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Economic Evaluation of the Cochlear Implant

Report prepared for Cochlear Ltd, Sydney

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ABSTRACT

A cost utility study of the cochlear implant has been undertaken from the perspective of 'government/service provider', covering its use in profoundly deaf adults, partially deafened adults and children. Costs include the selection of implant recipients, surgery/implantation, and rehabilitation/implant maintenance over the useful life of the implant. Costs for recipients and their families are included only in so far as they are related to the 'service provider' perspective. Costs borne purely by patients (travel time, foregone income, etc) are not included in the analysis. The measure of outcome chosen is the likely improvement in the quality of life for recipients over the useful life of the implant.

A brief review of the literature indicated that significant recent developments in cochlear implantation include improved reliability of the device, extension of the useful life of an implant to 15 years or more, further evidence of good outcomes for children who have cochlear implants, and indications that while achievement of a sensation of hearing provides benefits, additional and greater degrees of benefit are obtained from other quality of life consequences of the implant procedure.

The HRQOL-15D quality of life instrument developed by Sintonen has been used to derive utility values for the outcome measure, because of its sensitivity for the application and superiority of validation in the context of economic evaluation. Three values (low, middle and high) have been calculated for each of the patient groups considered, based on expert opinion. The different values reflect the number of dimensions from the HRQOL-15D instrument included in each scenario, and the extent of the health state improvement within each dimension.

For profoundly deafened adults the improvement in health-related quality of life through use of an implant ranges from 11% to 37%. Amelioration of the hearing disability contributes 3-4%, while the functional consequences of the hearing improvement result in a further 8-33% improvement. Corresponding results for partially deafened adults and for children are 2% and 4-5% improvement respectively through obtaining hearing sensation, and 9-28% and 13-32% improvement respectively due to functional consequences.

Values for cost per quality adjusted life year have been calculated for each patient group using a specified treatment pathway (with associated costs and probabilities); the three values obtained

from the HRQOL-15D instrument; and 10, 15 and 20 years as the useful life of the implant. A 5% discount rate was used for both costs and outcomes.

Results using a value of 15 years for the lifetime of the implant give an indication of the typical cost utility of the technology. Costs per quality adjusted life year range from $11,790 to $38,150 for profoundly deaf adults; $14,410 to $41,000 for partially deafened adults; and $5,070 to $11,100 for children.

The results for children in part reflect the offsetting savings through enabling education to be undertaken in mainstream schools. These savings (net present value) are estimated as $7,978 per child. The results also include a more comprehensive costing than in an earlier Australian study, with provisions made for regular software upgrades and on-going electrical maintenance.

These results are of the same order as other values reported in the literature, and are more optimistic for children than the values derived in the earlier Australian study. They indicate that the cochlear implant compares favourably with other health care technologies where resources are currently being committed. While there is no universally agreed benchmark on the appropriate trade-off between costs and quality adjusted life years, these results would normally be regarded as good ‘value for money’. Sensitivity testing indicates that the estimates are reasonably robust to changes in the discount rate and in the cost of the device. The estimates for children are sensitive to changes in the rates of long term rehabilitation and the proportion of those who participate in mainstream education.

Further work that might usefully be undertaken includes obtaining Australian values for quality of life factors from empirical studies and considering more specific groups of patients and interest groups than has been possible in the present analysis. The extent of the quality of life improvement due to functional consequences vis-a-vis the hearing impairment itself, reinforces the requirement for such research, as does the need to take a broader societal perspective to the economic appraisal.

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1 Introduction

In 1991 the Australian Institute of Health published a monograph on the cochlear implant which described the current status of the technology and discussed directions for future research (1). The monograph included a preliminary economic assessment of the technology, considering its cost utility on the basis of weightings derived by Kaplan and Anderson (2). The results indicated that, should the implantation process result in a 10% increase in quality of life, then costs per quality adjusted life year (QALY) might be of the order of $14,000 for children and $22,000 for adults, suggesting that the technology represented good value for money (1, 3).

Since then, there have been a number of technical developments, some extension of indications for implantation and further economic appraisals published overseas. The present paper extends the economic analysis in the earlier report, taking account of other quality of life instruments, including a more comprehensive costing, incorporating sensitivity analysis and including consideration of partially deafened adults. A brief description of recent developments in the application of this technology has also been included and has been used as a guide in the development of the approach taken in the economic analysis.

The status of the technology at the end of 1991 was summarised in the report from the Australian Institute of Health (1). At that stage, the technology was well established, with 5,000 to 6,000 procedures having been undertaken world-wide, including 300 in Australia. Some of the matters being debated at that time were the variation in hearing gain in response to an implant, the benefits of cochlear implantation for pre-lingually deafened children, long term safety of the device, changing selection criteria for implantation of severely deafened adults and of children, and the need for measures of the quality of life changes to implantees (1). There was also a need identified for refinement of radiological and other test procedures. Further results have since emerged in all these areas, as additional experience has been gained with the procedure, and results have started to become available from longer term follow-up of implantees. More than 10,000 procedures have now been undertaken world-wide, and the Australian total is now over 500.

2 Some Recent Developments in Cochlear Implantation Services

In order to provide some context for the economic analysis, the following brief overview covers some of the significant areas of development in cochlear implantation over the last three years. Seven general areas are considered - diagnosis and assessment, device development, implant procedure, rehabilitation and other services, outcome measures, safety, and economic factors.

Data for the review were based on searches of Medline from end 1992 to end 1994, a recent review by the French assessment agency ANDEM (4) and papers provided by Cochlear Ltd, Sydney. Much of the focus of recent work has been on the further development of services to paediatric cases.

2.1 Diagnosis and Assessment

The use of Electrically Evoked Auditory Brain-stem Response (EABR) in paediatric patients has been described by Kileny et al (5) who conclude that EABR is an integral part of the pre-operative selection process for such cases. Although EABR cannot replace behavioural measurements for device setting, in difficult cases EABR thresholds may be used as a starting point from which to estimate settings for the device (6). Siatkowski et al (7) recommend routine ophthalmological examination in children with congenital or pre-linguistic deafness following examination of children aged 2 to 14 years who were in a cochlear implant program. Of 54 children, 33 had some form of ophthalmological abnormality, with the majority (24 of 33) being refractive errors.

CT imaging continues to be regarded as helpful in evaluation of candidates for implantation, but has a more limited performance when used for assessing ossification(8,9). Ito recommends pre-operative CT or MRI to determine the condition of the cochlea, and exploratory tympanotomy in some cases. After insertion of the electrode, the position should be checked by X-ray (10). Small studies have confirmed the feasibility of using cochlear implants in patients who have extensive cochlear ossification, following extensive cochlea drill out (9, 11).

A case study has suggested that the cochlear implant should be considered in patients with traumatic sensorineural hearing loss who have relatively intact cognitive skills (12).

Psychological assessment of prospective cochlear implant recipients, and monitoring their progress following implantation have been seen as important processes in implantation programs (13). Shipp and Nedzelski (14) found that pre-implant psychophysical test results have value as predictors of post-implant, open-set speech recognition performance in adults. Gantz et al developed a multivariate predictor of audiological success with multichannel implants and tested this on 48 adults in a randomised cochlear implant-controlled trial (15). There was significant correlation with Iowa Sentences Test 7 word understanding scores.

2.2 Cochlear Implant Device Developments

Significant recent trends have been the extension of the useful life of the cochlear implant to 15 years or more and the further development of devices for children, with the recent announcement of an implant suitable for use in perinatal cases flagging an impressive technical achievement.

The reliability of the cochlear implant in terms of the cumulative experience with the Nucleus Mini 22 device has been considered by von Wallenberg and Brinch (16). They point out that the most valid measure of reliability is the cumulative experience report (CER). The CER results for the Nucleus device over 9 years, covering 8,804 patients, show a flat trend after 5 years of implant life, indicating that the majority of failures occurred early in the life of the device. More than 97% of implants were working after three years of operation and more than 96% after five years.

This level of reliability can be expected to improve as the result of introduction of design improvements. The most frequent failure mode for the device was with the antenna feed through connection, which accounted in a survival reduction to 98.9% after five years of operation. Introduction of a design change to improve mechanical robustness of the connection was made in late 1993. Since then more than 1,000 of the modified devices have been implanted, with accumulated experience of 444 implant years. During this time there were no failures of the type the design change addressed. The modification appears to have been effective, but the authors note that even with this large number of devices implanted, and a one year experience, future performance cannot be predicted.

Evaluation of expandable lead wires for paediatric implants has been undertaken in the context of development of cochlear implants for very young children. Performance measures indicated that five designs appeared to be appropriate candidates for further development (17).

The possibility of system failure with the technology has been considered by Battmer et al (18) who reported eight internal device failures in more than 450 cochlear implant patients. A battery of objective measurements is used clinically to distinguish possible causes of failure.

2.3 Implant Procedures

Increasing experience with implantation has led to identification of potential surgical pitfalls - improper patient selection, facial nerve damage, poor flap design and handling, and improper electrode placement and improper seating of the receiver stimulator (19). Marsh et al (20) have drawn attention to the importance of post operative X-ray to confirm intra cochlear position and detect possible electrode kinking. Surgical estimates of insertion depth have greater variation as compared with X-ray data.

