UNIVERSITY OF SOUTHAMPTON

FACULTY OF ENGINEERING AND THE ENVIRONMENT

INSTITUTE OF SOUND AND VIBRATION RESEARCH

DEVELOPMENT OF A QUALITY OF LIFE MEASURE FOR ADULTS WITH BILATERAL COCHLEAR IMPLANTS

ROBERTA BUHAGIAR

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ABSTRACT

FACULTY OF ENGINEERING AND THE ENVIRONMENT
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By Roberta Buhagiar

Cochlear implants (CI) provide a sense of hearing to people who are severely or profoundly deaf. A single CI (unilateral) has been shown to improve quality of life (QoL) substantially and clinical practice is evolving towards two per patient (bilateral), although the incremental benefit for QoL has not yet been established definitively. There is a need for self-report measures designed specifically to quantify benefits for QoL in patients who receive a second CI, in order to evaluate the relative benefits of unilateral and bilateral implantation. The aim of the present study was to develop and validate such a measure that is suitable for adults. The sample consisted of patients from the United Kingdom National Health Service who have received two CI sequentially. The study was based on the 'Rolls Royce' approach. A retrospective open-ended questionnaire and face to face interviews were carried out in the first stage. Categories from the qualitative data obtained from the responses were identified and these were the foundations on which a close-ended questionnaire was developed. In the second stage, face validity, test-retest reliability and correlations of each item were investigated and amendments were made to the questionnaire items to reflect these results. In the last stage participants were asked to fill in the amended questionnaire together with another three existing QoL questionnaires (generic and disease-specific ones). These results showed that the questionnaire under development is valid and reliable. Responses from the participants also gave an insight into the changes that they experienced as a result of receiving a second CI. The main reports were related to experiences of increased confidence and independence levels as a result of having bilateral CI. Improvement in listening in group situations and localisation ability were also noted. Changes in participant experience were evident when they filled in the questionnaire under development and also the Speech, Spatial and Qualities of Hearing questionnaire. Better understanding of changes in QoL after receiving a second CI will help professionals to understand the benefits of bilateral implantation in adults from the users' perspectives. This is considered to be important when deciding whether patients should be advised to opt for unilateral or bilateral CI in the future. This knowledge will also help prospective patients understand the practical benefits and limitations of one or two cochlear implants.

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Declaration of Authorship

I, Roberta Buhagiar declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

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I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;

2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;

3. Where I have consulted the published work of others, this is always clearly attributed;

4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;

5. I have acknowledged all main sources of help;

6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;

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Abbreviations

EQ-5D	EuroQol EQ-5D
CI	Cochlear implant(s)
GCBI	Glasgow Children's Benefit Inventory
GHSI	Glasgow Health Status Inventory
HMS	Hearing Measurement Scale
HRQL	Health related quality of life
HUI	Health Utilities Index
HUI3	Health Utilities Index Mark III
ICIDH	International classification of impairments, disabilities and handicaps
NCIQ	Nijmegen Cochlear Implant Questionnaire
NHP	Nottingham Health Profile
NICE	National Institute for Health and Clinical Excellence
PedsQL	Paediatric Quality of Life Inventory
QALY	Quality-adjust life years
QoL	Quality of life
ROC	Receiver Operating Curves
SOECIC	South of England Cochlear Implant Centre
SF-36	Short Form 36
SIP	Sickness Impact Profile
SSQ	Speech Spatial Qualities of Hearing Scale
UK	United Kingdom
VAS	Visual analogue scale
WHO	World Health Organisation

Chapter 1. Introduction

1.1 Overview

The majority of research related to quality of life stems from a functional or pragmatic need of the researcher. Quality of life has usage in many different disciplines: geography, literature, philosophy, health economics, advertising, health promotion and the medical and social sciences (Bowling, 2001). There are various meanings of the term 'quality of life' in social research. These range from individual fulfillment and satisfaction with life to the quality of the external environment. It has been argued that human needs are the drive force of quality of life and that the quality of life is the degree of satisfaction of those needs (Bowling, 2001). Some authors have proposed that quality of life at any particular time is the difference between the hopes and expectations of that particular individual and their present experience.

It has been well established that hearing difficulties can have an adverse effect on the quality of life of an individual. In terms of social functioning, the health perception of profoundly deaf patients is comparable to that of patients receiving haemodialysis or patients awaiting a heart transplant (Krabbe et al., 2000). Cochlear implants can improve this in the case of patients with a severe-to-profound hearing loss and a good outcome is comparable to renal transplantation and heart transplantation in some aspects of quality of life (Krabbe et al., 2000). Studies in America have shown that cochlear implantation is as cost-effective as coronary artery bypass, implantable defibrillators and cardiac transplantation (Wyatt et al., 1995), with the greatest improvements in social functioning and role functioning. Renal and heart transplantation on the other hand have a greater effect on physical abilities, but they still have a considerable effect on social functioning, comparable to that of a cochlear implant. Deafness has a greater effect on emotional problems than renal or cardiac pathologies, therefore a greater effect on these problems is expected by alleviating the effects of this difficulty (Krabbe et al., 2000).

Traditionally adult patients are implanted unilaterally, especially in the United Kingdom (UK). A review of the literature on benefits of unilateral implantation yields a number of papers that report the benefits of receiving a cochlear implant. These papers relate to benefits as seen in a clinical situation and also the perception of the recipients themselves. Over the last few years, there has been a growing interest in outcomes of bilaterally implanted patients. A national audit on the outcomes of bilateral implantation in the paediatric population is currently being carried out in the UK, which is looking at clinical outcomes and at parental perspectives related to bilateral implantation. There are two groups in this audit: those implanted simultaneously and those implanted sequentially. Presently the audit only involves the paediatric population (up to the age of 18 years). There are limited numbers of adult patients

who are implanted bilaterally, regardless of whether this was done simultaneously or sequentially. However, interest is starting to grow in this population although there remains very limited information related to adult patients' views on how their life changed when they got two cochlear implants sequentially. Adults' life experiences are different to those of the paediatric population. However, whilst there are situations which are specific to the adult population, such as social situations, work situations, there might also be comments made by adults which would be relevant to the paediatric population thus informing other areas of research too.

Even though there is a significant body of research into bilateral implantation in adults, most studies have concentrated on outcomes in a clinical setting. Everyday performance is more complex than the tasks in clinical tests and there is a debate as to whether these tests, such as speech perception in noise, reflect everyday performance (Hickson, 1997; Noble et al., 2004). Observational study of everyday performance is needed, however this is more difficult to achieve, consequently self-report studies using questionnaires have been used instead. Benefits of questionnaires include being low in cost, time, money and relative ease in obtaining information from the target population (Gillham, 2000). Generic questionnaires are relatively insensitive to some specific health-related aspects of illness (Krabbe et al., 2000). Although several studies have shown benefits of cochlear implantation, these studies all have a common limitation: they lack a standard quality of life instrument (Wyatt et al., 1995). Instruments used in these studies are not a valid measure to fully represent any changes in the quality of life of cochlear implant users. Sparreboom (2012) reported changes in quality of life of children after receiving (two) cochlear implants sequentially and used the Glasgow Children's Benefit Inventory, Nijmegen Cochlear Implant Questionnaire, Paediatric Quality of Life Inventory, Health Utilities Index (HUI) and Speech Spatial Qualities (SSQ) questionnaires for this purpose. The HUI results showed a ceiling effect and only the disease- specific SSQ was able to show change in this population. None of the other questionnaires were sufficiently sensitive to reflect a change. There is a lack of suitable validated instruments to measure changes in quality of life following bilateral cochlear implantation in a meaningful way.

1.2 Objectives of this study

The objectives of this study were twofold:

1. To investigate the changes in a patient's quality of life when they receive a second cochlear implant compared to one implant
2. To design and validate a questionnaire which measures the quality of life of patients with bilateral cochlear implants (received sequentially)

Constructing a questionnaire is straight forward but developing one that produces useful information is complicated and time-consuming (Gillham, 2000). There are a number of benefits to questionnaires – administration costs are minimal, closed questionnaires are uncomplicated to analyse, there is lack of interviewer bias and questionnaires can provide data for testing a hypothesis (Gillham, 2000). However, there are also disadvantages to using questionnaires in a clinical setting. /misunderstandings cannot always be corrected and respondents may have limited literacy, making use of written material problematic.

A well-developed questionnaire needs certain attributes to be a strong quality of life measure and these will be addressed in this study. These attributes are outlined in Table 1 below (Rapley, 2003).

Table 1: Attributes required for a questionnaire to be a strong measure (based on Rapley, 2003)

Attribute	Sub-type	Comments
Validity	Face	Issues covered are relevant to its users
	Construct	The measure shows a good relationship with other measures with the same construct
	Content	The measure contains items that are important to the population it covers
Reliability	Test-retest	Repeat administrations of the measure yield similar results
	Inter-rater	Different raters arrive at the same conclusions
	Internal consistency	High levels of internal consistency lead to the assumption of good reliability but there is also a possibility of item redundancy
Appropriateness		The measure needs to be sufficiently brief but also comprehensive. The format needs to be appropriate to the population it is targeting and also compatible with its culture.

Sensitivity		The measure needs to be sensitive to pick up any changes that are meaningful.
Interpretability		The measure needs to be easy to use and the results should be easily translated into implications for the individual.

The study reported here involves patients from the UK National Health Service who have received two implants sequentially and had their second implant for at least 6 months. The study was split into three stages:

1. Stage 1 – A retrospective open-ended questionnaire was given to the participants. This looked at investigating the areas where they felt that having a second cochlear implant affected their lives. Semi-structured interviews were carried out with a sample of the participants. The aims were to explore categories that were developed from the open-ended questionnaire and to explore important constructs to be included in the final questionnaire.
2. Stage 2 - Potential concepts that described the patient's experience formed the basis of questions in a close-ended questionnaire.
3. Stage 3 – Explored the reliability and validity of the resulting questionnaire - 'Outcomes from Bilateral Cochlear Implantation (Adults)'.

1.3 Rationale behind objectives of this project

Speech perception tests are used to assess performance with patients who have bilateral cochlear implants; these are mainly speech in noise tests and localisation tests. There are numerous reports in the literature that show improvements in performance in these tests as a result of bilateral implantation. However, these tests are limited in their ability to reflect daily functioning. Everyday performance is complex and debate continues as to whether these tests provide much information about hearing performance in the patients' daily life (Smith, 2003; Andersson et al., 1995; Hickson, 1997; Noble and Gatehouse, 2004; Sperling and Patel, 1999). Speech perception tests are an attempt to simulate the kind of environment that an individual encounters outside the clinic. However, the patient's own experience might be different from that resulting in the clinic (Hickson, 1997); for example, noise might be at a higher level or the speaker's voice at a lower level. Observational studies of everyday performance would be beneficial but are difficult to carry out. This has led to self-report studies being used instead, and such studies have been able to provide both qualitative and quantitative information (Smith, 2003).

For rehabilitation to be successful it is important to know what specific difficulties the patient experiences so that appropriate issues are targeted and sessions are planned and executed with these in mind (Lormore, 1994). Not all difficulties can be assumed to be general since patients are individuals. The extent to which a hearing loss affects a patient or their significant others can vary considerably and is dependent on lifestyle, personality and socialisation (Lormore, 1994). Information obtained from the patient is useful to counsel patients and their significant others about realistic expectations in a range of circumstances (Andersson et al., 1995; Lormore, 1994). However, research suggests that there are discrepancies between patients' and doctors' ratings of outcome after treatment (Bowling, 2001). Clinical assessments are not sensitive enough to pick up all issues which patients experience in their everyday life. Hence a subjective tool investigating the experience of patients with sequential bilateral cochlear implants was deemed to be a useful to aid to the rehabilitation process.

Adult patients are only able to be implanted unilaterally in the UK unless they are also visually impaired. There is growing interest in bilateral implantation for adults especially since NICE have approved guidelines for bilateral implantation in children in 2009. However, information regarding the cost utility of this is lacking. The preferred working method for NICE to obtain this cost-utility is via quality adjusted life years (QALY) measurements (Longworth and Rowen, 2011). This is usually done by administering the EuroQol -5D (EQ-5D) which is a generic quality of life measure. However, if the data from this measure is not available or appropriate, other measures can be used and the data is then 'mapped' to the EQ-5D data (Longworth and Rowen, 2011; Chorozoglou, 2012). It is argued the EQ-5D might not be appropriate for the population since it might not be sensitive enough to the changes experienced as a result of bilateral implantation. The development of an outcome measure that would be sensitive enough to these changes would be able to be used in this mapping process.

1.4 Contribution to knowledge

This study has been able to investigate the changes that participants experience when they were implanted with bilateral cochlear implants compared to their experiences with one implant. This was done via responses obtained from an open-ended questionnaire and interviews. The original aim for these tools was to use them in the development of the closed-ended questionnaire but in filling in the open-ended questionnaire and participating in interviews with the researcher, participants were able to describe their experiences with bilateral implants. All the participants in this study had been implanted unilaterally originally so could describe the specific differences between having one and two implants. This information would not be the same if gathered from participants who only had experience of bilateral implants. The

National Institute for Health and Clinical Excellence (NICE) issued guidance to say that patients under the age of 18 years were eligible to bilateral cochlear implants, but adults were only eligible to a unilateral implant (NICE, 2009). It is hoped that at a time of review of this guidance, the information about the incremental gain from having bilateral implants gathered from this project would also be useful to decision makers and funders when making decisions about the need for adults to be implanted bilaterally. The true benefit of having bilateral implants can be reported by patients who have had experience of both unilateral and bilateral implantation.

A review of the literature shows that no existing instrument fully reflects changes in the quality of life of adult patients who were implanted unilaterally and went on to receive a second implant. For example a review carried out by Raman et al. (2011) showed that numerous studies investigating quality of life changes in bilaterally implanted participants used adapted measures which were developed with the unilateral population in mind. There is therefore a need to develop such a measure with this specific population in mind. This outcome measure would help clinicians decide if changes to solve any shortcomings of bilateral implantation are possible and also when to review the patient's expectations of binaural hearing. Further, responses on a quality of life questionnaire would be useful when counselling prospective bilateral implantees. The procedure to develop a new questionnaire is discussed in more detail in Chapter 3. Chapter 4 describes the first part in the development of the questionnaire and reviews the patients' experience of receiving bilateral cochlear implants sequentially. Chapters 5 and 6 describe Stage 2 and 3 of the project.

Chapter 2. Literature Review – Quality of life and hearing impairment

2.1 Quality of Life

There is no general consensus on the definition of quality of life (Bowling, 1991; Coons and Kaplan, 1993). However, definitions existing in the literature have a shared concept – the fact that quality of life is multidimensional. It is also important to remember that the personal judgement of quality of life is based on a comparison with a standard that that individual sets himself or herself (Bowling, 2001; Tate et al., 1996). The meaning of 'quality of life' is dependent on the user of the term and their understanding of it, so will be different for different individuals (Bowling, 2001). However, in literature, there seems to be some consensus that there are aspects of QoL which are in common to most of the population.

The World Health Organisation (WHO) has defined quality of life as being 'the perception by individuals of their position in life, in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns' (Barbotte et al., 2001). Hence, it has been deemed important in the literature to study the effects on quality of life since a participant's functional life and subjective experiences are as important as the physical effects of a disability.

Commonly measured dimensions in quality of life assessment are presented in the table below (Coons and Kaplan, 1993; Spilker, 1990). Other researchers have also included other dimensions, such as cognition, sleep and rest, energy and vitality, health perception and general life and satisfaction (Bergner, 1989; Bowling, 1991; Tate et al., 1996).

Table 2: Commonly measured dimensions in quality of life assessment

Commonly measured dimensions in quality of life assessment
• Physical status and functioning
• Social/role functioning
• Emotional/psychological status
• Disease- and/or treatment-related symptomatology

Since quality of life measures are subjective in nature, unease has been expressed with these being used as a measure of patient outcomes of medical treatment. However, in some cases, for example arthritis treatment, quality of life may be the most important health outcome to consider in assessing treatment efficacy (Coons and Kaplan, 1993).

We cannot assume that any intervention produces the desired result for all the stakeholders. Outcomes research considers more than survival and biomedical parameters that have been traditionally measured (Coons and Kaplan, 1993). It is also important to examine if patients get the best value for health care money spent. Outcomes research can help make rational medical care-related choices based on better insight into the effect of choices on patients' lives.

Outcome measures can be divided into three areas: clinical, patient-reported, and economic. Clinical outcomes are intermediate measures and do not always reflect the full impact of the treatment since the outcome might not reflect that particular aspect. As a result, the use of quality of life measures as a patient-reported outcome measure has resulted from the need to describe the overall effect of medical treatments that is meaningful to both patients and health care providers (Coons and Kaplan, 1993). The economic outcome measurement is carried out via measurement of quality-adjusted life years (QALY) (Tate et al., 1996). When considering different perspectives, it can be examined using patient-reported measures. These measures can be either based on the clinician's ideas or on the patient's ideas. Depending on how they were developed, they would yield a different perspective on the same issue so one has to decide the purpose of the investigation and what needs to be investigated in order to make sure that the measure is sensitive enough for the purpose intended.

Quality of life measures will provide different information when different situations are analysed (Hétu et al., 1993). Different roles people play in the different life settings, such as work places and social gatherings, demand different roles and they need to be investigated independently. For example an individual might feel more relaxed at home about effects of hearing impairment, and find that this has a greater impact at work or socially. On the other hand, the family might be less tolerant and understanding of the communications needs by the hearing impaired individual so the quality of life at home would be greatly affected. Social gatherings can also present a problem for the partner (Hétu et al., 1993). The partner tends to become a protector, making sure that the hearing impaired individual is taking part in conversations. Role changes occur as a result of hearing impairment also between parents and children, and the child may in some situations become responsible for the communication. This can eventually result in frustration and tension build-up (Hétu et al., 1993). Resentment and anger possibly also become evident in the relationship (Hétu et al., 1993). This, in turn, might cause feelings of guilt in the hearing impaired person.

2.1.1 Health-related quality of life

Quality of life in relation to health is rarely explicitly defined in the literature. Where a definition is used, it is often a functional view of what it means to society. From a

health point of view, quality of life has referred to the social, emotional and physical wellbeing of patients following treatment (Bowling, 2001). Health-related quality of life is described as being the optimal level of mental, physical, role and social functioning, including relationships, and perceptions of health, fitness, life satisfaction and well-being (Bowling, 2001). Assessment of health-related quality of life includes assessment of the patient's level of satisfaction with treatment, outcome and health status and future prospects. A distinction from generic quality of life is drawn from the fact that it does not include information about income and perceptions of the environment. Quality of life as a whole can also be divided into subjective and objectives parts. It includes a description of what a person is capable of doing and the sense of wellbeing of that person.

Measurement related to health care should include survival rates, symptoms and complications, health status and quality of life, the experiences of the patient and carers, as well as the costs and use of resources (Bowling, 2001).

2.1.2 Impairment, disability and handicap

The WHO defines health as being 'a state of complete physical, mental and social well-being, not merely the absence of disease or infirmity' (WHO, 2012). From this, definitions of impairment, disability and handicap have been used to describe disease and it effects on individuals. The WHO defines these three terms in the International Classification of Impairments, Disabilities and Handicaps (ICIDH) (WHO, 1980) as follows seen in the table below.

Table 3: International classification of impairment, disability and handicap

	ICIDH Classification
Impairment	Any temporary or permanent loss or abnormality of a body structure or function, whether physiological or psychological.
Disability	A restriction or inability to perform an activity in the manner or within the range considered normal for a human being, mostly resulting from impairment.
Handicap	The result of an impairment or disability that limits or prevents the fulfilment of one or several roles regarded as normal, depending on age, sex and social and cultural factors.

The WHO has revised this classification to increase emphasis of patient functioning resulting from both health conditions and treatment (WHO, 1999). This classification is divided into three levels: body level, individual level and society level. These levels are similar to those involved in the original classification of impairment, disability and handicap. The overall difference between these two classifications is a strong

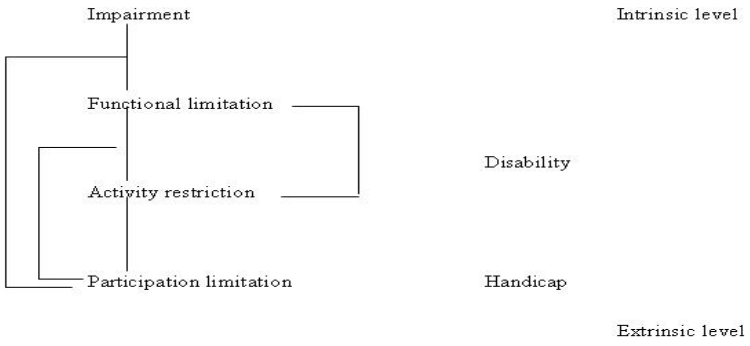
emphasis in the later classification on functioning and activities and the effect of health on these and a removal of the psychosocial aspect. The terms disability and handicap have been revised, referring to 'activity versus limitation' for the former and 'participation versus restriction' for the latter (Noble, 2000). However, these new terms seem less applicable to a hearing impairment (Noble, 2000).

When Schow and Gatehouse (1990) reviewed the way in which concepts of impairment, disability and handicap are used in the audiological literature they found that there are marked differences in the definitions of hearing disability and hearing handicap between European authors (who accept the WHO definitions) and the American authors (who use the context of financial compensation for a hearing loss as their origin for the definitions). 'Disability' in European and WHO terms is the equivalent of 'handicap' for the American authors.

In terms of a hearing loss, 'impairment' is the dysfunction measured in the clinic, 'disability' describes the auditory difficulties experienced by the individual and 'handicap' refers to the non-auditory effects of these on the patients' lives (Stephens, 1991). Different emphasis is placed on each concept depending on the setting (Hickson, 1997). However, there is no simple linear progression along the sequence since a hearing disability might be compensated for with a hearing aid but this in turn may introduce a new handicap, such as embarrassment from using a hearing aid, which in turn could lead to reduced social interaction.

Individuals with the same level of impairment do not always quantify their disability or handicap as being the same as each other (Patrick and Deyo, 1989). This depends on a number of factors including attitudes, and social and cultural situations. There is also an inter-relationship between impairment, disability and handicap, as shown in the figure below.

Figure 1: Inter-relationships between impairment, disability and handicap (Patrick and Deyo, 1989)



2.1.3 Experiences of disability and handicap with hearing impairment

The WHO (1980) listed disabilities that individuals could encounter and amongst them there are the auditory ones listed in Table 4. Other disabilities listed in the WHO document are related to the audiological rehabilitative process but do not refer to purely auditory factors, for example, the 'disability to present a favourable image in social situations'.

Table 4: Auditory disabilities listed in WHO (1980)

Auditory Disabilities
• Disability related to location in time and space
• Identification disability
• Disability in understanding speech
• Disability in listening to speech
• Other listening disability
• Disability relating to tolerance of noise

A number of classifications of auditory disabilities (summarised in Table 5 below) have been proposed which cover the same basic range of auditory disabilities as those of the WHO (1980).

Table 5: Classification of auditory disabilities (WHO, 1980)

Proposed classification of auditory disabilities
• **Disability listening to speech and discriminating in quiet or in noise** live voice one to one in groups/meetings theatre/opera from one side in the car strangers/dialects religious services non-live voice telephone TV/video radio public address systems cinema
• **Disability receiving other audible signals in quiet or in noise** telephone bell door bell other warnings music bird song water boiling
• **Disability relating to auditory localisation in space** warning signals footsteps birds, etc
• **Identification disability** music birdsong acoustical signals for crossroads
• **Environmental awareness** clock/watch birdsong wind traffic
• **Intolerance of noise**

The WHO classification defines handicap along six parallel dimensions referring to survival roles as seen in Table 6. Except for mobility, a hearing impairment will impose restrictions in all dimensions. Difficulty with social integration is the dimension that most people with a hearing impairment report experiencing (Stephens, 1991), and is due to increased effort, stress and fatigue trying to cope with the disability in social settings.

Table 6: Handicaps listed in WHO (1980)

Handicaps listed by WHO	Restrictions imposed
Orientation	• Individual's ability to orient him/herself in relation to his/her surroundings • Critical dependence on levels of background noise and competing signals • Assistance required from other people
Physical independence	• Individual's ability to sustain a customarily effective independent existence • Dependence on use of aids/implants • Difficulty in mobility outside the house that is overcome by the assistance of other people
Mobility	
Occupation	• Individual's ability to occupy his/her time in the manner customary to his/her age, sex and culture without alterations
Social integration	• Individual's ability to participate in and maintain customary social relationship • Diminished participation in social relationships • Impoverished relationships • Reduced relationships
Economic self-sufficiency	• Individual's ability to sustain customary socio-economic activity and independence without some alterations

Some studies have extended the WHO classification of handicaps along three lines: handicap experienced by the hearing impaired person in terms of reduced quality of life, handicap resulting from the cost of adapting to a disability, and handicap experienced by the significant others (Stephens, 1991). The extension in terms of reduced quality of life is further expanded as seen in Table 7.

Table 7: Extension of the WHO classification in terms of reduced quality of life (Stephens, 1991)

Extension of the WHO classification of handicaps in terms of reduced quality of life
For the hearing impaired person
• Anxiety
• Reduced satisfaction
pursuing normal occupations participating in social interactions
• Reduced quality of social interactions
isolation within the family
loss of privacy
loss of intimate interactions
• Negative self-image
embarrassment
being stigmatised
reduced self-esteem
For the significant others
• Annoyance due to noise
loud speaking
loud radio/television listening
effort to repeat things, speaking more slowly, articulating more
• Stress
irritation and tension due to misunderstandings
• Anxiety
not being able to rely on the hearing impaired person in dangerous situations
• Reduced satisfaction
burden of support in acting as an interpreter
• Reduced quality of social interactions
as a couple or family
• Negative self-image
embarrassment/being stigmatised

Hearing is not only a pre-requisite for oral communication but also for environmental orientation. Social life is affected in a major way once hearing loss occurs. Hearing handicap is the non-auditory problem that results from a hearing impairment and disability (Hickson, 1997). Communication in situations with background noise is troublesome for most people with a hearing impairment (Albera et. al, 2001; Andersson et al., 1995; Azzopardi et al., 1997; Karlsson et al., 2002) as is listening to someone speaking in a whisper. Other situations that are difficult include listening to the television, video or radio and phone. Other commonly cited problems are

embarrassment, nervousness, loneliness and family strain (Hickson, 1997). Handicaps can also be divided into primary and secondary; primary being anxiety and secondary resulting from the individual's effort to compensate for the difficulties, such as fatigue (Hickson, 1997).

