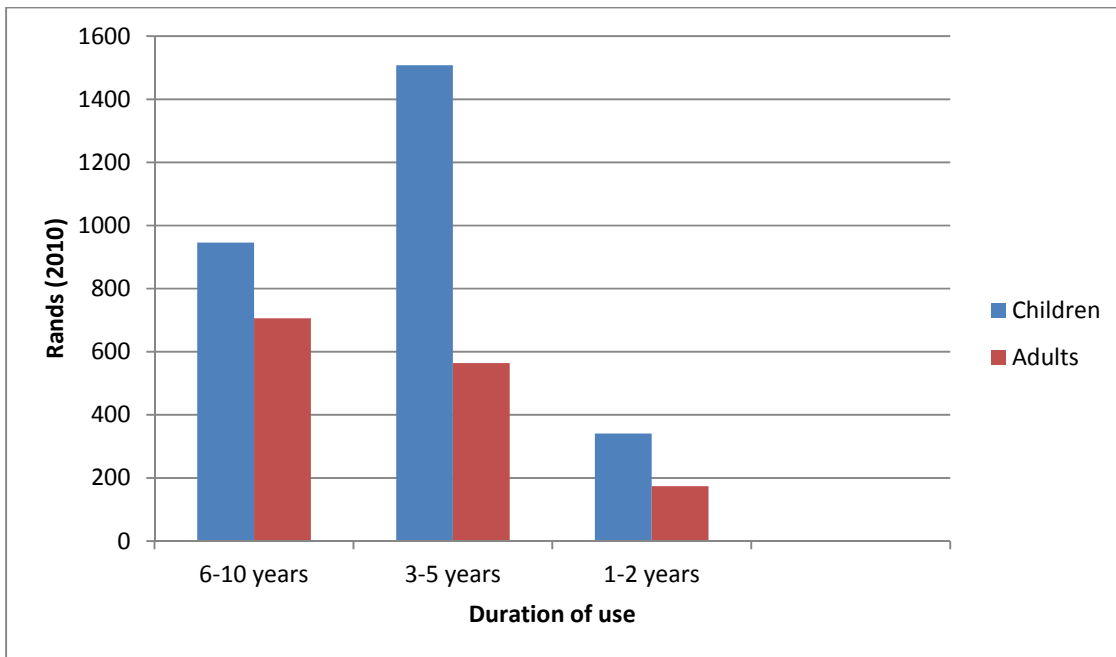
As seen in Table 6 the average spares costs was higher for those, who had been implanted for 4 years or more (between 2001 and 2006), and highest for those, who had been implanted the longest. Subjects implanted for 9-10 years had spent on average a total of R2672 on spares purchases (R268 per year), though some had spent nothing and some had spent up to R9164 (R916 per year). Those implanted for 7-8 years had spent an average of R234 per year on spares. The average annual spares expenses peaked for those implanted for 5-6 years, who had spent, on average, R394 per year on spares. Those implanted for 3-4 years had spent, on average, R210 per year on spares. Those implanted for the shortest time, 1-2 years, had incurred the lowest spares costs, on average R43 per year implanted. Most subjects implanted for more than 2 years (all those implanted before 2008) had had to

purchase spares. The average amount of money spent on spares by subjects implanted for less than 2 years (implanted 2009-2010) was minimal. Most of these subjects had not had to purchase any spares at all. Of the 22 subjects implanted for less than 2 years, only 4 had bought spares. The main item purchased by these subjects was drying capsules used to protect the processor from moisture. Some of these subjects had also bought a baby-worn accessory pack, to secure the processor when a young child was wearing it.

Very wide ranges of spares costs were noted (see Table 6), and some subjects had incurred significantly higher expenses than the average. The wide ranges indicated a large amount of individual variation in the purchase of spare parts among subjects. Different speech processor types could also have played a role in this variation, as the cost of parts is dependent on the speech processor. Spares purchases were skewed and possibly under-reported due to some implantees using second hand stock donated from other implantees as they were unable to afford the purchase of new stock from the distributor.

Another factor, which would have influenced the need to purchase spares, was upgrades to the speech processor. When implantees upgrade their speech processor, they receive new cables/coils and other spare parts. This will reduce the need to purchase spare parts in the time period following an upgrade. Implantees should, however, be aware that, when upgrading to more technologically advanced devices, some spare parts for the newer devices may be significantly more expensive than for their older devices. As an example, the coil-cable for the Freedom® speech processor is approximately two thirds more expensive than that of the ESPrit™ 3G, the ear-level processor which preceded it.

When the costs of spares were analysed separately for the children and adults (see Figure 5), spares costs were on average greater for the children than for the adults. The greatest spares costs for the children were incurred during the 3-5 year period following implantation. This may be because this was generally the time period when the spares initially received at the time of activation had been used and new spares had to thus be purchased as parts became older.



**Figure 5. Cost of spares**

There is little current research available regarding the long term repair issues associated with the external components of cochlear implants. Of the 2 previous studies cited in Silverman, Schoepflin, Linstrom and Gilston (2010), one examined issues of external reliability for 3 different types of cochlear implants, but the follow up period was less than 2 years. The other study looked at the rate of external component breakdowns for 25 children using Symbion Ineraid cochlear implants, but did not report on individual component breakdowns. Silverman et al. (2010) examined the number and type of repair issues associated with children using cochlear implants for 4 to 5 years. The children were all using Nucleus® devices, as were those in the current study. The mean age at implantation was 6 years, a year and a half older than the average age at implantation of children in the current study (4.5 years).

Silverman et al. (2010) examined the records of 22 children implanted between 1994 and 2002 and classified implant problems as internal or external. The records examined were almost 10 years older than those examined in the current study, which considered spares and repairs from between 2001 and 2010. Unlike the current study they included all repairs from the time of implantation. The current study only included repairs and spares which were needed after the warranty periods, as they incurred costs for the subjects. Silverman et al. (2010) found that repair problems with the external components were relatively frequent. The vast majority of children in the study had repair issues associated with the external

components of the cochlear implant. For the body-worn processor, repair issues largely affected the cables, microphone, coil and external magnet. The speech processor, coil and external magnet were most frequently involved for the ear-level speech processor.

The rates of repair were substantially higher for the body-worn style than for the ear-level style. The repair rate per year for the external components was 4.1 and 2.7 for the body-worn and ear-level speech processors respectively. The mean repair cost per year (based only on years 4 and 5 of use) was more than double for the body-worn in comparison to the ear-level. The authors hypothesized that several factors, including greater age and maturity at the time of use of the ear-level processor in comparison to the body-worn, could have influenced this finding. The mean number of repair problems declined over time, which the authors indicated suggested that children learn to look after their cochlear implant better over time. The authors anticipated that repair problems would increase beyond the 5 year follow-up investigated in their study, due to the equipment aging.

#### **3.4.2. Cables and coils**

Due to the relatively high cost of cables and coils, and the need to replace them immediately once they become faulty in order for the implantees to continue hearing, they were analysed separately from the rest of the spares, to try and establish trends relating to their purchase. As with the analysis of spares as a whole, only those subjects implanted from 2001 were included in this analysis, so that the complete records of spares purchased throughout the time they had been using their implant could be reviewed.

Patients received one spare cable or cable-coil with their device initially. When the replacement patterns of coils and cables was analysed for the subjects, grouped according to how long they had been using their implants, the following trends were noted:

*Eight-ten years of use (implanted 2001-2002):* Six of the 9 subjects (67%), who had been using their implants for 8-10 years had needed to replace coils/cables, on average costing the recipients R3827. Of these subjects one had replaced a cable/coil once and three had had to do so twice. Clustering of purchases was noted around two children; one of whom replaced 7 cables and 3 coils and one who replaced 8 cables or coils.

*Six-eight years of use (implanted 2003-2004):* Ten of the 21 subjects (48%), who had used an implant for 6-8 years, had had to replace cables or coils at an average cost of R2268 each. Four subjects had replaced cables or coils for an ear-level speech processor once, and four had done so twice. Clustering of purchases was again noted around two children, who were both using body-worn devices. One child had had to replace 4 cables and a coil, and the other 3 cables.

*Four-six years of use (implanted 2005-2006):* Thirteen of the twenty subjects (65%), who had used their implants for 4-6 years, had purchased cables/coils at least once, at an average cost of R2360 each. On average, subjects in this group had bought 1 cable or coil since they were implanted. There were, however, some notable exceptions, where purchases clustered around individual implantees. This clustering was noted particularly for two children; one of whom had had to replace 9 cables and a coil, and the other, who had replaced 6 cables and a coil. Both of these children were using body-worn devices.

*Two-four years of use (implanted 2007-2008):* Of the 31 subjects, who had been using their implants for 2-4 years, six (19%) had purchased a cable/coil at an average cost of R2897 each. The majority of these subjects were using ear-level speech processors.

*Less than 2 years use (implanted 2009-2010):* None of the 22 subjects, who had used their device for less than 2 years had had to replace a coil or a cable.

***In summary:*** As expected there was a direct relationship between the age of the implant and the need to replace **cables/coils**. Most subjects had to start replacing cables/coils from 4 years post implant, but individual variability was also noted. The purchase of coils and cables appeared to be sporadic. Purchases occurred at variable time intervals post implant and seemed to be influenced to an extent by the individual implantee. Some subjects seemed to replace significantly more cables/coils than others. This clustering of cable/coil purchases was primarily noted for some paediatric implant recipients. It suggests that young children receiving a cochlear implant system may potentially have to replace more cables/coils than those implanted as adults, and parents should be prepared for this possibility.

### 3.5. Speech processor repairs

The externally worn speech processor has a three year warranty from the date of fitting. After three years, any repairs to the speech processor have to be paid for by the implant recipient. Medical aids do not generally cover repair costs. Some insurance policies may. Subject recall of the number of post-warranty repairs to their speech processor was probed in the questionnaire and then validated by comparing to records kept by the current South African distributor of Nucleus® products, which date back to 2001. As accurate records were only available from 2001, the repairs were only analysed for subjects implanted from 2001 (n=103) so that a complete record of the repairs over the subjects' entire duration of use of their cochlear implant could be reviewed. Only repairs done outside of the warranty period were included. Table 7 details the number of speech processors needing repair and the average cost per repair, grouped according to how long subjects had been implanted for.

Table 7. *Speech processor repairs*

Year implanted	Duration of use (years)	N	Number of devices needing repair	Average cost per repair (2010 Rands)
2001-2002	8-10	9	5 (60%)	R3234 (R93250*)
2003-2004	6-8	21	9 (40%)	R3342 (R69130*)
2005-2006	4-6	20	3 (15%)	R3129
2007-2008	2-4	31	7 (22%)	R3104
2009-2010	0-2	22	Speech processor still under warranty	

\*One patient implanted during 2001-2002 and one implanted during 2003-2004 had to replace their faulty speech processors as they were declared beyond repair. The replacement cost (indicated in brackets\*) was substantially higher than the average repair cost.

As shown in Table 7, the percentage of speech processors requiring repair increased for those, who had been implanted for a longer period of time, and was greatest in the group that had been implanted the longest (8-10 years). Subjects implanted for longer than six years had, on average, had significantly more repairs than those implanted for less than six years. Subjects, who had had a processor repaired, had generally only paid for one repair in the 10 year period under review. One subject was a notable exception. He was implanted in 2002 and, over the 7 years 8 months he had been using his processor, it had been repaired four

times. A possible reason for the increased need for repairs for this subject's speech processor was his tendency to perspire excessively, which can cause moisture damage to the microphones of the speech processor. Implantees, who lead a very active lifestyle, such as sportsmen and women, and others who perspire heavily, should be made aware of the possibility of increased need for repairs to their speech processor, due to damage, which this can cause. They should also be particularly vigilant in using drying kits to reduce the possible damage which moisture can cause.

As seen in Table 7, the average cost per repair stayed fairly constant over time at around R3000. Currently there is a flat rate of R2950 charged for any repairs needed for a speech processor outside of its warranty period, and any processor found to be beyond repair has a fixed replacement cost of R5500. In the case of speech processors, which have been declared obsolete, implant recipients need to purchase a new speech processor, when their current obsolete processor becomes faulty. In earlier years, a fixed replacement rate was not an option, hence the very high replacement costs highlighted in Table 7 for two subjects, whose processor could not be repaired, and, who had to purchase a new speech processor instead.

The need for repairs to the speech processor appears to be influenced by the age and type of the processor, which are, in turn, affected by how frequently the processor is upgraded. Upgrading of the speech processor allows implant recipients access to more advanced technology. It also brings the concurrent benefit of a new three year warranty period, which reduces repair costs during that time period. Implant recipients, who are able to upgrade on a regular basis, could thus save on repair costs.

***In summary: Repairing a speech processor*** (after the three year warranty had expired) cost an average of R3000 per repair. The percentage of devices needing repair increased with increasing duration of implantation, and was, on average, higher for those who had been implanted for longer than 6 years. As expected, the highest percentage of devices needing repair (60%) was noted in the group of subjects, who had been implanted for the longest time period reviewed (implanted 8-10 years). With a few exceptions, most subjects, who had had a device repaired, had only had one repair in the 10 year time period reviewed.

### 3.6. Upgrades of the speech processor

Next to the cost of the implant system itself, upgrading the speech processor is the second largest single cost involved in implantation. The current cost of upgrading to the latest compatible speech processor (CP810) is R85 000. Upgrading instead of trading-in allows implant recipients the advantage of keeping their existing processor as a back-up device.

In order to gain a comprehensive view of upgrades over the longest possible time period, all subjects were included in the analysis of upgrades of their speech processor. This was possible as accurate records of all upgrades (including date of upgrade and processor type) were available in the Tygerberg Hospital Cochlear Implant Unit's database for all subjects. Subjects were grouped according to how long they had used their cochlear implant, and the number of upgrades in each group was reviewed. Table 8 details the upgrades of speech processors for all subjects, grouped according to the year they were implanted.

Table 8. *Speech processor upgrades (Subjects are grouped according to the year they were implanted) (N = number of subjects)*

Year implanted	Duration of use (years)	N	Total number of upgrades	Average number of upgrades/person
1987-1989	20+	5	14	2.8
1990-1995	15-20	12	21	1.75
1996-2000	11-15	26	33	1.3
2001-2005	6-10	44	28	0.6
2006-2010	0-5	67	4	0.06

As anticipated (see Table 8), the average number of upgrades increased significantly as the duration of use increased. Those, who had been implanted for twenty years or more, had on average upgraded their speech processor 2.8 times. Those implanted for 15-20 years had, on average, upgraded their speech processor 1.75 times.