The effect of electrode position on neural excitation was investigated by Shepherd et al (21). They suggest that improved placement should result in more localised neural excitation patterns, an increase in the number of bi-polar electrodes available, together with an increase in their dynamic range. These changes may lead to further improvements in speech perception among cochlear implant patients.

Nineteen anatomical/surgical landmarks with implications for implant surgery have been identified in human temporal bone (22). The results help define criteria for lead wires in paediatric cochlear implant design. From an anatomical and surgical point of view, implantation in very young children is feasible, provided the electrode array is secured and the design accommodates for controlled leadwire lengthening.

2.4 Rehabilitation and Support Services

Souliere, Quigley and Langman have published a detailed review of implantation in children (23), drawing attention to critical issues involved in such programs. They comment that criteria for treatment are in evolution and that implantation, particularly in children, requires a team commitment from many types of health care professionals. Post-operative rehabilitation requires a bigger commitment from the patient, the patient's family and the implant team than does adult rehabilitation.

Detailed consideration was given in a recent French study to the need of parents of congenitally deafened children for advice on the technology. Results from a review were presented to surgeons, speech pathologists, teachers, parents and the deaf community. All parties agreed that exhaustive information on the safety and the potential benefits in young congenitally deaf children must be provided to the parents who are responsible for making the decision as to whether implantation should be carried out (4).

Two technical papers in this area were identified during the review. Tait describes the use of video analysis to assess changes in preverbal and early linguistic communication after implantation. Early indications of progress over time generally predict the level of functioning achieved at 12 months post-implantation (24). Aerodynamic characteristics of the speech of implanted adults were investigated by Leeper et al Individual strategies for coordinated control of speech mechanism appear to be potent variables to consider when assessing speech production (25).

2.5 Outcomes for Implantees

Some significant progress has been made over the last few years in obtaining better measures of outcome for those with cochlear implants, especially with children. Further work has confirmed the superiority of multichannel devices over single channel implants. Cohen et al conducted a prospective randomised trial to compare different types of cochlear implant devices (26). While all patients were able to hear with their implants, multichannel implants were superior to single channel devices, especially for understanding speech. Also, changes in speech processing can improve patients' performance.

In commenting on this study, Balkany (27) suggested that caution in interpreting these findings would be prudent, in view of the wide range of results between patients. Nonetheless, the results were decisively favourable, when the goal of therapy of restoring some hearing to the profoundly deaf was considered. (In this and subsequent correspondence, the benefits of restoring hearing in terms of increasing the vocabulary of the child was discussed. While respecting the opinion of the deaf community, it was noted that the vast majority of deaf children are born to hearing parents, and most family members do not master signed language.)

Speech discrimination with the Nucleus 22-channel device has been shown in two studies to be better than that using a single channel device or a Tactaid II+ vibrotactile aid, in hearing -impaired children (28, 29). A further study showed that upgrading from a single channel to a multichannel device resulted in improved acoustic thresholds for five children, and improvements on identification tasks for two of them (30).

Souliere, Quigley and Langman (23) summarise data from studies with different types of implants, indicating the superiority of outcomes for those with a multichannel device. Data from those studies which have separately tracked subjects with pre-, per- and post-lingual deafness indicate chronological differences in speech perception following implantation. Postlingually deafened children quickly achieve 100% scores on closed-set testing, while those with prelingual deafness gradually achieved only 30-42% correct scores over 12 months. The performance of perilingually deafened children has been intermediate, with 40% correct scores at 2 years and 84% by 3 years after implantation.

Preliminary data suggest that children with prelingual deafness may gradually develop perceptual skills over a longer post transplantation period than children with post-lingual deafness. Post-implantation evaluation of 61 patients aged 2.4 to 17.8 years showed an increase in speech intelligibility from 18.1% to 33.5% after 1 year. Older children (10 to 17 years) had more marked improvement (14% to 61.5%), possibly due to better reading ability and longer language exposure.
Tait and Lutman, over a period of 12 months compared early communicative behaviour (preverbal behaviours) of nine children aged under 5 who used the Nucleus implant with two groups of nine children who used conventional hearing aids (31). One comparison group was comprised of proficient cochlear implant users, the other of poor users. Proficient cochlear implant and hearing aid users and implantees developed a primarily vocal and auditory style of communicative behaviour that contrasted with the primarily gestural style adopted by poor hearing aid users. The Nucleus device appears to promote similar preverbal conversational style that is similar to that of children with sufficient cochlear implant hearing to be proficient users of hearing aids. If this form of behaviour is predictive of ultimate performance with the implant, many young implanted children will go on to develop age-appropriate intelligible speech and understanding of intelligible language.

Tye-Murray and Kirk undertook a study on how vowel and diphthong production of young implantees varied over time and how performance on the Phonetic Level Evaluation corresponded with their producing spontaneous speech. Correlations between the PLE and spontaneous speech measures was weak. Results suggested that over time vowel and diphthong production became more diverse and also more accurate (32).

Variables that contribute to the large individual differences in the speech perception skills of children implanted with the Nucleus device have been studied by Miyamoto et al (33). Length of implant use accounted for the most variance on all speech perception measures used. Other significant variables included processor type, duration of deafness, communication mode, age at the onset of deafness and the age implanted. Age at implantation and age to deafness onset were positively correlated with test performance for pre- and peri-lingually deafened subjects in a group of 30 children studied by Shea et al (34).

Reid and Lehnhardt reported on post-operative speech perception results for 92 European children implanted with the Nucleus Mini System 22 (35). On average, the children were deafened very early in life, had a relatively long duration of deafness prior to implantation and had a mean period of implant experience of 13 months. Sixty eight per cent of those with a congenital hearing loss, 67% with pre-lingual loss, 85% with peri-lingual loss and 73% with post-lingual loss obtained test scores significantly above chance. All children could demonstrate detection of phonemes at a conversational level and all but one also perceived suprasegmental features; 65% could recognise speech in a closed set and 13% in a modified open set format. The results reflect early experience of the children with their implants, and can be expected to improve with further use.

Gantz et al (36) followed up 54 congenitally and pre-lingually deafened children implanted with the Nucleus device for between 1 and 5 years. Speech perception and production performance improved for both pre- and post-lingually deafened children over time, with the post-lingual group deriving significant benefit within the first year of implant use. Pre-lingually deafened children were able to develop pattern recognition within 1 year of implantation; more complex closed-set word identification requires considerable experience over two or more years.

There was continued improvement over the a five year interval. After 4 years, 80% of the pre-lingually deafened group had limited open-set word understanding and none had a deterioration in performance. Age of implantation (between 2 and 1 years) had little influence on speech understanding of pre-lingually deafened children. Pre-lingually deafened children derive significant benefit from implantation through improvement in speech perception and production. The data suggest that further improvement will occur with prolonged experience. Limited open-set word understanding was achieved by more than 80% after 4 years.

Further results have emerged on outcomes for very young children. Miyamoto et al studied the speech perception abilities of 19 children with onset of deafness before the age of 3 and found no difference between those with congenital deafness and those with onset of deafness after birth (37).

Waltzman et al studied the speech perception and production skills of 14 children (6 congenitally deaf and 8 pre-lingually deafened) who were implanted with Nucleus device before the age of 3 years (38). Follow-up was undertaken for 2-5 years. The results showed a continuous improvement in auditory perceptual skills in children who had been implanted for two years or more. All subjects demonstrated open-set speech recognition, used oral/aural communication, and attended age-appropriate nursery or mainstream schools. It was concluded that early implantation is beneficial to the development of speech perception in the congenitally and pre-lingually deafened child.

There are still no results on educational achievement for pre-lingually deafened children, with maximum follow-up being no more than 4 years. A major recommendation from the study in France by ANDEM was that all implanted children should be followed up, and that this follow-up should go beyond technical and medical aspects and consider familial and societal impact (4).

Useful additional results have also been obtained for adults. Kou et al reported evidence of subjective benefits from implantation on the basis of a questionnaire sent to a consecutive series of 23 adult post-lingually deafened implantees and their relatives (39). Substantial improvements were reported in speech recognition with lip reading, voice quality, independence and communication confidence. There was slightly less benefit in speech recognition without lip reading. Overall, 85% of implantees and 94% of their relatives were moderately to very satisfied with the device and most would recommend the device for others. Satisfaction correlated well with independence and confidence, but poorly with objective scores of sentence recognition.

Twelve adults and two children who were post-lingually deafened all showed improvement in ability to understand speech after implantation with the Ineraid 4 - channel device (40). Eight persons (57%) demonstrated some open set speech discrimination. Auditory results of 48/49 patients implanted with the Ineraid device indicated improvement in performance in identifying environmental sounds (average 61%) and auditory-only and auditory plus visual cued sentences (48.8% and 95.5% respectively) (41).

Waltzman et al (42) have discussed the benefits of implantation for the geriatric population, based on a study of 20 implantees between 65 and 85 years of age. The surgical procedure was tolerated well by all patients. Post-operative test results showed significant improvement in all aspects of auditory perception as a result of implant usage. It was concluded that the geriatric population with bilateral profound sensorineural hearing loss obtains significant benefits from cochlear implantation, despite the possible existence of age-related auditory processing problems.