Speech understanding presents a particular difficulty for older people since there is a natural decrease in speech discrimination, which occurs with increase in age (Hickson, 1997). This might be a result of central auditory processing problems, cognitive deficits, and attentional changes with age. Some patients therefore contend with this natural decrease in speech discrimination in addition to effects of hearing impairment.

Age has a significant effect on the perception of hearing disability and handicap for a given level of impairment. Several reasons for this have been offered (Gatehouse, 1990; Lutman et al., 1987; Lutman, 1991). Individuals affected by a chronic progressive hearing loss, as in the case of presbyacusis, might not always recognise that they have a hearing impairment. Also, older people tend to expect their hearing to deteriorate as a result of age and therefore would have reduced expectations too. Their families and friends might also share this view and therefore they will compensate by speaking louder and tolerate the television at a louder volume. Another factor that might influence the perception on hearing disability and handicap in older people is reduced demand on auditory function due to changes in lifestyle and social situations.

Disability may be assessed by asking the individual directly about his/her hearing difficulties or by use of an open-ended questionnaire (Stephens, 1991). Assessment of handicap is more complex since it involves considering the relationships between impairments, disabilities, life habits and the sociocultural and physical environment of the person (Stephens, 1991). The Hearing Handicap Inventory has been widely used to assess hearing disability and handicap, like for example in Azzopardi et al., (1997) when they looked at the effects of a hearing loss in non-English speaking adults in Australia. Another method of assessment is through performance testing, such as speech audiometry or self-assessment. It has been reported that the greater the perceived disability or handicap the greater the possibility of the patient accepting audiological rehabilitation (Azzopardi et al., 1997). A number of scales and measures do not clearly define if they are measuring hearing disability or hearing handicap and some scales for example the Hearing Handicap Inventory for the Elderly combine an element of both aspects.

2.2 Quality of life and hearing impairment

The consequences of a hearing loss extend beyond not being able to hear what is being said. It is well established that hearing loss has a big role in the emotional state of the individual (Hickson, 1997). It leads to limitations of functional activity and social isolation. Feelings of inferiority, fear, shame, bitterness, apathy and listlessness have been reported by people who are hearing impaired (Jerger et al., 1995; Mulrow et al., 1990a; Stein and Bienenfeld, 1992). The effects of a hearing loss also depend on the personality of the individual. Hearing impairment can also provoke negative feelings in other people; for example, regular requests for repetition or misunderstood messages may lead to frustration in communication partners. Hearing impaired people might seem to be unreliable as a result of misunderstanding messages (Bode, 1991) and they can find themselves being left out of conversations since the other people in a group find it frustrating having to repeat what has been said. This might exacerbate the feelings of isolation and depression in the hearing impaired person (Bode, 1991). A hearing loss in one partner can also result in restricted social participation for the other partner since hearing impaired individuals tend to avoid social encounters (Hétu et al., 1993; Jerger et al., 1995).

The degree of the hearing loss does not always predict the effect on the social, affective, cognitive and physical domains of the lives of the individuals affected (Jerger et al., 1995). Studies have reported that some individuals with a mild to moderate hearing loss report significant social and emotional handicap (Mulrow et al., 1990a; Weinstein and Ventry, 1982). Evidence of the effects of hearing impairment leading to depression exists but has not been consistent in the literature. Some authors have reported a positive correlation (Dye and Peak, 1983; Mulrow et al. 1990b; Thomas et al., 1893,) whilst others have reported the contrary (Carabellese et al., 1993; Herbst and Humphrey, 1980). Different studies may report different results since participants in the studies have different degrees of losses, different use of amplification and differ in age, health and socio-economic status. Quality of life has also been measured with different instruments which have varied specificity and sensitivity to changes in depression levels.

Hearing loss is present in some individuals who consider ‘old age’ as being responsible for problems affecting their functional life. The phenomenon of blaming ‘old age’ was not present with people who do not have a hearing loss. People without a hearing loss remain more active and do not feel that their growing age affects them as much (Williamson and Fried, 1996). Individuals who thought that ‘old age’ affected their functional life were also younger than those who did not.

Deafness also has an impact on other people who have a relationship with the hearing impaired individual (Hétu et al., 1993; Stephens, 1991). The closer the relationship, the stronger the impact of the hearing impairment on the relationship. Typically a relationship will suffer communication breakdown, tension and frustration build-up. The communication breakdown occurs due to misunderstandings and reduction in frequency and content of communication. Tension and frustration build-up at times occurs as a direct consequence of communication breakdown.

A frequent report from spouses of hearing impaired individuals is about the hearing impaired partners' speech and need for loud radio and television. They cannot rely on their partners in difficult situations and it is difficult to have private conversations in the presence of others (Stephens, 1991). Partners also share the stigma of 'deafness'. To these, one also has to add adjustments that need to be made, namely the effort of repeating things, the burden of support and acting as an interpreter when with other people. Older people tend to judge their auditory handicap as being less than their partner judgement (Jerger et al., 1995). Hearing impaired individuals might not always recognise the difficulties that their loss imposes on their partners and other communication partners. This might explain the reason partners tend to suggest the use of a hearing aid before the individual themself recognises the need.

Hearing impairment tends to affect men and women in different ways. Women tend to express their complaints more than men. The most common explanation for this is that women talk about their psychological problems more freely than men (Hétu et al., 1993; Ringdahl and Grimby, 2000). Women also tend to receive less encouragement to wear their hearing aids and they report feeling less understood by partners (Hétu et al., 1993). Men are reported to impose their needs on the family more than women (Hétu et al., 1993). Women are more upset at being left out of conversations but men actively withdraw from social gatherings more than women (Hétu et al., 1993).

2.2.1 Benefits of and quality of life changes after unilateral cochlear implantation

A considerable number of studies have concentrated on the audiologic gain and speech performance of patients who have received a cochlear implant. The change in quality of life of these patients has also been investigated – some of the papers reported on this aspect specifically whereas others report on quality of life as a secondary outcome of research. Most reports on the literature agree on the benefits of cochlear implantation even though differing methodologies were used. An increased sense of personal safety and comfort in social situations are two of the most common benefits found (Kou et al., 1994). An increased awareness of environmental sounds and improved voice modulation have also been noted (Kou et al., 1994; Noble, 2000; Zhao et al., 1997). Interpersonal communication skills and social confidence rate are

an important benefit (Hallberg and Ringdahl, 2004; Hogan, 1997; Zhao et al., 1997). Strengthening of self-worth, less dependency and increased social participation are also a result of improved ability to interact and communicate with other people. These outcomes aid occupational progress (Hallberg and Ringdahl, 2004).

Patients who have received a cochlear implant also note some disadvantages which are mainly related to equipment difficulties. Concerns about size and weight of the speech processors have been noted in the past, however these will become less in number as years go by since processors are becoming smaller and lighter across all manufacturers.

Kou et al. (1994) mailed closed-ended questionnaires to 23 adult cochlear implant users. The questionnaire consisted of two parts – one for the implant user and the other for a relative. It was designed to evaluate the following key issues: utilization, communication modalities used, confidence, independence, environmental sound recognition, speech recognition, voice quality and intensity, vocal implications of the implant, pain, tinnitus, vertigo and overall satisfaction with the implant. The greatest benefit noted was in user independence (70% of the participants in the group). Lipreading remained an important aid to hearing even post-implantation but hearing without lipreading replaced writing as the second most common communication modality when compared to pre-implant manner of communication. This fact was also backed by other studies (Dinner et al., 1989). Provision of environmental sound recognition reduced the sense of isolation that is often felt by deafened people. Tinnitus was eliminated or reduced in 86% of respondents. This figure is similar to results from previous studies (Tyler et al., 1990). Music appreciation did not rate very well with only 35% of respondents saying that they could listen to music and appreciate it. Listening in background noise resulted in both difficulties with speech recognition and decreased use of the device. Even though these studies are rather old, the outcomes described are still similar to those carried out more recently as can be seen further on in this section.

Open-ended questionnaires were used to examine particular hearing complaints of cochlear implant candidates and the specific benefits/shortcomings of cochlear implants experienced by the implanted wearers (Zhao et al., 1997). These were given to 26 participants who took part in the study before and after they received an implant. Participants were asked to make a list of difficulties they had experienced as a result of their hearing loss before they received the cochlear implant. The responses were divided into eight categories: live speech, electronic speech, environmental sounds, music, localisation, psychosocial problems, work/education and medical difficulties. Following nine months of cochlear implant use, the same participants were asked to

make a list of benefits that resulted from the implant and also a separate list its shortcomings. The responses were divided into four categories: acoustical, practical, medical and psychological. The most common difficulty experienced before the implant was in dealing with general conversation and this also affected the psychosocial domain of the participants' lives. However, this main difficulty was reversed when the participant received an implant. Other main benefits for this population included environmental sound awareness and improved self-confidence. Psychological benefits were reported by a large proportion after the hearing problems of participants are relieved by a cochlear implant. Cochlear implant patients showed fewer feelings of isolation and a decreased perception of being a burden on other family members. The shortcomings listed by these participants were mainly related to acoustical factors, which indicate that satisfaction with the implant did not stop at 'awareness of sound'. Open-ended questionnaires are useful in highlighting the specific disabilities and handicaps encountered by participants with a hearing loss. They can provide valuable insight for understanding disability and handicap (Zhao et al., 1997).

There have been a number of studies related to the aging population and how cochlear implantation works with cognitive changes that occur. There is evidence that shows that with age physical changes occur in the central auditory pathways (Waltzman et al., 1993). Cognitive deficits related to information processing and memory also appear with advancing age. On average from the different studies, about 65% of postlingually deafened younger adults implanted with multichannel cochlear implants obtain some degree of open-set speech recognition. However, theoretically, potential central auditory processing deficits which present in the older population could result in a lower percentage of older patients who obtain open-set speech recognition (Waltzman et al., 1993). In a study using 20 adults with a mean age of 70.9 years, central auditory processing deficits, which appeared to have detrimental effects on hearing aid usage, did not affect performance with a cochlear implant. Benefits were not limited to auditory values but also affected quality of life of the participants. Their ability to communicate in both professional and social situations increased, giving them more independence. This result was also reproduced by Kunimoto et al. (1999) and Shin et al. (2000).

Tyler (1994) conducted an extensive study of the advantages and disadvantages reported by cochlear implant patients. He even grouped those participants who performed better and analysed their results separately (Tyler, 1990). He had 41participants for the first study and 53 for the second one. Participants were asked to list all the advantages and disadvantages that they believed the cochlear implant had provided in order of importance. The following tables illustrate the advantages

and disadvantages reported by participants and also what the better performing patients reported.

Table 8: Advantages reported by cochlear implant users (Tyler, 1994)

Advantage	Number of responses from all participants (%)	Number of responses from the better-performing participants (%)
Speech perception with lipreading		
General	58.5	69.8
Familiar speakers	29.3	5.7
Television	19.5	13.2
One-on-one	12.2	3.8
With strangers	9.8	1.9
Children	7.3	7.5
In noise	2.4	5.7
Environmental sounds		
Recognition	51.2	28.3
Music	31.7	32.1
Warning sounds	31.7	7.5
Nature/birds singing	31.7	5.7
Environmental sounds	26.8	41.5
Telephone ringing	17.1	5.7
Doorbell	7.3	7.5
Microwave timer	7.3	
Children playing	4.9	1.9
Psychological		
Increased happiness	17.1	18.9
Escape from world of silence	14.6	28.3
Increased confidence	14.6	20.8
Feel more relaxed	14.6	13.2
Feel accepted by others	12.2	9.4
Improved psychological health	7.3	1.9
Overcome depression	2.4	3.8
Speech perception without lipreading		
Telephone calls	41.5	41.5
General speech recognition	14.6	3.8
Large group meetings	14.6	3.8
Speech awareness	9.8	22.6

Radio		5.7
Lifestyle		
Increased social life	17.1	26.4
Improvements for work	17.1	18.9
Independence	14.6	17.0
Family improvements	4.9	5.7
Ability to drive	4.9	3.8
Ability to shop	4.9	
Ability to play a musical instrument	2.4	5.7
Ability to learn	2.4	
Eat and talk simultaneously	2.4	
Improved physical health	2.4	
Speech production		
General improvement	9.8	18.9
Improved pronunciation	4.9	11.3
More control of voice	2.4	9.4
Other		
Decreased tinnitus	7.3	7.5
Option to turn it off	4.9	1.9
Improved balance	2.4	1.9
Works well	2.4	1.9
Convenient up-keep	2.4	
Decreased ear infections	2.4	
No longer need medication		1.9

Table 9: Disadvantages reported by cochlear implant users (Tyler, 1994)

Disadvantage	Number of responses from all participants (%)	Number of responses from the better-implanted participants (%)
Equipment		
Processor		
Restricts movement	14.6	9.4
Size and weight	7.3	30.2
Difficult controls	2.4	3.8
Headset		
Plug	9.8	5.7
Alignment of coils	4.9	7.5

Cable	4.9	16.9
Battery		
Drain	2.4	20.8
Weight	2.4	
Microphone		
Picks up wind	2.4	5.7
Colour		1.9
General		
Up-keep	24.4	7.5
Malfunctions	19.5	3.8
Physical appearance	2.4	24.5
Environmental sounds		
Quality of sounds	26.8	20.8
Background noise	26.8	15.1
Loudness of sounds	19.5	5.7
Music	17.1	13.2
Recognition of everyday sounds	7.3	5.7
Localisation of sounds	4.9	5.7
Speech perception with lipreading		
In background noise	14.6	5.7
Multitalker situations	14.6	3.8
General	2.4	5.7
Television	2.4	1.9
Psychological		
Frustration when it fails	9.8	9.4
Frustration when learning new sounds	2.4	1.9
Speech perception without lipreading		
Public address system	12.2	
Telephone	7.3	9.4
Speech recognition general	4.9	1.9
Lifestyle		
Misconception of others that hearing is perfect	7.3	
Need to explain it to others	4.9	3.8
Deaf at night	4.9	
Other		
Cost	14.6	
Headaches	4.9	
Static electricity shocks	4.9	

Facial nerve stimulation	2.4	1.9
Pain in ear canal	2.4	1.9
Speech production difficult	2.4	1.9
Not able to hear all they want	2.4	
Risk and inconvenience of surgery	2.4	
Little meaningful sound	2.4	
Increased tinnitus		1.9

Although lip-reading aids communication, only part of the speech signal is visible on the lips, and most people cannot communicate solely by this means. However, with the processor set at the most comfortable level for speech, participants can hear some soft, and most medium and loud sounds that occur in the environment. Participants also scored significantly above chance levels for closed-set and open-set auditory discrimination (Makhdoum et al., 1997). Participants cannot always understand speech with the implant alone, but those aspects of speech based on intensity and timing (stress patterns, rhythm, syllabication and so on) are accessible to the implant user. Most participants can distinguish between different voices and also control their own voice better. This helps tremendously in social situations by eliminating some embarrassing factors (Makhdoum et al., 1997).

Health-related quality of life in participants with one cochlear implant has been extensively researched. So far, most studies have been carried out through the use of open-ended questionnaires or interviews with participants. One study used a closed-ended questionnaire (Maillet et al., 1995) but the questions only covered the psychological and social domains (and these were aggregated into one score). It did not include the physical component. Both disease specific and generic questionnaires have shown improvements in different health domains pre- and post-cochlear implantation (Krabbe et al., 2000).

Numerous studies have documented the effectiveness of cochlear implantation in improving auditory and speech function of profoundly hearing impaired people. Over 60% of participants in some studies had some open set speech recognition. These individuals could not detect sound at levels of conversational speech before they received their implant (Cameron et al., 2011; Bond et al., 2009; Cohen et al., 1993; Miyamoto et al., 1992; Spitzer et al., 1992; Tyler et al., 1992). Implant recipients report improvements in their quality of life in a variety of domains such as vocational, social and psychological function (Rembar et al, 2009; Zhao et al., 2008; Hogan et al., 2001; Cunningham et al., 1992; Horn et al., 1991; Knutson et al., 1991; Spitzer et al., 1992).

Research looking at paediatric cochlear implantation and expectations of this population has shown that parents had high expectations in the fields of communication and development of spoken language (81% and 86% answered 'certainly yes' respectively) whereas expectations in the area of listening to speech without lipreading were much lower (35% answered 'certainly yes') (Nikolopoulos et al., 2001). These expectations were all reached or surpassed at each follow-up interval, where 98% of parents saw an improvement in the area of communication, 88% in the area of listening to speech without lipreading and 86% in the area of speech development by three years following implantation.

2.2.2 Patients' experiences with bilateral cochlear implants

Interest is growing in the potential benefits of bilateral implantation and a number of studies have been carried out to investigate the benefits of bilateral implantation over unilateral implantation. However, this area has still not been research as extensively as unilateral implantation and there is some suggestion that tests currently available are not sensitive enough for this population (Tyler et al., 2006). A number of studies that reported on this aspect of implantation used only clinical measures, including speech perception in noise and localisation abilities. It also needs to be noted that these clinical tests are valuable and important since the information which comes to light through them is not covered by subjective measures such as questionnaires. The area of quality of life has not been studied in detail as it has been in unilateral implantation.

2.2.2.1 Clinical results with bilateral implantation

Crathorne et al. (2012) carried out a systematic review of the effectiveness of bilateral cochlear implantation in adults. Their aim was to compare the benefits of bilateral implantation to either unilateral implants or bimodal hearing. Their initial search showed that there were 2892 studies which showed bilateral implantation in their abstracts, however only 19 studies were included in this review. Some of the reasons why studies were excluded were that they included old technology or the data was compared incorrectly and some had sued the wrong outcome measure. It was noted that the strength of evidence of individual studies that were included was not always robust due to number of participants in the studies and bias in the methodology. They also lacked follow up of the participants. However, the results that emerged gave a collective weight to the studies reviewed by the authors. As reported by Crawthorne et al (2012), Litovsky et al. (2006) was able to show that the speech in noise scores for bilateral patients were better than the unilateral scores even at the 3-month interval but the actual data was not reported in the study. Buss et al. (2008), found a similar finding at the 1 year interval. Dunn et al (2010) carried out a similar study but they

incorporated multisyllable tests and were able to show that participants were able to identify the words at 5dB better signal to noise ratio than their unilateral counterparts and the device type did not affect the results obtained. Similar results were observed in the adult population, such as reported by Ramsden et al (2005). and Tyler et al. (2007)

In the review by Crathorne et al. (2012), it is reported that some studies have been able to show gains in the bilateral domain with head shadow, summation and squelch effect in noise. This was shown by Buss et al. (2008), and Litovsky et al (2006). The improvements were noticed at different interval ranging from 3 months to 1 year post implantation. As shown in other studies too, advantages associated with interaural level differences or head shadow effect are readily available to participants with bilateral implants, however benefits related to interaural time delay perception, such as binaural unmasking (or squelch), might not be available (van Hoesel et al., 2002; van Hoesel et al., 2003, Basura et al., 2009; Raman et al., 2011). However, even when time delays are not perceived bilateral implant users can still obtain important benefits from using two devices as opposed to one. Participants appear able to determine sound source direction as well as choose the ear with the best signal-to-noise ratio for optimal speech perception in noisy environments. They do this by comparing intensity levels between the two ears (possibly on a channel by channel basis) (van Hoesel et al., 2002).

The ability to hear with both ears gives the advantages of binaural summation, head shadow effect, improved localisation, and better speech understanding in background noise (Au et al., 2003; Loizou et al., 2009, Basura et al., 2009; Raman et al., 2011). The hearing acuity from bilateral cochlear implants has been shown to effectively detect interaural amplitude difference in both binaural fusion and lateralisation experiments. Participants with bilateral implants had better speech perception scores in background noise compared with those who had unilateral implants (Au et al., 2003; van Hoesel, 2012). Bilateral stimulation also avoids auditory deprivation in the non-stimulated, hearing impaired ear (Au et al., 2003). Kerber and Seeber (2012) were also able to show that localisation performance decreases with a decreasing signal to noise ratio. Recipients of bilateral implants performed better than their unilateral counterparts in these test conditions.

A study investigating tone discrimination of the Cantonese language by bilateral implantees showed that even in the presence of background noise performance with bilateral cochlear implants was better than unilateral cochlear implants (Au et al., 2003). Cantonese has six contrastive tones which make the same phonemic segments carry a different meaning. These tonal changes are not detectable by lip-reading –

their perception requires good temporal and spectral auditory abilities. The four participants in this study required +5 dB signal-to-noise ratio to achieve significant discrimination scores in bilateral cochlear implant mode, whereas when in unilateral mode they required +10 dB signal-to-noise ratio to achieve the same result. This might be explained by the 'cocktail party' effect which is the ability to be able to concentrate on one stimulus and filter out others. This works best in the binaural condition (Au et al., 2003).

Speech data collected by van Hoesel et al. (2003) indicate a substantial and robust head shadow advantage for bilateral implantees. On the other hand, this head shadow effect would only be beneficial to unilateral implantees when the noise is contralateral to the microphone but can actually be a disadvantage when the noise is ipsilateral to the microphone. Bilateral implant users who show strong asymmetrical results for the separate ears in speech performance might not obtain large benefits from the head shadow effect (van Hoesel et al., 2003). However, improved localisation can assist in everyday communication by improving the ability to direct attention to the sound source. Improved localisation in bilateral cochlear implant users has been shown in a number of studies, for example, van Hoesel et al. (2003) have reported that when participants were asked to localise sounds on an array of eight loudspeakers, participants were able to be three times more accurate than when compared to use of one cochlear implant. Verschuur et al. (2005) have also shown that bilateral cochlear implant users are able to localise a sound with better accuracy than unilateral cochlear implant users. The latter performed at chance level in Verschuur's research. Summerfield et al. (2006) were able to show that participants themselves were aware that their localisation abilities had improved with bilateral implants. This observation was made at both the 3 month and 9 month interval by filling in the SSQ.

Bilateral cochlear implantees show abilities to fuse information from the two devices (van Hoesel et al., 2003). Loudness summation effects comparable to normal hearing have been seen in experimental situations. However, binaural benefit is not always evident in all participants (van Hoesel et al., 2003) but most of the time benefit of a head-shadow effect is evident when testing speech perception in noise and also in quiet.

The University of Wisconsin Hearing and Speech Lab have carried out a number of studies to investigate the benefits that bilateral implantation give to patients. Litovsky et al. (2012) have written a report to summarise these projects and their findings. Their findings complement those from other groups to show that sound localisation and understanding speech in a competing noise is much easier for participants to do in the bilateral mode. These results indicate that participants in their studies had an ear

with a poorer signal to noise ratio so the bilateral listening condition gave them an advantage in these situations. In similar results reported by Kerber and Seeber (2012), Litovsky et al. also reported that sound localisation in competing noise was not as accurate as in a quiet situation. The difficulty is much greater than that experienced by normal hearing participants as the signal to noise ration decreases.

2.2.2.2 Qualitative research in the field of bilateral implantation

Even though most of the studies were carried out in a clinical setting, there has been some research that has investigated the change in patients' lives as they received a second implant. In particular, Summerfield et al. (2006) explored the self-reported benefits of sequentially implanted adult patients. The purpose of the study was to investigate the effectiveness of the bilateral cochlear implantation in adult users. This was done in the context of setting priorities for expenditure on interventions. The study involved three condition-specific outcome measures obtained from the Speech, Spatial Qualities questionnaire, and four generic questionnaires – the Glasgow Health Status Inventory (GHSI), Health Utilities Index Mark III (HUI3), Overall Quality of Life (VAS) and EuroQol EQ-5D (EQ-5D). The questionnaires were administered 3 months and 9 months after the participants received the second cochlear implant. Measures of spatial hearing, quality of hearing and hearing for speech showed improvements when participants were implanted bilaterally compared to having one implant both at the 3-month and 9-month interval. However, there was no evidence of any change when generic quality of life measures where used at the 3-month interval. The GHSI showed a significant change in scores at the 9-month interval when the two conditions where compared. The authors discussed the fact that multivariate analyses showed that as a result of two participants experiencing worsened tinnitus, the results from the generic questionnaires could have occurred by chance. When it was assumed that tinnitus was not affected by implantation, there was a small gain of +0.03 in health utility. The study was compromised by ceiling effects and lack of resolution in the HUI3 scale. The authors did not follow the participants for a longer time than reported in the paper. This might have been important in this case since it seems that the tinnitus experienced by some of the participants had a negative effect on the overall results. Therefore, the conclusions of this study, although indicative of positive benefit, do not have as strong a quantitative value as one would wish.

In the systematic review carried out by Crathorne et al. (2012), they found that only 3 studies of the 19 they accepted for review had also included a quality of life measure. One of the studies was by Summerfield which is mentioned above. Litovsky et al (2006). also used the Abbreviated Profile of Hearing Aid Benefit and Noble et al (2009). used the Hearing Handicap Inventory for the Elderly and Hearing Handicap Questionnaire which also showed improvements in the bilateral condition.

Mather et al. wrote two papers in 2011(a and b) reporting the experiences of 15 young people with sequential bilateral implants. The papers reported these experiences from the point of view of the young people themselves and also those of their parents and teachers. The ages of the children were between 10 and 18 years. The participants had different experiences regarding the outcome for the second cochlear implant. Benefits of having two implants were reported by the participants in terms of localisation, listening in noise and ease of listening. Increase in confidence levels was mentioned and two participants also reported that listening to music was more pleasurable. However, there were some reports that the second implant was not as beneficial as the first one – one of the participants did not use the second implant and another one was reluctant to wear it. They both reported increase in noise levels which was disruptive to her listening abilities. It was also acknowledged by all participants that listening in background noise was still difficult. Interestingly, all participants, including those who did not derive as much benefit from their second implant commented that they would encourage other people to have a second implant. They felt that different people would have different experiences and did not want to share any negative experiences so as to discourage any potential patients. On the other hand, when their parents were asked the same question, only 33% (4 parents) said that they would not hesitate to recommend a sequential implant, 50% (n=6) said they would recommend a second implant but would also mention that the journey is not easy, and the other two parents said that they felt they could not make a recommendation either way.