Table 9 details the percentage of subjects, who had upgraded their speech processor and the number of times they upgraded over the duration of use of their implant. Subjects were

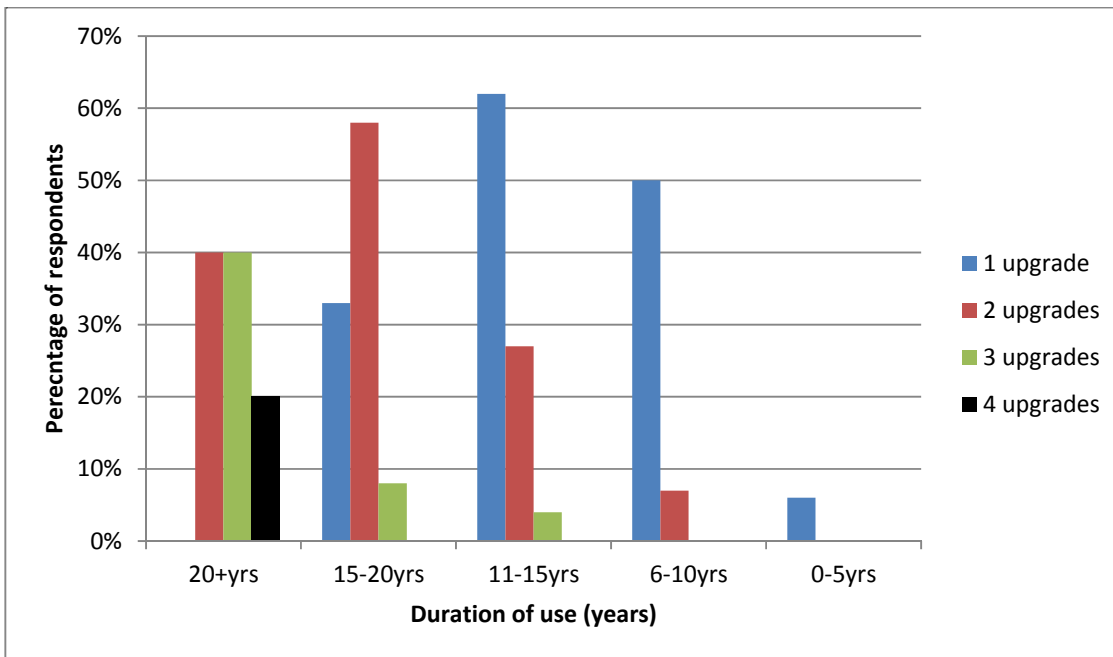


grouped according to the length of time they had been using their implant. Figure 6 presents this information in graphic form.

Table 9. *Percentage of subjects upgrading their speech processor (Subjects are grouped according to the duration of use of their cochlear implant)*

Duration of use (years)	No upgrades	Percentage upgrading at least once	1 upgrade	2 upgrades	3 upgrades	4 upgrades
20+	0	100%	0	2 (40%)	2 (40%)	1 (20%)
15-20	0	100%	4 (33%)	7 (58%)	1 (8%)	0
11-15	2 (7%)	93%	16 (62%)	7 (27%)	1 (4%)	0
6-10	19 (43%)	57%	22 (50%)	3 (7%)	0	0
0-5	62 (93%)	6%	4 (6%)	0	0	0

As can be seen in Table 9 all the subjects, who had been implanted for longer than 15 years, and most of those implanted for 11-15 years, had upgraded their speech processor at least once.



**Figure 6. Speech processor upgrades.** The percentage of subjects who upgraded their speech processors is shown, with the subjects grouped according to the duration of use of their cochlear implant

In summary, as can be seen in Figure 6 all those implanted for more than 20 years had upgraded at least twice, with 2 of the subjects in this group having upgraded three times, and 1 having upgraded four times. More than half the subjects implanted for between 15 and 20 years had upgraded twice over that period of time. All the subjects implanted for longer than 15 years had upgraded at least once. Most of the subjects implanted for between 11 and 15 years had upgraded at least once, with more than a quarter upgrading twice. More than half the subjects implanted for between 6 and 10 years had upgraded their speech processor. Most of them had upgraded only once and a small number twice. Most of the subjects using their processor for less than 5 years had not upgraded. A small number had upgraded once.

On average, the subjects upgraded every 7 years. The number of years between upgrades ranged from 1 year to 14 years. Two of the longest implanted subjects, who had never upgraded had used their same processor for 10.25 and 12.5 years respectively.

Upgrades among subjects were, on average, less frequent than the current usual practice in the United Kingdom, where speech processors, are upgraded free of charge on average every 4-5 years of use (S. Thomas, personal correspondence, November 18, 2010). The maximum length of time before an upgrade in the United Kingdom was estimated to be once

every 10 years in a study reviewing the cost effectiveness of paediatric bilateral cochlear implantation in that country (Summerfield, Lovett, Bellenger, & Batten, 2010).

An interesting trend was noted among subjects subscribing to one particular medical aid. These subjects tended to upgrade more frequently than others did. Most of them upgraded each time a new compatible speech processor was released. This increased frequency of upgrading appeared to be a direct result of their medical aid benefits, which included full coverage of the cost of an upgrade every 3 years. In response to the open-ended Question 8 of the questionnaire, which asked subjects what advice they would give potential implant recipients with regards to costs associated with a cochlear implant, many subjects advised others to move to this particular medical aid as a result of their known support for upgrades. This particular medical aid represented a large number of the subjects. Their upgrade policy enabled implantees to upgrade more frequently than they may otherwise have been able to do.

Those subjects, who did not have readily available funding (e.g. not on medical aid, or on a medical aid that did not fund their upgrades) tended to upgrade less often, if at all. Many of them had to save or fundraise in order to afford an upgrade. Of this latter group most had only upgraded once, primarily to move from a body-worn speech processor to a more conveniently worn ear-level speech processor, or because they were obliged to upgrade as a result of their speech processor becoming obsolete. At the time of the study, three subjects were still using processors, which had been declared obsolete. They were in the process of raising the funds needed to upgrade.

***In summary: Upgrading the speech processor*** (R85 000 at June 2010) was the second highest single cost, after the initial cost of the implant system (R221 000 at June 2010). All the subjects implanted for more than 15 years had upgraded at least once. Most of the subjects implanted for less than 5 years had not upgraded their speech processors yet. On average the subjects had upgraded every 7 years (range: 1 year to 14 years). Some subjects appeared to upgrade every time a new compatible speech processor was released, and others only to move from a body-worn to an ear-level speech processor, or because their processor had been declared obsolete. The subjects on one particular medical aid appeared to upgrade more regularly than other recipients, presumably due to the medical aid's policy of

funding upgrades at stipulated time intervals. Upgrading of the speech processor would have reduced both spares and repairs cost post upgrade due to the new warranty period.

### **3.7. Additional costs**

In addition to costs directly related to the cochlear implant system itself, some subjects had additional costs related to the use of their cochlear implant system and recommended by the cochlear implant team. These additional costs included: costs associated with hearing aid use, FM use and insurance.

#### **3.7.1. Hearing aids**

In addition to using the speech processor in the implanted ear, approximately a third of the subjects (32%) used a hearing aid in the non-implanted ear. Half these individuals had paid for the hearing aid themselves, 26% were on a medical aid, which paid for the hearing aid and a small number (3) used a combination of their own and medical aid funding to purchase the hearing aid. In the latter group, the portion, which subjects had to pay towards the hearing aid, ranged widely from 10% to 80% of the cost. Three subjects received their hearing aid from the state (free of charge to children under 6 years old). Four subjects did not indicate how they had paid for their hearing aid. Current hearing aid use was not reported by any of the subjects implanted before 1997.

The cost of the hearing aids varied widely, ranging from R3000 to R29800. Costs could not, however, be compared in real terms or averaged as the hearing aids were purchased at different times and costs were not linked to a specific year. Currently the price of a superpower digital hearing aid (the most likely choice for the non-implanted ear of a cochlear implant recipient) ranges between R3534 and R29750, depending on the make of the aid and the technological sophistication of the product. Subjects spent, on average, R31 per month on batteries for their hearing aid.

#### **3.7.2. FM system**

Of the 154 subjects implanted, only 23 (15%) indicated that they had bought an FM system. Most (87%) of the FM systems were purchased for children. Fourteen of the subjects (61%) paid for the assistive listening device themselves and 8 (35%) paid for the device through funds from their medical aid. One subject had had to pay a portion of the costs not covered by

his medical aid. Those, who bought an FM system themselves, paid varying amounts, ranging between R3800 and R32000 for a system. As these costs were not linked to a specific time period it was not possible to compare them in absolute terms or to determine the average amount which subjects had to pay. The FM system purchased has to be compatible with the particular speech processor, which the implantee is using. The available FM systems, which are compatible for use with a cochlear implant currently range in price from R9 964 to R21750. The findings of this study suggest that a high percentage of implant recipients, who choose to purchase an FM system, will need to fund the cost themselves.

### 3.7.3. Insurance

Forty two subjects (27%) indicated that their speech processor was insured. The average monthly insurance premium, which subjects were paying was R337. A wide variability was noted, with monthly premiums ranging from R50 to R800 per month. Eight subjects indicated that they had investigated insuring their speech processor, but were unable to afford the monthly premiums. One subject had stopped his insurance due to cost factors.

In response to Question 8 of the questionnaire, which asked the subjects to advise others on costs involved in cochlear implantation based on their own experience, 21 (17%) indicated that insuring the processor was very important. A number emphasised that insurance was particularly important, when young children were using a cochlear implant. One subject, whose child's processor had not been insured at the time it was lost, indicated that it had been very expensive to replace the speech processor. As a result, this parent had later taken out insurance for the new speech processor. While many subjects felt insurance was important, a number also commented on the high cost of monthly premiums.

Insuring the speech processor is optional, but recommended. It can spare implant recipients significant costs should the processor become lost or stolen, or be declared beyond repair and have to be replaced. Implant recipients, who are not insured, would have to fund the cost of a new speech processor. This currently equates to R85 000 (June 2010).

***In summary: Additional costs***, which some subjects incurred, included the cost of a hearing aid in the non-implanted ear, an FM system and insurance. The current cost of a **hearing aid** varied from R3534 to R29 750. Approximately a third of the subjects used a hearing aid in their non-implanted ear. Half the subjects had purchased the hearing aid themselves, and a

quarter had received funding from their medical aid. Fifteen percent of the subjects had purchased a personal **FM system**, whose current cost varied from R9964 to R21750. Most were purchased for children to use. Two thirds of the subjects had paid for the device themselves. The rest were funded partially or in full by their medical aid. Twenty seven percent of the subjects had **insured** their speech processors. Premiums were on average R4044 per year (R337 per month), but varied widely from R600 to R9600 per year (R50 to R800 per month). Some subjects, who wanted to insure their processors, found the monthly premiums too costly to afford.

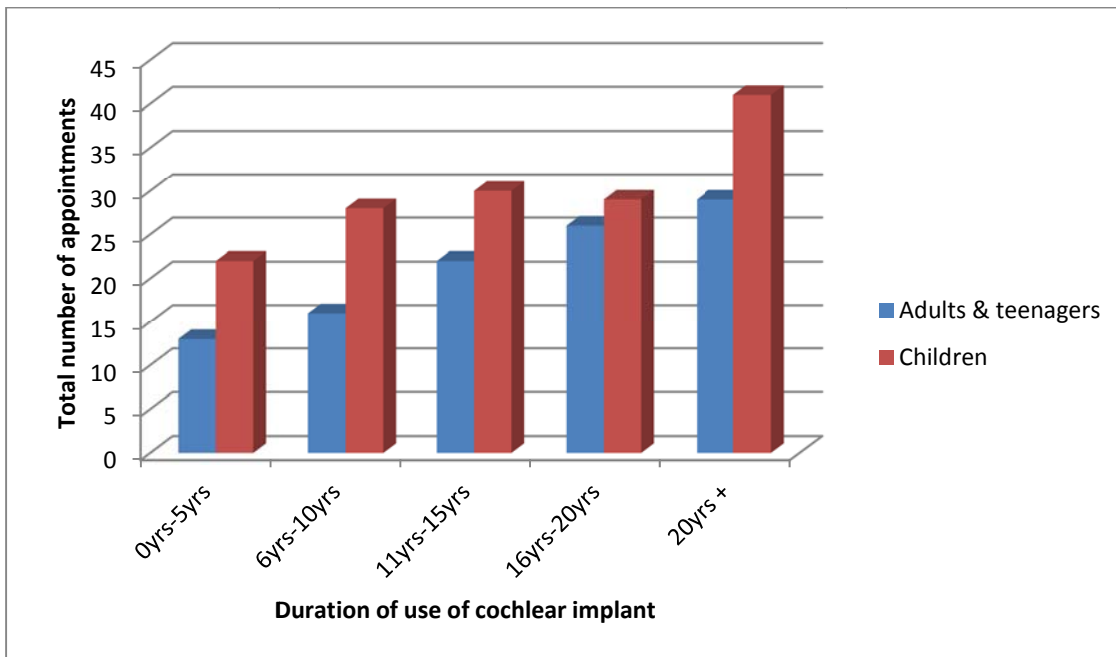
### **3.8. Accessing the Cochlear Implant Unit at Tygerberg Hospital**

The evaluation of accessing the services at the Tygerberg Hospital Cochlear Implant Unit took into account the following aspects: the number of appointments at the unit, travel costs and accommodation costs.

#### **3.8.1. Number of appointments for audiological management**

The Tygerberg Hospital Cochlear Implant Unit schedule of average number of electrode programming appointments (Appendix F) was used to estimate the average number of appointments attended by implantees at the different time intervals post implantation. Some implantees with complicated programming concerns, or those requiring extra support, may, however, have required additional visits over and above these averages.

Figure 7 shows a graphic representation of the average total number of appointments at the implant unit required by subjects over the time they had been implanted. The subjects were grouped according to the duration of time they had been using their implants. Children were considered separately from teenagers and adults.



**Figure 7. Average number of appointments for subjects** (Subjects are grouped according to the duration of use of their cochlear implant)

It can be seen that the age, at which a subject was implanted, influenced the number of appointments needed at the implant unit. Those implanted as children (i.e. under the age of 13 years) required on average more visits to the implant unit than those implanted as teenagers or adults. Also those subjects (adults and children) implanted for less than 5 years had already attended almost half as many appointments as those implanted for more than 20 years, which highlights the increased frequency of appointments in the earlier years following implantation.

All subjects required substantially more appointments at the implant unit in the first two years following implantation than during any other time period. The number of appointments in the first two years following implantation ranged between 15 and 22. Thereafter the frequency of appointments declined significantly. Young children implanted under the age of 3 years required more frequent visits and for longer time periods in order to monitor their progress and make the necessary programming changes. Congenitally deafened individuals, who were implanted as teenagers or adults, required more frequent visits in the first year of implantation than those with acquired hearing loss as they required a greater degree of aural rehabilitation to assist them in adjusting to the new signal type.