Horn et al (43) found 86% of older patients implanted with the Nucleus multichannel device reported improved quality of life, though there was no correlation between satisfaction and subjective perception of sound.

Sarant et al (44) reported significant improvements in speech perception results for two congenitally deaf adolescents. They suggest that though benefit in general may be low for such patients, individuals may attain significant benefits to speech perception after a short period of experience, and prospective patients from this group should be considered on an individual basis with regard to prognosis of benefit.

A study of the adult implantee’s ability to cope with communication breakdown suggested that the problem was complex and that ability to cope must be evaluated on an individual basis (45).

2.6 Safety Considerations

Mitchell (46) points out that with the increasing use of cochlear implants, complications after the immediate period will become increasingly drawn to the attention of the emergency medical practitioner. Surgical complications have been reviewed by Cohen and Hoffman (47).They note that the incidence of life-threatening complications is minimal, and that while the incidence of major complications is acceptable, many complications can be avoided by paying attention to detail. Facial nerve injury after implantation has been reported for eight cases and suggestions made on use of pre-operative imaging and intra-operative monitoring may assist in reducing such injuries.

The recent ANDEM review concluded there were no major biocompatibility safety issues related to transplantation in pre-lingually deafened children. Post-surgery symptoms occurred in 0.6 to 1% 0f cases, and 97% were symptom free after one year (4).
An in-vitro single blind controlled study of insertional trauma to the cochlea used three different multichannel electrodes with human temporal bones. All electrode designs caused damage, but this is unlikely to hinder implant performance. The Nucleus design was the least traumatic. The degree of trauma may be relevant for changing indications for insertion of implants as well as for those with device failure who require re-implantation (48). From work on the effects of long-term implantation in monkeys, Xu et al conclude that long-term cochlear implantation in very young children will not cause any significant deformity of the skull (49).

On the basis of a study on 35 patients and literature data, van den Brock et al (50) estimated the risk of losing pre-operative vestibular function to be about 60%. Improvement in implantation technique could probably reduce this risk considerably (50).

2.7 Economic Factors

Roberts (51) has briefly discussed costs and benefits of cochlear implants in Europe. The cost of the technology has probably decreased in real terms but remains high. She mentions that in the UK it has been calculated that the costs involved in implantation and management of a child amount to £30,000 in the first year, with follow-up costs of £1,000 a year. Costs for a post-lingually deafened adult could be assumed to be less. In the UK it has been suggested that savings of up to £10,000 a year per child can be made should they be able to be mainstreamed in the education system, suggesting a saving of approximately £60,000 over 10 years (net present value with 5% discount rate).

Rehabilitated adults who are able to return to work as a result of implantation will represent a financial saving to government through avoidance of social security expenditure. Also, earning potential of profoundly deaf adults may be increased by up to 20%, on the basis of results from some American studies. Roberts advocates the need to develop the concept of long-term benefit and also to consider benefits of implants that cannot be measured in financial terms.

A recent analysis in the UK (52) has pointed to the high and growing demand for implants for young children (242 cases per year in that country) compared with annual recurrent demand for adults (55 cases per year). Direct costs to service providers of managing a patient were estimated as £28,318 for adults and £42,565 for children, over a period of 12 years. This assumed a processor upgrade at 6 years, included maintenance contract costs, with future costs being discounted at 6%. These estimates did not take account of opportunity costs of factors such as time off work, potential cost savings in education of children or possible savings from reduced dependency on social services. Estimates of utilities in adults were made using both a direct approach with visual -analog scales and mapping pre and post operative measures of annoyance onto health states described in a standard text.

The analysis (52) suggested that post-lingual hearing loss in adults entails an average loss of quality of life (QOL) of about 0.4, of which between 0.1 and 0.3 is restored by multichannel cochlear implantation. With an average age at implantation of 49 years, accumulated net gain in QOL at a 6% discount rate is between 1.3 and 3.9 QALYs. Total cost of management of an adult patient is estimated at £33,641 so that the cost per QALY for the intervention is between £8,624 and £25,871, placing adult cochlear implantation in the middle range of cost utility for health technologies in the UK. Cost utility is likely to improve as the service matures and service costs decline. With the current estimates, cochlear implantation falls between neonatal intensive care (1 to 1.5 kg) and CABG for 3 vessel disease in terms of cost per QALY.

A US estimate of cost utility of adult implantation (53), based on a survey of 301 Nucleus 22 users who had used the device for two or more years (76% response rate), suggested that the cost per QALY was approximately US$9,325, with sensitivity analysis suggesting a true value of between US$7,988 and US$11,201. The potential value of cost benefit analysis in considering the paediatric population was noted, taking into account reduced education costs and increased employment prospects.

This group is also undertaking further work on assessment of patient outcomes following cochlear implantation. A pilot study in support of this work considered a number of assessment measures for inclusion in the appraisal of quality of life (54). Two condition-specific scales were developed. Each appeared capable of detecting quality of life differences related to the technology. An interesting aspect of this work was the indication of acceptability to patients from the high response rate from those participating in the study, high completion rates for questionnaires and extensive positive comments on the questionnaires.

2.8 Indications from the Review for the Economic Evaluation

Several points emerged from the review of the literature which were of relevance to the assumptions and perspectives of the economic analysis. These are:

- Available data show that the Nucleus implant is highly reliable, and that reliability will probably increase in future as a result of design modifications. For the purposes of the analysis, no provision was made for equipment failure or replacement, beyond inclusion of regular processor upgrades and ongoing electrical maintenance.

- Safety of the implant procedure appears to be good, with some potential risks capable of being minimised as further experience is gained. For the purposes of this study, no account was taken of possible adverse effects when deriving the utility weights. A more detailed analysis might appropriately consider such factors, including effects from the potential loss of vestibular function.

- Outcomes for children who have cochlear implants are good, and have now been obtained with follow-up over several years.

- Achievement of a sensation of hearing is only one of the benefits from cochlear implantation. Additional, and greater, degrees of benefit are obtained from other consequences of the implant procedure.

- Estimates of loss of quality of life due to hearing loss, and of the degree of restoration of quality of life due to implantation, are consistent with assumptions made in an earlier analysis, and give added confidence in the validity of the utility weights used in the present study.

3 Economic Evaluation

The economic evaluation is attempting to assess whether cochlear implantation represents ‘value for money’ compared to competing uses for the health resources involved. This comparison is necessary because costs and benefits of a new initiative are always incremental to what would have happened had the project not gone ahead. For this analysis, therefore, the research task is to estimate the net costs and net outcomes of the cochlear implantation program, compared to the situation with no implantation program. The analysis is undertaken from the perspective of the ‘government/service provider’, and focused on the costs associated with the selection of implant recipients, surgery/implantation, and rehabilitation/implant maintenance over the useful life of the implant. Costs for recipients and their families are included only in so far as they are related to the ‘service provider’ perspective. Costs borne purely by patients (travel time, forgone income, home expenditures etc) are not included in the analysis. Benefits enjoyed by the deaf community from their own culture and sign language are not included in the analysis. There would be value in taking a broader ‘societal perspective’ to the economic appraisal of cochlear implantation, when resources permit a more comprehensive approach.

3.1 Outcome Measure

The measure of outcome chosen for the preliminary economic assessment of the cochlear implant (1), and for this assessment, is the likely improvement in the quality of life for recipients over the useful life of the implant.

There is a large variation in the performance achieved by recipients of implants ranging from using the device to supplement lip reading to being able to converse effectively on the telephone. The ability of implant recipients to detect environmental sounds is associated with an enhancement of self-confidence and possibly also personal safety. Factors, excluding the amount of intensive rehabilitation received, which contribute to the individual variation in benefit include the length of time since loss of hearing, linguistic and cognitive skills, degree of education, length of learning and use of the implant, and aetiology of deafness.

In the preliminary assessment, the Quality of Well-Being Scale (QWBS) described by Kaplan and Anderson (2) was used to obtain an indication of the impact of cochlear implantation on quality of life for the profoundly deaf. The QWBS includes dimensions to measure both the symptoms of illness or disability, and the functional consequences in terms of mobility, physical activity and social activity. The weights given to these dimensions were obtained from random sample surveys in the San Diego community of the United States during two consecutive years.

For the symptom described as ‘any problem hearing - includes wearing a hearing aid’ the weighting was -0.170; that is, a 17% decrease in the quality of life as compared with a state of health with no specified symptoms or problems. This symptom measure did not include any additional weighting related to the functional consequences of profound deafness (for example, on the social activity scale), which might well be relevant for profoundly deaf persons. Use of the cochlear implant should improve the quality of life but would not be expected to remove all the deficit. As the degree of response following cochlear implantation is very variable, the preliminary assessment assumed two levels of improvement in quality of life based on the QWBS - a 15 per cent improvement and a 7.5 per cent improvement. A limitation of this approach was that the weights used in the QWBS are from the general community, not from recipients of cochlear implants or from the deaf community. The same limitation applies to the present study.