Whereas there is some research suggesting that in some aspects of binaural hearing (localisation and speech perception thresholds in noise), children might perform as well as normal-hearing children (Litovsky et al., 2006), this is not always the case especially with adults. There are some indications that elderly patients might not be able to fully benefit from the potential advantages that binaural hearing has to offer. Noble (2010) described a cohort of participants aged between 20-90 years old who were asked to fill in the Speech, Spatial Qualities questionnaire. The group of participants aged between 20 and 59 years was able to show high to very high benefit of bilateral cochlear implantation but the older group of participants showed a wider range of outcomes.

Sparreboom et al. (2012) carried out a study looking at changes in quality of life of 30 paediatric patients who received bilateral cochlear implants in a sequential manner. Quality of life was assessed before the participants received their second implant and then again after 12 and 24 months of bilateral use. Six questionnaires were used in this study – three generic QoL measures: overall health status using a Visual Analogue Scale (VAS), the HUI3, Paediatric Quality of Life Inventory (PedsQL); and three disease-

specific measures: Glasgow Children's Benefit Inventory (GCBI), Nijmegen Cochlear Implant Questionnaire (NCIQ), and the SSQ. The generic measures did not show a significant change in quality of life after bilateral cochlear implantation. On the other hand, the disease-specific measures were able to show a change in quality of life after bilateral cochlear implantation. More specifically, the SSQ showed that the spatial and qualities aspects of hearing improved first (change seen at the 12-month stage), and these were followed by improvements in the speech domain (change seen at the 24 months stage). The GCBI and NCIQ showed a significant benefit of sequential bilateral implantation after 24 months. The changes in the quality of life could be attributed with high certainty to having a sequential bilateral implant since the researchers had also asked a small group of unilateral patient to fill in these questionnaires at the same intervals. This was a comparison group to make sure that any changes seen were not a result of time.

The results obtained by Sparreboom et al. (2012) were similar to those obtained by Lovett et al. (2010) where the researchers looked at the health-related quality of life of nine unilaterally implanted children with that of 12 simultaneous and 18 sequential bilateral paediatric children. The questionnaires used in this study were the HUI3, the SSQ and the parents were asked to mark their child's general QoL on a VAS. The SSQ showed significantly higher ratings for the bilateral groups when compared to the unilateral group. On the other hand the VAS and HUI3 were not able to show a difference between the groups which is similar to the findings by Sparreboom (2012) and reflects the lack of sensitivity of the instrument. The authors also looked to see if there were any differences between the sequentially implanted and simultaneously implanted groups but no differences were found.

2.2.2.3 Cost-effectiveness of bilateral cochlear implantation in adults

Systematic reviews of research related to cost analysis of bilateral cochlear implantation in adults suggest that there is wide variation in results obtained in different studies since they take different approaches and a number of assumptions are made which influence the results. Crathorne et al.'s (2012) systematic review only showed 2 studies which were related to economic studies of adult bilateral implantation in adults in the UK. Both studies were carried out by Summerfield et al. In 2002, Summerfield et al. investigated the health state values given to bilateral implantation by 70 normal-hearing adults. Based on a model from the responses given by the participants in a time trade-off technique, the authors estimated that bilateral implantation was not financially viable based on the increase in quality of life. The model projected the costs into the future and also the benefits over an overall life expectancy. Participants were asked to also value unilateral implantation and these results were compared to those measured with existing patients. Even though this

comparison was positive, it does not imply that the participants' responses to bilateral implantation were accurate since different methods were used with existing patients so the comparison is not accurate.

In 2006, Summerfield et al. also included 24 adults in their study who were implanted bilaterally (split into 2 groups who received their second implant at different intervals). The HUI3 was used in this study and it was able to show a slight increase in utility but this was not significant. The VAS and EQ-5D showed a negative response to QoL at the 9 month interval but this result is questionable due to the small number of participants in the study and a negative effect based on worsening tinnitus that some participants experienced. The cost-effectiveness per QALY was calculated to be over £60,000 based on these 2 studies but these results were based on models and projecting into the future which is not always accurate.

Bond et al. (2009) also carried out a review of studies which investigated the clinical and cost effectiveness of bilateral cochlear implantation. They reviewed 33 papers which were described as being of moderate to poor quality. In general there was a consensus from the studies reviewed that the biggest advantage of bilateral implantation was in the speech in noise domain. There were also indications that this advantage was more evident in patients who had a small gap in between receiving their 2 implants. The cost-effectiveness review indicated that adult bilateral implantation gave £49,559 per QALY for simultaneous implantation and £60,301 per QALY for sequential implantation. However, these studies were also based on models so they introduce a high degree of uncertainty.

Lammers et al. (2011) also carried out a systematic review of the cost utility of bilateral cochlear implantation. Their report included 5 studies and most of these studies used the HII3 which is known to show a ceiling effect in relation to bilateral implantation. The studies which were reviewed in this paper have also been reviewed in other papers such as the Crathorne et al. (2012) and Bond et al. (2009). The conclusions that the review led to were similar to the ones by the other reviews mainly that with the present information bilateral implantation in adults is not cost-effective. However, the authors also acknowledge the fact that these studies have limitations which would affect the results portrayed. These are related to the fact that cost-utility research is based on assumptions and models. There is limited information based on actual costs of implantation and patient experience.

Turchetti et al. (2011)'s review of papers related to cost-utility studies included 4 articles. Only 2 of these studies were carried out in the UK and these 2 studies were

also covered in other review papers. Out of these 2 studies, only 1 of them included cost-utility analysis of bilateral implantation in adults (Summerfield et al., 2002).

Bichey and Miyamoto (2008) also explored the benefits of bilateral implantation in adults from a change in quality of life and cost-utility perspective. Twenty three bilateral participants were asked to fill in the HUI3 – the authors mention that this health utility index is able to measure hearing in noise as well as speech. All the participants were using both cochlear implants and were asked to fill in the index prior to their first surgery, prior to their second surgery (when they were only using one implant) and after their second surgery. They concluded that participants experienced a significant increase in quality of life after both the first and second surgery. After the second surgery, the average increase was 0.48 units when compared to no implant at all. The difference between before first surgery to having one implant was 0.36 units (level of measurement for HUI) which leave an increase of 0.12 units between the first and second surgery. The authors went on to perform a cost-utility analysis on bilateral implantation. Whilst doing this, they removed the data obtained from three participants since they had received their second implant after the age of seventy five. The authors explained that due to the possible changes in lifestyle as a result of their age, these participants would not be representative of the general population as the other participants did. By including the quality of life improvements into the cost-utility measurements, the results showed that a second implant given to a unilateral user was cost-efficient. The main difference between this study and that carried out by Summerfield et al. (2002) where a cost-utility scenario of bilateral implantation was carried out with normal hearing volunteers and unilateral cochlear implant users, is that in Summerfield's study the costs and benefits for implantation were projected into the future. The study by Bichey and Miyamoto also suffered from limitations of the HUI3 instrument and ceiling effects were evident in their data. They also had a wide range of age within their participants and they did not separate the date from the younger population which might have had an effect on the cost-utility results.

2.2.3 Issues arising from the literature

Most of the studies and reports on adult bilateral cochlear implant users involve a small number of participants. This is due to the fact that even if a study has participants from a number of centres, this population is still small. A number of conclusions reported in this literature review have been from studies of people from the same age cohort or similar background, for example a group of veterans. Thus the results may not be applicable to the whole cochlear implant population (Appollonio et al., 1996; Mulrow et al., 1990b; Mulrow et al., 1992). A major disadvantage of most studies carried out with bilateral implantees is that the unilateral mode is tested as part of the same experiment as testing bilaterally and therefore patients are not given

sufficient time to acclimatise to the unilateral mode. This might result in an unfair disadvantage compared to the bilateral mode since this is what participants would be used to Studies do not report on non-users so it is possible that any negative experience are not evident via the literature available.

Most quality of life studies are observational and placebo effects can occur – if a participant believes that an intervention is meant to improve the quality of life, then improvements are perceived where they have not occurred (Mulrow et al., 1990b; Mulrow et al., 1992). However, the large magnitude of the changes that occur in the studies reported in the literature are unlikely to be due solely due to placebo effects (Mulrow et al., 1990b). Quality of life measures depend on memory skills of respondents. This in itself includes some more bias since some participants might not have a clear memory of the situation in the past, or they might look at the past through 'rose-tinted glasses'. However, there are other issues related to this too. Respondents are usually asked to recall relatively recent situations, which they would have experienced for a long time. This makes it easier to recall since the experience would have been extensive and the participants would also be able to re-experience the situation when they remove the hearing aid. This makes memory problems less likely to affect outcomes (Joore et al., 2002). Another type of bias could be caused by the participant's wish to think positively of the intervention they would have undergone, however minimal this would be – social desirability responding (Joore et al., 2002). Face-to-face interviews could introduce the issue of good or social desirability bias due to participants saying what they think the interviewer would like to expect to hear (Joore et al., 2002).

Some studies have used a 'change' method, where participants were asked to compare their present status to that when they only had one implant, and some studies used a 'state' method, where they asked the participants to fill in the questionnaires before they got the second implant and then again after their surgery. Both these methods have benefits and disadvantages. It could be argued that the 'change' method would involve the participant needing to recall how the situation was prior to getting their second implant. This may involve its bias as explained earlier and also possibly involve a placebo effect. On the other hand, the 'state' method also has its own disadvantages since participants might change the starting point of their own internal scoring system. This would mean that they would rate the same point differently over time just because time has passed and not as a result of a change in their treatment. A change in state that is reflected in a questionnaire is then not truly reflected in the participant's life. The issue of 'change' versus 'state' is discussed in more detail in Section 3.1.

2.3 Conclusion

The available literature indicates that bilateral implantation is beneficial to adult patients. The studies that have been reviewed all have biases mainly related to the number of participants that have been used, however, as Crathorne at al. (2012) mention in their review paper, the fact that all the studies indicate that they have observed similar results, gives strength to the belief that bilateral implantation is beneficial in the areas of hearing speech in noise and localisation ability. However, it is not currently possible to show the improvement in the quality of life domain unequivocally due to the range of measures that have been used in the studies – these are not sensitive enough to pick up the benefit in all areas of participants' lives. The SSQ is the questionnaire that has been able to show a change between unilateral and bilateral implantation but this questionnaire does not reflect all the aspects of quality of life as described by WHO and other sources. Generic quality of life questionnaires were not able to show a change and when the HUI3 was used, this had a ceiling effect. In order to be able to show any change that a patient would experience themselves after bilateral implantation, there is a need for a specific measure which is patient oriented. The items used in the various instruments have generally been chosen by researchers and may not reflect the underlying changes actually taking place. There is a need to explore the dimensions of change more systematically and from a patient perspective rather than a researcher perspective. Chapter 3 explores how this measure should be developed.

Chapter 3. Literature Review – Measurement Scales

3.1 Quality of Life Measurement

Quality of life has been examined on a global scale and also specifically within the healthcare profession. Health-related quality of life has been used to refer to components of life that centre directly on health, disease, disorder and injury. However, the distinction between global and specific quality of life is not always clear. The terms quality of life and health status have also been interchanged (Coons and Kaplan, 1993) and in other cases they have been used separately (Bergner, 1989). While yet other studies have included quality of life as part of health status (Patrick and Deyo, 1989). It is difficult to decide which dimensions to look at when quality of life is being measured when there is no agreement in the literature what quality of life actually refers to. The choice of quality of life questionnaire is dependent on the aims of the study, the population being surveyed and where appropriate the intervention that is being assessed (Bergner, 1989).

There are two main techniques involved in quality of life measurement - the 'change' technique and the 'state' technique. In the former technique, participants are asked to describe their current status in comparison to status prior to the intervention. In the latter technique, participants are asked to fill in a questionnaire prior to the intervention and then again sometime after the intervention. The different responses in these questionnaires would then yield a result which shows the amount of change. Both these techniques are present in the literature but the 'change' technique has been able to show a greater sensitivity to a change in quality of life status when the questionnaire is used in relation to a technical solution, such as cochlear implants (Gatehouse, 1997). On the other hand, participants and patients can be reluctant to show dissatisfaction with a procedure they feel they ought to be grateful for having received to professionals involved in their treatment. Memory bias would also have an effect in the way this type of questionnaire is completed since participants are not always able to remember accurately their status prior to an intervention (Streiner and Norman, 1989).

It has been suggested that the 'state' technique for measuring quality of life changes is more appropriate when the intervention being used has an aim of restoration of the patient's function to 'normal' (Gatehouse, 1997). Bias errors are also seen when using this technique since a patient's standards might change as treatment progresses so the before and after questionnaires would be completed using different internal standards for comparison. Reasons internal standards might change vary from one person to another but these changes might reduce the validity of the responses since the intervention could be deemed effective when in fact the changes in responses are due to other reasons. There have been suggestions in the literature that changes in

internal standards might be more frequent in areas which are subjective to the patient (Spranger and Schwatrz, 1999). Changes in quality of life are usually subjective to the individual so responses on such questionnaires might be affected by changes in internal standards.

In order for the 'state' technique to be more reliable, suggestions have been made to introduce the 'then-test'. In this case, patients are asked to give their responses before their intervention and then again after the intervention. At the latter stage, they are also asked to fill in the questionnaire as they think they would have completed it before the intervention and the results from this and the original questionnaire are compared to test reliability (Howard et al., 1979). Just as social desirability has an effect in the 'change' technique, this would also play a part in this technique since most patients are grateful for their treatment and do not want to appear ungrateful. Levinson (1990) was able to show that social desirability is not always a confounding factor since participants in his/her study did not show social desirability on items that were not related to matters being studied. It is good practice to include items in a questionnaire which are known to test social desirability and also to test if observed changes are a result of time passing (Sprangers and Schwartz, 1999).

3.1.1 Questionnaire format

There are a number of methodological issues that must be considered in quality of life research (Bowling, 1991; Bowling, 2001; Coons and Kaplan, 1993; Tate et al., 1996). These issues are explained in the table below.

Table 10: Methodological issues in quality of life research

Methodological Issue	Concept explanation
General or disease-specific instrument	A generic measure is applicable across all diseases and different diseases are comparable with these measures; a disease-specific approach looks at the specific outcomes of a specific treatment.
Index or profile outcome measures	Health index results in a single outcome score – they do not require much interpretation and time; a health profile results in an array of scores for the individual quality of life dimensions.
Dimensions measured	There is great debate on which dimensions would be included. These change from one measure to another and depend on the need of the specific outcome.
Relative importance of dimensions	A decision on the relative importance of dimensions helps decide which ones are measured.

Reliability of the instrument	This concept will be explained in more detail in Section 3.1.2.1. This refers to the consistency of scores obtained on different administration.
Validity of the instrument	This concept will be explained in more detail in Section 3.1.2.2. It defines the range of inferences that are justifiable on the basis of a score or measure.

A generic scale is considered when the relevant variables are covered and when investigators wish to make comparisons of results between different diseases and conditions. A domain specific scale is used when the area covered is of particular relevance to the study and its hypotheses, and where the generic and disease specific instruments do not cover all aspects of that area. A disease specific scale is preferred when condition attributes need to be assessed with greater sensitivity (Bowling, 2001). Disease specific measurements aim at being more clinically relevant in relation to specific conditions. They can discriminate more finely between levels of severity of the effects of the condition on the patients' lives. They ensure sensitivity to small but clinically significant changes in health status and levels of disease severity (Bowling, 2001). However, disease specific information can also introduce a level of difficulty if it is so specific that it does not captive other important aspects (Smith, 2003).

The developer and administrator of the questionnaire would need to decide whether to use a self-completion format or an interview technique. The method of choice usually depends on the practical considerations of the study, such as participant literacy level, need for reading glasses. Postal self-report questionnaires are cheap to administer (expenses only include postage). They are also less taxing for the respondents. Interview questionnaires might be more sensitive since they could lead to information that was not included in the original script, but they are also more expensive to administer and analyse (Bowling, 2001). This is due to extra time and travel expenses; also analysis would need to be carried out, for example by Thematic Analysis, which is time consuming as described in Section 4.1.

The environment of completion of a questionnaire or interview should also be taken into consideration. An interview at the participant's own home is most desirable since this is in a personal and comfortable environment and therefore may lead to more valid results (Bowling, 2001). However, the practicalities of such decisions need to be taken into consideration when a questionnaire is being developed. If a questionnaire is going to be used in a clinical setting, interviews in a patient's house might not be practical due to the amount of time that it would demand from a clinician. The patient might also be worried about the way the house is presented when there are visitors and there might be interruptions which can't be avoided. Even though a clinic might

be less comfortable (emotionally and physically), it would lead to a more controlled environment.

3.1.2 Psychometric properties of questionnaires

Psychometric properties are statistical properties used to describe the performance of a questionnaire. The general agreement is that these are: reliability, validity and responsiveness to change. Any questionnaire that is chosen should have psychometric properties that meet these statistical requirements. All three properties are of equal importance and none of them can be answered. A questionnaire is also usually developed with a target population in mind and these psychometric properties are valid only for the intended population (Buchbinder et al., 1995; Tate et al., 1996; Field, 2009).

3.1.2.1 Reliability

Reliability refers to the ability to produce consistent results in people with similar difficulties and consistent results when administered on different occasions, when there is no evidence of change (Bowling, 2001, Smith, 2003). There are three types of reliability that are deemed important for health outcome questionnaires and all of them are relevant to freedom from random errors on measurement. A reliable questionnaire should have small random errors (Streiner and Norman, 1989; Tate et al,. 1996). Reliability of the proposed questionnaire is tested in stage three of this research.

3.1.2.1.1 Test-retest reliability

This type of reliability examines results of repeated trials to make sure that conducting the same procedure yields the same results under the same conditions (Bowling, 1991; Guyatt et al., 1987; Field, 2009). This is an important property when a questionnaire is assessing the change that occurs as a result of an intervention. It is essential to have a high test-retest repeatability in order to detect any changes due to intervention. However, it is difficult to obtain truly independent trials on replication and therefore this affects the measurement of this property. One important element of quality of life is that it might change over the course of time. This aspect can cause a problem in attempting to use test-retest methods to assess the reliability of quality of life measures since reliability assumes that things other than the intervention have remained constant (Coons and Kaplan, 1993; Tate et al., 1996). There is also the problem that participants may memorise their responses.

3.1.2.1.2 Internal consistency

This property concerns the reliability of a single application of the questionnaire and is defined as the ratio of the variance attributable to true differences among participants to the total variance (Coons and Kaplan, 1993; Kirshner and Guyatt, 1985; Streiner and

Norman, 1989). It is the extent to which all items intended to assess a particular dimension actually measure that said dimension. Correlations between the items and the dimension score are examined to provide an assessment of the overall homogeneity of the questionnaire dimensions. There are a number of different ways to calculate such correlations, such as Cronbach's alpha, Kuder-Richardson or split halves, and they tend to yield similar results (Streiner and Norman, 1989); however, Cronbach's alpha testing tends to be less complicated to carry out (Field, 2009). Since the method only involves a single administration of the questionnaire, it does not take into account day to day variation of performance or variation from observer to observer which are considered by other tests of reliability (Streiner and Norman, 1989).

It has been proposed that for internal consistency values above 0.90 are needed for making comparisons between individuals and above 0.50 for comparisons between groups (Coons and Kaplan, 1993).

3.1.2.1.3 Stability

A number of issues need to be taken into consideration when testing the stability of a questionnaire; a change in response needs to reflect a change in circumstance rather than any other reason. These include inter-observer reliability, intra-observer reliability and test-retest reliability (Streiner and Norman, 1989). Inter-observer reliability is important when different people administer the test and intra-observer reliability is important when the same tester administers the same test on different occasions (Streiner and Norman, 1989). Test-retest reliability refers to the consistency of responses on the questionnaire when administered by different testers. Although probably not a central concern in a study where the same person is involved in the administration of the questionnaire to all participants, it may be important when a questionnaire is intended to be used by many centres when results from those centres may be compared.

3.1.2.2 Validity

The validity of a questionnaire is the extent to which it measures what it claims to measure. Validity is related to the effects of non-random or systematic errors but these are not always clear in practice. We do not claim that an instrument is valid, but rather support its validity through research findings (Bowling, 2001; Coons and Kaplan, 1993; Field, 2009).

Although there are many different approaches to assessment of validity, in practice there is a choice of two methods depending on whether there are other available and acceptable scales of the same or similar attributes available (Streiner and Norman, 1989). In the former case the obvious approach is to administer the new experimental instrument together with the existing measure in order to see if there is a strong

correlation between the two. This approach has two main limitations: if there is a similar instrument which is accepted as a 'good' measure it will be difficult to justify the need for a new measure and if the old one is not as good as the new one, how can one justify a comparison between the two of them (Coons and Kaplan, 1993; Streiner and Norman, 1989)? In the latter case, which is more likely to happen, and is the case in the study presented in this thesis, the solution involves consideration of construct validity.

The different types of validity are discussed below.

3.1.2.2.1 Content validity

This refers to the completeness with which a questionnaire covers the important areas that it is attempting to represent (Bowling, 1991; Kirshner and Guyatt, 1985; Streiner and Norman, 1989). Since questionnaires have different purposes there are no standard procedures to demonstrate content validity. Reasoning supports scientific evidence to construct arguments and claims that the items included would be selected by a large number of representative judges and experts in the field, based on participant reports or from previous findings in published literature are used to demonstrate content validity. Content validity will be covered by stage one with regard to the questionnaire being developed in this thesis.

3.1.2.2.2 Criterion validity

Criterion validity is the degree to which the results obtained by the questionnaire correspond to those obtained using a superior measure or gold standard simultaneously (Bowling, 1991; Kirshner and Guyatt, 1985). In the area studied for this thesis, there is a lack of a gold standard instrument to assess this form of validity. If such an instrument did exist it would help to measure a concept regarding quality of life that the instrument under study is concerned with (de Bruin et al., 1997). Criterion validity is a mix of concurrent validity (correlations with an existing measure of the same construct) and predictive validity (correlations against other measures to assess predicative powers). Quality of life scales usually are reliant on predictive validity (Bowling, 2001). Criterion validity of the proposed questionnaire will be addressed in stage three of this research.

3.1.2.2.3 Construct validity

This form of validity is the extent to which a particular measure relates to other measures in a manner that is consistent with theoretically derived hypotheses (Kirshner and Guyatt, 1985). A gold standard does not exist for quality of life (Deyo and Centor, 1986; de Bruin et al., 1997; Guyatt et al., 1986; Kirshner and Guyatt, 1985) and therefore relationships with other relevant external criterion are proposed to assess the validity of quality of life questionnaires (Guyatt and Jaeschke, 1990). Construct

validation is an on-going process, of learning more about the construct, making new predictions and testing them (Bowling, 2001; Streiner and Norman, 1989). The theory and the measure are tested at the same time. There is no single experiment that unequivocally 'proves' a construct.

Construct validity exists in two forms (Bowling, 2001). The existence of a high correlation with a related questionnaire, but not a one to one correspondence provides evidence for what is referred to as convergent validity. The absence of a correlation between variables that should not be related provides evidence for what is referred to as discriminant validity.

3.1.2.3 Responsiveness to change

A questionnaire should be able to detect changes within patients and this property is at times referred to as the sensitivity to change of the questionnaire. There are subtle differences between definitions of responsiveness available. Examples include being concerned with the ability to detect minimal clinically significant change (Guyatt et al., 1987; Tate et al., 1996), the ability to detect changes in the concept being measured (de Bruin et al., 1997) and the ability to detect a treatment effect (Buchbinder et al., 1995). The absence of a gold standard for quality of life means that it is difficult to determine what constitutes the change to be detected. Although statistically significant difference is a condition for detecting change, not all statistically significant changes will represent a relevant change in the concept (de Bruin et al., 1997). In general, instruments that have been proven to be reliable are likely to be responsive too. However, a conventional measurement of reliability using an intraclass correlation relating between-person variance to total variance might be misleading if it is used as the only index of an instruments ability to generate consistent results over time (Guyatt et al., 1987). This is particularly true of instruments designed to measure disease-specific quality of life.

Responsiveness to change is hardly ever measured since it is difficult to completely identify significant changes that are of clinical importance. This convention will be followed in this thesis and no measurement of responsiveness to change will be attempted.

3.1.2.3.1 Methods to assess responsiveness

There appears to be a lack of standardised methodology to assess responsiveness (Deyo and Inui, 1984; Deyo and Centor, 1986). Methods reported differ both in their rationale for the assessment and the statistical methods used. Ideally, multiple baseline measurements are obtained before and after an intervention, but due to the design of this study this is not possible here.

The most appropriate measure of responsiveness would relate the variability in test score in stable participants to the clinically important difference of interest (Guyatt et al., 1987). Two methods have been proposed that assume that outcome questionnaires are clinical predictive tests of improvement or deterioration. These have involved the assessment of the sensitivity and specificity for detecting change (Deyo and Inui, 1984; Deyo and Centor, 1986) and the construction of Receiver Operating Curves (ROC) curves (a rating method to determine an outcome of an intervention) (Deyo and Centor, 1986). Both these approaches require an external criterion to define the presence of an improvement or deterioration. Here again, the lack of a gold standard for quality of life introduces difficulties in defining the external criterion. However, an advantage of such methods is that meaningful comparisons of the responsiveness can be made between questionnaires.

A different way to assess responsiveness is to examine correlations that exist between changes in the health outcome questionnaires and changes in clinical measures (Deyo and Centor, 1986).