### **3.8.2. Travel costs**

In examining the travel costs associated with visits to the cochlear implant unit, the distance, which subjects lived from the unit, as well as the type and cost of transport used were considered.

#### **3.8.2.1. Distance from the implant unit**

Most subjects (124) had lived the same distance from Tygerberg Hospital from the time they were evaluated to the time the study was conducted. Thirty subjects had lived at varying distances from the cochlear implant unit over time. Of the 124 subjects, who lived the same distance away from Tygerberg Hospital throughout, most (63%) lived within 50km of the hospital. Nineteen (15%) lived on average 75km from the hospital, 10 (8%) lived an average of 300km from the hospital, 10 (8%) lived an average of 750km from the hospital and 7 (6%) lived more than 1000km from the hospital.

Until 1990 the Tygerberg Hospital Cochlear Implant Unit was the only implant programme in South Africa. As a result, all individuals, who were implanted in South Africa, had to travel to Tygerberg Hospital to access cochlear implant services. With the subsequent gradual establishment of other implanting programmes in the country, some implantees originally implanted at Tygerberg Hospital were later able to transfer to programmes closer to their home for ongoing audiological management. Twelve subjects, who had initially been implanted and managed at Tygerberg later chose to transfer to closer programmes after they became established, to reduce travelling and accommodation costs, as well as travelling time, associated with ongoing follow-up appointments. Prior to transferring, 10 of these subjects had lived more than 1000km away, and two had lived an average of 750km from Tygerberg Hospital.

While some implantees transferred to other programmes, others relocated in order to be closer to the Tygerberg Hospital Cochlear Implant Unit and to the rehabilitation facilities it offers. Of the 12 subjects, who relocated, 9 were families of young children, who had received a cochlear implant. At the time of evaluation, 2 of those, who relocated lived an average of 750km from the implant unit and 10 lived more than 1000kms from the unit. Eight relocated to within 100km of the hospital within the first 2 years of implantation. One child's family relocated closer to Tygerberg Hospital after their child had been implanted for 5 years. While



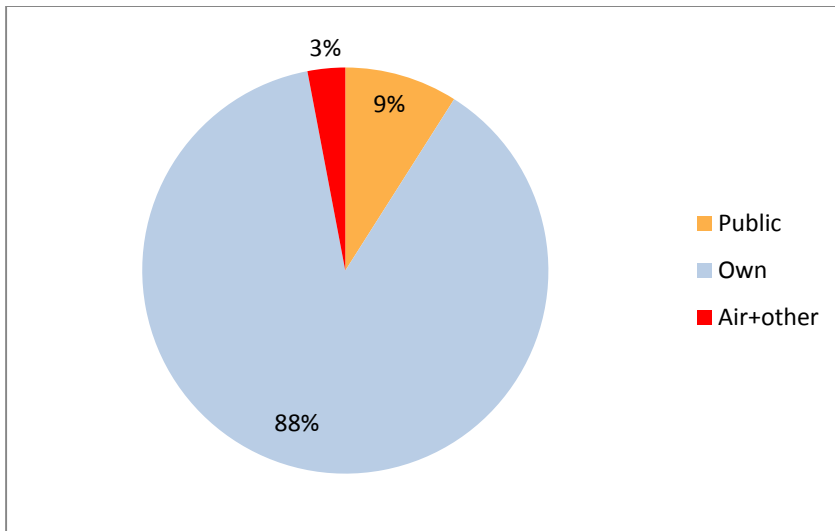
relocation costs were not specifically targeted in the present study, these costs would represent a significant additional expense to families. The majority of subjects, who had relocated indicated that they had done so in order to be able to access appropriate rehabilitation services for their young child, who had been implanted. The critical need for long-term rehabilitation services and support for young children being implanted, coupled with the increased frequency of programming and follow up appointments, was reflected in the relocation of some of these families, who chose to move closer to the Cochlear Implant Unit to facilitate their young child's needs as a result of undergoing cochlear implantation.

When individuals are implanted, it is important for them to be aware that they require life-long follow up and monitoring and that they will need to access an appropriate implant programme on a regular basis should they relocate their home. The programme will need to be able to manage the particular implant system, which the implantee is using. With the establishment of more implant programmes in South Africa, it is becoming easier to manage implantees, who move around the country. The programmes are, however, still located in 6 main city centres.

### 3.8.2.2. Transport

#### 3.8.2.2.1. Transport type

Figure 8 shows the type of transport subjects used in order to attend appointments at the Cochlear Implant Unit.

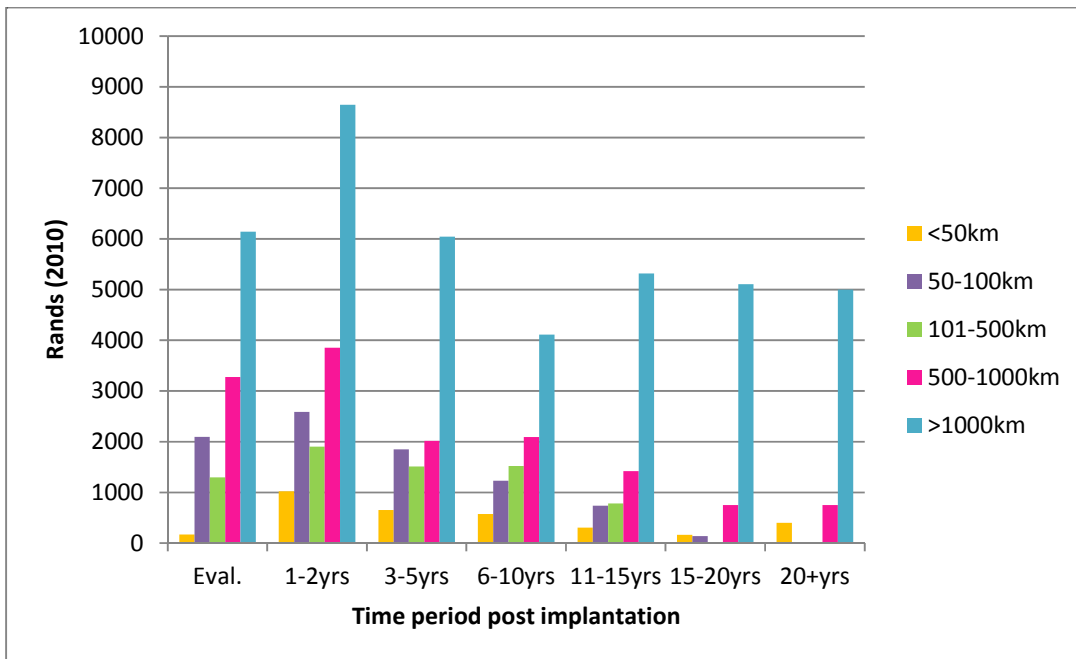


**Figure 8. Type of transport used by subjects to attend appointments at the implant unit**

Of the 134 subjects (81%), who used the same mode of transport throughout the different time periods in the implantation process, most (88%) used their own transport. A small percentage of subjects (9%) used public transport and an even smaller percentage (3%) used a combination of air travel and other transport. Subjects in the latter group all lived more than 1000km from the unit. Twenty subjects used varying modes of transport over the implantation period. These included 9 subjects, who initially lived more than 1000km away and used air travel, and later their own transport, and 8 subjects who initially used public transport, but later acquired their own transport.

#### 3.8.2.2.2. Transport costs

Figure 9 shows the average cost of transport the subjects estimated they had incurred per time interval in the implantation process. The costs were grouped according to the distance subjects stayed from the implant unit during that particular time period. The changing group size, as the time interval increased, was accounted for in the calculations.



**Figure 9. Average estimated transport costs incurred by subjects.** The total costs per time interval are shown with respondents grouped according to the distance they lived from the unit during the time interval

As shown in Figure 9 those living further away from the implant unit incurred higher transport costs during all the time intervals than did those living closer to the unit. The exception was the group living 100-500km from the implant unit, who incurred slightly lower costs than those living 50-100km during the first 3 time intervals. Subjects living more than 1000km from the unit incurred significantly higher transport costs than any of the other groups.

The highest transport costs were noted for all groups for the 1-2 year period post implantation. This was probably a reflection of the increased number of visits made to the implant unit during this time interval. Within groups a general trend was noted for transport costs to rise from that at the evaluation, peak during the 1-2 year period, then gradually decrease or plateau in the later time periods.

### 3.8.3. Accommodation

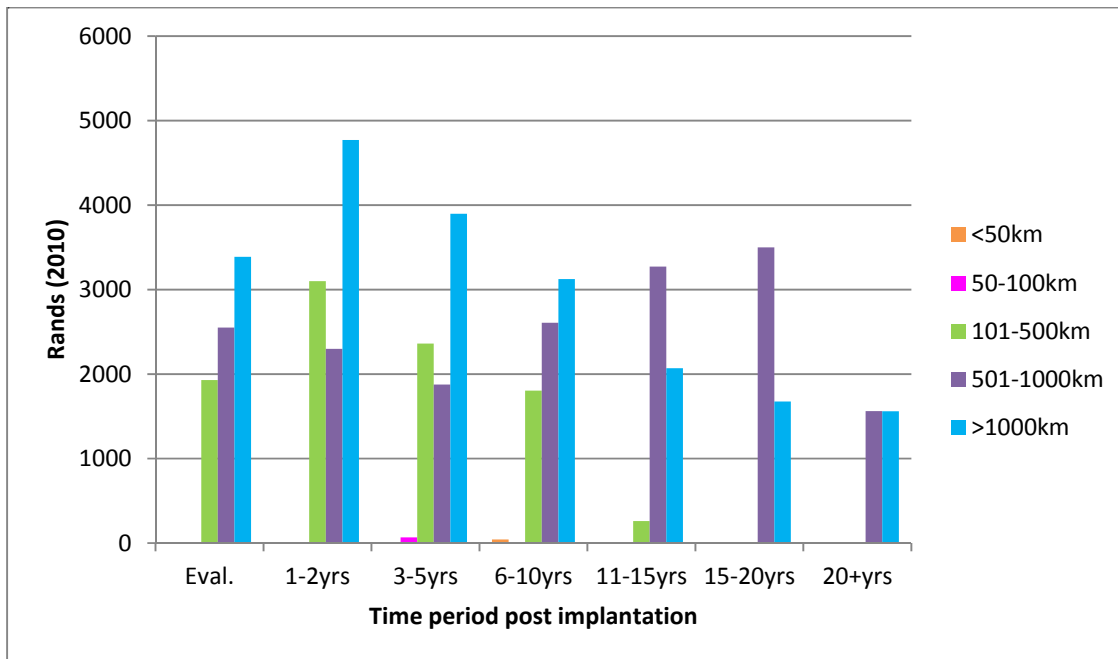
As a result of living far from Tygerberg Hospital, nearly a third of the subjects (32%) had been obliged to use alternate accommodation in order to attend appointments for their/their child's cochlear implant. Of these subjects 31(63%) had had to pay for accommodation, while 18 (37%) subjects had been able to stay with family or friends for free. Table 10 shows the

average cost of accommodation that those subjects, who had to pay for accommodation, estimated they had incurred at different time intervals in the implantation process. The costs were grouped according to the distance subjects stayed from the implant unit during that particular time period. Changing group size as the time interval increased was accounted for in the calculations. Figure 10 presents this information in a graphic format.

Table 10. *The average estimated total accommodation costs subjects incurred (2010 Rands). (Subjects are grouped according to the distance they lived from the unit. Costs represent the average total cost per time interval)*

Time interval	Distance from Cochlear Implant Unit				
	<50km	50-100km	101-500km	500-1000km	>1000km
Evaluation	R0	R0	R1930	R2552	R3389
1-2yrs	R0	R0	R3100	R2299	R4771
3-5yrs	R4	R67	R2363	R1875	R3898
6-10yrs	R43	R0	R1804	R2607	R3124
11-15yrs	R0	R0	R260	R3272	R2069
15-20yrs	R0	R0	No subjects	R3500	R1676
20+yrs	R0	R0	No subjects	R1562	R1561

As seen in Table 10, those living far away from the implant unit bore significant costs associated with accommodation in order to attend appointments. The type of accommodation which subjects chose to use would also have influenced the expenses they incurred.



**Figure 10. Average estimated accommodation costs for subjects9**(Costs shown are the total costs per time interval. Subjects are grouped according to the distance they lived from the implant unit)

As shown in Figure 10 those living less than 100km from the implant unit incurred minimal or no accommodation costs throughout the different time intervals. The general trend noted for groups living 101-500km and more than 1000km from the unit was for a peak in costs during the period 1-2 years post implantation, followed by a decline in costs in later time intervals. Similarly to the costs of transportation, this trend was probably as a result of more frequent appointments in the first two years following an implant, necessitating more frequent and longer stays during this time interval, but may also have been as a result of subjects sourcing cheaper accommodation on subsequent visits. The accommodation costs for those living 501-1000km from the implant unit did not follow the trend noted for the other groups living more than 100km from the unit.

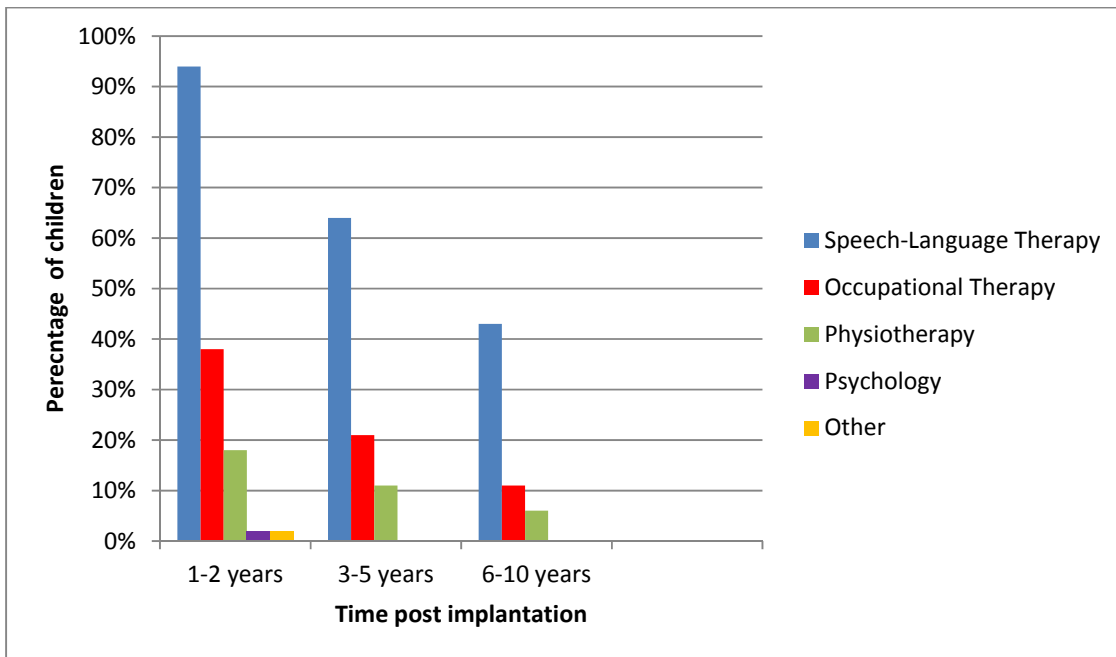
Comments from 6 of the non-local subjects in response to the open-ended Question 8, which asked subjects to advise potential implantees about costs involved in cochlear implantation, appeared to correlate with the trends noted in accommodation and travel costs. These subjects indicated that costs of travel and accommodation to attend appointments at the cochlear implant unit were high. They warned potential implant recipients that they should be aware of the frequency of trips needed, especially in the first few years after being implanted. They indicated that they needed to plan and/or save for these costs.