Methodology

For the present study several of the available health-related quality of life instruments were considered. These included the QWBS (2) used in the preliminary outcome assessment; the EuroQol (55); the McMaster Multi-Attribute Utility instrument (56,57) and the Sintonen HRQOL-15D (58,59).

Because of its sensitivity for application to evaluation of the cochlear implant and because of the superiority of its validation in the context of economic evaluation (58), it was decided to use the Sintonen fifteen dimensional measure of health-related quality of life (HRQOL-15D).

The HRQOL-15D has a specific hearing dimension, together with a range of functional consequences relevant to a hearing disability (such as speech, usual activities and distress). Each dimension has five item responses or descriptive statements, by which the level of the relevant dimension can be identified. For example, the responses for the hearing dimension are given in Table 1.

Some further details relating to use of this instrument for evaluation of the cochlear implant are given in Appendix 1.

TABLE 1
The Item Responses for the Hearing Dimension in HRQOL-15D

1	( )	I can hear normally. ie. normal speech (with or without a hearing aid)
2	( )	I hear normal speech with a little difficulty
3	( )	i hear normal speech with considerable difficulty; in conversation I need voices to be louder than normal
4	( )	I hear even loud voices poorly; I am almost deaf
5	( )	I am completely deaf

The design of the HRQOL-15D provides high sensitivity, in that it allows a great number of health-related quality of life states to be defined. In principle, it would be desirable to establish Australian weights to condense the 15D into a single score. However, this requires empirical survey work which is outside the scope of the current study. Instead, pre-existing weights based on a randomised survey of the Finnish population were used. Sintonen and Pekurinen (58) report that the reliability of the 'social' importance weights is quite good and that generally the subject's age, sex, education and duration of illness/disability were not found to be significantly correlated with the individual importance weights. EuroQol evidence also suggests that weights do not vary significantly between European countries. This adds confidence in using the Finnish weights for both the adult and children applications in the present study.

Just as there are various ways in which the social importance weights can be established, there are also various ways in which the health status for each of the dimensions can be completed. These generally range from asking patients or the recipients of the health service to rate their own health status before and after the procedure, to asking clinicians or health professionals their judgement of the relative improvement due to the intervention. With the resources available for this study, we were restricted to the latter approach, vis, seeking the judgements of health professionals, but serious consideration should be given to the former method in any larger scale study.

The results reflect the judgement of a doctor experienced in clinical aspects of cochlear implantation and of a researcher in the routine use and outcomes of the technology. Their judgements were obtained for three classes of implantee; (ie for profoundly deafened adults; for partially deafened adults; and for children) as to the appropriate dimensions to include, and the pre/post implantation values for each dimension.

There was substantial agreement between the two assessors, and their judgements were combined into one set of results, organised as a 'low value', a 'middle value', and a 'high value'. The range reflects the known variability in the quality of life improvement attributable to cochlear implantation. The variability is reflected in both the number of dimensions included in these values, and the extent of the health state improvement within each dimension.

The 'low value' is based on scores for four core dimensions (Hearing, Speech, Usual Activities and Distress); the 'middle values' on scores for seven dimensions (the four core dimensions, plus Sleeping, Depression and Vitality); and the 'high value' on scores for twelve of the fifteen available dimensions (the seven 'middle value' dimensions plus Mobility [for children and profoundly deaf adults], Mental Function, Discomfort/Symptoms [for adults, from cessation of tinnitus], Sexual Activity [for adults], and Vision [children only for reading-related improvements]).

Results

The results for each of the three classes of patient considered - profoundly deafened adults, partially deafened adults and children - are set out below in Tables 2,3, and 4 respectively.

TABLE 2
Outcome Measures for Profoundly Deaf Adults - Sintonen HRQOL (15D)

Dimensions	Low Value		Middle Value		High Value	
	Change in Level	Value	Change in Level	Value	Change in Level	Value
• Mobility					2-1	0.0264
• Vision (Children only)						
• Hearing	5-3	0.0295	5-3	0.0295	5-2	0.0434
• Sleeping			3-1	0.0304	3-1	0.0304
• Speech	3-2	0.0182	3-1	0.0387	3-1	0.0387
• Usual Activities	4-2	0.0378	4-1	0.0623	4-1	0.0623
• Mental Function					3-2	0.0231
• Discomfort symptoms					2-1	0.0229
• Depression			3-2	0.0108	3-1	0.0170
• Distress	4-2	0.0284	4-2	0.0284	4-1	0.0407
• Vitality			4-2	0.0357	4-1	0.0517
• Sexual Activity					3-2	0.0126
Total Change in Score		.1139		.2358		0.3692
Quality of Life Improvement	Hearing Disability 3%	11% 8% Consequences	Hearing Disability 3%	24% 21% Consequences	Hearing Disability 4%	37% 33% Consequences

TABLE 3
Outcome Measures for Partially Deaf Adults - Sintonen HRQOL (15D)

Dimensions	Low Value		Middle Value		High Value	
	Change in Level	Value	Change in Level	Value	Change in Level	Value
• Mobility	Only included for profoundly deafened adults and children					
• Vision	Only for children - reading skills					
• $\boxed{\text{Hearing}}$	3-1	0.0189	3-1	0.0189	3-1	0.0189
• Sleeping			2-1	0.0140	2-1	0.0140
• $\boxed{\text{Speech}}$	2-1	0.0205	2-1	0.0205	2-1	0.0205
• $\boxed{\text{Usual Activities}}$	4-2	0.0378	4-2	0.0378	4-1	0.0623
• Mental Function					4-2	0.0349
• Discomfort symptoms					2-1	0.0229
• Depression			3-2	0.0108	3-1	0.0407
• $\boxed{\text{Distress}}$	4-2	0.0284	4-2	0.0284	4-1	0.0407
• Vitality			3-2	0.0188	3-1	0.0348
• Sexual Activity					3-2	0.0126
Total Change in Score		0.1056		0.1492		0.3023
Quality of Life Improvement	Hearing Disability 2%	11% → 9% Consequences	Hearing Disability 2%	15% → 13% Consequences	Hearing Disability 2%	30% → 28% Consequences

TABLE 4
Outcome Measures for Children - Sintonen HRQ0L (15D)

Dimensions	Low Value		Middle Value		High Value	
	Change in Level	Value	Change in Level	Value	Change in Level	Value
• Mobility					2-1	0.0264
• Vision (Reading)			2-1	0.0074	3-1	0.0209
• Hearing	5-2	0.0434	5-2	0.0434	5-1	0.0484
• Breathing						
• Sleeping			3-1	0.0304	3-1	0.0304
• Eating						
• Speech	3-1	0.0387	3-1	0.0387	4-1	0.0508
• Elimination						
• Usual Activities	4-1	0.0623	4-1	0.0623	5-1	0.0712
• Mental Function					2-1	0.0407
• Discomfort symptoms					**N/A Children**	
• Depression			3-2	0.0108	3-2	0.0108
• Distress	4-2	0.0284	4-2	0.0284	4-2	0.0284
• Vitality			4-2	0.0357	4-1	0.0517
• Sexual Activity					**N/A Children**	
Total Change in Score		0.1728		0.2571		0.3797
Quality of Life Improvement	Hearing Disability 4%	17%	Hearing Disability 4%	26%	Hearing Disability 5%	38%
		13% Consequences		21% Consequences		32% Consequences

For profoundly deafened adults the improvement in health-related quality of life ranges from 11% (‘low value’) to 37% (‘high value’). Amelioration of the hearing disability itself contributes 3-4%, while the functional consequences of the hearing improvement result in a further 8-33%.

A similar pattern is exhibited by the results for partially deafened adults (2% hearing improvement and 9-28% improvement due to functional consequences) and for children (4-5% hearing improvement and 13-32% improvement due to functional consequences).

It is clear for all patient categories that the variability in the outcome measure is not so much due to the value placed on hearing per se, as to the impact hearing has on other quality of life dimensions (such as carrying out usual activities, mental and emotional well-being, and social outcome measures for relationships with others).

In incorporating these results into the cost-utility analysis we have provided results with the 'low', 'middle', and 'high' values as a guide to what improvement in quality of life might be anticipated from cochlear implantation. If asked to provide a single value we would opt for the more conservative 'low' estimate. In so doing we are conscious of the principle that attributing a quality of life improvement to an intervention, of say 25%, is the same thing as stating that four such interventions is equivalent to saving one life. This simple 'test' is a sobering thought for those who may tend to over-value morbidity-related improvements in the quality of life. Further, we are also conscious that the selection of dimensions and health state improvements were not empirically tested with actual implant recipients; that there are those in the deaf community who would hold quite divergent views as to the benefit of ameliorating the hearing disability; and that no account was taken of possible adverse effects when deriving the utility scores. A more detailed analysis might appropriately consider such factors, including effects from potential loss of vestibular function.

Comparison with the Literature

Table 5 summarises published results obtained by researchers using other instruments to assess the health-related quality of life improvement attributable to multichannel cochlear implantation.