Questionnaire score changes have been examined as a result of a treatment of known efficacy to indicate the responsiveness of the questionnaire (Deyo and Centor, 1986). The statistical significance of the score change reflects the responsiveness, with higher significance indicating greater responsiveness. A number of indices of responsiveness have been proposed that involve a ratio based on score changes and an indicator of the precision of the measurement (de Bruin et al., 1997). Such methods were developed to provide a standardised and dimensionless representation of the changes observed. Although these are claimed as measures of responsiveness, they quantify the changes demonstrated by the questionnaire under study rather than the validity or clinical relevance of the change (de Bruin et al., 1997). An external criterion is required to determine the validity of the changes observed.

The ratio of clinically important difference to the variability of scores in stable participants has been proposed as the index of responsiveness (Guyatt et al., 1986). This method is limited because of the difficulty in knowing what constitutes a clinically important difference (Liang et al., 1990). Two similar ratios are the effect size (Kazis et al., 1989) and the standardised response mean (SRM) (Liang et al., 1990; Stucki et al., 1995). The effect size has been reported as the ratio of the mean change in score obtained on the questionnaire to the standard deviation of scores at baseline – this is sometimes used to characterise responsiveness. A non-parametric version of the effect size is available for those cases where scores are highly skewed (Kazis et al., 1989). The emphasis of the effect size appears to be a tool for quantifying (de Bruin et

al., 1997) and interpreting score changes (Kazis et al., 1989) rather than as a measure of responsiveness.

3.1.3 Requirements for health outcome questionnaires

Health questionnaires fulfil different roles: discriminative, predictive or evaluative and the statistical requirements for each role are different and can be conflicting (Kirshner and Guyatt, 1985). Several considerations need to be made when choosing a health outcome questionnaire. These are described in the table below.

Table 11: Considerations for the choice of health measure (Jette, 1980)

Consideration	Description
Intended use of measure	In the measure to be used for comparing treatments, monitoring patients or assessing patient needs?
Conceptual focus	What is the domain of assessment – impairment, disability, handicap, quality of life, activities of daily living or general well-being? Is this relevant to the population under study?
Quality of the measure	What are the psychometric properties of the measure including reliability, validity, responsiveness, ceiling and floor effects, length and acceptability?

The usefulness of questionnaires designed to evaluate change within persons over time (such as the one being devised in this project) is dependent not only on the reliability and validity of the questionnaire, but also on the ability to detect changes that occur (Guyatt et al., 1987; Kirshner and Guyatt, 1985). However, questionnaires developed for either discriminative or predictive purposes need only demonstrate the validity and reliability of the measure (Kirshner and Guyatt, 1985).

3.2 Devising a questionnaire

Several steps need to be taken before a final draft of a new questionnaire is subjected to reliability and validity checks (Streiner and Norman, 1989). The theory that is being tested should be clearly stated since this enables the researcher to demonstrate those areas that are relevant and those which can be left out. This should be strengthened by comprehensive investigation of past research in similar areas including instruments used to investigate those areas. Experts in the area of interest including participants themselves in certain circumstances should assess the content validity of the proposed questionnaire. A final draft should then be subjected to reliability and validity checks (Streiner and Norman, 1989, Smith, 2003) such as those described in section 3.2.1.

Guyatt et al. (1986) have described a method called the Rolls Royce Model to develop an instrument to measure quality of life, which has also been supported and used in other research, for example Hinderink et al. (2000), Smith (2003), Archbold et al. (2002) and Ruiz et al. (2008). The last section of this chapter describes in detail the process by which an established questionnaire was developed (Parent outcome profile from paediatric cochlear implantation). The table below goes through the six steps, which were taken to achieve development one by one.

Table 12: Rolls Royce Model for development of questionnaires (Guyatt et al., 1986)

Stage	Roll-Royce Model
Item selection	• Literature review • Consultation with health care workers • Use of existing instruments • Semistructured interviews with 50 to 100 participants to determine the frequency and importance of each item
Reduction of number of items	• Choice of items with highest frequency-important product or principal-component analysis – could be done via factor analysis or multiplication of the frequency of each item by its mean importance • The final questionnaire should preferably not take longer than 20 minutes to administer.
Questionnaire format	• Choice of response-options scale: 7- to 10-point Likert Scale or visual analogue scale
Pretesting	• Use of about 20 participants • Determine which questions need to be modified due to inappropriateness, misunderstandings or causing confusion • Analysis of results to ensure that full range of response options is used • Pretesting procedure is repeated when modifications to questionnaire are made
Reliability and responsiveness	• Look at the ratio of the variability between participants to the total variability in responses (use Pearson's correlation coefficient but this may give misleading results)
Validity	• Use of construct validity due to lack of gold standard • Use of *a priori* predictions

The steps involved in the initial selection of items of a closed-set questionnaire are as follows (Streiner and Norman, 1989):

1. pre-test the items to ensure that they:
   - are understandable
   - are not ambiguous
   - ask only a single question
2. eliminate or rewrite any items which do not meet these criteria, and pretest again
3. discard items endorsed by a few or a majority of participants
4. if the questionnaire is homogenous and unidimensional, check for internal consistency of the scale using:
   - Item-Total correlation
     - correlate each item with the scale total omitting that item
     - eliminate or rewrite any Pearson *r*'s less than 0.20
     - rank order the remaining ones and select items starting with the highest correlation
   - coefficient α or KR-20
     - calculate α eliminating one item at a time
     - discard any item where α significantly decreases
   - check that all the item response categories are endorsed with relatively the same frequency, using α or some equivalent measure
   - for multi-scale questionnaires, check that the item is in the 'right' scale by:
     - correlating it with the totals of all scales, eliminating items which correlate more highly on scales other than one it belongs to, or
     - factor-analysing the questionnaire, eliminating items which load more highly on other factors than the one it should belong to (factor analysis might be carried out earlier in the process to help determine the dimensionality of the questionnaire).

3.2.1 Social Desirability Bias

The measurement process should be made as rigorous as possible by examining the way subjective responses towards the questions affect the way participants respond. This is done via the pre-checking testing of the final questionnaire. The potential for bias is present in all social research, but can be minimized by using interviewers who have been properly trained, briefed to be as objective as possible, and by ensuring that they do not include health professional that the participant may want to influence or subconsciously give positive replies to (Bowling, 2001; Streiner and Norman, 1989).

3.2.2 Response format and response scales

There is a wide variety of scaling methods for item responses. The finer the distinctions that can be made, the greater the theoretical precision of the measure

(Bowling, 1991). Offering a wide range of choices is likely to reduce the potential for error due to confusion, although the continuum should not be too great, or meaningless responses may be made.

A response format is usually in the form of category rating scales (for example yes/no responses) however other formats are also available. Categorical scales provide discrete response categories in the form of a series of descriptive phrases (Bowling, 2001; Streiner and Norman, 1989). There are several scaling methods, the most common being the Likert – using a descriptor along a continuum which usually related to whether agreement, acceptance or probability. This is a rating system, which is subdivided numerically into a series of ordered responses. The categories are assigned scores and the participants' attitudes are measured by the total score (Bowling, 2001). Since it is an ordinal scale, rather than an interval scale, no conclusions can be drawn from the distances between the scale points.

The second most common response scale is the visual analogue scale. This requires the participants to place a mark on a line on which opposing statements are placed at either end of the line. The point at which the mark is made represents where the participants perceive their response to be (Bowling, 2001). Participants have reported that they find it difficult to understand and complete (Streiner and Norman, 1989). This type of scale is also more difficult to analyse, than categorical scales but on the other hand it provides a greater range of response choices, which makes it more valid, reliable and sensitive (Bowling, 2001). By implication, it is an interval scale.

Other types of response scaling are described briefly in Table 13.

Table 13: Response scales available (Bowling, 1991; Bowling, 2001)

Type of scale	Description
Guttman scale	The respondent is required to endorse all the items less extreme than the ones with which s/he agrees. This type of scale is quite complex and there is no guarantee that the whole scale covers the concept of interest.
Semantic-differential scale	This is a popular attitude measurement technique that asks respondents to rate an attitude object on a number of adjective scales.
Thurstone scale	Respondents are asked to rank statements relating to the variable of interest, which are typed onto cards, into hierarchical order, from the most desirable to the

	least. This involves choosing the attitude object to be measured and then collecting a wide range of belief statements expressing favourable or unfavourable statements. Numerical values are derived by judges who sort the statements in groups according to the degree of favourable or unfavourable evaluation each one expresses. A continuum is derived from the range of statements obtained.

The choice of number of categories given, at times poses some difficulties. Too many categories may lead to difficulties in decision making, whereas the use of too few may not provide enough choice and therefore allow the participant to choose falsely from adjacent categories that resemble less their true response (Bowling, 2001; Streiner and Norman, 1989). The literature provides no consensus on the optimum number of response choices that should be given. However, a review of the literature suggests that a 4- or 5-point scale is appropriate since this provides enough information without making the questionnaire too onerous to fill in (Streiner and Norman, 1989).

Odd numbers are not usually used to label scales since by providing a middle number neutral choices are offered. Some participants might prefer not to commit themselves and therefore choose this option regularly which would not offer reliable information (Bowling, 2001). The researcher might want to force the participants to make a choice which is when a middle number should be omitted.

Different scoring scales are suitable for different purposes. The type of scoring depends on what concept the instrument is based on, what data it yields and what statistical analysis will be used.

3.2.2.1 Weighting scale items

The easiest solution to the scale scoring problem is to sum the item scores with an equal weighting. However, there is a fundamental problem with this method: some items which might be more important to the construct than others contribute as much as the lesser items to the total score (Bowling, 1991, Streiner and Norman, 1989). In this way a given score can be arrived at in several different ways, so a score might not give a specific indication of the participant's quality of life status. One solution to this would be to assign different values to the different scale items for scoring purposes. Streiner and Norman (1989) reviewed methods how this would be achieved and the conclusion derived from this review was that if a questionnaire has more than 40 items, different weighting would not add any information. When a questionnaire has

less items (closer to 20), different weighting might add some more information to the meaning of the final score of the questionnaire, but this might not always be the case.

3.2.3 Biases in responding questionnaires

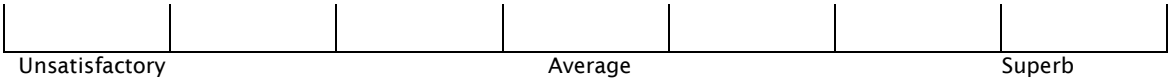
One of the most basic and most important qualities of a questionnaire is that it is well written, with the wording being sufficiently simple and the concepts clear so as to avoid any misunderstandings on the part of test-takers (Smith, 2003). Part of the process of devising a questionnaire is achievement of and piloting the questionnaire - this forms an important part of the process since it helps avoid some aspects of bias (section 4.6 describes how this was carried out for this project).

Social desirability and faking good are quite common in responses to questionnaires (Streiner and Norman, 1989). This may or may not be deliberately. Their existence depends on a number of factors: the individual, cultural background, whether the questionnaire is done in the presence of the researcher and the structure and content of questions themselves (Streiner and Norman, 1989; Gillham, 2000). Answers affected by social desirability or faking good affect the validity of the questionnaire and therefore need to be minimized as much as possible. Careful instructions and use of clear wording would help minimise this bias however, there is a lot of speculation in the literature as to whether these are sufficient to solve the issue. The opposite of social desirability and faking good, deviation and faking bad might also occur in answers to questionnaires.

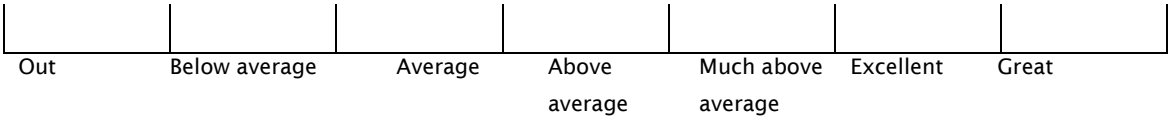
'Yea-saying' or acquiescence, where people tend to give positive responses to all questions, may also occur (Streiner and Norman, 1989, Smith, 2003). Research has shown that this tendency is very common although only a few people are at the extremes. The usual way to correct for this bias is to have an equal number of items keyed in the positive and negative directions.

Scales that are scored on a continuum are prone to other types of bias. End aversion bias occurs when participants tend to avoid the extreme categories of a scale since they find it difficult to make an absolute judgement (Smith, 2003). One solution would be to avoid absolute terms by for example 'almost never' instead of 'never'. The disadvantage with this is that other people would prefer to have the absolute term included and would then not be able to include their preferred option. Another solution is to include an extreme on both sides of the continuum but then not include these responses in the analysis. This ensures that the continuum that is used is of interest to the researcher, because the end aversion bias would be excluded. However, by doing this, the researcher could also be missing out on some important information if the true reply would be an extreme response and this is omitted from the analysis.

A positive skew towards the favourable end of a scale might also occur and the effect of this would be to produce a ceiling effect. This would reduce the possibility of demonstrating any change. Methods to counteract this are based on the fact that 'average' might not be the middle. A traditional Likert Scale would result in most of the scores bunching at an extreme:



But if the centre is shifted as seen below, the average does not remain in the middle as seen below in the example given by Streiner and Norman (1989). A way to do this is to clearly distinguish the extremes and divide the average into several sections.



The halo phenomenon might occur, this is when the overall impression of what is being looked at is reported in every question, rather than rating each characteristic separately. Framing might also be seen and the response to the question would depend on how two alternatives are explained, for example there would be a different response to an intervention if the morbidity was presented as 0.1% instead of saying that there is a 99.9% chance that nothing would go wrong. It is the responsibility of the questionnaire designer to make sure that questions are not biased since this could lead to framing. It is important in questionnaire development to assume that all these biases might occur and take the necessary precautions to make sure that they will not.

Measurement of change has its own set of possible biases. Asking people to compare their present to past status involves the person's memory of previous events. Such memories change over and asking them to compare their present and past status produces potential inaccuracies. It has also been acknowledged that some people are able to remember events that happened a year earlier better than something that had happened a week before they are questioned (Streiner and Norman, 1989). However, measurements of change tend to be biased more towards the present state and much research has explored reasons why this happens and ways it can be avoided or limited. The two relevant opposing theories are 'response shift' and 'theory of change' (Streiner and Norman, 1989). Response shift implies that any changes observed are a direct result of changes in the internal state of the person responding to the questionnaire. This assumes that the person is able to reflect on their past experience based on their present status and sees situations from a changed perspective compared to how it was in the past. It is argued that this would make the responses to queries about past health state more reliable. On the other hand, the theory of change implies that people are not able to remember their previous status accurately and therefore are not

able to compare their past with their present. Their view of the past is based on an 'implicit theory' of how their past must have been based on their present status. It is therefore argued that to avoid this bias, one needs to enquire about the present status, then intervene over a period of time and enquire again post-intervention. A direct comparison of responses pre-past intervention is then made. Any instrument which lies on recall has potential for bias and this needs to be kept in mind during development and interpretation of responses.

3.2.4 Administration of questionnaires

As already mentioned in section 3.1.1, each method of questionnaire administration has its advantages and disadvantages (Streiner and Norman, 1989). These are discussed below.

3.2.4.1 Face-to-face interviews

During face-to-face interviews a trained interviewer administers the questionnaire usually in an office or the participant's home. The latter option may be more desirable since the surroundings might put the participant more at ease. However, this also might incur more expense for the researcher and there would be potentially more interruptions (telephone, other family members, and so on).

3.2.4.2 Telephone questionnaires

An alternative to meeting the people is to conduct thee questionnaire over the phone. This might save money over travel costs to go for a home interview and it also incurs less time usage for the interviewer. However, this would potentially create a disadvantage for some of the participants in this study since not all of them might be able to use the telephone.

3.2.4.3 Mailing questionnaires

This has the advantage of being the cheapest way to issue questionnaires especially to a large number of participants. A disadvantage is the possibility of a poor return rate which might result in a limited amount of data being collected. There are several ways to increase the return rate. A covering letter usually helps. This can include information on why the study is important before describing what a participant will be required to do. The promise of anonymity and confidentiality might increase response rates. Personalisation of choosing the participants also has an effect on the response rate since keeping it open might make the questionnaire seen as 'junk mail'. A provision stamped self-addressed envelope for return of the questionnaire does not impose any extra costs on the participants, so will increase the likelihood of return.

Due to the design of this study, some other techniques which in other circumstances may be successful could not be implemented. These include following up participants

who have not replied within a given amount of time or advance warning of a questionnaire being given to them.

The following tables (14 and 15) illustrate the advantages and disadvantages of these methods compared to one another.

Table 14: Comparison of advantages of different questionnaire methods

Advantage	Face-to-face	Telephone	Mailing
Interviewer sure who is responding	x		
Reduces the number of items omitted	x	x	
Determine whether a participant is having difficulties understanding the questions	x	x	
Gather more information than the question asks	x	x	
Avoid questions which are not appropriate for specific participants	x	x	
Less bias caused by appearance of interviewer		x	x
Less time usage for interviewer		x	x
Low administrative costs		x	x
Can be co-ordinated from one central office		x	x
Social desirability is minimised			x

Table 15: Comparison of disadvantages of different questionnaire methods

Disadvantage	Face-to-face	Telephone	Mailing
Incur greater cost	x	x	
Take time for interviewer	x	x	
Attributes of the interviewer might affect response	x	x	
Prompting from other members of the household might occur		x	x
Difficulty with questions that require a reply chosen from a scale		x	
Lower response rate			x
Omission of items			x
No assurance that participants will			x

follow the order of the questionnaire	
Delay until all questionnaires are returned	x

3.3 Review of questionnaires used with cochlear implant patients

3.3.1 The EuroQol -5D (EQ-5D)

The EQ-5D is a standardised questionnaire used as a measure of health outcome and was developed by the EuroQol Group (Grutters et al., 1997). It is applicable to a wide range of health conditions and treatments and provides a simple descriptive profile and a single index value for health status. It is short, well tested and has population norms. It has also been translated and validated in different languages and an example is in Appendix 14.

The EQ-5D website (2012) describes the questionnaire as being a descriptive profile that asks the respondent to indicate his/her health state by ticking in the box against the most appropriate statement in each of five dimensions. These dimensions cover mobility, self-care, usual activities, pain or discomfort and anxiety or depression. This results in a one-digit number expressing the level selected for that dimension. The digits for five dimensions can be combined in a five-digit number describing the respondent's health state. The health status is generated through a visual analogue scale. It should be used with the 5-digit health state classification to build a composite picture of the respondent's health status.

3.3.2 The Short Form (SF-36)

The SF-36 is a health-related measure of quality of life. It is well tested and has population norms. It has also been translated and validated in different languages and an example is in Appendix 15. It is usually used as a generic measure alongside a disease-specific outcome measures (Bowling, 2001). It was derived from the Rand health batteries in the USA and then adapted for use in the UK. It is a less skewed measure than the Nottingham Health Profile (see section 3.3.4) and is being used more often in studies.

The SF-36 has 36 items which were derived from an original 149 items. The items used in the SF-36 were deemed to be the best on a factor analyses. This was tested on 22,000 participants in the USA. It takes five to ten minutes to complete. The 36 items measure different dimensions, mainly physical functioning (10 items), social functioning (2 items), role limitations due to physical problems (4 items), role limitations due to emotional problems (3 items), mental health (5 items), energy/vitality (4 items), pain (2 items), general health perception (5 items) and perceptions of health changes over the past twelve months (1 item). Item scores for

these dimensions are summed and transformed, using a scoring algorithm, into scale from 0% (poor health) to 100% (good health). The coding format requires recoding before the sub-scales can be summed.

The UK version has been modified slightly compared with the US version The language has been Anglicised and there was a slight alteration in the positioning and coding of one of the social functioning item in order to facilitate reliability and ease of administration (Bowling, 2001).

The SF-36 has been found to have good construct validity and it is more sensitive to gradations of poor health than the EuroQol and Nottingham Health Profile. It has been reported by some authors to have a higher rate of non-response among older people, although this was contradicted by other authors (Bowling, 2001). The SF-36 is positively correlated with quality of life (e.g. housing, neighbourhood, standard of living, family life and friendships). Since this is a generic measure, the questions are general in scope.

The short form of the assay has good internal consistency and test-retest reliability (Bowling, 2001). The internal correlation coefficients for the eight scales range from 0.60 to 0.81, with a median of 0.76. High inter-item correlations are reported for the sub-scales. It has high internal consistency within dimensions, with high Cronbach's alphas (0.76-0.90). The reliability coefficients for internal consistency range from 0.62 to 0.94 for the sub-scales; for test-retest reliability, the coefficients range from 0.43 to 0.90; and for alternate form reliability the coefficient was 0.92 (Bowling, 2001).

Different medical conditions give different score profiles, which indicates that the SF-36 can discriminate between conditions. The SF-36 includes a manual which provides the listings of studies made using it and also the validity and reliability of the questionnaire (Bowling, 2001).

3.3.3 The Health Utilities Index (HUI)

The HUI is a questionnaire which measures health-related quality of life and produces a utility score. It is generic, comprehensive and used worldwide with people who are over the age of five years. It provides a utility score to reflect health-related quality of life. The questionnaire was first developed in the 1980's in response to the need to evaluate outcomes for very-low birth-weight babies (Horsman et al., 2003), and went on to be developed for use in a wide variety of research topics and studies. There are three versions – HUI1, HUI2 and HUI3 – with each version having a different health status classification system. The HUI2 and HUI3 are the two measures most commonly used, with the HUI3 being developed from the HUI2 for use in studies related to both

clinical and general population. The HUI is commonly used when measuring outcomes of an intervention in relation to its cost-effectiveness and cost-utility analysis. There are eight rating categories – vision, hearing, speech, ambulation, dexterity, emotion, cognition and pain. These categories are structurally independent of each other (Horsman et al, 2003).

The HUI has been used in numerous studies in different languages. It also has population norms which are used for comparisons in studies. The HUI3 has been used in several large studies of the general population in the USA and Canada (Furlong et al., 2001). Used in other studies in other countries has led to the conclusion that one does not need to get specific population norms for each country since available norms are valid for use in all countries (Furlong et al., 2001). Furlong et al. (2001) also reported on a number of studies where the HUI3 has been used alongside other established questionnaires, like the EuroQol, (cross reference) which have confirmed that it is a reliable and valid measure that adds information the other measures do not examine. A number of papers report using the HUI when measuring the effectiveness of an intervention in patients with a hearing loss (Grutters et al. 2007; Klopp et al., 2008). However, a disadvantage is that in the hearing category there are only two ratings that would be able to show the difference between a unilateral and bilateral fitting which would make the measure less sensitive for study of this area. If the measure were used to measure the effectiveness of a first fitting, the HUI would be more sensitive since one would expect to see a difference within the other ratings post fitting when compared to pre-fitting.

3.3.4 The Nottingham Health Profile (NHP)

The NHP has been used to measure health-related quality of life (HRQL). It is based on lay perceptions of health status (Bowling, 1991). It helps indicate the degree of loss of quality of life experienced by people with a particular condition. It was developed after interviews with over a hundred people about the effects of illness on behaviour. As a survey tool it is useful in assessing whether people have a severe health problem (Bowling, 1991). It does not attempt to be a comprehensive measure of health related quality of life. The NHP is designed for self-completion, is concise and easily administered, and population norms exist.

The NHP has been tested for validity and reliability and has normative data (Bowling, 1991). It is divided into two parts. The first part concentrates on the participant's degree of discomfort or distress within the dimensions of lack of energy, pain, emotional reactions, sleep, social isolation and physical mobility. This is done via 38 yes/no questions. The second part contains 7 yes/no statements referring to health

induced problems within the areas of occupation, looking after the home, social life, sex life, personal relations at home, interests and hobbies, and holidays.

A study conducted by Ringdahl and Grimby (2000) aimed at obtaining measures of HRQL using the NHP as a function of age for people with severe-profound post-lingual hearing impairment. It compared the HRQL of this group with age-matched samples from the general population. The results from this study confirm the findings of other studies, such as that is that hearing impairment gives lowered HRQL regarding the emotional, social and energy dimensions of the participant's life. The differences in HRQL between the hearing impaired population and participants with normal hearing was more evident in the psychosocial and energy dimensions which seems to indicate that hearing impairment is a big factor in reducing life satisfaction rather than affecting the physical dimension of life. Higher distress levels were recorded for the hearing impaired group compared to the normal hearing group too. Persons with hearing impairment who had a full-time job had better HRQL than those with a part-time or no job. This did not seem to be age-specific however, this might be as a result of the small sample sizes in each age-group.

3.3.5 The Sickness Impact Profile (SIP)

The SIP is a 136-item standardised questionnaire about the physical and psychosocial effects of sickness-related dysfunction (Bess, 2000; Hickson, 1997). It is essentially a health-related quality of life measure. Multivariate analyses were used to adjust for age, race, sex, education level, number of illnesses, presence of diabetes and ischemic heart disease, number of medications, near visual acuity and mental status. The higher the SIP score, the greater the functional impairment (Bess, 2000).
Results obtained with hearing impaired individuals were compared to those obtained with heart transplant patients and patients with chronic obstructive airway disease (Bess, 2000; Hickson, 1997). The hearing impaired individuals' scores lay between those of the other two populations.

3.3.6 The Speech, Spatial and Qualities of Hearing Scale (SSQ)

The SSQ measures a range of hearing disabilities across several domains; a copy of this questionnaire is in Appendix 13. The questionnaire was developed based on previous work of one of the developers (Noble et al, 1995). It evaluates interventions that particularly implicate binaural function since attention is given to the directional, distance and movement components of spatial hearing. The abilities to segregate sounds and to attend to simultaneous speech streams are also assessed, reflecting aspects of the reality of hearing in the everyday world. Qualities of hearing experience include ease of listening, and the naturalness, clarity and identifiably of different

speakers, different musical instruments, and different everyday sounds (Gatehouse and Noble, 2004).

The questionnaire has 50 questions and was designed to be used as a clinician-patient interview. A scale from 0 to 10 is used to answer each question. One hundred and fifty three participants using hearing aids were involved in to finalising the development of this questionnaire and it was found to have highly inter-correlated items. The three subscales were shown to have independent domains of hearing ability.