***In summary:*** The age at implantation influenced the **number of audiological appointments** needed, with those implanted as children requiring on average more appointments than those implanted as teenagers or adults. There was a peak in the number of appointments for all subjects in the first 2 years following implantation. In general, subjects living further away from the cochlear implant unit incurred higher **travel** costs during all time periods than those living closer to the cochlear implant unit. Those living more than 1000km away incurred significantly greater costs than did other groups. The highest travel costs were noted for all groups (regardless of distance from the implant unit) during the first 2 years after implantation. Nearly a third of the subjects had required alternative **accommodation** in order to attend cochlear implant related appointments. Two thirds of these subjects had had to pay for accommodation; the others had saved on accommodation costs by staying with family or friends. Generally there was a peak in accommodation costs during the first 2 years post implantation.

### **3.9. Rehabilitation for paediatric implantees**

#### **3.9.1. Types of therapies received**

Almost half the subjects (53%) were implanted as children, i.e. under the age of 13 years. The complete breakdown of therapies attended by the children at different intervals post implantation is shown in Appendix G. Figure 11 displays the summarised findings in graphic format.



**Figure 11. Percentage of children attending different therapies post implantation**

Of the 82 children implanted 76 (93%) attended speech-language therapy in the first two years following implantation. Five of the 6 children, who did not receive speech-language therapy, were aged between 7 and 13 years old at the time of implantation and had either an acquired or a progressive hearing loss with age-appropriate speech and language acquisition pre-implantation. The sixth child was born profoundly deaf, but his speech and language development proceeded at an age appropriate rate, following early implantation at 8 months of age. This child did, however, receive physiotherapy for five years after implantation, and occupational therapy up until 6-10 years post implantation.

As seen in Figure 11 many children continued to need rehabilitation services for many years post implantation. In addition to speech-language therapy, a significant number of children required occupational therapy and, to a lesser extent, physiotherapy. The highest percentage of children received therapies in the first two years after receiving their cochlear implant. A steady decrease in the percentage of children receiving speech-language therapy, occupational therapy and physiotherapy was noted as the time interval post implantation increased.

Expectedly speech-language therapy was the most frequently required therapy for most of the children. Ninety-three percent of the children received speech-language therapy after being

implanted, and 43% of the children, who had been using their implant for 6-10 years, were still receiving speech-language therapy 6-10 years post implantation. The need for so many of the children to still be requiring speech therapy services 6-10 years post implantation may have been linked to the relatively high average age at implantation of the paediatric subjects (4 years 5 months). The current trend towards earlier implantation may ultimately ease the need for such long term rehabilitation intervention. The significant advantage for earlier age at implantation (below 24 months) was shown on language measures in a study by Nicholas & Geers (2007), who also showed that the expected mean language score of children implanted between 12 and 16 months of age was within one standard deviation of the normative sample of hearing age equivalents.

At the Tygerberg Hospital Cochlear Implant Unit aural rehabilitation is generally conducted with teenage and adult implant recipients at the implant unit as part of the programming and follow up visits. Implanted children, however, require additional, intensive speech-language therapy to develop an effective oral communication system. At the Tygerberg Hospital Cochlear Implant Unit, speech-language therapy is conducted off site. If the child is attending a pre- or primary school for hearing impaired children, therapy will usually be conducted at the child's school by the speech-language therapist on site. Implanted children attending mainstream schools will usually need to attend speech-language therapy either at a private practice or a state facility.

In addition to hearing loss, an estimated 40% of hearing impaired children present with an identified additional disorder (Perigoe & Perigoe, 2004; Picard, 2004). This percentage does not include children with undiagnosed learning difficulties or those with different learning styles. Additional disorders can potentially also affect a hearing-impaired child's speech and communication development. As children are implanted earlier, many of these extra needs may only come to the fore some time after they have been using their cochlear implants. While one cannot always predict what extra needs may arise later, parents should be aware that their children may require additional rehabilitation therapies as they grow older. Due to the very thorough evaluation prior to implantation, other areas of concern may be identified and addressed prior to, or concomitant with, the implantation process and subsequent rehabilitation.



### **3.9.2. Cost of therapy**

In addition to being asked what types of therapies their child attended during different time intervals post implantation, the parents were also asked to estimate the cost of these therapies. Some of the parents could provide exact figures, but many were unsure of this information. The cost of rehabilitation for the children varied greatly as the number of therapies, as well as their frequency and duration varied from child to child. In addition, the costs were influenced by where therapy was received, and varied depending on whether the child was seen at a state facility, a private practice or within the school which they attended. In the latter case, one or more of the therapies were often included in the cost of school fees, and parents could not often provide an estimate of the therapy cost as the school fee was all inclusive. Children seen in the state sector would have been charged per session on a sliding scale based on the family's income.

The need for rehabilitation is influenced by many factors including age of onset of hearing loss, age at implantation, and the presence of additional difficulties. Some paediatric subjects required only monthly speech and language monitoring once sufficient progress had been noted, while others continued to require weekly or twice weekly therapy sessions for an extended period of time. As a result of the variability in types, frequency and duration of therapy, the parents' estimates of the amount they spent on rehabilitation showed a wide range of variability. Table 11 provides the average costs for the different therapies, which the children required during the different time intervals post implantation, as estimated by the subjects. Due to the differing length of the time periods, the variability of costs as well as some subjects' difficulty in recalling this information, results in this table should be interpreted cautiously.

Table 11. *The estimated costs of therapy received by children during different time intervals post implantation (2010 Rands) (Total cost per time period, as well as cost per year are shown. The small group size of those receiving therapies other than speech-language therapy, as well as subjects' recall, could have influenced the accuracy of these costs)*

Therapy type	Time period post implantation		
	1-2 years	3-5 years	6-10 years
Speech-language therapy	R12398 (R6199 per year)	R24761 (R8254 per year)	R33785 (R6757 per year)
Occupational therapy	R5167 (R2584 per year)	No subjects	R6000 (R3000 per year)
Physiotherapy	R6889 (R3445 per year)	No subjects	No subjects
Speech therapy + Occupational therapy	R13418 (R6709 per year)	R10488 (R3496 per year)	R28599 (R5719 per year)
Speech therapy + Physiotherapy	R12789 (R6394 per year)	R9600 (R3200 per year)	No subjects
Occupational therapy + Physiotherapy	R30717 (R15359 per year)	R6000 (R3000 per year)	R14916 (R2983 per year)
Speech therapy + Occupational therapy + Physiotherapy	R48811 (R24406 per year)	R21920 (R7303 per year)	No subjects

As seen in Table 11, therapy costs represented a significant expense to subjects. Speech-language therapy cost subjects on average approximately R6199 per year during the first 2 years, R8254 per year during years 3-5 and R6757 per year during years 6-10 post implantation. Those requiring a combination of speech-language therapy, occupational therapy and physiotherapy had significantly higher costs, particularly in the first 2 years following implantation, spending an estimated average of R24406 per year on therapies for their child.

The subjects' contribution to these costs varied. Many subjects received partial funding from their medical aids. Few received full funding from their medical aids. Those, not on a medical aid, had to pay the full costs themselves. The therapy costs for implantees attending a pre- or primary school for hearing impaired learners was generally included in their school fees.

***In summary:*** Most of the **children** (93%) had received speech-language **therapy** in the first 2 years following implantation, at an average cost of R7 070 per year. A lesser number of children had required additional therapies, primarily occupational therapy and physiotherapy, during this time period. A decrease was noted in the percentage of children attending all therapies as the time interval post implantation increased. The cost of rehabilitation services varied. It was influenced by the frequency and duration of therapy, the number of therapies involved (single or multiple) and where therapy took place (at private practices, state institutions or within the schooling environment).

### **3.10. Advice to future implantees regarding costs involved in cochlear implantation**

In this section, the themes of the subjects' answers to the open ended Question 8 of the questionnaire, will be presented and discussed. In the question subjects were asked what advice they would offer future implant recipients, with regards to costs involved in cochlear implantation, based on their own experience.

One hundred and twenty six subjects responded to Question 8. Two major themes (indicated by more than 40% of the subjects) and six minor themes (indicated by 15-25% of the subjects) were identified.

#### **3.10.1. Main themes**

##### **3.10.1.1. The need to budget carefully, plan and save for costs**

Sixty-three subjects (50%) highlighted the need for planning ahead for cochlear implant related expenses, including the maintenance costs once the warranty had expired, and for future upgrades of the speech processor. Many found that careful budgeting was necessary to cover the monthly cost of batteries and highlighted the importance of planning for the expense of spares. Some subjects indicated that they had had to forgo luxuries and limit other

expenses in order to afford the costs associated with the implant. They felt the cochlear implant had to be prioritised over other costs so that the implantee could continue hearing. They cautioned potential implant recipients or family members that they would “Sometimes have to sacrifice luxuries for cochlear implant costs”. One state sponsored implantee said that it was very difficult to afford spares as he was unemployed. He warned implant recipients that they had to have enough money to keep the speech processor switched on, and to buy spares if needed. A number of subjects highlighted the importance of keeping spares on hand.

Parents of young children emphasized the need for budgeting for coils and cables which broke more frequently, when children were young and, which they found expensive to replace. A number of subjects cautioned parents that without careful planning for future possible costs, great expenses could ensue from unexpected costs such as repairs. Subjects warned that maintenance costs were very high. In one implantee’s words “People don’t always realise how expensive it is to maintain a cochlear implant. I would still not have hesitated, but you must budget for unexpected costs and for repair of the processor from time to time”.

The subjects highlighted the need to have savings from which to cover ongoing costs, such as batteries and spare parts, and for unexpected costs such as repairs. Many advised that the implant users should keep a separate savings account for funds that could be used towards these costs.

Many subjects on medical aids urged the need for savings to cover those costs not covered by their medical aid. They also indicated that those, not on medical aid, had to pay careful attention to setting money aside in a savings account to cover cochlear implant expenses. Many indicated that maintenance and repair costs were very high, and that one needed to be able to access significant savings to cover these costs. One subject recommended that access to at least R10 000 was needed in an implant savings account for repairs and daily costs.

The subjects also pointed out the need to save for future technology and for upgrades when needed. One subject indicated that access to between R60 000 and R100 000 was needed for replacements and upgrades. Some subjects living far from the cochlear implant unit

indicated an additional need for saving for accommodation and travel costs in order to attend appointments.

### **3.10.1.2. The importance of belonging to a medical aid**

Fifty five of the subjects (44%) emphasised the importance of belonging to a medical aid that assisted with the costs of a cochlear implant. Many urged finding out about the benefits, which the potential implantee's current medical aid offered, and strongly advocated changing medical aids to one which was more sympathetic and financially supportive towards cochlear implants, if better benefits could be obtained. One particular medical aid was recommended by many of the subjects. This medical aid is known for being supportive towards individuals requiring a cochlear implant, as it assists in paying a portion of the system cost of an implant, as well as assisting financially with upgrading of speech processors over time.

While those on medical aids acknowledged the financial assistance they had received towards their cochlear implant, many cautioned that the medical aid did not cover all costs. They warned that ongoing costs, notably batteries, were not covered by the medical aids. Some subjects indicated that medical aids should cover more of the ongoing costs e.g. batteries, spare parts needed for the speech processor and maintenance of the device. Those on hospital plans warned about the potentially high additional medical costs, which were not covered by their medical aid. Some subjects, not on a medical aid, echoed this implantee who wrote: "Cochlear implant expenses are very expensive...without medical aid I find it very difficult".

### **3.10.2. Minor themes**

#### **3.10.2.1. Do whatever it takes to get the funds together in order to have the implant**

Thirty of the subjects (24%) emphasised that numerous different sources needed to be utilised in order to obtain the necessary funds for the implant system, as the initial cost was very high. They recommended using fundraising, help from family and friends, help from employers, the greater community, donations, sponsorships or bank loans. For many the initial cost of the cochlear implant system required securing funds above and beyond their own personal available funds. Many acknowledged that they would not have been able to do it on their own. One subject cautioned that potential implantees should make completely sure

that they could afford a cochlear implant, and be able to afford repayments, if they took out a loan to fund the initial cost, so that they did not place themselves in financial difficulties afterwards.

Despite the expressed difficulty of obtaining the necessary funds, many subjects' comments mirrored the ideas of the implantee, who urged others to "Try everything and anything to get money for a cochlear implant...be open minded, use everything at your disposal, let everyone know of your need, think big, ask for help..."and another who indicated that it was "...imperative that you secure the necessary funds, explore all options until you reach your objective".

### **3.10.2.2. The cost of batteries**

Twenty eight subjects (23%) commented on the high cost of batteries and indicated the need to budget monthly for this expense. Those living far away from the cochlear implant unit recommended keeping spare batteries on hand, and a number of subjects recommended ordering batteries in bulk to save on postage costs. Some subjects indicated that rechargeable batteries worked well. Others, who could have chosen to buy their own rechargeable batteries for their ear-level speech processors indicated that this was not a cost effective option. Some subjects recommended investigating different sources of batteries or trying different types of disposable batteries (providing they were endorsed for use with an implant), in order to find the most cost effective type for them. One subject urged others to make sure they had enough money to afford batteries so that they could keep using their speech processor. The subjects' comments indicated that battery costs are a significant expense, which is essential to plan for, to ensure that users will be able to use their implants consistently.