TABLE 5
Other Health Related Quality of Life (HRQOL) Results for Cochlear Implantation

Study	Instrument	HRQOL Improvement
• Summerfield et al (52).	• Study specific direct question using visual analogue scale • Torrance MAU 1992 (57).	• Adults : 14% (Pre: 0.63 to Post: 0.77)
• EuroQol Group (55).	• EuroQol	• Adults : 10% (Pre: 0.68 to Post: 0.78)
• Wyatt and Niparko (53)	• Study specific using two visual analogue scales	• Adults : 30%
• Lea (1)	• Kaplan and Anderson Quality of Well-Being Scale (QWBS)	• Adults and Children: 7.5% and 15% for each

These studies suggest that, pre-operatively, profound bilateral post-lingual hearing loss in adulthood entails an average loss in health-related quality of life of approximately 40%, of which between 10% and 30% is restored by cochlear implantation. The results achieved with the Sintonen HRQOL (15D) instrument are consistent with the results of these studies.

3.2 Cost Analysis

Calculation of the cost data for the three patient groups considered in this analysis follows the approach taken in the earlier work by Lea (1). For each group (ie profoundly deaf adults, partially deaf adults and children), on-going costs for consecutive cohorts of patients have been calculated over the effective life of the implant, with the first cohort starting in 1994. Calculations have been based on cohort sizes of 40 adults and 40 children, which are similar to the annual number of implants that can be undertaken in Australia, given supply constraints.

In the earlier analysis (1), a ten year period was covered. In the present work, cohorts have also been followed for 15 years and 20 years to take account of changes in the expected lifetime of the device. In the case of children, account has also been taken for each cohort of the offsetting savings achieved through being able to attend ordinary schools, rather than requiring special education.

The ongoing costs for each cohort have been discounted back to the various starting years, and the sums of these discounted costs then discounted back to 1994. A discount rate of 5% has been used for both costs and life years.

The project pathways (Figures 1 and 2) show the costs and probabilities used for adults and children. Costs assumed for implantation over the first year are also summarised in Table 6.

FIGURE 1

Project Pathway - Post Lingually and Partially Deafened Adults

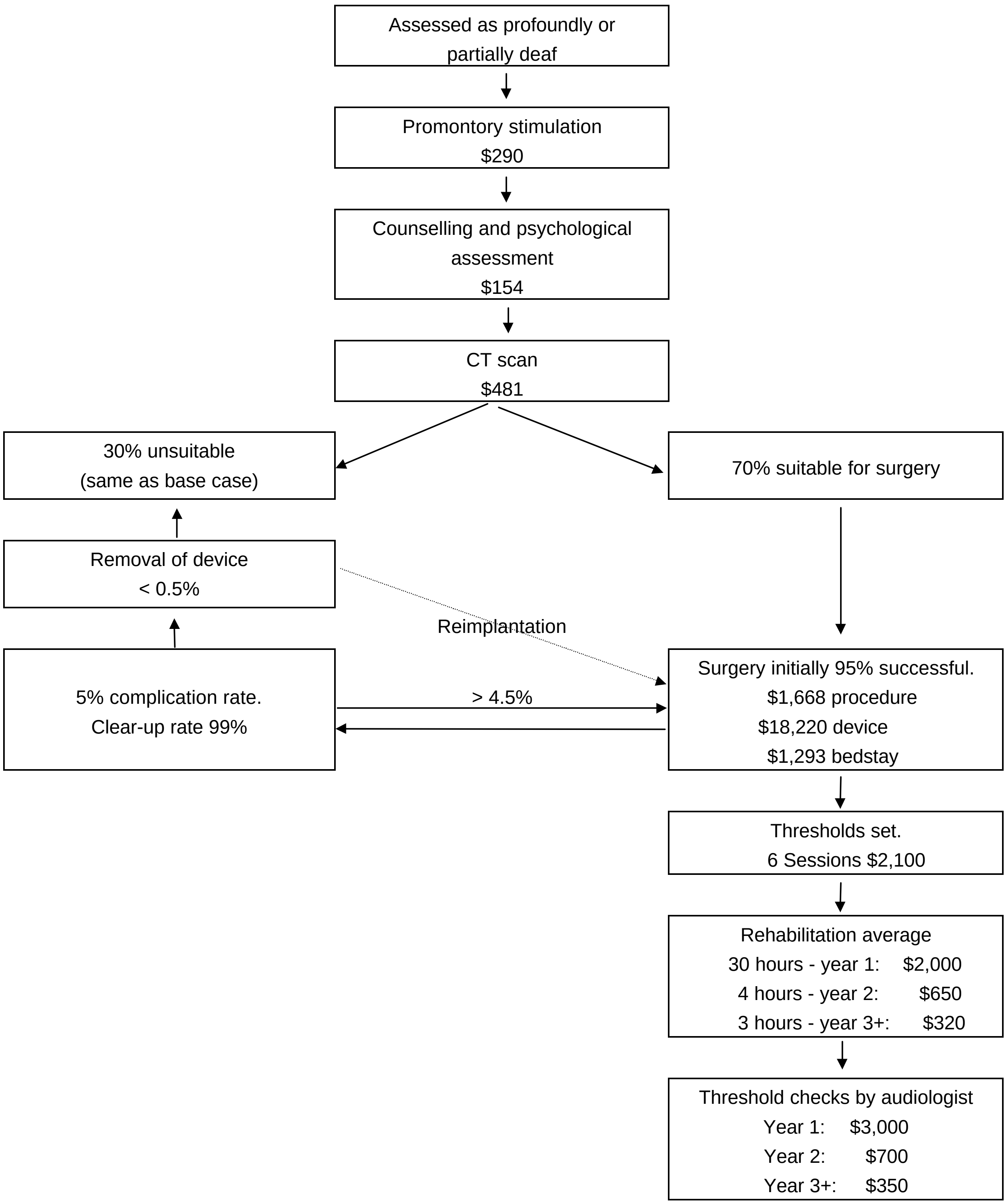


FIGURE 2

Project Pathway - Children

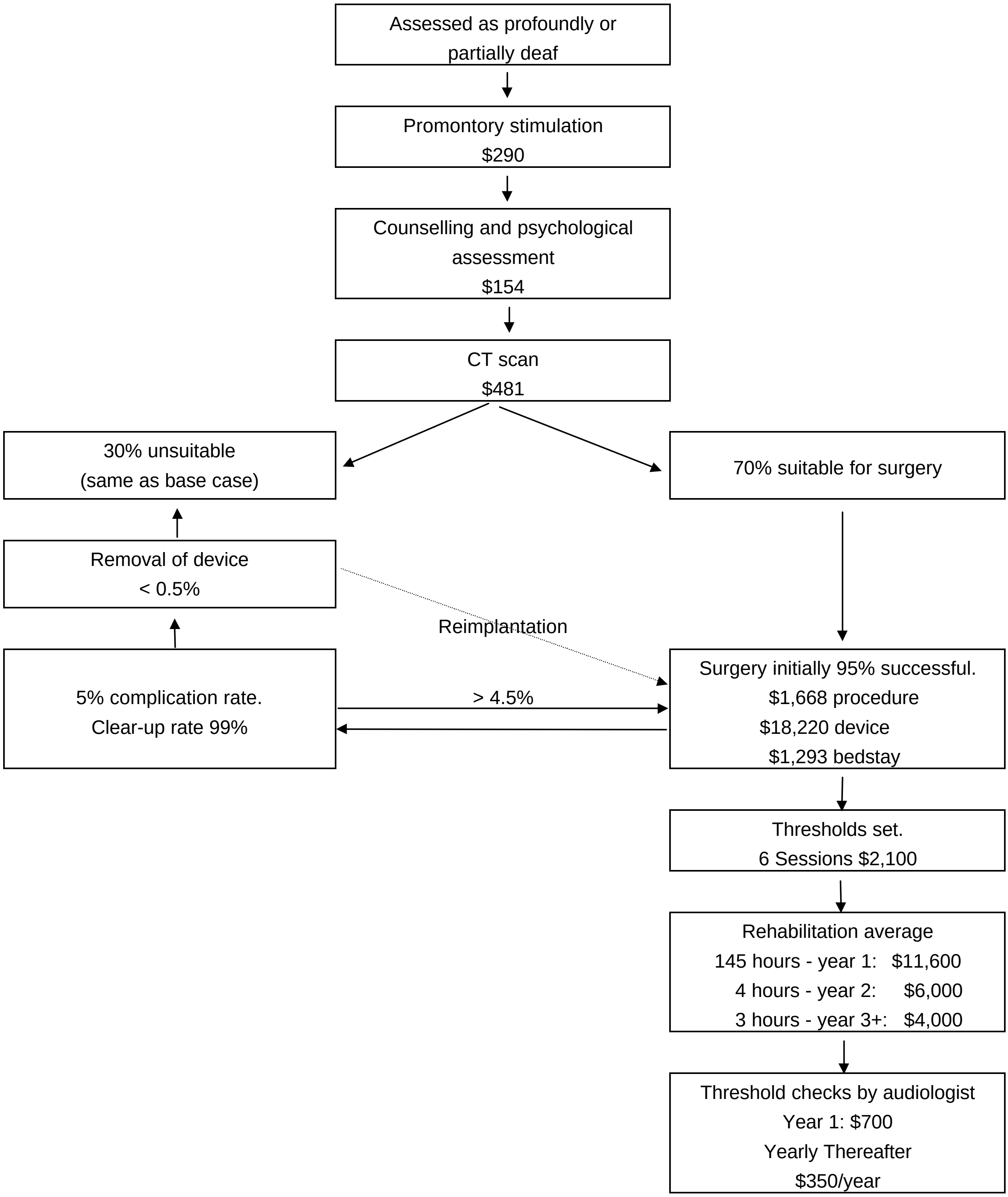


TABLE 6
Costs Incurred in the First Year

Item	Adults ($)	Children ($)
CT scan	481	481
Surgery	1,668	1,668
3-day bed stay @ $431/day	1,293	1,293
Habilitationist	2,000	11,600
Psychologist	154	154
Promontory stimulation	290	290
Cochlear implant	18,220	18,220
Threshold checks @$350/ session	2,100	2,100