In Noble and Gatehouse (2006), the authors demonstrated that the questionnaire could be used with binaural hearing aids and that it was sensitive enough to pick up difference between this type of fitting and participants with unilateral hearing aids. The questionnaire was completed by three groups – 144 participants who were awaiting fitting of hearing aids, 118 who had been fitted with a unilateral hearing aid for six months and 42 participants who been fitted with binaural hearing aids for six months. This study was able to show that in areas where one would not expect binaural fitting to lead to an improvement over a unilateral fitting, for example listening in quiet situations, the questionnaire did not demonstrate difference between the two aided groups. On the other hand, the SSQ was sensitive enough to pick up benefits of binaural fittings in specific situations, for example being able to track the location of a sound source. This study was able to show that this questionnaire can be used to demonstrate benefits on binaural or bilateral fittings. Noble (2010) also used the SSQ in a study which assessed binaural hearing and this questionnaire was sensitive enough to show the differences in abilities with one implant versus with two, even though this change was not as marked as with hearing aid participants. This finding was also supported by Sparreboom et al. (2012) as described in section 2.2.2.

3.3.7 The Hearing Measurement Scale (HMS)

The HMS was originally used with patients with noise-induced hearing loss but has since been used with elderly patients with a sensorineural hearing loss. The HMS consists of forty-four items of which two are non-scoring (Eriksson et. al, 1992). The scale is divided into seven sections: hearing for speech (11 items), hearing for non-speech (8 items), spatial location (7 items), emotional response (7 items), speech distortion (3 items), tinnitus (3 items) and personal opinion (3 items). The items are rated on 5-point scales ranging from ‘always’ to ‘never’ and are weighted at scoring. An important question scores 9, 8 or 7 as a maximal disability or handicap experience, whilst a less important question only scores 5, 3 or 1 as a maximum (Eriksson et. al, 1992).

3.4 Methodology of development and validation of an established questionnaire

One of the aims of this project is to develop and validate a questionnaire for use in sequentially implanted bilateral cochlear implant adult users. The methodology chosen for the project has been based on theoretical information from the literature as described earlier in this chapter and also on previous studies that have looked at developing questionnaires. For the purpose of this project, the development of the questionnaire called 'Parent outcome profile from paediatric cochlear implantation' will be described here. This is a close-ended questionnaire which assesses the views of parents of children who have been implanted. The authors first sent out open-ended questionnaire to thirty families of children who had been implanted for a minimum of two years. The questions asked specifically about particular categories such as the child's functioning and family implications to gather the parents' views regarding areas that the authors thought would be affected by cochlear implantation. The responses to these questions underwent content analysis which helped the authors decide which issues were thought important by this population. The themes of the final questionnaire began to emerge as a result of content analysis (Archbold et al., 2002). These themes led to the items for the close-ended questionnaire and there were ten different categories that emerged from this analysis.

The next stage was to test the retest reliability of the questionnaire – this was done by asking a further twenty parents to fill it in twice with a month interval between (O'Neill et al., 2004). The parents participating in this stage were different to the ones who had filled in the open-ended questionnaire. The researchers then carried out correlation tests to examine the reliability of the responses for all the items (same response on 95% of the items). The standard deviations of the responses were also investigated since these gave some insight into the difference in responses on replication – this explained whether there was a high variability in responses across participants. The authors also investigated the change in responses between the two intervals when parents were asked to fill in the questionnaire. At the end of this stage, it was concluded that the questionnaire was a valid and reliable method to look into parental perspectives of children with cochlear implants due to its high test-retest reliability. This means that it is able to report the parents' thoughts in a meaningful way (O'Neill et al., 2004).

In a separate study, an independent group of researchers looked at the validation of this questionnaire (Nunes et al., 2004). These researchers looked in detail at the content, criterion and construct validity of this questionnaire. Content validity was assessed by asking a separate group of parents (sixty one sets of parents) from the ones who had taken part in the previous studies to fill in the questionnaire and also to

take part in a semi-structured interview which looked at similar themes to those the questionnaire included. The responses from these two methods were compared and the researchers felt that some new themes emerged from the interviews that were not included in the close-ended questionnaire so recommendations to include these were made. Criterion validity was assessed by examining responses that led to very low or very high scores in each scale. These cases were investigated further by looking at the responses given during the interviews that were carried out. Factor analysis was also carried out, thus investigating the construct validity. This identified four subscales which was different to the original authors' suggestion. Details of the methodology used in this validation will be discussed in more detail in the following chapters in relation to the methodology used in this project.

3.5 Conclusion

Chapter 2 reviewed the literature in relation to benefits of bilateral hearing. There is much research which describes the way human beings are able to hear and combine sounds. The benefits of binaural hearing in a clinical situation are well explored and documented, however, as clinicians it is also important to listen to and learn from what patients say about their experiences and counsel them about their expectations or investigate ways to improve any shortcomings. This is best done via self-report measures such as questionnaires however presently there isn't a measure which would be useful to do this with patients who received bilateral cochlear implants sequentially – this is mainly due to the fact that the questionnaires that are available are state measures whereas a change measure is needed in order to be able to pick up these changes. These patients had the experience of using one implant and would be able to compare this experience with that of listening bilaterally. The lack of such a measure led to the development of the aims of this project which are described in section 1.2. Chapter 3 reviewed issues to take into consideration when developing a valid and reliable outcome measure related to quality of life changes. The next chapters will explore the ways how this has been carried out for this project.

Chapter 4. Questionnaire development

4.1 Introduction

In order to assess psychosocial consequences, and gain a deeper understanding of how adults perceive the gain in quality of life after receiving a second cochlear implant, a questionnaire was selected as the most suitable method of outcome evaluation. However, there was no questionnaire available that would fit these purposes. Quality of life measures currently available are either generic or health related and these are not suitable evaluation of outcomes in adults with hearing impairment. As a result, it was necessary for this study to devise and evaluate a customised closed-set questionnaire. This was achieved by basing the questionnaire on responses obtained from the administration of an open-ended questionnaire and interviews carried out with 13 profoundly and postlingually deafened adults who have received their second cochlear implant after having had their first cochlear implant for some time. The number of participants was not larger than this since there were not many participants who fulfilled the criteria at the time.

The development of the questionnaire was split in two stages. Initially an open-ended questionnaire was designed and utilised to find out what aspects of the participants were aware of and what issues were of concern to them. This process was previously used by Archbold et al. (2002) when the authors investigated the perceptions of parents regarding their children's cochlear implantation and is also a well-established method of data collection in the first stages of questionnaire development (Merriam, 2009) . Data collection for this stage could also occur via interviews, observations, or review of records and literature (Merriam, 2009). Due to the nature of this study, observations and review of literature or records would have not been an appropriate method since they would have not yielded appropriate data. The rationale to use open-ended questionnaires in the first instance was based on the theory that these are less intrusive than interviews so more participants would possibly agree to take part in the study. It was important to try and recruit as many participants as possible since the number of eligible patients in the UK was already low so a low return rate would mean a low number of participants which would have possibly affected the results.. Thirteen participants agreed to take part in the study at the open-ended questionnaires stage, but this number dropped to 11 at the interview stage.

In this study by Archbold et al (2002), an open-ended questionnaire was sent to the parents of 30 implanted children. The aim of administration of the questionnaire was to obtain common themes reported by these parents. Responses were analysed and split into themes and the authors reported the number of times a theme or a factor within the theme was mentioned by the participants.

In the present study, responses from the open-ended questionnaires (see section 4.3) sent to the participants, raised a number of issues. Some issues were clear, but some required further investigation and so a decision was made to carry out face to face interviews (Gillham, 2000). These helped clarify any themes that needed further investigation after the open-ended questionnaires and also investigate if there were any new issues that would emerge from the interviews. During these interviews, the researcher was able to ask questions again, or rephrase some questions and ask for clarification if it was felt that extra information was needed. For example, both on the questionnaire and during the initial stages of the interview, one participant did not mention that she had returned to work at a bingo hall, but when the researcher asked more about her experience of having two cochlear implants at work, she reported that since her second implant she is now working more independently than when she had one implant.

The open-ended questionnaire used in this study was designed to be completed by the participants themselves and was sent out by post. This was an economical and reliable way of obtaining subjective information compared with employing an interviewer to administer the questionnaire. A quantitative method of analysis was used to analyse the responses obtained from the open-ended questionnaires as will be described in section 4.3.2. Lormore (1994) conducted a study on the use of open-ended questionnaires with patients and their significant others. This study was not in the field of hearing impairment, however there are still applicable findings that are valid across topics. The information from this study led to the decision that it was important to start this project with open-ended questionnaires since one could miss subtle points. Lormore (1994) reported that general trends were identified when the results of open-ended questionnaires were analysed. The author decided to dismiss the premise that people listed their difficulties in order as requested since they would have been under pressure to fill in the questionnaire. It is also arguable that since problems are perceived differently on different days, the order of importance could change accordingly.

The second stage of the closed-ended questionnaire development was carried out via interviews held with 11 participants. Since the open-ended questionnaires were based on data that had been anticipated by the researcher through a literature review, the interviews allowed issues that were not raised via the questionnaire to be explored. Face-to-face interviews with participants have encouraged informal discussions. The objective was to elicit frank and sincere opinions about the issues being investigated than participants might have felt comfortable writing about. The written form can at times lead to some misunderstandings if something is not clearly explained and may

result in deviation from the intended discussion. However, if this occurred during the interviews, clarifications were sought.

Lack of training in interview techniques can lead to difficulties in securing information that is relevant and realistic (Flick, 1998). In order to minimise the element of researcher bias during the interview phase, the researcher attended one-to-one tuition with a trained and licensed counsellor at the University of Southampton. Tuition indicated how to conduct interviews for the purposes of this study, for example probing and interview methods were discussed in order to help motivate the participants to communicate fully about their experiences. It has been acknowledged in the literature that most of the bias during interviews arises from the interviewer's method of asking questions and their reaction to the responses. Although bias cannot be eliminated completely, the aim was to minimise this as much as possible (Mishler, 1986).

The approach during the open-ended questionnaire and the interviews used was based on Grounded Theory which is widely used in social sciences. The Grounded Theory approach works on generating a theory from data gathered rather than testing a hypothesis (Strauss and Corbin, 1990). The researcher felt that it was important not to have a hypothesis about the data that would emerge from the first stage of the study since this might result in pre-conceived ideas and data that would have emerged would be lost. The researcher needs to formulate hypotheses based on conceptual ideas and these can be verified by comparing the emerging data with what has already been obtained (Strauss and Corbin, 1990). The approach also allows the researcher to discover the participants' main concerns. The question the researcher repeatedly asks is 'What's going on?'

The basis of the approach is that the data is read and re-read in order to be able to extract different categories and concepts and explore how these work together within the data. This is also very similar to Thematic Analysis which looks at all the data collected from the different participants as a whole. Thematic Analysis aids in analysing the data and applying different codes. In the case of this study, this was done with Atlas.ti software which was designed to facilitate thematic coding. The first step is to identify general categories and codes (the sub-categories) and to make memos as the data is explored. These memos are important for further discussion of the data. Once the initial coding is complete, the data can be analysed again in order to indicate relationships between the different codes, as can be seen in section 4.4.1.

4.2 Participants

Participants who took part were from three cochlear implant centres in the UK - Southampton, Manchester and Birmingham. The inclusion criteria for participants for the study were:

- 18 years old & above
- English as their first language so as to increase the likelihood participants could understand the questions and were able to answer it themselves without external influences from people who might have been needed to translate the questions
- able to give their own consent because they needed to be able to give permission for the data to be used for research purposes
- had their second cochlear implant for at least 6 months (this was expected to be the length of time required for performance to reach a plateau after a second implantation as described by Kou et al., 1994).

The exclusion criteria were:

- participants who were dependent on other people for everyday tasks (since if someone else filled in their questionnaire there could have been other influences).

The Metropolitan Multi Research Ethical Committee (MREC) gave ethical approval for the study to go ahead. The Audiology Heads of Department approached all the Research and Development departments in the participating hospitals and their approval was obtained too. Further approval was obtained from the University of Southampton Institute of Sound and Vibration Research Human Experimentation Safety and Ethics Committee. A Risk Assessment was also carried out by the Institute of Sound and Vibration Research.

Staff in local services were sent an information letter which explained the purpose for the study and the way the data was going to be collected. They were also sent participant packs (described in section 4.3) and asked to send them to all the patients in their centre who would be eligible to participate. Participants then contacted the researcher directly if they wished to participate.

4.3 The open-ended questionnaire

Questionnaire packs given to participants during the first stage of this part of the research contained an invitation letter to participate in the study, an information sheet, a consent form, a questionnaire and a business-reply envelope. Copies of these can be found in Appendices 1 to 4. The invitation letter was designed to encourage participation in the study. It gave a brief summary of what the study was about and what it would entail for participants. It also emphasised the issue of confidentiality and stated that the staff in local services would not be given any information about

individual patients. It was anticipated that if participants thought the centres had access to individual responses, it might deter participants from giving truthful but negative responses. The information sheets were designed to give a detailed explanation of the study. The purpose of the study was explained and a brief explanation of how participants were chosen was also given. It also reiterated what participants would have to do if they chose to participate in the study. The advantages and disadvantages of the study were explained. The issues of confidentiality and insurance cover for the study, and results of the research study were discussed too.

Table 16 illustrates the participants who took part in this stage of the research.

Table 16: Details of participants in the first stage of the study

Participant number	Age (years)	Gender	Time between implants (months)
1	59	m	27
2	71	f	24
3	84	m	45
4	61	f	12
5	59	f	7
6	71	m	36
7	69	m	21
8	63	m	48
9	62	m	24
10	57	f	24
11	70	m	36
12	72	m	24
13	57	m	36

4.3.1 Open-ended questionnaire design

The aim for this questionnaire was to test which areas are relevant to the topic of bilateral cochlear implantation and which areas can be omitted from the final questionnaire. The information collected in this study was augmented by findings from past research in similar areas and also by examining instruments used to investigate similar areas. The Rolls Royce model described by Guyatt et al. (1986) in section 3.2 was followed in this study and a review of the literature indicated items that participants with one cochlear implant mention in quality of life measures.

The construction of a questionnaire is complex and needs to be evaluated thoroughly. Since this particular questionnaire relates to quality of life measures it has a focus on

attitude factors which are difficult to measure. Detection of changes in attitude through a questionnaire relies on achieving a high degree of internal consistency, reliability and validity. Factors that may influence any of these items include unclear or ambiguous wording and clarity of meaning of questions.

The results of any survey questionnaire are affected by its design. Inaccuracies in recollection of events and their effects on the results should also be taken into consideration during the design phase. It has been reported that people recall incidents in chronological order so a successful question format would also follow this structure to aid success and accuracy of responses.

The open-ended format allows participants to use their own preferred vocabulary and phraseology, and it is less likely that their responses are biased by the questions themselves. Participants might choose to include items for discussion that the researcher did not include in the original questions and it is important to make sure that all the relevant information is investigated. This is only possible when it is certain that the expectations of the researcher did not bias the construction of a questionnaire.

Open questions allow the participants to give any response they would like to give, and in the open-ended questionnaire they were accompanied by blank spaces to encourage a detailed written reply. The questions require the participants to think carefully about their answers and recall relevant information. As a result, such questionnaires can be time consuming to complete and if participants have experienced too many questionnaires, they may feel unmotivated which may affect the overall response rate.

The nature of this study was retrospective since all the participants had already received their second implant. As can be seen in Appendix 4, items at the beginning of the questionnaire were considered by the researcher to be the most 'neutral' and factual questions. These questions were easy to answer and impersonal, for example 'How long have you had your second implant for?'. Attitudinal and more personal questions that required a more emotional response were introduced at a later stage.

The questionnaire consisted of 26 questions in total and the questions were structured in a chronological order to guide the subject through the process of implantation including receiving a second implant. It began with reasons that lead to the decision to have a second cochlear implant, then examined issues on how the participants' life changed as a result of the second implant. This was then followed by questions dealing with a retrospective comparison between having one and two implants, and finally to thoughts and concerns about the future. Participants were encouraged to

express both the positive and negative aspects of having the second implant. Certain key areas were addressed through the questions, based on areas of importance that emerged from a review of the literature. These included social and family relationships and the effect that the second implant had on the personality of the subject.

Every attempt was made to avoid leading questions (for example asking yes/no questions), instead encouraging the participants to initiate the perceived areas of improvement/shortcomings in their lives themselves. The wording of the questions was such that participants were encouraged to construct sentences as opposed to jotting down key words and lists since this would mean that the investigator would then have to interpret these lists and misunderstanding might have arisen from this. A final question at the end of the questionnaire invited the participants to make any further comments and add any relevant information they did not feel was covered in the earlier questions.

4.3.2 Data analysis of the open-ended questionnaire

A response rate of 46% (13 participants) was achieved from the administration of the open-set questionnaires. Participants ranged in age from 57 – 84 years (see Table 16). It was crucial that the data was not vulnerable to interpretation by the researcher and so an illuminative approach to open question response analysis was employed. Each questionnaire was studied to identify key words and statements and these statements were further examined. A matrix was constructed profiling the different aspects that the participants mentioned in their responses. The emerging key words and phrases were then grouped into categories. The data was first separated into advantages and disadvantages of having a second implant. The open response questionnaire was classified within these two major subsections according to keywords and phrases in the text of the responses. Categories were then identified within these two major subsections. These categories were identified to reflect the data. This method of analysis is consistent with the 'grounded theory' where the common categories are broken down into key sub-groups constituting the category to reduce data semantically. The analysis showed there to be nine main categories (see section 4.3.2.1) taking into account all the reported advantages and disadvantages. Some expectations were also mentioned by the participants. The main categories were then divided further to identify concepts that were emerging.

4.3.2.1 Categorisation of data

Categories from the qualitative data collected from the open-ended questionnaire were identified. The advantages section had the following categories: speech perception with lip-reading, speech perception without lip-reading, environmental sounds, psychological, lifestyle and general. Lifestyle was common to both the advantages and

disadvantages sections. There were two other main categories in the disadvantages section: implant issues and music. Most of the participants also spoke about the expectations that they had for their second implant. These formed a third section and it had the following categories: speech perception with lip-reading, speech perception without lip-reading, environmental sounds and psychological.

It is evident that different participants used different words and phrases to describe similar events. This also occurred within the same subject where an event would be described using a certain word and then a different word is used later on in the questionnaire which is related to a similar event. This different wording was classified as a same category.

A single reference made to any issue was marked as a category and every comment that was made within that category was marked with a '1'. This procedure was also carried out for each individual participant. The sum of results per category are displayed in Tables 17, 18 and 19. A mean value of responses per subject for each of the categories was calculated to represent the relative frequency for this group. Tables 20, 21 and 22 show the number of respondents who mentioned the particular sub-group, and the percentage of the total number of respondents within each of the sub-groups for the 'advantages' and 'disadvantages' respectively.

Table 17: Total number of responses in each of the 'advantage' categories

Perceived advantage	Speech perception with lip-reading	Speech perception without lip-reading	Environ-mental sounds	Psycholo-gical	Lifestyle	General
Total	21	50	34	22	26	10
Mean number of responses per subject	1.6	3.8	2.6	1.7	2	0.8

Table 18: Total number of responses in each of the 'disadvantage' categories

Perceived disadvantage	Lifestyle	Cochlear implant issues	Music
Total	7	8	1
Mean number of responses per subject	0.5	0.6	0.07

Table 19: Total number of responses in each of the 'expectations' categories

Expectations	Speech perception with lip-reading	Speech perception without lip-reading	Environmental sounds	Psychological
Total	11	3	15	4
Mean number of responses per subject	0.8	0.2	1.2	0.3

Table 20: Advantages of having a second implant reported by cochlear implant users

Advantages	Number of participants	Percentage of total participants (%)
Speech perception with lip-reading		
One-to-one	2	15
Familiar speakers	3	23
Strangers	1	8
Television/cinema	3	23
General conversations	10	77
Speech perception without lip-reading		
Conversation with car passenger	9	69
Group meeting	9	69
Noisy situation	6	46
Telephone	7	54
Radio	3	23
Environmental sounds		
Alerting	5	38
Music	4	31
Nature	5	38
Localisation	12	92
Warning sounds	1	8
Psychological		
Reduced sense of isolation	3	23
Increased happiness	3	23
Increased energy	1	8
More relaxed	3	23
Reduced depression	1	8
More confident	7	54
Increased independence	8	62
Lifestyle		
Improvement for work	2	15
Improved social life	9	69

Increased independence	4	31
Increased drive	2	15
Better family relationships	3	23
Have an extra cochlear implant in case one fails	2	15
General lifestyle	1	8
General		
Things sound better	4	31
Own voice sounds better	1	8
All round hearing	5	38

Table 21: Disadvantages of having a second implant reported by cochlear implant users

Disadvantages	Number of participants	Percentage of total participants (%)
Lifestyle		
Intrusive to family	1	8
Balance problems	2	15
Not considered as a deaf person any more	1	8
Cochlear implant issues		
Mapping issues	2	15
Imbalance between cochlear implants	3	23
Lack of improvement with second implant	1	8
Rehabilitation issues	1	8
Getting used to second implant	1	8
Practical issues	2	15
Residual hearing lost with second implant	1	8
Music		
Not understanding music	1	8

Table 22: Expectation that the implant users had of their second cochlear implant

Expectations	Number of participants	Percentage of total participants (%)
Speech perception with lip-reading		
Better communication	7	54
Hear in theatre	1	8
More clarity	1	8
Help with one-sided conversations	1	8
Sharper sound	1	8
Speech perception without lip-reading		
Telephone	2	15
Hear in noise	1	8
Environmental sounds		
Directional hearing	9	69

Hear music	4	31
Stereo effect	2	15
Psychological		
Insurance in case first implant fails	2	15
Increased safety	1	8

4.3.3 Limitations to the open-ended questionnaire

Quality of life might not be a simple continuum but the questionnaire attempts to place a person's attitude on a continuum, therefore ignoring the possibility of three-dimensional formations. Even though there is no proof that the questionnaire model is the correct one to capture these different dimensions, this allows it to be quantified for measurement purposes.

Participants also had to base their responses to this questionnaire on recall of the implant process. However, these memories could also be influenced by other contemporaneous factors. Therefore, there remains the possibility that the perceived improvement in quality of life could reflect a factor other than receiving the second cochlear implant. The emotional state of participants when they filled in their questionnaire could have influenced their memory of how the quality of life changed since they received their second implant. This could have been overcome by following patients who have one implant and are undergoing assessment for a second implant but this proved to be difficult to carry out due to time restrictions and location of patients across the UK.

This stage of the study only included participants who had received the Nucleus (Cochlear) cochlear implant. This was not a deliberate choice. This manufacturer started the study looking into the benefits of having a second cochlear implant before the other manufacturers in the UK and therefore the participants wore Nucleus devices. It was not possible to select participants who were still in the work environment since the researcher was not able to choose which participants take part in the study. This might mean that some relevant themes did not emerge in the data. However, the researcher could refer back to the literature and include information that emerged from this source in the final close-ended questionnaire.

4.4 The interviews

The participants who answered the open-ended questionnaire were approached for interviews and 11 agreed to participate in this part of the study. They were given Patient Information Sheets (Appendix 5) and the procedure for the interviews was explained to them.

4.4.1 Data analysis of the interviews

Since the data was not going to be analysed in a way where inter-subject variability would have been an issue, the participants did not need to be matched for any criteria except having received two cochlear implants in a sequential manner. The interviews were carried out in a flexible manner in order to be able to accommodate introduction of issues that were not brought up by the researcher. The information obtained by the open-ended questionnaires was used as a basis to start the interviews but then the individual circumstances of the subject being interviewed at the time was explored in more detail.

Some of the interviews were analysed soon after the interview was carried out as per Corbin and Strauss (2008), but this was not possible for all interviews since a few of them were carried out in a block due to the travel requirements of the researcher. However, notes were made as soon as was practical after the interview was carried out in order to mark interesting observations that might be relevant at subsequent interviews. The researcher attempted to use similar language in all the interviews but some modifications were made when it became clear that some participants needed to be encouraged to explain some issues in more detail. This was deemed to be important in order to fully understand all the relevant issues.

One of the bases of Grounded Theory is that collection of data should stop once saturation point is reached, that is when new categories stop emerging from the data. At the time of this study the number of cochlear implant participants in the UK who had received their bilateral cochlear implants sequentially was limited due to funding issues. Therefore only eleven interviews were carried out. However, once the transcripts were analysed, it emerged that the major categories had been developed and therefore saturation point was close to being reached. Therefore the limited number of participants available did not affect the outcome of the project. It must be acknowledged that complete saturation is hardly ever reached but one must determine when considerable depth would have been achieved and stop the data collection (Corbin and Strauss, 2008).

Once the data was transcribed, the researcher read through the transcripts in order to gain a general idea of what was said within the whole group (Corbin and Strauss, 2008). Once this was done, the data was examined in more detail and codes and categories began to emerge. The data was analysed using a combination of methods. Manifest-content analysis and latent-content analysis are two ways that coding can be carried out (Boyatzis, 1998). Manifest-content analysis is based on taking language that is used by the participants at face value. Latent-content analysis involves looking at the language that is used and trying to understand the deeper meaning of what is

being said. Both methods were used for this project since the issues related to quality of life were regarded as personal and emotional, therefore also requiring in-depth analysis. The combination of methods also allowed for codes to be combined together to form more generic ones.

The codes that were created were built on connected speech and not single words. By doing this, the whole utterance was meaningful and the coding manual could be revised to make sure that all the codes that were present in the text did emerge. The same utterances also created different codes – multiple coding. These were at times related but there were instances when this did not happen (for example '*The directionality gives you more confidence*' related to localisation of sound and levels of confidence). One disadvantage of multiple coding is that this could lead to a complicated analysis if too many codes overlapped (Boyatzis, 1998; Corbin and Strauss, 2008). However, this did not occur in this project.