### **3.10.2.3. The importance of insuring the speech processor**

Twenty one subjects (17%) indicated that insuring the processor was very important, especially to help cover the potential cost of replacing it if it became broken or lost. A number emphasised the need for insurance, particularly, when young children were using a cochlear implant. One subject, whose child's uninsured speech processor had been lost, indicated that this had been very expensive to replace. As a result he now considered insuring the speech processor essential. While many subjects indicated insurance was important, a number

commented on the high cost of monthly premiums. Eight subjects had investigated insurance but found it too expensive.

#### **3.10.2.4. The need to look after the speech processor**

Twenty subjects (16%) highlighted the importance of looking after the speech processor in order to prolong its lifespan and to minimise maintenance and repair costs. A number of parents indicated the importance of teaching their children to look after their device, and to handle it safely. They recommended that this should be done even with very young children. The subjects' advice for looking after the processor included keeping it safe and clean, carefully following the care instructions, protecting it from moisture, by using appropriate dry aid kits, keeping it in a safe place and protecting it from things that could damage it.

#### **3.10.2.5. Worth the expense**

Eighteen subjects (15%) indicated that the benefits of the cochlear implant outweighed the high costs involved, due to the life changing effects for both the implant recipient and their family. These subjects' comments were reflected in the words of this implantee, who wrote that a cochlear implant is "...expensive but worth the struggle for the costs, it changes your life completely".

#### **3.10.2.6. Travel and accommodation costs**

Six of the non-local subjects commented on the high costs of travel and accommodation to attend appointments. They warned potential implant recipients that they should be aware of the frequency of trips needed, especially in the first few years after being implanted and that they needed to plan and/or save for these costs. One subject also commented on the expense of travelling to an appropriate school for their implanted child and felt this was a consideration for those, who lived far from a cochlear implant programme.

Two subjects urged others to investigate the tax relief benefits that one could obtain for purchase of cochlear implant equipment in order to claim back some of the costs involved.

***In summary:*** The two main themes which emerged from the **advice** which subjects offered **to future implant recipients** regarding costs was, firstly the need to plan and budget for the high costs involved in implantation, and secondly to belong to a medical aid which assisted

with the costs involved. Other themes which emerged included doing whatever necessary to obtain the funds for an implant, a warning about the high cost of batteries, the need to insure the speech processor, the need to look after the processor to reduce maintenance costs, the benefits of the cochlear implant outweighing the costs and the high costs of travel and accommodation for non-local implantees.

### **3.11. State implantees: Special case for the Tygerberg Hospital Cochlear Implant Unit**

Since the inception of the program in 1986, 50 state patients have been assisted by Tygerberg Hospital with funds for obtaining a cochlear implant. As these implantees are particularly vulnerable in terms of being able to afford the long-term costs associated with their devices, their current status was reviewed at the time of this study in order to try and gain some insight into their current financial needs.

Thirty six of these implantees (72%) are considered to have poor financial status, and will require future financial assistance for upgrading of their speech processors, when they become obsolete. Currently Tygerberg Hospital Cochlear Implant Unit is assisting 10 of these implantees (20%) by providing second hand spares donated by other implantees to ensure that they can continue using their devices. Current funding made available by the hospital to assist state patients may only be used towards covering the costs of the initial implantation itself. All long-term costs, including maintenance and later upgrades, are for the implant recipient's own account.

Four of the state implantees are currently still using speech processors, which have been declared obsolete. These implantees do not have access to funds to upgrade or to an infrastructure, where they can potentially fundraise for this expense. They were implanted 12-21 years ago and, without financial assistance to upgrade, will be unable to continue using their implant systems should their current speech processors break. These four patients, are all still using body-worn devices, and will need assistance with battery costs, when they are upgraded to an ear-level speech processor.

The current financial situation of some of the hospital assisted state patients at the Tygerberg Hospital Cochlear Implant Unit, highlights how critical it is that implant units carefully consider



the potential financial ability of such implant recipients to continue using their implants long-term. Such considerations were also highlighted in a study by Khan et al. (2007), which focussed on availability of cochlear implantation in Pakistan. The researchers emphasized that in developing countries without state funding for cochlear implantation, the ability of patient's financial resources to bear the ongoing cost of the rehabilitation and maintenance of the device must be considered, to avoid later device non-use. Implant units in South Africa may be well advised to ensure that some of the funds made available for state recipients are earmarked for assisting with long-term use and maintenance of devices, rather than merely for the initial outlay.

### **3.12. The probability of requiring spares, repairs and upgrades**

Based on the relative frequencies of occurrence of repairs and upgrades, as well as the purchase of each type of spare, for subjects in the study, a probability of occurrence for each of these events was determined, for each time period post implantation. This information, which shows the chance for each type of occurrence at different time periods, is presented below. Upgrades and repairs are presented first, followed by spares purchases, ordered from most to least expensive. Only purchased spares have been included i.e. those who relied on donated spares are not included. As a result the probability of needing spares is slightly under-reported.

#### **3.12.1. Upgrades of speech processor**

Table 12 shows the likelihood of upgrading the speech processor during the different time intervals post implantation.

Table 12. *The probability of need to upgrade speech processors during the different time intervals post implantation*

Upgrades	Likelihood of upgrading once	Likelihood of upgrading twice	Likelihood of upgrading 3 times
20+ yrs			
15-20yrs	37.5%		
11-15yrs	38.1%		
6-10yrs	37.6%	3.5%	1.2%
3-5yrs	24%		
1-2yrs	4.6%		

As seen in Table 12 there is almost a 40% chance that implantees would upgrade their speech processor 6-10 years after implantation, with a similar chance of upgrading in the following 5 year period and the one thereafter. There is approximately a 24% chance that implantees would upgrade during the 3-5 year period post implantation, with a relatively small likelihood of upgrading in the first 2 years. With the current cost of an upgrade being R85000, implant recipients can expect almost a 40% chance that they will need to pay this amount for an upgrade during the 6-10, 11-15 or 16-20 year period post implantation.

### 3.12.2. Repairs

Table 13 shows the likelihood of an out-of-warranty repair to a speech processor during the different time intervals post implantation. The current cost of a repair is R2950.

Table 13. *The probability of a repair to the speech processor during the different time intervals post implantation*

Repairs	1 repair	2 repairs
20+ yrs		
15-20yrs	18.8%	
11-15yrs	19%	
6-10yrs	15%	2.5%
3-5yrs	6.4%	1.8%
1-2yrs	0.9%	

As seen in Table 13 the likelihood of an out of warranty repair is significantly higher for those who have been using their processors for longer. At the current repair rate, implantees have almost a 20% chance of having to pay R2950 per repair 11-15 and 15-20 years post implantation, and a slightly lower chance (15%) of having to do so during the 6-10 year period

after being implanted. There is a much smaller chance of repair costs in the first 5 years. There is a relatively small chance of having to pay for a repair twice within the 3-5 year period, or the 6-10 year period.

### 3.12.3. Microphone

Table 14 shows the likelihood of replacing a microphone for the body-worn SPrint™ or Spectra speech processors during the different time intervals post implantation.

Table 14. *The probability of need to replace the SPrint™ or Spectra microphone during the different time intervals post implantation*

Microphone	1 replacement	2 replacements
20+ yrs	20%	
15-20yrs		6.3%
11-15yrs	2.4%	
6-10yrs		
3-5yrs		
1-2yrs		

A microphone for the SPrint™ speech processor currently costs R2850, and a microphone for the Spectra processor costs R2150. As seen in Table 14 it is most likely that the microphone will only have to be replaced after 10 years of use. There is a small chance that implant recipients will have to replace the microphone in the 11-15 years after implantation, a greater chance of having to replace it twice in the 15-20 year period and a significantly higher chance (20%) of having to replace it after 20 years of use.

### 3.12.4. Cable-coil

Table 15 shows the likelihood of replacing a cable-coil (for ear-level speech processors) during the different time intervals post implantation.

Table 15. *The probability of need to replace the cable-coil during the different time intervals post implantation*

Coil-cables	1 Replacement	2 Replacements	3 Replacements	5 Replacements
20+ yrs				
15-20 yrs	18.8%			
11-15 yrs	7.1%	4.8%	2.4%	
6-10 yrs	17.7%	2.5%		2.5%
3-5 yrs	13.6%	1.8%		
1-2 yrs	6%			

As seen in Table 15, it is three times more likely that implant recipients will have to replace the cable-coil in the 6-10 year and 15-20 year period after implantation than during the first two years. The current cost of replacing a cable-coil for the ESPrit™3G processor is R580, and R1670 to replace that of the Freedom® processor. Although the likelihood of replacing a cable-coil in the 11-15 year period was lower than in the other periods post 2 years, there was also a small chance of implant recipients having to replace their cable-coil twice and others three times, in this same time period. These implantees would have to spend two or three times the cost of a single cable-coil within a 5 year period.

### 3.12.5. Coils

Table 16 shows the likelihood of replacing the coil during the different time intervals post implantation.

Table 16. *The probability of need to replace the coil during the different time intervals post implantation*

Coils	1 Replacement	2 Replacements
20+ yrs		
15-20 yrs		
11-15yrs		
6-10 yrs	1.3%	1.3%
3-5 years	3.6%	
1-2 yrs		

As seen in Table 16, implant recipients have a low likelihood of having to replace the coil once 3-5 years after implantation (at the current cost of R620), and an even lower chance of having to replace it once or twice in the 6-10 year period post implantation.

### 3.12.6. Cables

Table 17 shows the likelihood of replacing cables for body-worn devices during the different time intervals post implantation. The current average cost of cables for body worn devices ranges between R130 and R160.

Table 17. *The probability of need to replace cables for a body-worn speech processor during the different time intervals post implantation*

Cables	Replace 1 cable	Replace 2 cables	Replace 3 cables	Replace 4 cables	Replace 5 cables
20+yrs			20%		
15-20yrs	6.3%		6.3%		
11-15yrs	2.4%	4.8%		2.4%	2.4%
6-10yrs	1.3%	8.9%	1.3%		
3-5yrs	2.7%	2.7%	0.9%	0.9%	0.9%
1-2yrs				0.1%	0.9%

As seen in Table 17, the likelihood of replacing cables 20 years post implantation (ranging from R130 to R160 each) was significantly higher than at any other time period. The total chance of having to replace a cable during the other time intervals varied between 8 and 12%. The greatest chance of having to buy multiple cables was 2 cables during the 6-10 year period post implantation.

### 3.12.7. Miscellaneous spares

Table 18 shows the likelihood of having to purchase miscellaneous spares (e.g. drying capsules, microphone covers, ear-hooks) during the different time intervals post implantation.

Table18. *The probability of need to purchase miscellaneous spares during different time intervals post implantation*

Miscellaneous spares	
20+ yrs	20%
15-20 yrs	6.3%
11-15 yrs	9.5%
6-10 yrs	15.2%
3-5 yrs	13.6%
1-2 yrs	18.8%

As seen in Table 18, the greatest likelihood of purchasing miscellaneous spares was in the period 20 years after implantation. There was a slightly lower likelihood (13.6-18.8%) of implant recipients purchasing miscellaneous spares during the 6-10, 3-5 and 1-2 year periods. The lowest chance of having to purchase spares was noted 15-20 years post implantation, followed by the 11-15 year period.

### **3.13. Estimated total costs for the first 5 and 10 years following implantation**

Based on the findings of this study, the total estimated cost incurred in the first 5 years after implantation for a private child with no additional difficulties, who lives within 50km of the unit, was approximately R298 961. The estimated total cost for the same child over the first 10 years of using their implant was R445 225.

The estimated total costs during the first 5 years of implantation incurred by a private adult patient with an acquired hearing loss and living within 50km of the unit was R257 956. For the same adult, the total estimated cost over the first 10 years of implantation is estimated to be R379 626. The additional costs of a hearing aid and FM system were not included in these estimates. Table 19 shows the breakdown of the costs involved, as well as their most likely source of funding.

Table 19. *Estimated total costs for implant recipients for the first 5 and first 10 years after implantation (2010 Rands) (Costs shown are for private implantees living within 50km of the implant unit)*

	1 <sup>st</sup> 5 years (Child)	1 <sup>st</sup> 5 years (Adult)	1 <sup>st</sup> 10 years (Child)	1 <sup>st</sup> 10years (Adult)	Most likely source of funds
Implant system	R221 000	R221 000	R221 000	R221 000	Medical aid full/partial else self
Batteries (CI)	R11 400	R11 400	R22 800	R22 800	Self
Spares	R1849	R738	R2795	R1444	Self
Repairs			R2950	R2950	Self/insurance
Travel (<50km)	R2093	R688	R2746	R752	Self
Mapping*	R5240	R3930	R6550	R5240	Self/some medical aids
Insurance	R20 220	R20 200	R40 440	R40 440	Self
Upgrade			R85 000**	R85 000**	Medical aid full/partial else self
Total	R261802	R257 956	R384 281	R379 626	
Speech therapy	R37 159		R70 944		Medical aid full/partial else self
<b>TOTAL</b>	<b>R298 961</b>	<b>R257 956</b>	<b>R455 225</b>	<b>R379 626</b>	

\* Average cost was used. This will be higher for younger children and lower for older children due to the different number of appointments needed (see Table 20).

\*\*Upgrade price.

Table 20. *Estimated cost of appointments for children during the first 5 and first 10 years post implantation (2010 Rands) (Costs shown are for private implantees living within 50km of the implant unit)*

Age (years)	Number of visits first 5 years	Estimated cost: 1 <sup>st</sup> 5 years (2010 Rands)	Number of visits first 10 years	Estimated cost: 1 <sup>st</sup> 10 years (2010 Rands)
0-4 (Mean 2yrs)	29	R7598	34	R8908
5-8	18	R4716	23	R6026
8-13	13	R3406	18	R4716

As seen in Table 20 the total estimated costs for paediatric implantees are, on average, significantly higher than those for adults. The increased estimated costs for children in comparison to adults' costs were mostly a result of the need for additional rehabilitation, mainly in the form of speech therapy. In addition, mapping costs were higher due to the increased number of mapping appointments needed. Spares costs were, on average, greater for children (40-50% more than for those implanted as older children or adults). The difference in the estimated costs between the first 5 years and the first 10 years reflects the greater likelihood that increased repair and upgrade costs will occur in the longer term in comparison to the shorter time period. Within the first 10 years it can be assumed that implantees are likely to need at least one repair and one upgrade to the speech processor. Neither of these is very likely to occur during the first 5 years of use.

Those, who live further than 50km from the cochlear implant unit, will bear greater travel costs than those used in Table 20, and may also have additional accommodation costs to bear (refer to section 3.8., pp. 59-67 in this presentation).