A number of other assumptions have been made in this model:

- Of those assessed as candidates for implantation, 70% are considered suitable for surgery.
- The project pathway in Figure 1 applies to both post-lingually deafened and partially deafened adults.
- A three day bed stay is associated with the surgery.
- A 5% complication rate was incorporated within the expenses of the first year.
- For children, there are 145 hours of rehabilitation in the first year following implantation, followed by another 75 hours in each of years two and three. A further 50 hours are provided in the fourth and subsequent years up until 15 years, when the levels of support drop to those given to adults.
- The potential cost savings following implantation of children through mainstreaming their education does not commence until 18 months following implantation. The figure used for the saving ($7,978 per child) was derived from the public school costs given by Pickering, Szaday and Duerdoth (60) and applied to 65% of the children in each cohort. This figure was adjusted according to the CPI to 1993/94 dollars.
- For the savings in secondary school it is assumed that a 100% retention rate is achieved for years 10 to 12.
- A tertiary education entrance rate of 20% is included in the 20 year model for children. The savings included for tertiary education are derived from those given by Andrews and Smith (61).
- The amount of rehabilitation and audiology services received by partially deafened adults was the same as that received by profoundly deafened adults.
- The costs of rehabilitation received by adults were $2000, $650 and $320 in years 1,2 and subsequent years respectively. The contribution from audiology was $3000, $700 and $350 for the same years

- No savings through education apply to adults.
- Processor upgrades are accepted by 100% of users at $4,378 per upgrade every five years.
- Electrical maintenance of $400 per year, commencing after the first year.

3.3 Cost Utility Results

The estimates of costs derived from the model were then used with the utility weights given in Tables 2, 3 and 4 to calculate costs per QALY for each type of patient over 10, 15 and 20 years. The results are presented in Tables 7, 8 and 9. They compare favourably with the values of $15,067 - $30,135 for adults and $9,400 to $18,800 for children obtained in the preliminary study (1), particularly given the inclusion of regular software upgrades and electrical maintenance costs. It is of interest that, when a discount rate is applied, extending the lifetime of the implant to 20 years makes comparatively little difference to the cost per QALY results for adults.

TABLE 7
Cost Per Quality Adjusted Life Year (QALY) for Profoundly Deafened Adults

Quality of life factor*	Cost per quality adjusted life year ($)		
	10 years	15 years	20 years
low value	45,630	38,150	35,250
middle value	22,045	18,435	16,825
upper value	14,115	11,790	10,895

* See Table 2

TABLE 8
Cost Per Quality Adjusted Life Year (QALY) for Partially Deafened Adults

Quality of life factor*	Cost per quality adjusted life year ($)		
	10 years	15 years	20 years
low value	49,070	41,000	37,915
middle value	34,920	29,175	26,995
upper value	17,240	14,410	13,310

* See Table 3

TABLE 9
Cost Per Quality Adjusted Life Year (QALY) for Children

Quality of life factor*	Cost per quality of life adjusted year ($)		
	10 years	15 years	20 years
low value	13,020	11,100	3,465
middle value	8,440	7,480	2,330
high value	5,940	5,070	1,580

* See Table 4

3.4 Sensitivity Analysis

A sensitivity analysis was undertaken using the estimates derived for each patient group for the 15 years time period and the middle value for the quality of life. Variations were made to the discount rate and the cost of the device for all patient categories. In addition, variations were made to the rate of long term rehabilitation and to the proportion in mainstream schooling in respect of the estimates for children.

Results are shown in Table 10. The estimates are relatively insensitive to changes in the cost of the device, but moderately sensitive to increases in the discount rate. Even a doubling of the interest rate to 10%, however, still yields results that would normally be regarded as reasonable to good ‘value for money’. The estimated costs per QALY for children are sensitive to the assumptions made on the rates of long term rehabilitation required and to the proportion of implantees who are able to attend normal schools; but again, all results fall in the range that would normally be regarded as good ‘value for money’.

TABLE 10
Sensitivity Testing for Estimates of Costs Per QALY Over 15 Years*

Factor	Cost per QALY $		
	Profoundly deaf adults	Partially deaf adults	Children
Unchanged values (from Tables 7,8 & 9)	18,435	29,175	7,480
Increase discount rate to 7.5%	19,820	31,422	9,750
Increase discount rate to 10%	21,270	33,700	12,110
Increase cost of device to $22,500 (24% increase)	20,110	31,820	8,820
Increase electrical maintenance to $800/year	19,975	31,610	8,900
Increase cost of upgrades to $6,000 /5 year	19,680	31,680	8,625
Year 1 Rehabilitation increased to 200/hrs	-	-	9,055
Year 1 Rehabilitation increased to 200/hrs; Year 2 & 3 to 100/hrs; and Year 4 to 75/hrs	-	-	16,125
Decrease proportion in mainstream schooling to 50%	-	-	13,680

* Analysis has been based on estimates shown in Tables 7, 8 and 9 for 15 years using the middle values for the quality of life.

4 Discussion

The results of this study reflect the further development of cochlear implantation and give a strong indication that it is an effective technology which is good value for money when compared to a range of programs where resources are currently being committed (refer Table 11). The improvements in the reliability and lifetime of the technology, and the increasing evidence of benefits in children after several years of follow-up are important factors.

The HRQOL-15D instrument has proved useful in providing a means of considering a number of quality of life attributes associated with cochlear implantation. The quality of life measures derived indicate that achievement of hearing sensation is an important, but minor component of improvements to quality of life following implantation. As with other technologies for managing disability, the benefits of using the cochlear implant extend well beyond alleviation of an impairment and include major improvements to several aspects of everyday living.

The costs per QALY values calculated for each of the patient groups considered confirm earlier assessments of the status of the technology as representing good to reasonable value for money. The results obtained again indicate that implantation is especially good value for profoundly deaf children. The sensitivity of the estimates for children to changes in the rate of long term rehabilitation and to the proportion who are able to attend normal schools gives an indication of the importance of good quality support services following implantation. One possible reservation relates to the adaptability of children to the existence of an impairment, and as a consequence, what the correct quality of life comparator is for children who have the implantation. The deaf community might argue, for example, that profoundly deaf children can lead a normal 'healthy' lifestyle. Others may argue that profoundly deaf children are often born to hearing adults, who never really learn or cope with sign language, and that significant quality of life improvements are possible with implantation.

Various assumptions have been made in deriving these estimates. Firstly, while there have been further improvements in the device, the effectiveness of this technology will depend very much on the availability of audiology and other support services. These will need to be in place and readily accessible to implantees if the full benefits from cochlear implantation are to be realised.

Secondly, the weights assigned the quality of life dimensions used in the analysis were derived for another country (Finland) and it may be that some modification might be needed to reflect Australian values. This would require a further study. Further, the improvements in the quality of life dimensions reflect the perspective of experts in the field of cochlear implantation. It would be of interest to extend the analysis to take account of the perceptions of other groups, including implantees and their families, and possibly the deaf community. The impact on the families and carers of implantees could extend to major improvements in everyday living. It would also be useful to take account of possible adverse effects of cochlear implantation, such as loss in vestibular function. Finally, there may be an overall impact of the technology on health and education programs. Both areas would provide important topics for future economic assessment.

TABLE 11
Australian Cost Utility/Cost Effectiveness Results for Selected Medical Procedures

Program	Adjusted cost per life year or per QALY at 1988-89 prices
Hospital dialysis	$47,789 per QALY
Cervical cancer screening using recommended approach	$30,782 per life year
Cochlear Implants: Partially deaf adults	$29,175 per QALY (1994 prices)
Profoundly deaf adults	$18,435 per QALY (1994 prices)
Breast cancer screening	$6,600-$11,000 per life year*
Neonatal intensive care, babies <801 g	$3,600-$4,600 per life year
Kidney transplant	$4,596 per life year
Neonatal intensive care, babies 1000-1500 g	$1,200-$3,000 per life year
Non-drug blood pressure reduction clinic	$5,000 per life year
Cochlear Implants: Children	$7,480 per QALY (1994 prices)

Source: Cervical Cancer Screening in Australia: Options for Change. Australian Institute of Health: Prevention Program Evaluation Series No 2, AGPS, Canberra, 1991

Note * The cost effectiveness results for breast cancer screening have since been updated to $20,300 (Carter et al 'Cost-effectiveness of mammographic screening in Australia', *Australian Journal of Public Health*, vol 17, no 1, 1993).