The coding procedure was carried out using the Atlas.ti software. A coding manual was created using the data from all the interviews. This allowed the data from each participant to remain separate but the codes to be combined together as if they came from one set of data. Appendix 6 illustrates an example of data from different participants being combined together in codes. The data was reviewed twice by the researcher in order to make sure that codes were not missed out. An independent coder was asked to review two of the interviews. This was done to make sure that the codes that were emerging were reliable and consistent (Boyatzis, 1998). The second coder did not have any previous experience of working with cochlear implant patients and was not aware of the codes that had emerged through the initial analysis carried out by the researcher. This had the advantage that he was not influenced by his own experience of working with these patients and was looking at the data as new information. Inter-coder consistency of higher than 70% is deemed to be acceptable (Boyatzis, 1998). This would reflect consistency of judgement in the data analysis. The two interviews that were analysed by the second coder were compared to the original analysis carried out by the researcher and the codes and categories were compared to see if these emerged in both set of analysis. The inter-coder reliability was established at 94.2%

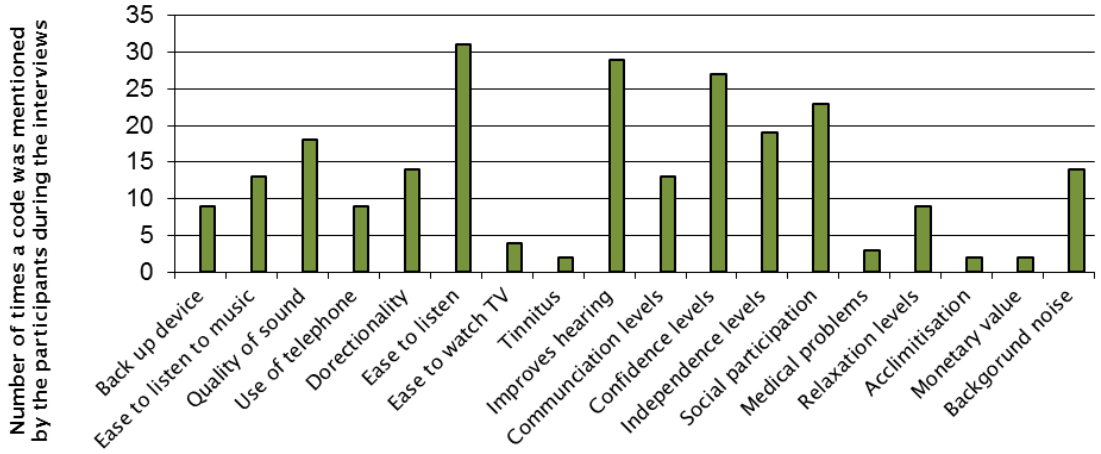
Once the codes started to emerge, these were put into categories. The categories were similar to those that had emerged from the open-ended questionnaires. These can be seen in Table 23.

Table 23: Categories and codes resulting from interview data

Category	Code
Communication	hearing levels
	communication
	listening in background noise
	use of telephone
	quality of sound
Everyday sounds	ease of listening
	ease of listening to music
	ease of watching TV
	directionality
Happiness and well-being	level of confidence
	more relaxed
Lifestyle and social relationships	level of independence
	participation in social activities
Cochlear implant issues	medical problem post second cochlear implant
	acclimatisation to having two cochlear implants
	back up device
Other	monetary value
	level of tinnitus

Figure 2 illustrates the list of codes with number of occurrence in each interview. The greatest percentage (32%) of codes comes from the happiness and well-being, and lifestyle and social relationships categories. These are the categories that solely relate to quality of life issues.

Figure 2: List of codes with corresponding number of times that these were mentioned during the interviews



The general theme of the interviews was that the major improvement in the participants' quality of life was after they received the first cochlear implant. However, all the participants agreed that benefit from the second cochlear implant added to that of the first and had an impact on their life. All of the participants except one had stopped working by the time the interviews were held. However, one subject said that she started helping again at the bingo hall. This was a job that she had enjoyed doing before she became profoundly deaf but had stopped doing and did not feel that she could go back to do even when she had one implant.

'At work they were not able to always give me verbal instructions but it is different now.'

Some participants commented that listening to other people had become easier following receiving a second implant due to knowing where sounds were coming from and in turn this made conversations more pleasant.

'Because with one all the sounds are confusing, I had to look around a lot, whereas now I don't look around as much and it makes things more easy and relaxing.'

Participants mentioned that they felt they had access to more sounds.
'I found that (with two implants) I could pick that bit much more in a conversation that it makes it easier to communicate in places like banks, and airports.'

This also affected their confidence levels.

'The main difference is that now I am confident to baby sit for my family.' (This participant was asked if she was more confident to babysit her grandchildren because the children were older but she mentioned that there were some new grandchildren who needed her input more than the older ones).

'If people stop me to ask for directions I'll stop and help them and then come home and say 'guess what I did today'… whereas before I would have just said 'sorry I'm deaf I can't help you'. And that was when I had one implant. I have now actually gone up to people when they are looking lost and said 'can I help you?' I would have never done that before.'

Increase in independence as a result of increase in confidence and ability was also mentioned by participants and one of them said *'I'll go to the shops now without a care in the world - I had stopped doing that.'*

One of the participants who was interviewed described having two cochlear implants as:

'Emm, hearing one sided - how can one describe what it is to hear….. To have one implant is like having a meal of well-cooked plate of chips but to have two implants is like having a meal on Mount Olympus. One implant is a star; two implants are diamonds and stars together.'

Total saturation of newly emerging categories is an unrealistic goal (Corbin & Strauss, 2008), but after analysis of the interview data, it was decided that there were no new major themes or categories emerging. One issue to note is that the majority of the participant population had retired from work. There is a possibility that some themes related to this situation did not emerge completely, therefore. One of the participants was still working and two others were doing voluntary work. It was felt that the themes that emerged as a result of these interviews covered the general work environment.

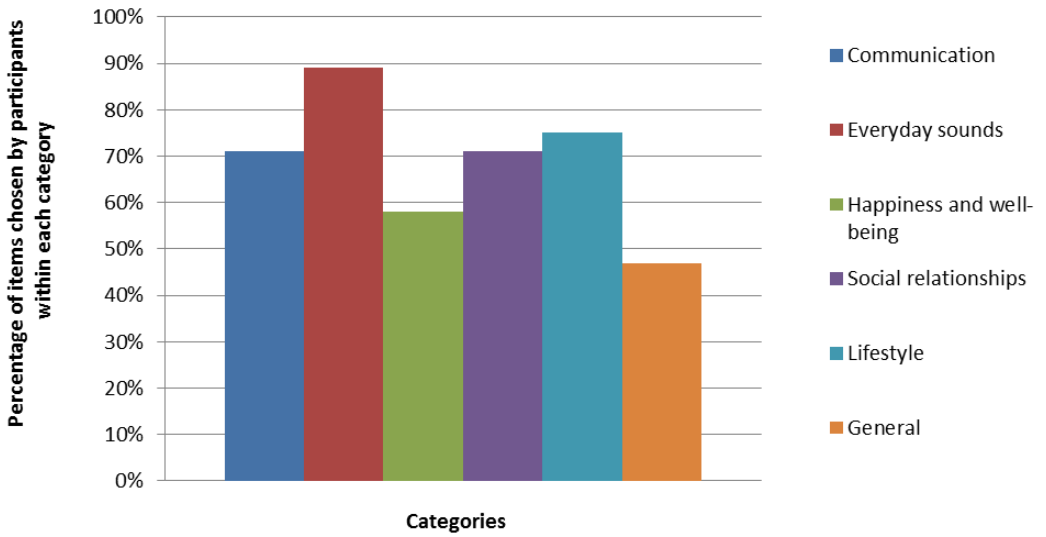
4.4.2 Feedback regarding results from the open-ended questionnaire during the interview stage

The first stage of this research involved the participants answering some open-ended questionnaires which yielded the basis on which the new questionnaire would be built. The responses from the questionnaires generated 74 separate statements in the different categories that the questionnaire included. The first stage of refinement was to ask the participants to go through the questions and give their opinion on whether the statement ought to be included in the questionnaire or if it could be left out. They were asked to base this decision on the semantics of the statement: was the topic already asked/discussed in a separate statement? Each statement was put on an individual card and the participants were asked to put them in separate piles according to whether they wanted them included or not. They were asked not to judge on whether they agreed with the statement but to think of the relevance of the issue it raised. This was emphasised on a number of occasions during the interviews. Completion of this task also generated some discussion about some of the statements which were included in the interviews. Ruiz et al. (2008) carried out focus groups in order to determine the pertinence of the items which were initially included in their questionnaire as a result of discussion with experts. This method was not practical in this instance since the participants lived across the UK and the researcher thought that it would be very disruptive to ask them to travel extensively for a focus group.

Out of the 74 statements, participants chose to keep 48 in the questionnaire. This is 66% of all the questions that the open-ended questionnaire had yielded. Figure 3 illustrates how many statements were chosen in the individual categories. The

'General' category combined the sections that dealt with the process of having a second implant and also the effects of having a second implant during the open-ended questionnaire stage.

Figure 3: Statements chosen by participants to be in closed-ended questionnaire



The three sections which ask questions about the aspects of quality of life – happiness and well-being, social relationships and lifestyle – had the biggest retention level. These three sections have 18 questions out of the 48 in total, which is 37.5%.

4.4.3 Sources of possible bias

The participants' mood on the day of the interview/questionnaire completion would have played a role in the type of responses that were given. Even if the participants mentioned that they were not having a favourable day, it would have been hard to quantify the effect that this would have on the data collected. Effects of memory also play an intricate role in questionnaire and interview responses that require recollection of the status of something (in this case quality of life) having changed. The response may be associated with unrelated experiences which at the time of completing the questionnaire may not be remembered.

The researcher addressed all the questions to the participants themselves but in eight out of eleven interviews the subject's significant other was also present in the room whilst the interview took place. This led to the significant other offering his/her opinion about a particular issue or introducing a new issue. The researcher always

attempted to draw the subject back to the topic under discussion but certain topics introduced by the significant other were investigated further too.

4.5 Transferring codes and statements into questionnaire items

The information from the open-ended questionnaire and interviews was collated in a table (Table 24). This table also illustrates which statements were chosen to be included in the first version of the questionnaire. Their selection was based on a combination of whether the item was mentioned in the interviews and whether the participants wished it to be retained from the original list of statements that originated from the open-ended questionnaire. The table also offers some explanation for the retainment of certain items. For example, the statement that involved the appreciation of music was retained since the researcher noticed that this was given a high importance value during the interview process. The value of the statement was given more importance than the amount of times it was mentioned. The question related to work was also included in the questionnaire. It was noted that a number of participants who took part in the study did not work due to their age but it was felt that this concept was important if the questionnaire was to cover different aspects of people's lives, and be relevant for use with adults younger than the participants in this study.

Table 24: Information collated from open-ended questionnaire and interviews leading to statements to be included in final questionnaire

No.	Summary of statement obtained from responses to open-ended questionnaire	Issue mentioned in interviews	Issue covered by another statement	Participants thought item should be included	Participants thought item should not be included	Inclusion in questionnaire Version 1.0
1	Aiding lip-reading	√	5, 8	3	8	X - Covered by another statement
2	Control of volume of own speech	X		9	2	X- Not deemed to be related to QoL
3	Conversations on the telephone	√	14	9	2	√ - Mentioned in interviews and chosen by participants as important item
4	Help in understanding people	√		11	0	√ - Mentioned in interviews and chosen by participants as important item
5	Relying on lip-reading	√	1, 8	8	3	√ - Mentioned in interviews and chosen by participants as important item
6	Understanding more speech sounds	√		11	0	√ - Mentioned in interviews and chosen by participants as important item
7	Confidence to initiate conversations	√		11	0	√ - Mentioned in interviews and chosen by participants as important item
8	Less dependent on lip-reading	X	1, 5	5	6	X - Covered by another statement
9	Joining in group discussions	√	10	10	1	√ - Mentioned in interviews and chosen by participants as important item
10	Difficulty in joining conversation when many people are speaking	√	9	4	7	X - Covered by another statement
11	Improvement in clarity of speech	X		6	5	√ - Chosen by participants as important item

12	Listening to the radio	√		6	5	√ - Mentioned in interviews and chosen by participants as important item
13	Appreciation of jokes and humour	X		5	6	X - Issue not mentioned in interviews and item not chosen by participants
14	Telephone use	√	3	5	6	X - Covered by another statement
15	Understanding the TV	√		9	2	√ - Mentioned in interviews and chosen by participants as important item
16	Distinguishing between voices	√		11	0	√ - Mentioned in interviews and chosen by participants as important item
17	Discriminating speech sounds from background noise	√	18, 25	11	0	X - Covered by another statement
18	Ease to carry out a conversation in background noise	√	17, 25	11	0	√ - Mentioned in interviews and chosen by participants as important item
19	Conversations with a passenger in a car	√		10	1	√ - Mentioned in interviews and chosen by participants as important item
20	Hearing at the cinema	X		3	8	X - Issue not mentioned in interviews and item not chosen by participants
21	Sound of own voice	X		4	7	X - Issue not mentioned in interviews and item not chosen by participants
22	Awareness of everyday sounds	√		7	4	√ - Mentioned in interviews and chosen by participants as important item
23	Discrimination between more everyday sounds	√		6	4	√ - Mentioned in interviews and chosen by participants as important item
24	Music appreciation	√		4	7	√ - Mentioned by a great number of participants during interviews
25	Avoidance of background noise situations	√	17, 18	8	3	X - Covered by another statement
26	Ability to hear warning sounds	X		9	2	√ - Mentioned in interviews and chosen by participants as important item

27	Ability to hear sounds of nature	√		9	2	√ - Mentioned in interviews and chosen by participants as important item
28	Better location of sounds	√		10	1	√ - Mentioned in interviews and chosen by participants as important item
29	Sharpness of sounds	√	30	10	1	X - Covered by another statement
30	Clarity of sounds	√	29	10	1	√ - Mentioned in interviews and chosen by participants as important item
31	Feeling more cheerful	√		10	1	√ - Mentioned in interviews and chosen by participants as important item
32	Feeling less lonely	√		8	3	√ - Mentioned in interviews and chosen by participants as important item
33	Being the same person as before losing hearing	√		10	1	√ - Mentioned in interviews and chosen by participants as important item
34	Increase in confidence levels	√		11	0	√ - Mentioned in interviews and chosen by participants as important item
35	Change in level of depression	X		7	4	√ - Chosen by participants as important item
36	Change in energy level	X		4	7	X - Issue not mentioned in interviews and item not chosen by participants
37	Feelings of frustration related to expectations	X	70, 72	4	7	X - Issue not mentioned in interviews and item not chosen by participants. The theme of this statement would also be covered in other statements left in the questionnaire
38	Adjusting to life with two implants	X		4	7	X - Issue not mentioned in interviews and item not chosen by participants
39	Feelings of disappointment with two implants	X	41	2	9	X - Issue not mentioned in interviews and item not chosen by participants. The theme of this statement would also be covered in other statements left in the questionnaire
40	Change in level of self-esteem	√		11	0	√ - Mentioned in interviews and chosen by participants as important item

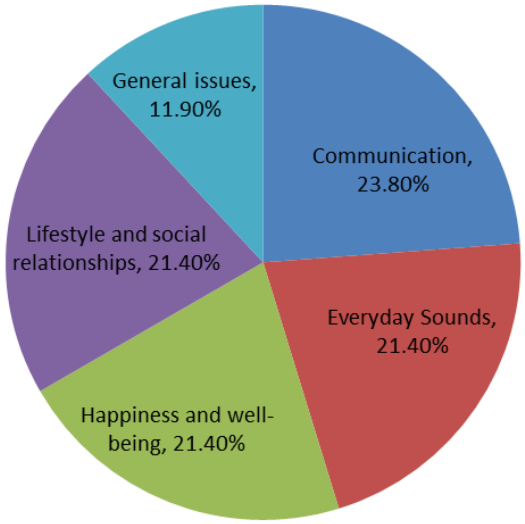
41	Feeling of disappointment related to progress with second implant	X	39	3	8	X - Issue not mentioned in interviews and item not chosen by participants. The theme of this statement would also be covered in other statements left in the questionnaire
42	Sense of security in having two implants	√	66	10	1	X - Covered by another statement
43	Change in desire to join in more social activities	√		10	1	√ - Mentioned in interviews and chosen by participants as important item
44	Regaining more close relationships	√		7	4	√ - Mentioned in interviews and chosen by participants as important item
45	Feeling pressured by other people's high expectations	X		4	7	X - Issue not mentioned in interviews and item not chosen by participants
46	Willingness of other people to initiate conversation	√		7	4	√ - Mentioned in interviews and chosen by participants as important item
47	Benefit of bilateral implantation to family members	√		9	2	√ - Mentioned in interviews and chosen by participants as important item
48	Change in confidence to approach others	√		11	0	√ - Mentioned in interviews and chosen by participants as important item
49	Avoidance of social events	X		2	9	X - Issue not mentioned in interviews and item not chosen by participants. The theme of this statement would also be covered in other statements left in the questionnaire
50	Change in independence level	√	53, 54	11	0	√ - Mentioned in interviews and chosen by participants as important item
51	Feeling self-conscious wearing two devices	X		3	8	X - Issue not mentioned in interviews and item not chosen by participants. The theme of this statement would also be covered in other statements left in the questionnaire
52	Help at work from having two implants	√		10	1	√ - Mentioned in interviews and chosen by participants as important item
53	Dependence on others in certain	X	50,	8	3	X - Covered by another statement

	situations		54			
54	Ability to do activities on one's own	√	50, 53	10	1	X - Covered by another statement
55	Change in being sociable	√		10	1	√ - Mentioned in interviews and chosen by participants as important item
56	Change in confidence in driving	√		7	4	√ - Mentioned in interviews and chosen by participants as important item
57	Annoyance at having to wear more external equipment (processors)	X		1	10	X - Issue not mentioned in interviews and item not chosen by participants. The theme of this statement would also be covered in other statements left in the questionnaire
58	Level of intrusion of having the second assessment and surgery	X		0	10	X - Issue not mentioned in interviews and item not chosen by participants
59	Level of support from family and friends	√		7	4	√ - Mentioned in interviews and chosen by participants as important item
60	Level of disappointment at initial stages after getting the second implant	X		4	8	X - Issue not mentioned in interviews and item not chosen by participants
61	Difficult in adjusting to the sound of the second implant	√	64, 74	5	6	√ - Issue mentioned in several statements and interviews
62	Benefits of two implants compared to minor problems	√		9	2	√ - Mentioned in interviews and chosen by participants as important item
63	Effects on balance system	√		5	6	X - Issue not mentioned in interviews and item not chosen by participants
64	Effects of any imbalance between the two implants	√	61, 74	3	8	X - Issue not mentioned in interviews and item not chosen by participants. The theme of this statement would also be covered in other statements left in the questionnaire
65	Effects of losing residual hearing	X		4	7	X - Issue not mentioned in interviews and item not chosen by participants

66	Feeling that the second implant serves as an insurance	√	42	7	4	√ - Mentioned in interviews and chosen by participants as important item
67	Feeling that life is fuller	√		8	3	√ - Mentioned in interviews and chosen by participants as important item
68	Level of optimism about the future	√	73	10	1	X - Covered by another statement
69	Concerned about the long-term effects of electrical stimulation	X		4	7	X - Issue not mentioned in interviews and item not chosen by participants
70	Expectations from second implant	X	37, 72	2	9	X - Issue not mentioned in interviews and item not chosen by participants. The theme of this statement would also be covered in other statements left in the questionnaire
71	Advice to other people interesting in bilateral implants	√		10	1	√ - Mentioned in interviews and chosen by participants as important item
72	Expectations from second implant	√	37, 70	11	0	√ - Mentioned in interviews and chosen by participants as important item
73	Outlook on life	√	68	11	0	√ - Mentioned in interviews and chosen by participants as important item
74	Effects of adapting to listen with two cochlear implants	√	61, 64	3	8	X - Issue not mentioned in interviews and item not chosen by participants. The theme of this statement would also be covered in other statements left in the questionnaire

Based on these responses, the first version of the questionnaire was established as seen in Appendix 7. Version 1.0 of the questionnaire had 42 statements. The breakdown of this questionnaire can be seen in Figure 4.

Figure 4: Breakdown of item numbers included in questionnaire version 1.0



Content validity ensures that a scale covers all the aspects that are relevant to the topic that is being investigated and it also needs to ensure that there are enough items to fully investigate it (Streiner and Norman, 1989). This aspect of a scale can change over time as more information emerges about the topic being investigated. It is an effective procedure to begin with a large number of items to be included and review them with the intent of removing items that do not need to be included in the final scale. This can be achieved via use of a variety of statistical tests, for example correlation analysis. The results from the open-ended questionnaires and data produced from the interviews were deemed to provide an important step towards achieving good content validity for the new questionnaire. These, together with a detailed literature review, ensured that at least most of the aspects relevant to the topic of this research would be included in the questionnaire.

4.6 Questionnaire scaling

A Likert Scale was used for this questionnaire (a description of Likert scales can be found in section 3.2.2). The number of response options that is given should be influenced by the purpose of the questionnaire. Different authors explain how different scales offer different levels of information. Streiner and Norman (1989) recommend between 5 and 15 options or a visual-analogue scale. For the purpose of this study, a 5-point Likert scale was used since a greater number of options might

have made the differences non-distinguishable (Bowling, 1991; Oppenheim, 1992). Having an odd number of responses allowed the researcher to include a neutral position ('neither agree nor disagree') for those situations which were not applicable to particular participants. This was considered to be necessary in this questionnaire since not all questions would be applicable to all participants, depending on their lifestyle. Version 3.0 of the questionnaire had the neutral position as 'no change' since the questionnaire was a 'change' questionnaire.

A decision was made to word the questionnaire items in a manner that discouraged participants to give the same answer to all the questions. This was achieved by phrasing some of the items in a positive manner and some in a negative manner.

A criticism of the Likert Scale is that there is a possibility that the same total score can be obtained in many different ways (Oppenheim, 1992). As part of good clinical practice, clinicians are always encouraged to look at the pattern of responses (or sub-scale scores) rather than just the total score, before making inferences based on those scores.

4.7 Face validity

Once the first version of the questionnaire was developed, pre-testing was carried out to ensure that it was easy to read and follow, and not ambiguous. Once this was achieved, the next step was to work on statistical refinement of the questionnaire to ensure that it fulfils the psychometric properties desirable in a questionnaire.

Some literature suggests that this step can be redundant (Oppenheim, 1992). However, it was thought that if patients find the questionnaire difficult to read and complete, this would have an adverse effect on its success. If patients scored the questionnaire without having fully understood what is being asked of them, this would make the scale unreliable and clinicians would lose trust in it.

The pre-testing was carried out by some of the participants who took part in the interviews. All 11 participants were sent a copy of the first version of the questionnaire and seven of them replied with their comments. It was recognised that using the same participants that participated in the interviews might introduce some bias since the topic had already been discussed in detail. However, due to the limited number of participants who were able to take part in this study, it was decided to use their responses. Their comments were quite wide-ranging and therefore could be considered valid for the purpose of this study. The participants were asked to review the questionnaire and make comments about its format and content. They were asked

to write the comments on the questionnaire itself and return this to the researcher. Participants would be concerned about the relevance of the content to their experience.

The general comments that were made in the feedback were that the questionnaire covered their experience with having two cochlear implants. Some participants also commented that it asked them questions that were relevant to their experience but they had not thought about them themselves. Several of the participants also completed the questionnaire.

One of the participants asked for the instructions to be clearer about the fact that this questionnaire is looking specifically at the difference between having two cochlear implants to having just the one.

Four out of the seven participants who replied were concerned about the number of statements that were worded in a negative way. They reported that they found this wording difficult to understand throughout the questionnaire.

The face validity feedback of Version 1.0 (Appendix 7) prompted some modifications to the questionnaire resulting in Version 2.0 (Appendix 8). The changes were mainly to clarify the instructions at the beginning of the questionnaire, and some of the layout. A few other statements needed to be modified to be made clearer and more easily understood. The researcher also thought that by splitting the questionnaire into different sections, it would make it more obvious to the patient which section of quality of life was being explored.

Version 2.0 of the questionnaire was given to some staff members of the South of England Cochlear Implant Centre and they were asked to review it. Some changes were made to the questionnaire which resulted in Version 3.0 (Appendix 9). The main changes were to the response format. Since the structure of the statements was changed to 'Compared to when you have one cochlear implant….', the response needed to be changed to reflect this. Since the questionnaire was a 'change' questionnaire, the middle point was created to reflect a 'no change' and the ends show a change to the better or worse.

The objective of the face validity stage of the development of this questionnaire was to make the final scale more user-friendly and easier to administer than previous versions.

4.8 Questionnaire scoring

As mentioned in section 3.2.2.1, scale scoring can pose some problems and a decision needed to be made whether to give the same scoring to all the items or score the items according to their level of importance. Scoring all the items on the same level was chosen since the questionnaire was envisaged to be used as part of a discussion between clinician and patient. The scoring of items and sub-scales within the questionnaire would identify the areas of importance for the rehabilitation process and inform the discussion between patient and clinician. In a clinical setting it can be beneficial to use a simple and effective scoring system such as this.

Some items were worded in a positive manner whereas some were worded in a negative way. This affected how these items are scored. Items worded in a positive manner were scored as -2, -1, 0, +1 and +2; but if the item was worded in a negative manner the scoring was reversed, for example item no. 2 in Version 3.0.

4.9 Conclusions

This chapter describes the results obtained from the open-ended questionnaires and interviews carried out with the participants. A number of themes emerged from the analysis of these questionnaire and interviews that indicate the effect of having two cochlear implants on the lives of participants and their families. Some of these themes are found in the literature when the effects of unilateral cochlear implantation have been discussed. Further changes in these areas of life were mentioned by participants in this study when bilateral implantation was discussed. These themes were transferred into a close-ended questionnaire which is further examined regarding its psychometric properties in the next chapter.

Chapter 7 discusses the results obtained from the open-ended questionnaire and interviews in view of fulfilling the first objective of this study – to investigate the changes in a patient's quality of life when they receive a second cochlear implant compared to one implant.