## 4. SUMMARY, CRITIQUE AND CLINICAL APPLICATIONS

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This chapter will present a summary of the cost results, followed by a critique of the study, clinical applications, a consideration of present trends which may influence future cost patterns and suggestions for future studies.

### 4.1. Summary of findings related to the costs investigated in this study

In this summary the summarised estimated costs of the first 5 and 10 years post implantation are presented first and then findings are presented in order of highest to lowest costs. Some cost items were not incurred by all subjects. Finally a summary of the advice given by subjects to potential implantees is presented.

#### 4.1.1. Estimated total costs of first 5 and 10 years post implantation

Based on the findings of this study, the total estimated cost incurred in the first 5 years after implantation for child was approximately R298 961. The estimated total cost for the same child over the first 10 years of using their implant was R445 225. The estimated total cost during the first 5 years of implantation incurred by an adult patient was R257 956. For the same adult, the total estimated cost over the first 10 years of implantation was estimated to be R379 626. These estimates did not include the additional costs of a hearing aid and FM system.

**4.1.2. Implant system:** The most substantial single cost was that of the cochlear implant system, which currently costs R221 000 (June 2010). The portion of this cost, which subjects had to pay themselves varied. For a third of the subjects their medical aids had paid the amount in full. Some of the remaining two-thirds of the subjects had received partial contribution from a medical aid (on average 50% of the cost); some had received, full or partial funding from a donor, while others had paid the total cost of the system themselves.

**4.1.3. Upgrades:** The cost of upgrading the speech processor was almost 40% of the initial system cost, and was second only to the initial cost of the implant system itself. The current price of upgrading to the latest speech processor is R85 000. All subjects implanted for more

than 15 years had upgraded at least once. Most of the subjects implanted for less than 5 years had not upgraded their speech processors yet. On average the subjects had upgraded every 7 years (range: 1 year to 14 years). Some subjects appeared to upgrade every time a new compatible speech processor was released, and others only to move from a body-worn to an ear-level speech processor, or because their processor had been declared obsolete. The subjects on one particular medical aid appeared to upgrade more regularly than other subjects, presumably due to the medical aid's policy of funding upgrades at stipulated time intervals. Upgrading of the speech processor led to a reduction in both spares and repairs cost post upgrade due to the new warranty period.

**4.1.4. Using a hearing aid in the non-implanted ear:** The current cost of a hearing aid varied from R3534 to R29 750. Approximately a third of the subjects used a hearing aid in their non-implanted ear. All of these subjects had been implanted after 1997. Half the subjects had purchased the hearing aid themselves, and a quarter had received funding from their medical aid. Subjects had paid, on average, R31 a month for hearing aid batteries. This was significantly lower than the average monthly battery costs noted for the use of a speech processor.

**4.1.5. Personal FM system:** Fifteen percent of the subjects had purchased a personal FM system, whose current cost varied from R9964 to R21750. Most were purchased for children to use. Two thirds of the subjects had paid for the device themselves. The rest were funded partially or in full by their medical aid.

**4.1.6. Rehabilitation for children:** On average speech-language therapy, required by 93% of subjects in the first 2 years following implantation, cost R7 070 per year. A lesser number of children had required additional therapies, primarily occupational therapy and physiotherapy, during this time period. A decrease was noted in the percentage of children attending all therapies as the time interval post implantation increased. The cost of rehabilitation services was influenced by the frequency and duration of therapy, the number of therapies involved (single or multiple) and where therapy took place (at private practices, state institutions or within the schooling environment).

**4.1.7. Insurance:** Premiums were on average R4044 per year (R337 per month), but varied widely from R600 to R9600 per year (R50 to R800 per month). Twenty seven percent of the

subjects had insured their speech processors. Some subjects, who wanted to insure their processors, found the monthly premiums too costly to afford.

**4.1.8. Travel costs:** The highest travel costs were noted for all groups (regardless of distance from the implant unit) during the first 2 years after implantation. On average those living within 50km of Tygerberg Hospital spent R1024 on travel in the first 2 years, while those living more than 1000km spent R8645 during the same time period. Subjects living 50-100km, 101-500km and 501-1000km spent R1294, R951 and R1927 respectively during the first 2 years after implantation. In general, those living further away from the cochlear implant unit incurred higher travel costs during all time periods than those living closer to the cochlear implant unit. Those living more than 1000km away incurred significantly greater costs than did other groups.

**4.1.9. Accommodation:** Nearly a third of the subjects had required alternative accommodation in order to attend cochlear implant related appointments. Two thirds of these subjects had had to pay for accommodation; the others had saved on accommodation costs by staying with family or friends. The average total accommodation cost for those living more than 100km from the implant unit was R3390 for the first two years after implantation. Those living within 100km of the cochlear implant unit incurred minimal accommodation costs. Generally there was a peak in accommodation costs noted for those living further from the centre during the first 2 years post implantation. Those living 101-500km from the centre did not follow this trend.

**4.1.10. Repair costs:** Repairing a speech processor cost an average of R3000 per repair. No costs for repairs of speech processors were incurred in the first 3 years following implantation due to the device still being under warranty. The percentage of devices needing repair increased with increasing duration of implantation, and was, on average, higher for those who had been implanted for longer than 6 years. As expected, the highest percentage of devices needing repair was noted in the group of subjects who had been implanted for the longest time period reviewed (implanted 8-10 years). With a few exceptions, most subjects, who had had a device repaired, had only had one repair in the 10 year time period reviewed.

**4.1.11. Battery costs:** The average battery costs for the subjects varied from R1200 to R3372 per year (R100 to R281 per month). The costs were influenced by the speech

processor being used, and were generally lower for body-worn devices than for ear-level speech processors. Purchasing the currently available rechargeable batteries for the ear-level speech processors appeared to be less cost effective for subjects than purchasing disposable batteries.

**4.1.12. Cables and coils:** On average, replacing cables and coils cost R2838 to each subject who had to replace them. The purchase of cables and coils occurred sporadically at different time intervals post implantation. Clustering of purchases was noted for a few subjects. Children in general and a few children in particular, seemed to require more frequent replacement of coils and cables than other subjects. In general, most subjects only started replacing coils and cables from 4 years post implantation.

**4.1.13. Spare parts:** Those, who had been implanted for more than 2 years, had spent on average R276 on spare parts for each year they had been implanted. Considerable individual variation, however, was noted, e.g. some of those implanted for 10 years had spent up to R916 for each year implanted, while others had not spent any money on spares. The subjects implanted for less than 2 years had on average spent little or no money on spares. Spares costs were on average greater for the children than for the adults and were greatest for the children during the 3-5 year period following implantation.

## **4.2. Advice from subjects to potential implantees**

The two main themes which emerged from the advice, which subjects offered to future implant recipients regarding costs was, firstly the need to plan and budget for the high costs involved in implantation, and secondly to belong to a medical aid which assisted with the costs involved. Other themes, which emerged, included doing whatever necessary to obtain the funds for an implant, a warning about the high cost of batteries, the need to insure the speech processor, the need to look after the processor to reduce maintenance costs, the benefits of the cochlear implant outweighing the costs and the high costs of travel and accommodation for non-local implantees.

## **4.3. Critique**

The findings of this study and their clinical applications are dependent on the data used to generate them. Consideration must thus be given to the manner, in which the data was

collected, and the data itself, and the possible limitations of the study, which may have arisen as a result. These include the following:

- The Tygerberg Hospital Cochlear Implant Unit only uses the Nucleus® cochlear implant system, and the costs in the study were specific to this system only. There are currently two implant systems being used in South Africa, of which Nucleus® is one. While this limitation should be considered, the types of costs needing to be covered over time are thought to be relevant to all individuals implanted in South Africa.
- As a result of the lack of records for spares and repairs prior to 2001, some of the long-term information for these items has been lost, and all the subjects could not be included in the analysis of purchase of spares and repairs over the entire duration of their implant use.
- Poor recall may have influenced the accuracy of some of the costs indicated by subjects to an extent. To reduce the effect of recall, subjects could have been asked to record annual costs for the year leading up to the study, instead of over the entire duration of use. Previous studies by Barton et al. (2006b) and Sach et al. (2005) used one year's costs, which were then extrapolated. Some of the rich information provided by considering costs over the duration of the subject's use of the implant would, however, have been lost, if data had been collected in this manner in this study. An attempt to minimise the effect of subject recall was made by utilising information from records, wherever possible, and by validating information provided against records, wherever possible.
- By analysing groups of subjects according to the duration of time they had used their implants, group size varied, becoming progressively smaller for the groups, who had used their implants the longest. It would have been ideal to use groups that were the same size but this was not possible. The presence of a smaller number of people in the groups implanted in the earliest years accurately reflected the overall pattern seen in the implant unit.
- While most parents were able to indicate the type of therapy or therapies their child had received, it appeared more difficult for them to recall the costs involved. This seemed to be most difficult, when there were multiple therapies involved, and when

they did not pay themselves, or when the costs were included in school fees. As a result the information in response to the rehabilitation question (Question 9) was variable and the cost information was not always completed. In retrospect, it might have been better to ask subjects to complete that question just for the previous year, and then to correlate this with how long the child was post implantation. However, while doing this might have increased the accuracy of recall, it would have reduced the number of children involved, as only those currently within 10 years of implantation would have been included.

- Costs are tied to a particular time and will not stay constant. As a result, the cost figures need to be adjusted frequently and current costs need to be taken into account, when information about the costs implant recipients will need to pay is discussed with them.

#### **4.4. Clinical application of findings**

The initial cost of a cochlear implant system is prohibitively expensive. In a developing country such as South Africa, where cochlear implants are not state funded, access to such technology is out of reach for many hearing impaired adults and children, who need and could potentially benefit from it. Due to the assistance of some medical aids, donors, or concerted fundraising efforts, some individuals manage to source the necessary funding needed for the implant system. Once the individual has been implanted, however, costs related to their implant need to be covered for the rest of their life, and assistance for these ongoing costs is less forthcoming. Focussing primarily on the funding needed for the initial implant system, and failing to consider the costs/potential costs, which arise as a result of implantation, as well as the implant recipient's ability to fund these costs, could result in a lifelong unexpected financial burden to the implantee, or the implant programme. It could also result in poorer than expected outcomes, if implantees are unable to access all the support services required to ensure their implant use is successful.

This study considered the long-term costs involved in implantation in an attempt to provide some guidance regarding expected costs of implantation. Cochlear implant programmes have a responsibility to select individuals, who not only meet the clinical criteria for implantation

(audiological, medical, radiological and rehabilitation criteria), but, who will also be able to afford and continue using and benefiting from a cochlear implant over their lifetime. Based on the findings of this study, to be successful users of their implant system over the long-term in South Africa, the implantees need to be able to:

- Obtain the funds for the **initial purchase** of the cochlear implant system (R221 000 at June 2010).
- Pay or obtain funds for **upgrading the speech processor**, at a current cost of R85 000 (June 2010), every 10-15 years once their speech processor becomes obsolete, or approximately every 3-5 years, if they want to stay abreast of the latest technology.
- Afford to spend between R1200 and R3372 per year (R100-R281 per month) on **batteries**.
- **Purchase spare parts** as needed, and be prepared to spend on average R276 on spares for each year they are implanted. Some will need to spend significantly more as some subjects implanted for 8-10 years had spent up to R916 per year implanted on spares. Greater spares expenses are likely to occur for children than adults. As purchases were not spread evenly over the years and due to the need to replace parts immediately once they break, implantees should always have immediate access to savings, which can be used for this purpose. The implantees should also be prepared to replace cable/coils at an average cost of R2838, when they break.
- Pay speech processor **repair costs** of R2950 **per repair** or R5500 if it cannot be repaired, once the device is out of its warranty period.
- **Afford the time and money to access the implant unit** for scheduled appointments. Implant recipients need to be able to afford the travel costs associated with attending appointments. Those living further away will have significantly higher travel costs than those living nearby the unit. They also need to be prepared to cover significant accommodation costs, if they do not have friends or family to stay with, when they attend appointments. Implant recipients can expect that travel and accommodation costs will generally be greatest in the first 2 years post implantation, but due to the need for ongoing follow-ups will remain a significant cost for the duration of their

implant use. On average, the costs for a person, who lives far away (1000km or further from the unit), could add up to R13 416 during the first 2 years after being implanted.

- Afford the **MAPping appointments**. The expected number of appointments will depend on the age at onset of the hearing loss and age at implantation, as well as the duration of time since implantation. At Tygerberg Hospital the cost of each appointment is determined by a sliding scale based on the patient's monthly income. This ranges from no charge for children under 6, who are not on a medical aid, or individuals on a disability grant, to R262 per appointment for patients on a medical aid or those classified as private due to their monthly income. In a private facility these fees will differ.
- Access and afford the necessary additional **rehabilitation** required, if a child is being implanted, and be able to do so for as long as it is deemed necessary. The type, frequency and duration of required therapies are difficult to predict as they are dependent on many factors (e.g. age at onset of hearing loss, age at implantation, additional needs) and needs to be determined for each individual child. The likelihood of a child, who is implanted needing at least one additional form of intervention (most commonly speech-language therapy) is very high, and parents should expect an average additional cost of at least R7070 for one year's speech-language therapy.
- Purchase and maintain a suitable **hearing aid for the non-implanted ear** should the implantee have residual hearing in that ear. These costs could range from R3 534 to R29 750.
- Purchase and maintain a **personal FM system** at an average cost of ± R16 000 (currently ranging from R9 964 to R21 750) for use with their cochlear implant system, if the implantee is a school aged child.
- **Insure** the speech processor to avoid significant expenses should their/their child's processor become lost or stolen and need to be replaced. Insurance could cost R600-R9600 per year (R50-R800 per month).



Professionals at cochlear implant programmes need to inform the implantees and their families of these potential costs and, as much as possible, ensure that implant recipients are better prepared for the long-term costs.

Where implant programmes are instrumental in assisting implantees with the initial costs of a cochlear implant system, they need to ensure that these implantees will be able to afford the ongoing maintenance, access and necessary rehabilitation costs. The cost of upgrading speech processors over time is of particular concern in this scenario, due to the very high costs involved. As it is unlikely that those, who are assisted with the initial purchase costs, will be assisted with upgrading each time a new speech processor is introduced, these implantees must be prepared to afford upgrading once their speech processor become obsolete. Maximum use of a speech processor in this study was 15 years. Thus it is assumed that most implant recipients will need to upgrade their speech processor, at least once every 10-15 years. If cochlear implant programmes want to ensure that individuals implanted by them are able to continue using their cochlear implant systems, they will need to encourage implantees, who do not have ready access to funds, to save or fundraise the necessary funds timeously. Alternately the implant programme will need to budget to assist the implantees to upgrade.