APPENDIX 1

Basis for Decisions on Score Selection from the HRQOL-15D Quality of Life Scale

Attribute	Relevance to Cochlear Implantation
MOBILITY	Improved awareness of the environment is a significant factor for implantees and helps mobility in a functional sense. The safety element is significant.
VISION:	Relevant in that reading skills will improve after implantation, especially for children.
HEARING:	Substantial improvement for most implantees.
BREATHING	Not relevant.
SLEEPING:	Tinnitus and feelings of increased safety are relevant, improvement for both adults and children.
EATING:	Not relevant.
SPEECH	Important effects. For adults, the implant is of major benefit in enabling them to retain speech, which otherwise deteriorates. For children, an implant will help in development of speech.
ELIMINATION	Not relevant.

Attribute	Relevance to Cochlear Implantation
USUAL ACTIVITIES	A major factor. For example, with adults an implant may be a major factor in keeping employment. For children, major improvement in group communication and activities; applies to both family and wider social settings.
MENTAL FUNCTION	Cognition improves.
DISCOMFORT AND SYMPTOMS	A minority are dizzy and this improves. Not seen as relevant to the analysis.
DEPRESSION	A real issue for implantees and their families, though for many it is less of a factor than “distress”.
DISTRESS:	Can be very significant.
VITALITY	A real issue. Even individuals with good skills can get very tired through concentrating on lip reading.
SEXUAL ACTIVITY	Of some significance for adults because of improved communication making it easier to find a partner, and to stay in a relationship.

Possible Changes Of Scores From HRQOL-15D Quality Of Life Scale Following Implantation *

Attribute	Children	Adults	Partially deafened adults
Mobility	2-1	2-1	? less significant
Vision	2-1	?no change	no change
Hearing	5-2 ; 5-1	5-2	3-1
Breathing	N/A	N/A	N/A
Sleeping	3-1	3-1	2-1
Eating	N/A	N/A	N/A
Speech	3-1; 4-1	3-1	2-1
Elimination	N/A	N/A	N/A
Usual activities	4-1; 5-1	4-1	4-2
Mental function	? 2-1	?	? N/A
Discomfort	N/A	N/A	N/A
Depression	3-2	3-2	3-2
Distress	4-2	4-2	4-2
Vitality	4-1	4-2	3-2
Sexual activity	N/A	3-2	?3-2

* Judgements on a five point scale, with 5 being the least desirable score.
N/A = not applicable.

APPENDIX 2

Quality of Life Questionnaire (New 15D)

Please read through all the alternative responses to each question before placing a tick (✓) against the alternative which best describes your health status over the <u>last week</u> (previous 7 days). Continue through all 15 questions in this manner, giving only <u>one</u> answer to each. <u>Please check you have answered all questions</u>.

QUESTION 1 MOBILITY

1	( )	I am able to walk normally (without difficulty) indoors, outdoors and on stairs.
2	( )	I am able to walk without difficulty indoors, but outdoors and/or on stairs I have slight difficulties.
3	( )	I am able to walk without help indoors (with or without an appliance), but outdoors and/or on stairs only with considerable difficulty or with help from others.
4	( )	I am able to walk indoors only with help from others.
5	( )	I am completely bed-ridden and unable to move about.

QUESTION 2 VISION

1	( )	I see normally, ie I can read newspapers and TV text without difficulty (with or without glasses).
2	( )	I can read papers and/or TV text with slight difficulty (with or without glasses).
3	( )	I can read papers and/or TV text with considerable difficulty (with or without glasses).
4	( )	I cannot read papers or TV text either with glasses or without, but I can see enough to walk about without guidance.
5	( )	I cannot see enough to walk about without a guide, ie I am almost or completely blind.

QUESTION 3 HEARING

1 ( ) I can hear normally, ie normal speech (with or without a hearing aid).
2 ( ) I hear normal speech with a little difficulty.
3 ( ) I hear normal speech with considerable difficulty; in conversation I need voices to be louder than normal.
4 ( ) I hear even loud voices poorly; I am almost deaf.
5 ( ) I am completely deaf.

QUESTION 4 BREATHING

1 ( ) I am able to breathe normally, ie with no shortness of breath or other breathing difficulty.
2 ( ) I have shortness of breath during heavy work or sports, or when walking briskly on flat ground or slightly uphill.
3 ( ) I have shortness of breath when walking on flat ground at the same speed as others my age.
4 ( ) I get shortness of breath even after light activity, eg washing or dressing myself.
5 ( ) I have breathing difficulties almost all the time, even when resting.

QUESTION 5 SLEEPING

1 ( ) I am able to sleep normally, ie I have no problems with sleeping.
2 ( ) I have slight problems with sleeping, eg difficulty in falling asleep, or sometimes waking at night.
3 ( ) I have moderate problems with sleeping, eg disturbed sleep, or feeling I have not slept enough.
4 ( ) I have great problems with sleeping, eg having to use sleeping pills often or routinely, or usually waking at night and/or too early in the morning.
5 ( ) I suffer severe sleeplessness, eg sleep is almost impossible even with full use of sleeping pills, or staying awake most of the night.

QUESTION 6 EATING

1 ( ) I am able to eat normally, ie with no help from others.
2 ( ) I am able to eat by myself with minor difficulty (eg slowly, clumsily, shakily, or with special appliances.
3 ( ) I need some help from another person in eating.
4 ( ) I am unable to eat by myself at all, so I must be fed by another person.
5 ( ) I am unable to eat at all, so I am fed either by tube or intravenously.

QUESTION 7 SPEECH

1 ( ) I am able to speak normally, ie clearly, audibly and fluently.
2 ( ) I have slight speech difficulties, eg occasional fumbling for words, mumbling, or changes of pitch.
3 ( ) I can make myself understood, but my speech is eg disjointed, faltering, stuttering or stammering.
4 ( ) Most people have great difficulty understanding my speech.

5 ( ) I can only make myself understood by gestures.

QUESTION 8 ELIMINATION

1 ( ) My bladder and bowel work normally and without problems.
2 ( ) I have slight problems with my bladder and/or bowel function, eg difficulties with urination, or loose or hard bowels.
3 ( ) I have marked problems with my bladder and/or bowel function, eg occasional ‘accidents’, or severe constipation or diarrhoea.
4 ( ) I have serious problems with my bladder and/or bowel function, eg routine ‘accidents’, or need of catheterisation or enemas.
5 ( ) I have no control over my bladder and/or bowel function.

QUESTION 9 USUAL ACTIVITIES

1 ( ) I am able to perform my usual activities (eg employment, studying, housework, free-time activities) without difficulty.
2 ( ) I am able to perform my usual activities slightly less effectively or with minor difficulty.
3 ( ) I am able to perform my usual activities much less effectively, with considerable difficulty, or not completely.
4 ( ) I can only manage a small proportion of my previously usual activities.
5 ( ) I am unable to manage any of my previously usual activities.

QUESTION 10 MENTAL FUNCTION

1 ( ) I am able to think clearly and logically, and my memory functions well.
2 ( ) I have slight difficulties in thinking clearly and logically, or my memory sometimes fails me.
3 ( ) I have marked difficulties in thinking clearly and logically, or my memory is somewhat impaired.
4 ( ) I have great difficulties in thinking clearly and logically, or my memory is seriously impaired.
5 ( ) I am permanently confused and disoriented in place and time.

QUESTION 11 DISCOMFORT AND SYMPTOMS

1 ( ) I have no physical discomfort or symptoms, eg pain, ache, nausea, itching etc.
2 ( ) I have mild physical discomfort or symptoms, eg pain, ache, nausea, itching etc.
3 ( ) I have marked physical discomfort or symptoms, eg pain, ache, nausea, itching etc.
4 ( ) I have severe physical discomfort or symptoms, eg pain, ache, nausea, itching etc.
5 ( ) I have unbearable physical discomfort or symptoms, eg pain, ache, nausea, itching etc.

QUESTION 12 DEPRESSION

1	( )	I do not feel at all sad, melancholic or depressed.
2	( )	I feel slightly sad, melancholic or depressed.
3	( )	I feel moderately sad, melancholic or depressed.
4	( )	I feel very sad, melancholic or depressed.
5	( )	I feel extremely sad, melancholic or depressed.