Chapter 5. Questionnaire refinement

5.1 Introduction

Participant responses from the open-ended questionnaire and interviews led to the development of Version 3.0 of the close-ended questionnaire. The aim for this part of the study was to refine and finalise the questionnaire before its psychometric properties were investigated.

The questionnaire (version 3.0) had 42 items and it was intended for use in clinical situations. Therefore it was important to consider if any of the items could be eliminated to make its administration as time efficient as possible and to ensure that there is no redundancy in the items in the questionnaire. Correlations between items and their reliability were investigated to help with item reduction. Factor analysis was carried out to ensure that items were grouped in a meaningful way. Finally, internal consistency was investigated to demonstrate that the questionnaire had good construct validity.

5.2 Participants

Once ethical approval was obtained, participants were recruited from three cochlear implant centres in the UK (Southampton, Manchester and Birmingham). The recruitment criteria were the same as those for the first part of the study (section 4.2). Forty-five participants were eligible to participate and they were all approached via an Invitation Letter which was sent via the centre which was responsible for their care (Appendix 10). Twenty-five participants replied (55%) and took part in this part of the study. They were sent a copy of Version 3.0 of the questionnaire and asked to complete it, then a second copy of the same questionnaire a month later. Three participants required a reminder letter and this led to a 100% return rate for the second questionnaire.

5.3 Data analysis

When the questionnaires were returned by the participants, they were scored and the data was analysed both using statistical methods and subjectively by the researcher. Due to the scarcity of adult sequentially implanted users in the UK, the number of participants in this study was limited. This meant that item reduction would be done via statistical analysis combined with subjective analysis by the researcher since the statistics had limited power. The subjective analysis also ensured that the final item list included items which would be meaningful to the patient population that was being targeted with this questionnaire.

5.3.1 Tests for normality

A combination of histograms, measures of skewness and kurtosis were used to check if the data was distributed normally. As this was a small study, sample data may not be normally distributed, and the histograms that were examined confirmed this assumption. However, since interpretation can be subjective, skewness and kurtosis were also investigated. The values for skewness were mainly negative which showed an increased number of high scores. Both skewness and kurtosis indicated that the data was not normally distributed since the values were not close to zero. The Kolmorgov-Smirnov and Shapiro-Wilk tests were also carried out. Results for both these tests showed that the data was not normally distributed ($p < 0.05$). Therefore non-parametric tests were used.

5.3.2 Item reduction

5.3.2.1 Test-retest analysis

Test-retest analysis of each item was carried out at this stage, whereas the test-retest of the whole questionnaire was carried out in the next stage of the project. The purpose for carrying out test-retest analysis of each item was to help with the item reduction.

Two items (6 and 33) were found to have low repeatability so were removed from the questionnaire.

5.3.2.2 Correlations between items

Kendall's tau and Spearman's correlation coefficient are non-parametric measures and both were used since even though they are similar, they cater for different sample sizes. These gave similar results but the results from Kendall's tau were used since the sample size was small (Field, 2009). There is also some evidence in the literature to show that this measure is a better estimate of correlations in populations (Field, 2009).

Correlations higher than 0.6 were used as a guide when making a decision for an item to be removed from the final questionnaire on account of redundancy. Some items were still retained even if they had a high correlation with other levels, based on the subjective opinion of the researcher in relation to the importance of the concept that the item represented. Two items that are correlated do not necessarily give the same information (Field, 2009). This can be seen, for example in items 21 and 22. Item 21 relates to extent of loneliness and item 22 is related to whether the respondent thinks s/he feels like their old self – these two concepts are not intrinsically related even though they are correlated to each other. Opinion was influenced by the clinical

experience of the researcher and discussion with other clinicians in the field of cochlear implantation (members of staff at the South of England Cochlear Implant Centre, SOECIC).

Table 25 summaries the justification for the decision on whether to retain or reject the items in the final questionnaire. This is based on a combination of the reliability of the item, standard deviation and correlation with other items. As a result of this analysis nine items were rejected from the questionnaire.

Table 25: Justification for decision on retention or rejection of item from questionnaire

	Reliability	Correlation more than 0.6 (0.01 level)	Retain	Rationale
1.	Compared to when I had one cochlear implant, I can now understand speech sounds			
	0.102	Q3, 11, 20, 27, 41	x	High correlation with other questions
2.	Compared to when I had one cochlear implant, I now rely on lip-reading			
	0.705	Q3, 25, 33	✓	Q3, 33 not retained. Q25 refers to a possible effect of Q2
3.	Compared to when I had one cochlear implant, I now understand people			
	0.739	Q1, 2, 6, 23, **25**	x	High correlation with other questions
4.	Compared to when I had one cochlear implant, I now can distinguish between voices			
	0.527		✓	
5.	Compared to when I had one cochlear implant, I can now carry out a conversation in background noise			
	0.739	Q6	✓	Q6 removed
6.	Compared to when I had one cochlear implant, I am now confident in starting conversations with people I don't know well			
	0.035	Q3, 5, 7, 22, 25, 27, **33**	x	Poor reliability, high correlation with other questions
7.	Compared to when I had one cochlear implant, I now join in group discussions			
	0.096	Q6, 21	✓	Q6 removed, Q21 refers to a possible effect of Q7
8.	Compared to when I had one cochlear implant, the clarity of my speech is			
	0.285		✓	
9.	Compared to when I had one cochlear implant, carrying out a general telephone conversation is			
	0.458		✓	Even though there is no trend in the population, it is important for individuals
10.	Compared to when I had one cochlear implant, conversations in a car are			
	0.739		✓	

11.	Compared to when I had one cochlear implant, I am now aware of everyday sounds			
	0.180	Q1	✓	Q1 removed
12.	Compared to when I had one cochlear implant, I am now able to discriminate between everyday sounds			
	0.157	Q13	✓	Q13 removed
13.	Compared to when I had one cochlear implant, the clarity of sounds has become			
	0.366	Q12	x	Retaining Q12, high correlation
14.	Compared to when I had one cochlear implant, I now enjoy listening to speech programmes on the radio			
	0.480		✓	
15.	Compared to when I had one cochlear implant, I can now understand the television			
	0.414		✓	
16.	Compared to when I had one cochlear implant, I now can enjoy music			
	0.564		✓	
17.	Compared to when I had one cochlear implant, I can now hear warning sounds			
	0.527		✓	
18.	Compared to when I had one cochlear implant, I can now enjoy the sounds of nature			
	1.000		✓	
19.	Compared to when I had one cochlear implant, I am now able to tell immediately where sounds are coming from			
	0.589		✓	
20.	Compared to when I had one cochlear implant, I am now cheerful			
	0.257	Q1, 21, 22, 27, 28, 30, 33	✓	Important concept
21.	Compared to when I had one cochlear implant, I now feel lonely			
	0.527	Q20, 22, 24, 33	✓	Important concept
22.	Compared to when I had one cochlear implant, I now feel like my old self			
	0.102	Q6, 21, 33	✓	Important concept
23.	Compared to when I had one cochlear implant, I am now a confident person			
	0.705	Q3, 20, 21, 23, 33	✓	Important concept
24.	Compared to when I had one cochlear implant, I now feel depressed			
	0.655	Q21, 22, 25, 27, 21	x	High correlation, Q21 very similar concept
25.	Compared to when I had one cochlear implant, my self-esteem is			
	0.257	Q6, 21, 23, 27, 33	✓	Important concept
26.	Compared to when I had one cochlear implant, I now worry about having an implant failure			
	0.783		✓	
27.	Compared to when I had one cochlear implant, I now feel my life is fuller			
	0.206	Q6, 20, **22**, 23, **33**, 36	x	Too generic, high correlation

28.	Compared to when I had one cochlear implant, I now look upon life in a positive manner			
	0.414	Q29, 33	✓	
29.	Compared to when I had one cochlear implant, I now have a desire to join in with social activities			
	0.480	Q7, **27**, 28, 33, 36	✓	Highly correlated Q removed
30.	Compared to when I had one cochlear implant, I now have close relationships			
	0.705	Q20	x	High correlations
31.	Compared to when I had one cochlear implant, people are now willing to talk to me			
	1.000	Q11	✓	
32.	Compared to when I had one cochlear implant, I feel that others close to me have benefited from me having cochlear implants			
	0.763	Q33	✓	Q33 removed
33.	Compared to when I had one cochlear implant, I am now confident to approach others			
	0.059	Q2, 20, 21, 22, **23**, **25**, **27**, 28, 29, 32, 36	x	Poor reliability, high correlation with other questions
34.	Compared to when I had one cochlear implant, my independence is			
	1.000		✓	
35.	Compared to when I had one cochlear implant, I experience difficulties at work			
	0.739		✓	Even though participants commented that they did not work, this was a reflection of the population age, important for general population
36.	Compared to when I had one cochlear implant, I am now sociable			
	1.000	Q22, 27, 29, 33	x	Similar concept to Q29
37.	Compared to when I had one cochlear implant, I am now confident driving a car or another vehicle			
	0.102		✓	Even though participants commented that they did not work, this was a reflection of the population age, important for general population
38.	Compared to when I had one cochlear implant, my family and friends need to support me			
	0.317		✓	
39.	Compared to when I had one cochlear implant, the difficulty initially adjusting to the sound of the second cochlear implant was			
	1.000		✓	
40.	Compared to when I had one cochlear implant, I now feel that the benefits of having cochlear implants outweigh any disadvantages			
	0.250		✓	There is no trend in the population, but it is important for individuals

41.	Compared to when I had one cochlear implant, I now feel that my implants have exceeded my expectations			
	0.206	Q1	✓	
42.	Compared to when I had one cochlear implant, the strength of my positive recommendation to another person thinking about a second implant would be			
	1.000		✓	

5.3.3 Factor Analysis

Factor analysis can be used to identify the separate factors within a scale. This occurs because questions in the same questionnaire do not necessarily tap the same dimensions and therefore they might not have high item-total or full item-total correlations (Field, 2009; Bowling, 2001). Factor analysis is a technique which estimates a small number of underlying dimensions (factors that account for a high proportion of the common variance of the items). Therefore it demonstrates whether items group together in a consistent and coherent way (Bowling, 2001). A factor is considered important, and its items worthy of retaining in the scale, if its eigenvalue (a measure of its power to explain variation between subjects) exceeds a certain value. This value should be 1.1 but 1.5 is commonly reported in the literature (Field, 2009; Bowling, 2001).

Once nine items were removed from the questionnaire, factor analysis was carried out on the remaining 33 items. Varimax rotation was chosen to maximise the dispersion of loadings within factors (Field, 2009). This would leave the results more easy to interpret. The sample size was small so there was a concern that the factor solutions would not be reliable. However, Field (2009) has argued that if a factor has at least four loadings that are at least 0.6, then the factor can be considered as reliable regardless of the sample size. The Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) was also investigated to check reliability of the factor loadings. The value for this test was 0.787 which shows that factor analysis was suitable.

The factor loadings after rotation are shown in Table 26, where sets of items interpreted as forming a factor are sorted by factor. Key factor loadings are shown in bold.

Table 26: Factor loadings for items after rotation

Questionnaire item	Factor					
	1	2	3	4	5	6
Q16 – enjoyment of music	**0.87**					
Q14 – listening to speech programmes on the radio	**0.87**					
Q18 – enjoyment of nature sounds	**0.74**	0.49				
Q15 – understanding television	**0.64**	0.43				
Q42 – recommending second implant to others	**0.63**	0.44				
Q28 – looking upon life in a positive manner	**0.61**			0.43		
Q10 – conversations in a car	**0.53**				0.52	
Q12 – discrimination between everyday sounds	**0.53**	0.52				
Q19 – location of sound	**0.51**		0.43			
Q9 – telephone conversations		**0.80**				
Q11 – awareness of everyday sounds		**0.63**			0.48	
Q17 – ability to hear warning sounds	0.59	**0.61**				
Q25 – change in self-esteem		**0.61**				
Q31 – willingness of others to talk to implant user		**0.59**			.40	
Q32 – benefit of bilateral implantation to family and friends		**0.59**	0.47			
Q20 – change in feeling cheerful	0.40	**0.59**				0.43
Q5 – ability to carry out conversation in background noise	0.46	**0.56**	0.41			
Q23 – change in confidence levels	0.43	**0.55**	0.42			
Q2 – reliance on lip-reading		**-0.55**	-0.46			
Q8 – change in clarity of own speech		**0.51**		0.46		
Q21 – change in loneliness		**-0.50**	-0.48	-0.48		
Q26 – worry about implant failure			**-0.80**			
Q29 – desire to join in with social activities	0.52		**0.66**			
Q38 – support from family and friends	-0.46		**-0.58**			
Q4 – ability to distinguish between voices	0.47		**0.53**			
Q22 – feeling like old self	0.49	0.41	**0.53**			

Q7 – joining in group conversations	0.49		**0.51**			
Q35 – difficulties at work				**-0.83**		
Q37 – confidence in driving				**0.81**		
Q40 – benefits of bilateral implantation compared to disadvantages					**0.75**	
Q34 – level of independence			0.40		**0.56**	
Q39 – adjusting to second implant						**-0.77**
Q41 – expectations with second implant	0.41	0.45				**0.49**

Three main factors were evident from the data, which can be interpreted as Hearing ability (factor 1), Relations with others (factor 2), Psychological and lifestyle aspects (factor 3). The other factors were difficult to interpret meaningfully. The results from the factor analysis were also viewed subjectively by the researcher to see if there were more suitable ways to group the items based semantically. As a result of this procedure a fourth subscale emerged - Reflection on implantation. Changes made to the factor classification can be seen in Table 27.

Table 27: Changes made to factor classification after subjective analysis

Questionnaire item	Classification through factor analysis	Subscale item moved to after subjective analysis
Q42 – recommending second implant to others	1	Reflection on implantation
Q17 – ability to hear warning sounds	2	Hearing ability
Q4 – ability to distinguish between voices	3	Hearing ability
Q5 – ability to carry out conversation in background noise	2	Hearing ability
Q21 – change in loneliness	2	Psychological and lifestyle aspects
Q23 – change in confidence levels	2	Psychological and lifestyle aspects
Q34 – level of independence	5	Psychological and lifestyle aspects
Q35 – difficulties at work	4	Relations with others
Q37 – confidence in driving	4	Psychological and lifestyle aspects
Q39 – adjusting to second implant	6	Reflection on implantation
Q41 – expectations with second implant	6	Reflection on implantation
Q40 – benefits of bilateral implantation compared to	5	Reflection on implantation

disadvantages	

Item 7 could be part of hearing ability and also lifestyle aspects. It was decided to keep it in the latter subscale since the lack of ability to participate in group discussions would affect a person's lifestyle. The practical aspects of hearing in these situations were reflected in item 5.

Item 26 was kept in the psychological and lifestyle aspects subscale since it was felt that worrying about implant failure would have an impact on the psychological wellbeing of a patient. This was based on the clinical experience of the researcher and further discussion with members of staff from SOECIC. However, it is acknowledged that this could also have been part of the fourth subscale – Reflection on implantation.

Items 35 and 37 were specific to individual experience which may explain their assignment to a common factor.

Table 28 shows which items were assigned to each subscale.

Table 28: Questionnaire items as assigned to each factor

Hearing ability	
4.	Compared to when I had one cochlear implant, I now can distinguish between voices
10.	Compared to when I had one cochlear implant, conversations in a car are
12.	Compared to when I had one cochlear implant, I am now able to discriminate between everyday sounds
14.	Compared to when I had one cochlear implant, I now enjoy listening to speech programmes on the radio
15.	Compared to when I had one cochlear implant, I can now understand the television
16.	Compared to when I had one cochlear implant, I now can enjoy music
17.	Compared to when I had one cochlear implant, I can now hear warning sounds
18.	Compared to when I had one cochlear implant, I can now enjoy the sounds of nature
19.	Compared to when I had one cochlear implant, I am now able to tell immediately where sounds are coming from
28.	Compared to when I had one cochlear implant, I now look upon life in a positive manner

5.	Compared to when I had one cochlear implant, I can now carry out a conversation in background noise

Relations with others	
2.	Compared to when I had one cochlear implant, I now rely on lip-reading
8.	Compared to when I had one cochlear implant, the clarity of my speech is
9.	Compared to when I had one cochlear implant, carrying out a general telephone conversation is
11.	Compared to when I had one cochlear implant, I am now aware of everyday sounds
20.	Compared to when I had one cochlear implant, I am now cheerful
25.	Compared to when I had one cochlear implant, my self-esteem is
31.	Compared to when I had one cochlear implant, people are now willing to talk to me
32.	Compared to when I had one cochlear implant, I feel that others close to me have benefited from me having cochlear implants
35.	Compared to when I had one cochlear implant, I experience difficulties at work

Psychological and lifestyle aspects	
7.	Compared to when I had one cochlear implant, I now join in group discussions
21.	Compared to when I had one cochlear implant, I now feel lonely
22.	Compared to when I had one cochlear implant, I now feel like my old self
23.	Compared to when I had one cochlear implant, I am now a confident person
26.	Compared to when I had one cochlear implant, I now worry about having an implant failure
29.	Compared to when I had one cochlear implant, I now have a desire to join in with social activities
38.	Compared to when I had one cochlear implant, my family and friends need to support me
34.	Compared to when I had one cochlear implant, my independence is
37.	Compared to when I had one cochlear implant, I am now confident driving a car or another vehicle

Reflection on implantation	
39.	Compared to when I had one cochlear implant, the difficulty initially adjusting to the sound of the second cochlear implant was

40.	Compared to when I had one cochlear implant, I now feel that the benefits of having cochlear implants outweigh any disadvantages
42.	Compared to when I had one cochlear implant, the strength of my positive recommendation to another person thinking about a second implant would be
41.	Compared to when I had one cochlear implant, I now feel that my implants have exceeded my expectations

5.3.4 Internal consistency

Factor analysis and subsequent fine tuning led to this questionnaire being split into four subscales. The internal consistency of these subscales needed to be investigated as part of its construct validity. This was achieved by calculating the Cronbach's Alpha score (α) for each subscale (Field, 2009). If an item placed in a particular subscale is not consistent with the other items within the same subscale, the value of the Cronbach's Alpha score would decrease and this would subsequently increase once the item is removed from the scale. The results of this analysis showed that the three subscales had a good level of internal consistency (Table 29) and there was no requirement to delete items from any subscale (>0.8 is considered to be good consistency (Field, 2009; Ruiz et al., 2008)). The subscale 'Reflection on implantation' had only four items and this resulted in a lower value, however semantic consideration led to the conclusion that these four items did belong to the same construct.

Table 29: Cronbach's Alpha score for questionnaire version 3.0 subscales

Subscale	Number of items	Cronbach's Alpha score	Suggestions for deletion of items within the scale
Hearing ability	11	0.941	None
Relations with others	9	0.916	None
Psychological and lifestyle aspects	9	0.908	None
Reflection on implantation	4	0.738	None

5.4 Limitations of the study

The number of participants in this section was small compared to some other studies which involved the development of a new questionnaire. For example Ruiz et al. (2008) had 150 participants for the section investigating item reduction. It was not possible to recruit this number of participants in this study since the number of adult patients who were sequentially implanted in the UK was small. This would have had an impact on the strength of the results obtained from statistical analysis. It is important

to point out that the results obtained from statistical methods were not simply taken at face value - the researcher also examined the results to ensure that they were meaningful.

5.5 Conclusion

The changes to version 3.0 of the questionnaire led to production of version 4.0 (Appendix 11). This new version had 33 items in four subscales. This version of the questionnaire needed to be investigated further in the new format and compared to other existing measures that are used with the population being targeted in this study to ensure its reliability and validity as an outcome measure. This work is described in Chapter 6.

Chapter 6. Questionnaire validation

6.1 Introduction

Chapter 5 described the refinement process of the questionnaire which led to production of the final version of the questionnaire named Outcomes of Bilateral Cochlear Implantation (Adults). This version of the questionnaire (version 4.0) needed to be tested in its new format and, in addition, its psychometric properties needed to be investigated with the help of other established questionnaires. The present chapter describes how these aims were achieved.

6.2 Participants

The participants of this part of the study were those who participated in Stage 2 of the study (see section 5.2). They were 25 participants from three cochlear implant centres in the UK.

6.3 Methodology

Ethical committee approval for this part of the study was obtained at the same time as for Stage 2 of the study. Participants were sent information packs which included an information letter (Appendix 12) and the questionnaires to be completed (Appendices 13, 14 and 15). Participants were asked to fill in a copy of the questionnaire being investigated in this study together with another three established questionnaires – the EQ-5D, SF-36 and SSQ. These questionnaires were chosen since they are well established and validated as described in section 3.3 and have been widely used. The EQ-5D and SF-36 are generic quality of life measures, whereas the SSQ is a disease specific measure. These three questionnaires are state measures which means that they explore the state of the respondent as it is at time of filling in the questionnaire. On the other hand, the Outcome of Bilateral Cochlear Implantation (Adults) is a change measure which means that it is compared the present state to a past state. There is no change measure available for the field of adult cochlear implantation so the questionnaires were adapted for the purpose of this study by being asked to fill in a version of each questionnaire with life with a single implant in mind and then filling in a second version describing their experience with bilateral implants. This created a way to compare experiences with one implant versus two. The results obtained from these questionnaires were used in the analysis of the different measures to ensure construct validity of the questionnaire being developed in this study.

Participants were asked to fill in the questionnaires in a certain order which was balanced across the participants to reduce any effect of completion order. Table 30 shows the orders that participants were asked to fill in the questionnaires.

Table 30: Order in which participants filled in questionnaires

Formation 1	Outcomes from Bilateral Cochlear Implantation (Adults) Speech, Spatial and Quality of Hearing Scale (SSQ) Euro-Qol (EQ-5D) SF-36
Formation 2	Outcomes from Bilateral Cochlear Implantation (Adults) Euro-Qol (EQ-5D) SF-36 Speech, Spatial and Quality of Hearing Scale (SSQ)
Formation 3	Outcomes from Bilateral Cochlear Implantation (Adults) SF-36 Speech, Spatial and Quality of Hearing Scale (SSQ) Euro-Qol (EQ-5D)
Formation 4	Outcomes from Bilateral Cochlear Implantation (Adults) Euro-Qol (EQ-5D) Speech, Spatial and Quality of Hearing Scale (SSQ) SF-36
Formation 5	Outcomes from Bilateral Cochlear Implantation (Adults) SF-36 Euro-Qol (EQ-5D) Speech, Spatial and Quality of Hearing Scale (SSQ)
Formation 6	Outcomes from Bilateral Cochlear Implantation (Adults) Speech, Spatial and Quality of Hearing Scale (SSQ) SF-36 Euro-Qol (EQ-5D)

Participants were asked to complete this set of questionnaires twice with a month interval in between, using a different formation each time they filled in the questionnaires.

6.4 Data analysis

The data analysis for this part of the study was in two parts. Part one investigated the psychometric properties of the questionnaire itself and part 2 compared the questionnaire to the existing questionnaires that were used in the study to ensure its reliability and validity. A combination of histograms, results of skewness and kurtosis were once again used to check if the data was distributed normally (also see section 5.3.1 for more information). These again showed that the data was not normally distributed, which was supported by Kolmorgov-Smirnov and Shapiro-Wilk tests.

6.4.1 Data analysis – part one

The reliability of each item in the questionnaire was investigated, as were the correlations between items and the subscales of the questionnaire.

6.4.1.1 Test-retest analysis

Test-retest of each item was carried out and all the items except one (item number 32) were found to be repeatable (p=>0.05). Item number 32 related to the perception of benefits with a second implant when compared to their disadvantages. This item was kept in the questionnaire since it had a high reliability scoring in Stage 2.

6.4.1.2 Correlations between items

Kendall's tau was used since the sample size was small (Field, 2009). Correlations higher than 0.7 were investigated further through subjective analysis in relation to the importance of the concept that the item represented – two items that are correlated do not necessarily give the same information (Field, 2009). The analysis was influenced by the clinical experience of the researcher.

Table 31 illustrates the results of the tests described above including explanation of which factor a particular item belonged to.