Despite careful candidate selection, potential changes in the implantees' financial status may occur over time that cannot always be predicted. Some implant recipients, who appear to be financially secure when they receive a cochlear implant system, may not remain this way over the ensuing years. In reality, implantees, who are employed at the time they receive their implants, may lose their jobs. Implantees, who are married, may become divorced and implantees, who retire may move to substantially lower monthly earnings, when they stop working. Alternately, some implantees may move into a better financial standing by obtaining, or improving their employment and earning potential. Due to the fluctuations over time, implant programmes need to review their implantee base on a regular basis to assess the number of implantees, who are likely to need potential financial assistance. While steps should put in place to try and ensure, as far as possible, that individuals, who are implanted, are able to afford the future costs, implant programmes should be aware that over a long period of time, there will be implantees, who will require assistance. Cochlear implant programmes have a responsibility to plan for such occurrences. It is imperative that implant

professionals consider the long-term financial requirements for cochlear implant recipients and pay heed to Archbold (2001), when she warned that, “Without careful contemplation of the future and planning for it, a nightmare scenario could emerge where patients (or some of them) have out-of-date devices, lack access to appropriate technical support and stop wearing their devices” (Archbold, 2001, p.108).

In order for the implantees to be prepared for the financial costs they will encounter as a result of implantation, they need to know, what these costs might be, the proportion they will need to pay and, when they are most likely to have to pay them. The chance of recipients having to pay for spares, repairs or upgrades during a particular time period post implantation, based on their relative frequencies of occurrence in the study, was outlined in Chapter 3 of this presentation (Section 3.12., pp. 78-83). Clinicians could use this information, to discuss the predicted possibility of replacing parts or paying for repairs or upgrades with implant recipients, in combination with the current pricing structure. By providing implant recipients with this information, together with the cost estimates provided in the summary (Sections 4.1& 4.2, pp. 86-89), they could be better informed about the costs involved and thus better prepared to cover them. As the price of spare parts varies for different speech processors, implantees should be provided with a price list of different spare parts particular to their speech processor.

#### **4.5. Present trends, changes in cost patterns and future cost implications**

Some present trends may change the cost patterns and hold future cost implications for implant recipients. Three trends which may impact on future costs will be considered in this context. These include: earlier implantation of children with a congenital severe-to-profound hearing loss, bimodal stimulation and bilateral cochlear implantation.

##### **4.5.1. Earlier implantation of children**

In recent years there has been a trend towards an earlier implantation for children born with a severe-to-profound hearing loss. This trend is motivated by the goal of providing children with access to auditory stimulation as early as possible, in order to access the neuro-behavioural advantages of the critical periods for speech and language development (Niparko et al.,

2009). With early intervention, many children using cochlear implants have far surpassed basic speech recognition skills. Prospective studies of early cochlear implantation have now incorporated normal hearing children as controls, signifying the expectation that deaf children with cochlear implants can be expected to make significant gains with respect to language (Lin et al., 2009). Improved outcomes in spoken language development have been shown for children implanted below the age of two years, and especially for those implanted between 12-16 months (Nicholas & Geers, 2007). At some implant programmes, including the Tygerberg Hospital Cochlear Implant Unit, congenitally deaf children are being implanted as young as 6 months of age.

Earlier implantation is expected to lead to a reduction in the length of time some rehabilitation services, particularly speech-language therapy, are needed for the children, particularly those without additional difficulties. This may reduce the overall cost of rehabilitation services needed. Implantation at a younger age, however, also implies that implantees will be using their cochlear implants for longer. The increased duration of use has implications for maintenance costs associated with using the implant. It is also predicted that more upgrades of the speech processor would be needed as implants are used for longer.

#### **4.5.2. Bimodal stimulation**

Recently there has been an increasing trend for cochlear implant recipients to use a hearing aid in the non-implanted ear (so called bimodal stimulation). This trend has occurred as a result of the expansion of audiological criteria for implant candidates, resulting in adults and children with a greater amount of residual hearing being implanted, and as a result of the proven benefits of bimodal stimulation for those who have residual hearing in the non-implanted ear (Tange et al., 2008). Implantees using a hearing aid in the non-implanted ear show significant benefits in speech perception in noise and horizontal localization as a result of access to head shadow and binaural redundancy cues, and the complementary speech information, which is provided (Ching, Incerti, Hill & Van Wanrooy, 2006). Bimodal stimulation may also be an advantage, when listening to music and other non-speech sounds (Sucher & Mc Dermontt, 2009).

In 2004, Ching, Incerti, Hill and Brew recommended that bimodal stimulation be the standard practice for clinical management of children and adults, who receive one cochlear implant,

unless there was a clear indication that bimodal device use was counter-productive for the individual. Later studies have continued to support this recommendation for those who have residual hearing in the non-implanted ear (Ching et al., 2006; Firszt, Reeder & Skinner, 2008). As a result, the Tygerberg Hospital Cochlear Implant Unit and other implant programmes now recommend the use of a hearing aid in the non-implanted ear. The hearing aid needs to be upgraded over time in order for implantees to continue deriving maximum benefit from it. Expected additional costs associated with using a hearing aid include visits to an audiologist for programming of the hearing aid and loudness balancing with the cochlear implant, battery and maintenance costs.

#### **4.5.3. Bilateral cochlear implantation**

Bilateral cochlear implantation (i.e. using two cochlear implants) can provide bilateral input into the auditory system for adults and for children (Tange et al., 2008), and can provide sound localization and better speech recognition in noise than a unilateral implant (Johnston, Durieux-Smith, Angus, O'Connor & Fitzpatrick, 2009). Worldwide, there is an increasing trend towards bilateral cochlear implantation, especially for severe-to-profoundly deaf children. Thirty subjects (19%), who took part in the current study, were bilaterally implanted. Eighty seven percent of those, who were bilaterally implanted, were children. Twenty three children had been implanted sequentially (i.e. there was a delay between the implantation of the first and second cochlear implant) and 3 had received bilateral implants simultaneously. The 4 adult subjects, who were bilaterally implanted, had all received sequential implants.

In the United Kingdom the National Institute for Health and Clinical Excellence (NICE), which determines health policy for England and Wales, now recommends bilateral implantation for all young deaf children and allows a second implant for some, who already have one implant (Summerfield et al., 2010.) Following a review of twenty-nine articles investigating bilateral cochlear implantation, Johnston et al. (2009) acknowledged the benefits of bilateral implantation. They indicated the need for further studies to investigate, among others, cost-effectiveness, speech, language, psycho-educational measures and quality of life with bilateral implants so that parents and clinicians could be better supported in the decision about a second implant. In a recent study by Summerfield et al. (2010), the authors concluded that paediatric bilateral cochlear implantation could possibly be a cost-effective use of healthcare resources in the United Kingdom. This conclusion was based on the perception of

a group of adults that giving children two implants instead of one would add significantly to their quality of life. There was, however, considerable uncertainty surrounding that conclusion, and they indicated that more information about costs and benefits of bilateral implants was needed.

The cost implications of bilateral implantation for implantees also need to be considered, in addition to considering the cost to society and to healthcare systems. While further research will give clinical guidelines regarding bilateral implantation, clinicians and implantees living in South Africa cannot afford to ignore the potential cost implications of a second implant. Those implantees, who have access to funding for a second implant system, must also have funding available for maintenance, repairs and future upgrading for both implants. A possible doubling of costs to implantees as a result of a second implant could add a significant financial burden to those who may already be struggling to maintain one implant system.

#### **4.6. Suggestions for future studies**

This study was the first to investigate the costs related to cochlear implantation in South Africa. It has initiated the importance of considering the role of economic factors on cochlear implantation in the country. The long-term cost implications of unilateral implantation for implant recipients were considered in this study. With the increasing trend towards bilateral implantation, the economic impact of bilateral implantation, on implantees in South Africa, could be investigated in the future. The economic effect for South African implantees, of the increasing trend towards younger implantation of severe-to-profound congenitally deaf children, and the resulting changes in cost patterns, could also be investigated. Investigating known non-users implanted in the country, to assess what role financial factors may have played in the non-use of their implants, could also yield useful information.

Future studies conducted in South Africa may want to consider some of the indirect costs not included in this study e.g. time away from work to attend appointments and loss of earnings, in order to develop an even more comprehensive picture of the costs borne by the implant recipient. The cost of appropriate or specialised education for children implanted in South Africa is another potentially significant cost which parents have to bear, but one which was

considered beyond the scope of this study. Future cost studies could investigate this area in depth.

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## APPENDICES

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### Appendix A

#### Ethical approval to conduct the study from the Health Research Ethics Committee of the University of Stellenbosch



UNIVERSITEIT-STELLENBOSCH-UNIVERSITY  
jou kennisvenoot - your knowledge partner

17 September 2009

**MAILED**

Ms G Kerr  
Dept of Speech Language and Hearing  
4th Floor, Teaching building  
Stellenbosch University  
Tygerberg campus  
7505

Dear Ms Kerr

"Cochlear implantation in South Africa: Cost implications for patients."

**ETHICS REFERENCE NO: N09/08/220**

**RE : DIRECT APPROVAL**

It is a pleasure to inform you that the Health Research Ethics Committee has approved the above-mentioned project on 16 September 2009, including the ethical aspects involved, for a period of one year from this date.

This project is therefore now registered and you can proceed with the work. Please quote the above-mentioned project number in ALL future correspondence.

Please note a template of the progress report is obtainable on [www.sun.ac.za/rds/](http://www.sun.ac.za/rds/) and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly and subjected to an external audit.

Translations of the consent document in the languages applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372  
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Approval Date: 16 September 2009

Expiry Date: 16 September 2010

17 September 2009 11:26

Page 1 of 2



Fakulteit Gesondheidswetenskappe · Faculty of Health Sciences



Verbind tot Optimale Gesondheid · Committed to Optimal Health  
Afdeling Navorsingsontwikkeling en -steun · Division of Research Development and Support  
Postbus/PO Box 19063 · Tygerberg 7505 · Suid-Afrika/South Africa  
Tel.: +27 21 938 9075 · Faks/Fax: +27 21 931 3352

**Appendix B**

**Permission to conduct the study from the Medical Superintendent of Tygerberg Hospital**

Departement van Gesondheid  
Department of Health  
iSebe lezeMpilo



Verwysing  
Reference  
Isalathiso

Navrae  
Enquiries  
Imibuzo

Telefoon  
Telephone  
Ifowuni

Dr MA. Mukosi

021-938 5966

Tygerberg Akademiese Hospitaal en  
Mitchellsplein & Tygerberg Mondgesondheidsentrums

Tygerberg Academic Hospital and  
Mitchells Plain & Tygerberg Oral Health Centres

Isibhedlele Sase Tygerberg Kwakunye Ne  
Mitchells Plain Neziko Lamazinyo Lase Tygerberg

Privaatsak X3/ Private Bag X3  
Tygerberg, 7505

Date: 14<sup>th</sup> May 2010

Ref: Your Research / Clinical trial No N09/08/220:  
Cochlear implantation in South Africa. Cost implications for patients.

Dear Ms Kerr

**PERMISSION TO CONDUCT YOUR RESEARCH/CLINICAL TRIAL AT TYGERBERG HOSPITAL**

In accordance with the Provincial Research policy and Tygerberg Hospital Notice No. 40/2009, permission is hereby granted for you to conduct the above-mentioned research/clinical trial here at Tygerberg Hospital.

DR D ERASMUS  
Acting CHIEF DIRECTOR : TYGERBERG HOSPITAL

.04.2010

## **Appendix C**

### **Information and consent letters**

#### **PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM**

TITLE OF THE RESEARCH PROJECT: Cochlear Implantation in South Africa: Cost Implications for patients

REFERENCE NUMBER: N09/08/220

PRINCIPAL INVESTIGATOR: Gill Kerr: Audiologist: Tygerberg Hospital Cochlear Implant Unit

ADDRESS: Cochlear Implant Unit, Department of Speech and Hearing, Private Bag X3, Tygerberg Hospital, Tygerberg, 7505

CONTACT NUMBER: 021 938 4818

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this study. Please ask Gill Kerr any questions about any part of this study that you do not fully understand. It is very important that you clearly understand what this research entails and how you could be involved. Your participation is voluntary and you can choose not to participate. If you don't participate, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the Committee for Human Research at Stellenbosch University and will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

### **What is this research study all about?**

This study aims to examine the costs patients in South Africa have to cover during the process of getting and using a cochlear implant over their lifetime.

The study will take place at the Cochlear Implant Centre at Tygerberg Hospital. All patients who received a cochlear implant at the centre, and are still using it, will be asked to participate.

Knowing what costs are involved over the long term will help patients using a cochlear implant to plan and prepare financially for long term use of their cochlear implant. It will also help clinicians choose and counsel patients who will be able to keep using their implants successfully.

If you choose to participate in the study you will be asked to complete and return the attached questionnaire asking questions about the costs you had during assessment, implantation, rehabilitation and maintenance of your/your child's cochlear implant. Information from the current database and at Southern ENT will be looked at to gather further information about the costs involved.

### **Why have you been invited to participate?**

As a patient, or a parent of a patient, who uses a cochlear implant you have valuable experience and first hand information about the costs involved.

### **What will your responsibilities be?**

You will need to complete and return the attached questionnaire. It will take approximately 20 minutes.

### **Will you benefit from taking part in this research?**

The information gathered in this study will help you and other cochlear implant patients be better prepared and more able to plan for the future use of your cochlear implant. It will also help those working in cochlear implant centres in South Africa to choose patients and counsel them regarding expected costs.

### **Are there any risks involved in your taking part in this research?**

There are no risks involved in taking part. You will only be required to complete a questionnaire.

**Who will have access to your records?**

Gill Kerr, one of the audiologists in the Cochlear Implant Centre, will have access to the information. The information collected will be treated as confidential. If it is used in a publication or thesis your identity will remain anonymous.

**Will you be paid to take part in this study? Are there any costs involved?**

No you will not be paid to take part in the study and there will be no costs involved for you if you do take part.

**Is there any thing else that you should know or do?**

If you have any further queries you can contact Gill Kerr (Tel. 021 938 48181) or her supervisor Mrs. L. Müller (Tel 021 938 5080). You can contact the Committee for Human Research at 021-938 9207 if you have any additional queries or concerns.

You may keep this information, as well as a copy of the consent form, if you would like to.

Please complete the page below and **return it with the answered questionnaire.**

## Declaration by participant

By signing below, I ..... agree to take part in a research study entitled COCHLEAR IMPLANTATION IN SOUTH AFRICA: COST IMPLICATIONS FOR PATIENTS.