QUESTION 13 DISTRESS

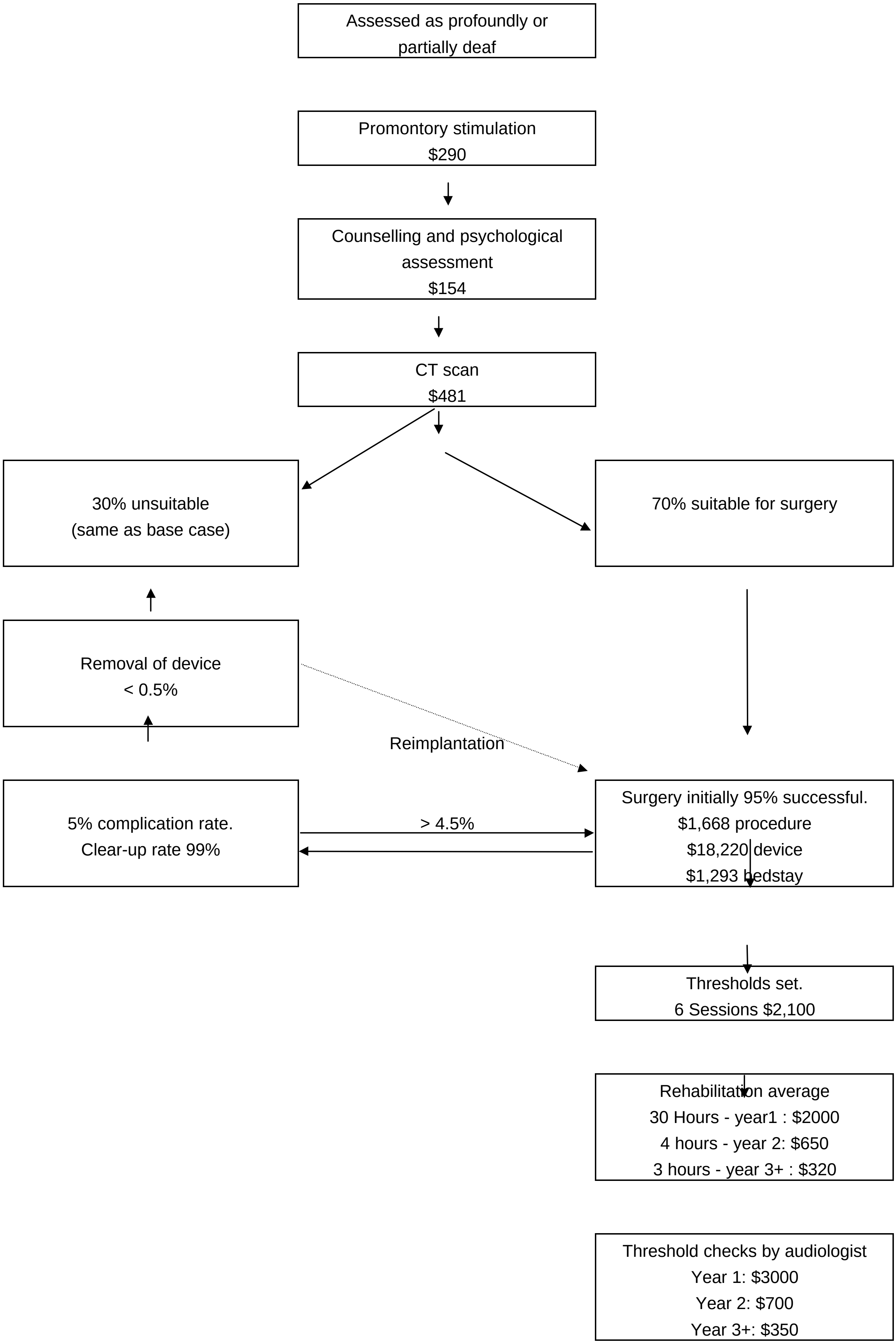
1	( )	I do not feel at all anxious, stressed or nervous.
2	( )	I feel slightly anxious, stressed or nervous.
3	( )	I feel moderately anxious, stressed or nervous.
4	( )	I feel very anxious, stressed or nervous.
5	( )	I feel extremely anxious, stressed or nervous.

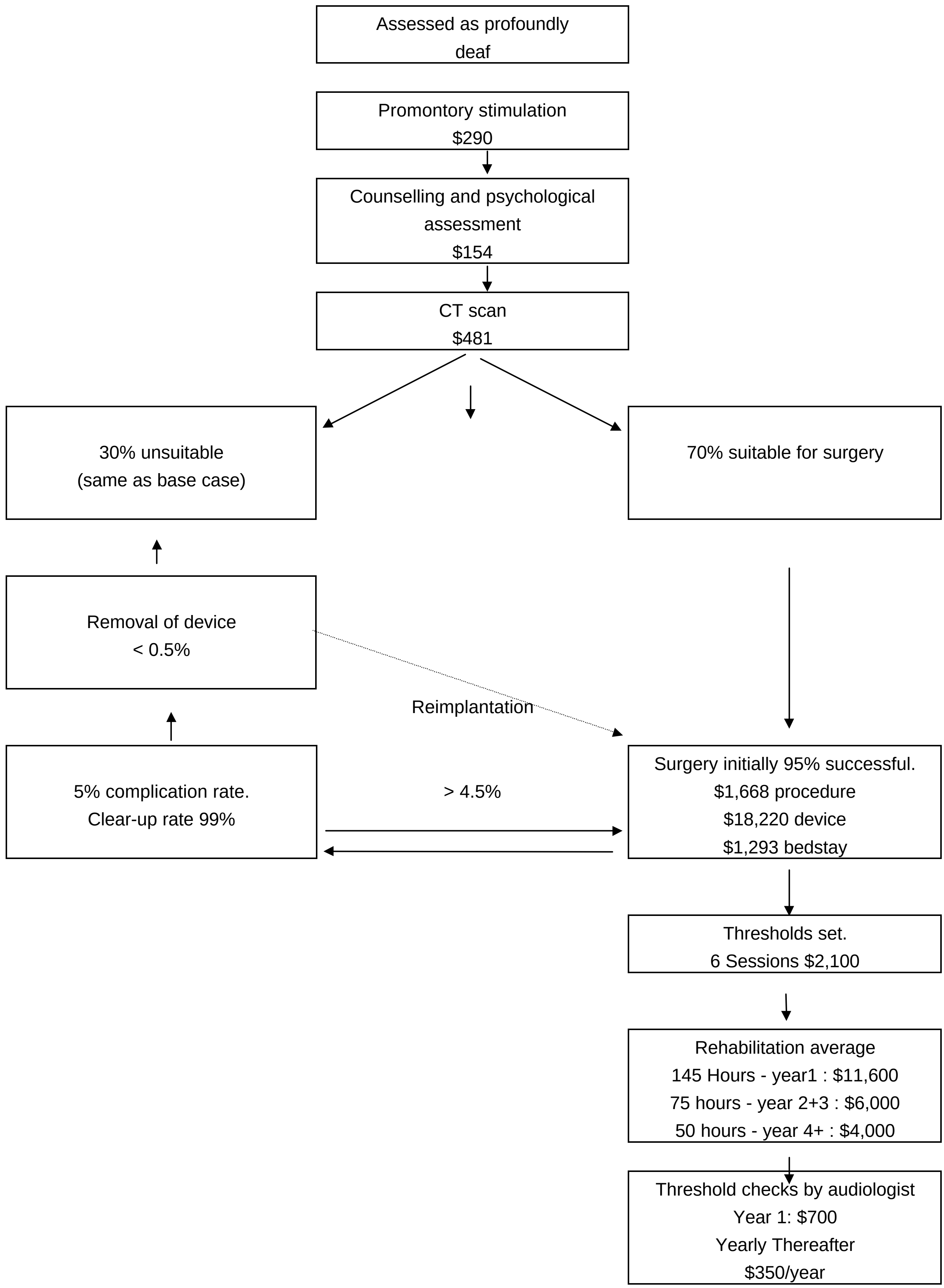
QUESTION 14 VITALITY

1	( )	I feel healthy and energetic.
2	( )	I feel slightly weary, tired or feeble.
3	( )	I feel moderately weary, tired or feeble.
4	( )	I feel very weary, tired or feeble, almost exhausted.
5	( )	I feel extremely weary, tired or feeble, totally exhausted.

QUESTION 15 SEXUAL ACTIVITY

1	( )	My state of health has no adverse effect on my sexual activity.
2	( )	My state of health has a slight effect on my sexual activity.
3	( )	My state of health has a considerable effect on my sexual activity.
4	( )	My state of health makes sexual activity almost impossible.
5	( )	My state of health makes sexual activity impossible.


Assessed as profoundly or partially deaf
Promontory stimulation $290
Counselling and psychological assessment $154
CT scan $481
30% unsuitable (same as base case)
70% suitable for surgery
Removal of device < 0.5%
Reimplantation
5% complication rate. Clear-up rate 99%
> 4.5%
Surgery initially 95% successful. $1,668 procedure $18,220 device $1,293 bedstay
Thresholds set. 6 Sessions $2,100
Rehabilitation average 30 Hours - year1 : $2000 4 hours - year 2: $650 3 hours - year 3+ : $320
Threshold checks by audiologist Year 1: $3000 Year 2: $700 Year 3+: $350


Assessed as profoundly deaf
Promontory stimulation $290
Counselling and psychological assessment $154
CT scan $481
30% unsuitable (same as base case)
70% suitable for surgery
Removal of device < 0.5%
Reimplantation
5% complication rate. Clear-up rate 99%
> 4.5%
Surgery initially 95% successful. $1,668 procedure $18,220 device $1,293 bedstay
Thresholds set. 6 Sessions $2,100
Rehabilitation average 145 Hours - year1 : $11,600 75 hours - year 2+3 : $6,000 50 hours - year 4+ : $4,000
Threshold checks by audiologist Year 1: $700 Yearly Thereafter $350/year

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