### I declare that:

- I have read, or had read to me, this information and consent form and it is written in a language which I understand.
- I understand that taking part in this study is voluntary and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be negatively affected in any way.

Signed at (*place*) ..... on (*date*) ..... 2010.

.....  
Signature of participant

.....  
**Witness**

**Appendix D**

**Cochlear Implant Cost Questionnaire**

**Instructions:** Please complete the following questionnaire. The information is important, please try and fill in all the questions. If you don't know the exact data please give as close an approximation as you can.

For those who have two cochlear implants please answer all questions with regard to the **first** cochlear implant (CI).

Date completed: \_\_\_\_\_

Name of implant user: \_\_\_\_\_

Date of birth: \_\_\_\_\_

**QUESTION 1. DISTANCE TO THE COCHLEAR IMPLANT CENTRE**

1.1. How far did you live from the CI Centre while you were **being evaluated** for the cochlear implant? (Mark one block)

Within 50 km	51-100km	101-500km	501-1000km	More than 1000km

1.2. How far did you live from the CI centre during the first **2 years** after receiving the implant? (Mark one block)

No Change	Within 50km	51-100km	101-500km	501-1000km	More than 1000km

1.3. How far did you live from the CI centre during **years 3-5** after receiving the implant? (Mark one block)

No Change	Within 50km	51-100km	101-500km	501-1000km	More than 1000km

1.4. How far did you live from the CI centre during **years 6-10** after you received the implant? (Mark one block)

No Change	Within 50km	51-100km	101-500km	501-1000km	More than 1000km

1.5. How far did you live from the CI centre during **years11-15** after the implant? (Mark one block)

No Change	Within 50km	51-100km	101-500km	501-1000km	More than 1000km

1.6. How far did you live from the CI centre during **years15-20** after the implant? (Mark one block)

No Change	Within 50km	51-100km	101-500km	501-1000km	More than 1000km

1.7. How far did you live from the CI centre from **20 years** after the implant? (Mark one block)

No Change	Within 50km	51-100km	101-500km	501-1000km	More than 1000km

1.8. Did you move to be closer to the CI centre?

Yes\_\_\_\_\_ No\_\_\_\_\_



If YES please explain the reason(s):

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1.9. Did you transfer to another cochlear implant program because of costs?

Yes \_\_\_\_\_ No \_\_\_\_\_

## QUESTION 2. TRANSPORT TO THE CI CENTRE

2.1. How did you get to the CI centre at different points in time? (Mark all relevant blocks)

<b>Evaluation:</b>	Own transport	Public transport	Air travel + other
<b>First 2 years:</b>	Own transport	Public transport	Air travel + other
<b>Year 3-5:</b>	Own transport	Public transport	Air travel + other
<b>Year 6-10:</b>	Own transport	Public transport	Air travel + other
<b>Year 11-15:</b>	Own transport	Public transport	Air travel +other
<b>Year 15-20:</b>	Own transport	Public transport	Air travel +other
<b>Years20 +:</b>	Own transport	Public transport	Air travel +other

2.2. What was the total transport cost during each time period? (Mark relevant blocks).

<b>Evaluation:</b>	R0-R100	R101-R500	R501-R1000	R1001-R5000	More than R5000
<b>First 2 years:</b>	R0-R100	R101-R500	R501-R1000	R1001-R5000	More than R5000
<b>Year 3-5:</b>	R0-R100	R101-R500	R501-R1000	R1001-R5000	More than R5000
<b>Year 6-10:</b>	R0-R100	R101-R500	R501-R1000	R1001-R5000	More than R5000
<b>Year 11-15:</b>	R0-R100	R101-R500	R501-R1000	R1001-R5000	More than R5000
<b>Year 15-20:</b>	R0-R100	R101-R500	R501-R1000	R1001-R5000	More than R5000
<b>Years 20 + :</b>	R0-R100	R101-R500	R501-R1000	R1001-R5000	More than R5000

### QUESTION 3. ACCOMMODATION TO ATTEND APPOINTMENTS

3.1. Did you ever have to stay away from home overnight as a result of attending appointments for your/your child's cochlear implant?

Yes \_\_\_\_\_ No \_\_\_\_\_

If YES please indicate:

Did you stay with friends/relatives \_\_\_\_\_ or

Did you pay for accommodation \_\_\_\_\_ ?

If you paid for accommodation please complete the following table:

Indicate the **total accommodation cost** during each time period. (Mark relevant blocks)

<b>Evaluation</b>	Less than R500	R501-R1000	R1001-R2000	R2001-R5000	More than R5000
<b>First 2 years</b>	Less than R500	R501-R1000	R1001-R2000	R2001-R5000	More than R5000
<b>Year 3-5</b>	Less than R500	R501-R1000	R1001-R2000	R2001-R5000	More than R5000
<b>Year 6-10</b>	Less than R500	R501-R1000	R1001-R2000	R2001-R5000	More than R5000
<b>Year 11-15</b>	Less than R500	R501-R1000	R1001-R2000	R2001-R5000	More than R5000
<b>Year 15-20</b>	Less than R500	R501-R1000	R1001-R2000	R2001-R5000	More than R5000
<b>Years 20+</b>	Less than R500	R501-R1000	R1001-R2000	R2001-R5000	More than R5000

## QUESTION 4. REPAIR OF SPEECH PROCESSOR

4.1. How many times did your speech processor have to be repaired after its warranty expired?

\_\_\_\_\_

## QUESTION 5. INSURANCE

Is your speech processor insured?

Yes \_\_\_\_\_ No \_\_\_\_\_

If YES please indicate:

- Monthly premium: R \_\_\_\_\_
- How long has it been insured for? \_\_\_\_\_

## QUESTION 6. THE USE OF AN FM SYSTEM

Have you bought an FM system to use with the CI?

Yes \_\_\_\_\_ No \_\_\_\_\_

If YES, please indicate:

- Cost: R \_\_\_\_\_
- How did you pay for it?  
Self \_\_\_\_\_ Medical aid \_\_\_\_\_

## QUESTION 7. THE EAR WITHOUT THE IMPLANT

Do you/your child use a hearing aid in the ear that is **not implanted**?

Yes \_\_\_\_\_ No \_\_\_\_\_

If YES please indicate:

- Cost: R \_\_\_\_\_

- How did you pay for it?  
Self \_\_\_\_\_ Medical aid \_\_\_\_\_

Monthly cost of batteries: \_\_\_\_\_

### QUESTION 8. ADVICE TO OTHERS:

From your own experience with a cochlear implant, what advice would you give potential patients **with regards to costs** and **planning for costs** involved in obtaining and maintaining a cochlear implant?

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If you/your child were/was implanted **before the age of 13 years** please continue to Question 9.

If you/your child were/was implanted **after the age of 13 years** you have now completed the questionnaire. Thank you very much for taking the time to complete the questionnaire.

## QUESTION 9. REHABILITATION SERVICES FOR CHILDREN WITH COCHLEAR IMPLANTS

**Please only answer this question if you/your child were/was implanted before the age of 13 years.**

What extra costs did you have in the **first year** after implantation as a result of extra rehabilitation needed? (Mark relevant blocks)

THERAPY	HOW OFTEN?	COST PER YEAR	HOW DID YOU PAY?
<b>SPEECH THERAPY</b>	Daily	R_____	Self
	Weekly	Can't remember	Medical Aid
	Monthly	_____	Included in school fees
<b>OCCUPATIONAL THERAPY</b>	Daily	R_____	Self
	Weekly	Can't remember	Medical Aid
	Monthly	_____	Included in school fees
<b>PHYSIOTHERAPY</b>	Daily	R_____	Self
	Weekly	Can't remember	Medical Aid
	Monthly	_____	Included in school fees
<b>CLINICAL PSYCHOLOGY</b>	Daily	R_____	Self
	Weekly	Can't remember	Medical Aid
	Monthly	_____	Included in school fees
<b>OTHER: PLEASE SPECIFY</b>	Daily	R_____	Self
	Weekly	Can't remember	Medical Aid
	Monthly	_____	Included in school fees

If you continued any of these services after the first year please complete the following table:  
(mark relevant blocks)

	<b>THERAPY (TICK ALL RELEVANT)</b>	<b>ESTIMATE TOTAL COST OF THERAPIES</b>	<b>HOW DID YOU PAY?</b>
<b>Year</b>	None	R_____	Self
<b>2-3 after CI</b>	Speech therapy	Can't remember	Medical Aid
	Occupational therapy		
	Physiotherapy		Included in school fees
	Clinical psychology		
	Other:		
<b>Year</b>	None	R_____	Self
<b>3-5 after CI</b>	Speech therapy	Can't remember	Medical Aid
	Occupational therapy		
	Physiotherapy		Included in school fees
	Clinical psychology		
	Other:		

<b>Year</b>  <b>5-10</b> <b>after CI</b>	None	R_____	Self
	Speech therapy	Can't remember	
	Occupational therapy		Medical Aid
	Physiotherapy		
	Clinical psychology		Included in school fees
	Other:		

Thank you very much for taking the time to complete this questionnaire.



**Appendix E****Tygerberg Hospital Income Classification System**

Classification	Criteria	Cost per appointment (2010 Rands)
H0	<ul style="list-style-type: none"> <li>• Under 6 years (not on medical aid)</li> <li>• Disability grant</li> </ul>	<ul style="list-style-type: none"> <li>• Free</li> </ul>
H1	<ul style="list-style-type: none"> <li>• Single: &lt;R2999 per month</li> <li>• Family: &lt; R4166 per month</li> </ul>	<ul style="list-style-type: none"> <li>• R15 first appointment</li> <li>• R10 follow up</li> </ul>
H2	<ul style="list-style-type: none"> <li>• Single: R3000-R5999 per month</li> <li>• Family: R4167-R8333 per month</li> </ul>	<ul style="list-style-type: none"> <li>• R45</li> </ul>
H3	<ul style="list-style-type: none"> <li>• Single: &gt; R6000 per month</li> <li>• Family: &gt;R8334 per month</li> </ul>	<ul style="list-style-type: none"> <li>• R262</li> </ul>
Private	<ul style="list-style-type: none"> <li>• On medical aid (including children under 6 years)</li> </ul>	<ul style="list-style-type: none"> <li>• R262</li> </ul>

**Appendix F****Tygerberg Hospital Cochlear Implant Unit follow-up schedule****Average number of appointments at the implant unit**

Time post activation	Age at implantation				
	0-4 years	5-8 years	8-13 years	> 13 years (congenital loss)	>13 years (acquired loss)
<b>1<sup>st</sup> Year</b>					
1 <sup>st</sup> month	8	5	5	5	5
3 months	2	2	1	7*	1
6 months	2	2	1	1	1
9 months	2	2	1	1	1
12 months	2	2	1	1	1
<b>Total Yr 1</b>	<b>16</b>	<b>13</b>	<b>9</b>	<b>15</b>	<b>9</b>
<b>2<sup>nd</sup> Year</b>					
3 months	2				
6 months	2	1			
9 months	2				
12 months	2	1	1	1	1
<b>Total Yr 2</b>	<b>8</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>After 2<sup>nd</sup> year</b>	2 visits 6 monthly (until age 6) then 1 visit annually	1 visit annually	1 visit annually	1 visit annually	1 visit annually

\*The first 3 months include an additional 6 visits for aural rehabilitation (on average every 2 weeks for 1<sup>st</sup> 3 months)

**Appendix G****Therapies attended by paediatric implantees at different time intervals post implantation**

Key to symbols used in table:

S= Speech therapy

O=Occupational therapy

P=Physiotherapy

Psy=Psychology

Other= other form of therapy

<b>Subject</b>	<b>Age implanted (months)</b>	<b>Duration of use (months)</b>	<b>Year 1-2</b>	<b>Year 3-5</b>	<b>Year 6-10</b>
8	6	17	S,P		
7	7	14	S		
50	8	104	O,P	O,P	O
30	9	71	S,O,P,Psy	S,O,P	
27	10	60	S	S	
56	11	118	O,P	O,P	S,O
51	14	104	S,O,P	S,O,P	S,O,P
3	15	9	S,P		
63	17	142	S	S	S
11	18	29	S,O		
15	18	36	S		
36	18	76	S,O	S,O	

Subject	Age implanted (months)	Duration of use (months)	Year 1-2	Year 3-5	Year 6-10
26	20	56	S	S	
32	21	74	S,O	S,O	
61	22	139	S	S	
65	22	146	S,O,P	S,O,P	O,P
47	23	100	S	S,O	S,O
17	24	45	S,O	S,O,P	
29	25	70	S,O	S,O	
19	26	47	S,O	S,O	
41	26	82	S,O,P	S,O,P	S,O,P
13	27	30	S	S	
39	27	81	S,O		S
28	28	64	S	S	
73	29	175	S	S	
33	31	75	S,O	S	S
14	33	36	S,O	S	
24	33	53	S	S	
5	34	12	S,O		
34	34	75	S		
70	34	150	S	S	S
18	35	46	S	S	
21	35	51	S	S	

Subject	Age implanted (months)	Duration of use (months)	Year 1-2	Year 3-5	Year 6-10
6	36	13	S+ OTHER		
16	38	36	S		
53	38	111	S	S	
72	38	165	S,O		
64	39	144	S,O	S	S
12	40	30	S		
10	41	24	S,O		
48	41	102	S,O	S	S
75	41	182	S	S	
57	42	120	S,O,P	S	
66	42	147	S	S,O	S
44	43	92	S,O	S	
45	43	96	S,O,Psy	S,O	S
59	46	123	S		
52	47	107	S,O,P	S	S
55	50	118	S,O,P	S	S
20	51	51	S,P	S	S
23	53	53	S,O		
25	56	56	S,P	S,P	
71	57	152	S	S	S
1	59	3	S,O		

Subject	Age implanted (months)	Duration of use (months)	Year 1-2	Year 3-5	Year 6-10
81	59	254	S, O	S	
67	60	147	S,O	S,O	S, Psy
79	60	203	S	S	S
76	65	186	S		S
31	74	74	S		
69	77	150	S	S	S
35	80	75	S	S	S
58	82	121			
80	83	237	S	S	
62	87	139	S,O	S	
77	88	189	S	S	S
22	94	51	S		
2	99	9	S,P		
46	100	100	S		
78	102	198	S		
4	103	10	S		
38	104	78	S,O,P		
68	106	148	S	S	S
40	108	82	S		
42	108	82	S	S	
54	119	116			
37	121	77	S	S	

<b>Subject</b>	<b>Age implanted (months)</b>	<b>Duration of use (months)</b>	<b>Year 1-2</b>	<b>Year 3-5</b>	<b>Year 6-10</b>
60	127	135			
74	141	182			
9	148	20	S +OTHER		
43	151	89			
49	153	103	S		