Table 31: Results from statistical tests investigating the reliability of the items in the final version of the questionnaire

Reliability	Correlation more than 0.6 (0.01 level) *Bold – strong correlation (more than 0.7)*	Factor component
Compared to when I had one cochlear implant, I am now able to discriminate between everyday sounds		
0.564	Q**2**, 3, 8, 10, 25, **26**, 29	Hearing ability
Compared to when I had one cochlear implant, I now can distinguish between voices		
1.000	Q**1**, 5, 13, 17, 26	Hearing ability
Compared to when I had one cochlear implant, I can now carry out a conversation in background noise		
1.000	Q1, 18, 20, 22, 24, 26	Hearing ability
Compared to when I had one cochlear implant, conversations in a car are		
0.102		Hearing ability
Compared to when I had one cochlear implant, I now enjoy listening to speech programmes on the radio		
0.739	Q2	Hearing ability
Compared to when I had one cochlear implant, I can now understand the television		
0.655	Q**13**	Hearing ability
Compared to when I had one cochlear implant, I now can enjoy music		
0.317		Hearing ability

Compared to when I had one cochlear implant, I can now hear warning sounds		
0.257	Q1, 13	Hearing ability
Compared to when I had one cochlear implant, I can now enjoy the sounds of nature		
1.000	Q13	Hearing ability
Compared to when I had one cochlear implant, I am now able to tell immediately where sounds are coming from		
0.317	Q1	Hearing ability
Compared to when I had one cochlear implant, I now look upon life in a positive manner		
0.655	Q**17**, 18, 20, 23, **24**, **25**, 26, 28	Psychological and lifestyle
Compared to when I had one cochlear implant, I now rely on lip-reading		
0.257		Hearing ability
Compared to when I had one cochlear implant, I am now aware of everyday sounds		
0.705	Q1, 2, **6**, 8, 9, 33	Hearing ability
Compared to when I had one cochlear implant, the clarity of my speech is		
0.564		Hearing ability
Compared to when I had one cochlear implant, carrying out a general telephone conversation is		
0.317		Psychological and lifestyle
Compared to when I had one cochlear implant, I experience difficulties at work		
0.317		Psychological and lifestyle
Compared to when I had one cochlear implant, I am now cheerful		
0.655	Q2, 18, 23, 24, 25, 26	Psychological and lifestyle
Compared to when I had one cochlear implant, my self-esteem is		
0.480	Q3, 17, 19, **23, 24, 25, 26, 28**, 32, 33	Psychological and lifestyle
Compared to when I had one cochlear implant, people are now willing to talk to me		
0.480	Q23, 24, 25	Psychological and lifestyle
Compared to when I had one cochlear implant, I feel that others close to me have benefited from me having cochlear implants		
0.480	Q3, 11, 22, **24**, 25, 28, 32, 33	Psychological and lifestyle
Compared to when I had one cochlear implant, the strength of my positive recommendation to another person thinking about a second implant would be		
0.257		Reflection on implantation
Compared to when I had one cochlear implant, I now join in group discussions		
0.564	Q3, 20, 26	Psychological and lifestyle
Compared to when I had one cochlear implant, I now feel lonely		
0.739	Q11, 17, 19, **24, 25, 26, 28, 29**	Psychological and lifestyle
Compared to when I had one cochlear implant, I now feel like my old self		
0.102	Q2, **11**, 17, 19, **20, 23, 25, 26, 28, 29, 32**	Psychological and lifestyle
Compared to when I had one cochlear implant, I am now a confident person		
0.705	Q1, **11**, 17, **18**, 19, 20, **23, 24, 26, 28**, 33	Psychological and lifestyle

Compared to when I had one cochlear implant, I now have a desire to join in with social activities		
0.414	Q**1**, 2, 3, 11, 17, **18**, 22, **23, 24, 25, 28, 29**	Psychological and lifestyle
Compared to when I had one cochlear implant, I am now confident driving a car or another vehicle		
0.705		Psychological and lifestyle
Compared to when I had one cochlear implant, my independence is		
0.257	Q11, 12, **18**, 20, **23, 24, 25, 26, 29**, 32, 33	Psychological and lifestyle
Compared to when I had one cochlear implant, my family and friends need to support me		
0.429	Q1, 18, **23**, 24, **25, 26, 28**, 33	Psychological and lifestyle
Compared to when I had one cochlear implant, I now worry about having an implant failure		
0.248		Reflection on implantation
Compared to when I had one cochlear implant, the difficulty initially adjusting to the sound of the second cochlear implant was		
1.000		Reflection on implantation
Compared to when I had one cochlear implant, I now feel that the benefits of having cochlear implants outweigh any disadvantages		
0.025	Q18, 20, 23, **24**, 25, 28	Reflection on implantation
Compared to when I had one cochlear implant, I now feel that my implants have exceeded my expectations		
1.000	Q13, 18, 20, 25, 28, 29	Reflection on implantation

6.4.1.3 Factor Analysis

Factor analysis was repeated with the new version of the questionnaire. Varimax rotation was used in this instance (as also in section 5.3.3).

Two main subscales were evident from the data – Psychological and lifestyle aspects (factor 1) and Hearing ability (factor 2). The other factors were difficult to interpret and the items on these factors were associated with other subscales. The results from the factor analysis were also subjectively viewed by the researcher to establish if there were better ways of grouping the items based on content of the item. As a result, a third subscale emerged - Reflection on implantation. Table 32 shows the factor loadings for the items. Key factor loadings are shown in bold. Changes made to the subscale structure can be seen in Table 33 with an explanation for these changes. These changes were made after subjective analysis of the results obtained from factor analysis. This is recommended practice to make sure that the subscales are meaningful (Field, 2009).

Table 32: Factor loading for items in questionnaire version 4.0

Questionnaire item	Factor				
	1	2	3	4	5
Q18 – change in self esteem	**0.86**				
Q24 – feeling like old self	**0.85**				
Q23 – change in feeling lonely	**0.82**				
Q19 – willingness of people to talk to implant user	**0.80**				
Q25 – change in confidence level	**0.79**	0.42			
Q20 – benefit of bilateral implants to family and friends	**0.78**	0.50			
Q28 – change in independence level	**0.78**	0.45			
Q32 – benefits of bilateral implants	**0.77**				
Q11 – looking on life in a positive manner	**0.71**	0.46			
Q26 – change in desire to join social activities	**0.66**	0.58			
Q29 – support from family and friends	**0.65**	0.50			
Q33 – expectations of bilateral implants	**0.64**	0.55			
Q3 – ability to carry out a conversation in background noise	**0.61**	0.60			
Q17 – change in cheerfulness	**0.56**	0.40			0.54
Q4 – conversations in a car	**0.56**	0.54			
Q22 – joining group discussions	**0.49**				
Q7 – ability to enjoy music		**0.86**			
Q2 – ability to distinguish between voices		**0.83**			
Q9 – enjoyment of nature sounds		**0.81**			
Q8 – ability to hear warning sounds		**0.81**			
Q1 – discrimination of everyday sounds	0.46	**0.80**			
Q5 – listening to speech programmes on radio		**0.76**			
Q10 – location of sound		**0.74**			
Q13 – awareness of everyday sounds	0.53	**0.72**			
Q6 – understanding television	0.47	**0.69**			
Q21 – recommendation for bilateral implants	0.51	**0.60**			
Q12 – reliance on lip-reading	0.56	**0.58**			
Q27 – change in confidence to drive a car			**0.81**		
Q16 – experience of difficulties at work			**0.74**		
Q14 – change in clarity of own speech		0.41	**0.48**		

Q30 – worry regarding implant failure			**-0.86**	
Q15 – carrying out a telephone conversation	0.62		**0.68**	
Q31 – adjustment to sound from second implant				**0.85**

Table 33: Changes made to the subscale structure

Questionnaire item	Loading through factor analysis	Subscale item moved to after subjective analysis
Q3 – ability to carry out a conversation in background noise	1	Hearing ability – the loading factor was very similar for both factors and the concept fitted better in this subscale
Q4 – conversations in a car	1	Hearing ability – the loading factor was very similar for both factors and the concept fitted better in this subscale
Q14 – change in clarity of own speech	3	Hearing ability
Q15 – carrying out a telephone conversation	4	Psychological and lifestyle aspects
Q16 – experience of difficulties at work	3	Psychological and lifestyle aspects
Q21 – recommendation for bilateral implants	2	Reflection on implantation – since it was more appropriate
Q27 – change in confidence to drive a car	3	Psychological and lifestyle aspects
Q30 – worry regarding implant failure	4	Reflection on implantation – since it was more appropriate
Q32 – benefits of bilateral implants	1	Reflection on implantation – since it was more appropriate
Q33 – expectations of bilateral implants	1	Reflection on implantation – since it was more appropriate
Q31 – adjustment to sound from second implant	5	Reflection on implantation – since it was more appropriate

6.4.1.4 Internal consistency

The internal consistency of the three new subscales of the questionnaire was investigated by calculating the Cronbach's Alpha score. This showed that two of the subscales (hearing ability and psychological and lifestyle aspects) had good internal consistency ($\alpha = >0.8$). However, the score for the third subscale (reflection of

implantation) had a lower score and a suggestion that deletion of two items from the scale would improve the score. These items (item 30 and 31) were important to the overall questionnaire, since they asked the respondents to reflect on their concerns regarding implant failure and also their adjustment to having a second implant. Had they been removed, the subscale would have only had three items which might make it an unreliable subscale. Subscales with small numbers of items tend to be regarded as unreliable, since it is more difficult to test their internal consistency. Therefore, a decision was made to retain these two items for the same reason as before which is to help with the rehabilitation process.

Table 34: Cronbach's Alpha score for questionnaire version 4.0 subscales

Subscale	Number of items	Cronbach's Alpha score	Suggestions for deletion of items within the scale
Hearing ability	13	0.964	None
Psychological and lifestyle aspects	15	0.960	None
Reflection on implantation	5	0.530	Overall low score, suggestion to remove Q30 and Q31 but these are important to the overall questionnaire

6.4.2 Data analysis – part two

The reliability and construct validity of the questionnaire was investigated. Reliability is easily understood if we think of consistency (Oppenheim, 1992). Both the characteristics of the questionnaire and the conditions of administration need to be consistent even though total consistency is unattainable. Validity indicates the degree to which an instrument measures what it proposes to measure (Oppenheim, 1992). If good theoretical grounds for making predictions exist, the fulfilment of such predictions could be regarded as construct validity. Reliability and validity are highly related. Without reliability, the measure is not able to be valid (Oppenheim, 1992).

6.4.2.1 Correlations between questionnaires

Test re-test analysis of the questionnaires used in this study for comparison with the Outcome of Bilateral Cochlear Implantation (Adults) showed good reliability (p= >0.05).

Construct validity, as described in section 3.1.2.2.3, is the extent to which a particular measure relates to other measures in a manner that is consistent with theoretically

derived hypotheses (Kirshner and Guyatt, 1985). Participants were asked to fill in the state measures as they remembered their experiences with one cochlear implant and then again with bilateral implants. The difference in responses were computed and these results were used in the correlation analysis.

Table 35 summarises the results obtained by running the Kendall's test on the questionnaires and investigating the correlation between the results. The correlations were reported as None r = <0.2; Weak r = 0.2 – 0.4; Moderate r = 0.4 – 0.6; Strong r = >0.6 (Field, 2009). As can be seen in the table, the Outcome of Bilateral Cochlear Implantation (Adults) did not have a strong correlation with any of the questionnaires or their subscales. In fact, most of the results showed either no or weak correlation. The poor correlations would lead to a conclusion that it is not possible to compare the new questionnaire to these existing ones. One possible reason for this is that the EQ-5D and SF-36 focus on performance rather than underlying level of impairment (Barton et al., 2005). Even though they are health related questionnaires, they are not disease specific which the Outcome of Bilateral Cochlear Implantation (Adults) is. Even though the SSQ is related to hearing impairments and its effects, it is also a performance questionnaire and there is no single questionnaire that can be identified as being optimal for investigating quality of life in adults.

Table 35: Correlation results between questionnaires used in the validation stage

	Bilateral Outcomes Questionnaire (Adults)			
	Total Score	Psych & lifestyle Score	Hearing ability Score	Reflection on implantation Score
SSQ Speech	Moderate	Weak	Moderate	Moderate
SSQ Spatial	Weak	None	Weak	Weak
SSQ Qualities	Weak	Weak	Weak	Weak
EuroQol	Weak	Weak	Weak	Weak
EuroQol State	Weak	Weak	Weak	Weak
SF36 Physical Function	None	None	None	None
SF36 Role Function	None	None	Weak	None
SF36 Body Pain	None	None	Weak	None
SF36 General Health	None	None	None	None

SF36 Vitality	None	None	None	None
SF36 Social Functioning	Weak	Weak	Moderate	Weak
SF36 Role Emotional	None	None	None	None
SF36 Mental Health	Weak	None	Weak	None
SF36 Dimension A	Weak	None	Weak	None
SF36 Dimension B	Weak	Weak	Weak	Weak
SF36 Total Score	Weak	Weak	Weak	Weak

6.5 Scoring system

Table 36 illustrates the items of the questionnaire as they were placed in factors and also the scoring system for every item. The term positive scoring means that the items were scored as -2, -1, 0, +1 and +2, whereas negative scoring was +2, +1, 0, -1, -2.

Table 36: Summary of scoring system and subscale for individual items in the questionnaire

	Item	Subscale	Scoring
1	Compared to when I had one cochlear implant, I am now able to discriminate between everyday sounds	Hearing ability	Positive
2	Compared to when I had one cochlear implant, I now can distinguish between voices	Hearing ability	Positive
3	Compared to when I had one cochlear implant, I can now carry out a conversation in background noise	Hearing ability	Positive
4	Compared to when I had one cochlear implant, conversations in a car are	Hearing ability	Positive
5	Compared to when I had one cochlear implant, I now enjoy listening to speech programmes on the radio	Hearing ability	Positive
6	Compared to when I had one cochlear implant, I can now understand the television	Hearing ability	Positive

7	Compared to when I had one cochlear implant, I now can enjoy music	Hearing ability	Positive
8	Compared to when I had one cochlear implant, I can now hear warning sounds	Hearing ability	Positive
9	Compared to when I had one cochlear implant, I can now enjoy the sounds of nature	Hearing ability	Positive
10	Compared to when I had one cochlear implant, I am now able to tell immediately where sounds are coming from	Hearing ability	Positive
11	Compared to when I had one cochlear implant, I now look upon life in a positive manner	Psychological and lifestyle	Positive
12	Compared to when I had one cochlear implant, I now rely on lip-reading	Hearing ability	Negative
13	Compared to when I had one cochlear implant, I am now aware of everyday sounds	Hearing ability	Positive
14	Compared to when I had one cochlear implant, the clarity of my speech is	Hearing ability	Positive
15	Compared to when I had one cochlear implant, carrying out a general telephone conversation is	Psychological and lifestyle	Positive
16	Compared to when I had one cochlear implant, I experience difficulties at work	Psychological and lifestyle	Negative
17	Compared to when I had one cochlear implant, I am now cheerful	Psychological and lifestyle	Positive
18	Compared to when I had one cochlear implant, my self-esteem is	Psychological and lifestyle	Positive
19	Compared to when I had one cochlear implant, people are now willing to talk to me	Psychological and lifestyle	Positive
20	Compared to when I had one cochlear implant, I feel that others close to me have benefited from me having cochlear implants	Psychological and lifestyle	Positive
21	Compared to when I had one cochlear implant, the strength of my positive recommendation to another person thinking about a second implant would be	Reflection on implantation	Positive

22	Compared to when I had one cochlear implant, I now join in group discussions	Psychological and lifestyle	Positive
23	Compared to when I had one cochlear implant, I now feel lonely	Psychological and lifestyle	Negative
24	Compared to when I had one cochlear implant, I now feel like my old self	Psychological and lifestyle	Positive
25	Compared to when I had one cochlear implant, I am now a confident person	Psychological and lifestyle	Positive
26	Compared to when I had one cochlear implant, I now have a desire to join in with social activities	Psychological and lifestyle	Positive
27	Compared to when I had one cochlear implant, I am now confident driving a car or another vehicle	Psychological and lifestyle	Positive
28	Compared to when I had one cochlear implant, my independence is	Psychological and lifestyle	Positive
29	Compared to when I had one cochlear implant, my family and friends need to support me	Psychological and lifestyle	Negative
30	Compared to when I had one cochlear implant, I now worry about having an implant failure	Reflection on implantation	Negative
31	Compared to when I had one cochlear implant, the difficulty initially adjusting to the sound of the second cochlear implant was	Reflection on implantation	Negative
32	Compared to when I had one cochlear implant, I now feel that the benefits of having cochlear implants outweigh any disadvantages	Psychological and lifestyle	Positive
33	Compared to when I had one cochlear implant, I now feel that my implants have exceeded my expectations	Psychological and lifestyle	Positive

6.6 Limitations of the study

As reported in section 6.4.2.1, the existing questionnaires used in this study (EQ-5D, SF-36 and SSQ) are state questionnaires whereas the Outcome of Bilateral Cochlear Implantation (Adults) is a change questionnaire. In the field of cochlear implantation there presently is no change questionnaire so the researcher could not use one for this

purpose but had to adapt the way in which these questionnaires were used in this study.

The number of the participants remains limited when compared to other studies carried out with a similar methodology (for example, Ruiz et al., 2008). However, when the number of participants is compared to the number of potential participants from the three centres used in this study, they represented 55% of the population. The exact number of potential participants across all the UK cochlear implant centres is not known, however it is estimated that the number of participants in this study would have been at least 33% of the whole population of adult bilateral cochlear implant users in the UK at the time of recruitment. This estimate shows that the participants in this study were a good proportion of the whole population and hence are likely to be fairly representative.

6.7 Conclusion

The present chapter investigated the psychometric properties of the questionnaire Outcome of Bilateral Cochlear Implantation (Adults). The reliability and internal consistency of the questionnaire were found to be good. Factor analysis was repeated and as a result, there was some refinement of the results obtained in chapter 5. The new questionnaire was compared to existing outcome measures and this showed poor correlations between the existing measures and the new one. Criterion and construct validity are only part of the psychometric properties that needed to be investigated for this new questionnaire. Chapters 4 and 5 have been able to show that the new questionnaire has good face and content validity. Chapter 8 discusses the implications of the lack of correlations seen in section 6.4.2.1 in relation to the new outcome measure.

Chapter 7. Participants' experience of sequential bilateral cochlear implantation

One of the aims of this study was to investigate the changes in patients' quality of life when they received a second cochlear implant compared to one implant. This was achieved by investigating the responses that participants gave when they filled in the open-ended questionnaire and underwent interviews in stage one of the study (as described in Chapter 4); and also their responses when they filled in the questionnaires in the last stage of the study (as described in Chapter 6).

7.1 The open-ended questionnaire and interviews

Results from the responses to the open-ended questionnaire and interviews used in the initial stages of this study can be found in Chapter 4 since these responses were the basis of items included in the closed-ended questionnaire.

Increase in confidence and independence were themes that were most frequently mentioned by the participants when they were speaking about the perceived benefits of having two implants instead of one. Responses to the open-ended questionnaire showed that seven participants (54%) mentioned they felt more confident to do things and eight participants (62%) mentioned that they felt they had regained more independence in doing things (as described in Table 20). Nine participants(69%) also mentioned when they filled in the questionnaire that they felt that their social life benefitted as a result of the second implant. One of the participants reported that he did not feel there was a difference in this area of life. This issue was investigated further during the interview stage and the participant felt that since he lived on his own and did not go out a lot, he did not feel that having two implants improved his social life but he acknowledged that if a person led a different lifestyle to his, he felt that having two implants would improve this aspect of life since a person might feel able to hear better and with more ease.

Twelve participants (92%) mentioned in the responses to the open-ended questionnaire that they were able to locate a sound more easily with two implants. This helped with listening to environmental sounds and also speaking to more than one person. As described in Section 2.2.2, Verschuur et al. (2005) were able to show improvements in localisation for participants with bilateral cochlear implants in a clinical setting, and Kerber and Seeber (2012) were able to show this improvement was more pronounced in a noisy situation.

Improvement in listening in a group situation was mentioned by nine respondents (69%). The same number of people mentioned that is was easier to have a conversation with a car passenger. This issue was explored further in the interview stage – there were reports that this situation was easier for two reasons – having an implant on the closest side to the conversational partner and also being able to hear with more ease so did not need to concentrate as much as with one implant in a car situation.

Interestingly, participants also mentioned that having two implants was helpful in situations where they could lip-read the person who was speaking (as seen in Table 20), but there were more instances when participants mentioned that they found situations where it was hard to lip-read easier to hear with two cochlear implants.

None of the participants experienced permanent balance difficulties post the second surgery. Two participants (15%) experienced balance difficulties after the second surgery – these difficulties were temporary as it was explained in both the questionnaire responses and interviews. Issues with balance and tinnitus difficulties post-surgery emerged in the study by Summerfield (2006). However, one possible explanation for this mismatch in reports might be due to the timings when participants reported their experiences. The participants in Summerfield's study were asked about their experiences less than a year post implantation so their recall would be better and the difficulties might still have not been fully resolved. The reports from participants in this project indicate that any difficulties experienced post-surgery were not permanent. It still has to be acknowledged that there might be some patients who have permanent difficulties in these areas but they did not choose to participate in the study.

Three participants (23%) who responded to the open-ended questionnaire also felt that there was an imbalance between the two implants. One of the participants explained this is more detail during the interview stage. His surgeon had explained that it was not possible to insert the second implant to the same depth as the first one so there was a perceived pitch mismatch. Extensive tuning had been carried out but it was not possible to make this better. Even though the participant experienced this, he still felt that he gained benefit from having bilateral implants and did not want to stop wearing one of them.

All the participants who participated in this study had received their second cochlear implant as a result of a national UK study of the benefits of bilateral implantation, more specifically at the benefit of a second implant to understanding speech in noise

and to localisation of sound. Therefore, the second implant in each case was funded by the relevant manufacturing company. All the participants agreed that they would recommend another implant recipient to have a second implant and that they would not go back to using one implant. However, there were some concerns raised about the perceived lack of preservation of hearing for any future developments that might occur in the cochlear implant field. As surgical techniques change over time, surgeons are able to use less traumatic approaches to cochlear implant surgery and hearing preservation has been more successful in recent years (Carlson et al., 2011; Bruce et al., 2011).

Comments made by the participants included that most of the expectations that the participants had before receiving the second implant were met with the exception of music appreciation (Table 22 shows the expectations that participants listed in the first stage of this project). It was also agreed by the participants that they needed less rehabilitation after receiving the second implant than for the first and their experience from the first one helped them adapt to the new sound.

The general consensus (all except one participant) was that the participants would make the same decision again if they were asked if they wished to receive a second implant but they would have to think about it more seriously if they would have had to pay for it. The participant who said he would not have a second implant again, was the same one who felt that he did not gain the full benefits of bilateral implantation due to his lifestyle – living on his own with not a lot of contact with other people. He mentioned that he was not unhappy being on his own so did not feel the need to socialise with other people.

The change in their quality of life was judged to be much greater following the first implant than when they received the second one having already had experience of one cochlear implant. It was also mentioned that if performance with the first implant was excellent they thought that the impact of the second implant would be less than for a person who is performing averagely with the first implant. Related to this there is also the possibility that if a patient was performing well with the first implant then they would immediately say 'yes' to a second. However if a patient was not doing so well, s/he might be resistant to a second one or might not even be offered one.

Due to the age group of the participants, they did not mention the impact the second implant would have had on their work. Most of the participants had retired from their jobs but they did mention that it would have given them more confidence at work had they received the second implant whilst they were still employed.

A number of themes mentioned by participants in this study were also mentioned by participants in a study carried out by Mather et al. (2011a) (as mentioned in section 2.2.2). Fifteen young people were interviewed to discuss their experience of sequential bilateral implants and the themes of improved localisation, hearing better in background noise, increase in confidence levels and ease of listening were all brought up by these participants.

Table 5 in Chapter 2 lists the classification of auditory disabilities according to the World Health Organisation. It was noted that most of the disabilities listed in this classification were mentioned by the participants interviewed and it was also reported that having two cochlear implants versus one helped alleviate them. On the other hand, Table 7 in Chapter 2 lists the extension of the WHO classification in terms of reduced quality of life. In the participants interviewed for this study, these issues seem to be resolved with the introduction of the second cochlear implant.

7.2 The Outcome of Bilateral Cochlear Implantation (Adults)

Participants filled in the questionnaire in the last stage of the study. Out of the 25 participants, there was one responder who felt that her quality of life was worse with bilateral implants when compared to one implant – all the responses from this participant indicated that the hearing ability and life experience was worse with bilateral CI than with one implant. Due to the design of this study, it was not possible to follow up these issues with this participant. Had the questionnaire been filled in a clinical setting, the participant could have been offered more rehabilitation and/or tuning sessions if these were appropriate. Expectations could be revisited and ultimately, a decision could be made for the participant to become a non-user of this cochlear implant if the quality of life was better with one implant.

Once the responses from this participant were removed, it was noticed that there is a variation between the most negative and positive scores which show that different participants had different experiences and the questionnaire was able to capture these differences. One of the participants (participant 8 as can be seen in Figure 5) felt that there was improvement in the hearing ability (scored 22 out of a possible 26) but this did not translate into an improvement in the psychological and lifestyle subscale (scored 3 out of a possible 30). There were another 2 participants who showed that they experienced a smaller improvement in the hearing ability but this did not translate in any change in the psychological and lifestyle factor.

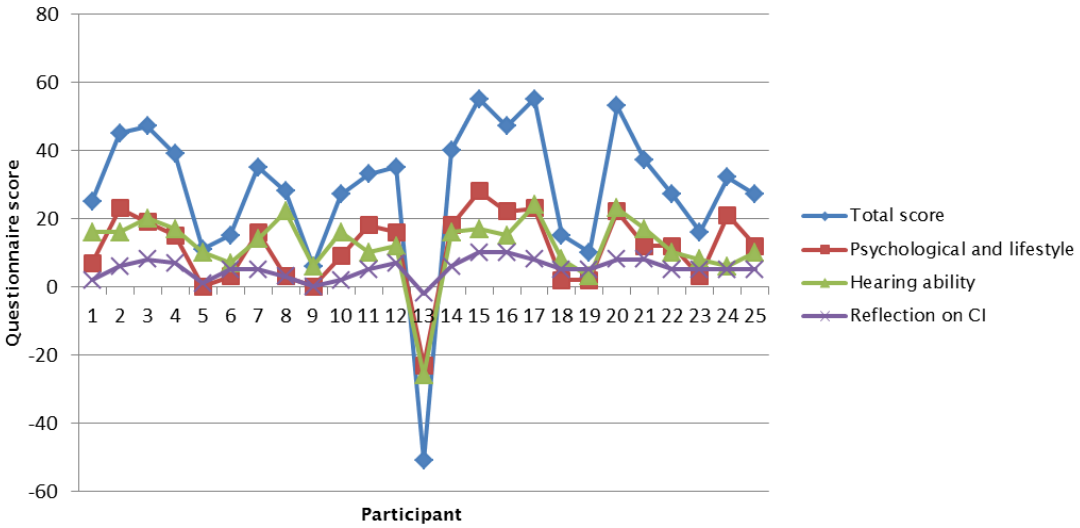
Responses from 8 participants (32%) indicated that they were able to see greater improvements in the psychological and lifestyle factor when compared to the responses on the hearing ability factor.

Table 37 illustrates the responses given by the participants and figure 5 illustrates the scores given by the participants across the different factors One of the participants was an outlier since the responses indicated that the second CI had a negative impact. Table 37 also shows the responses obtained from the other participants once the responses from the outlier were removed. The 'Reflection on cochlear implantation' subscale was the only scale were some participants scored the maximum score possible for this scale.

Table 37: Description of scores obtained from participants responses onthe Outcome of Bilateral Cochlear Implantation (Adults) questionnaire

	Total Score	Psych & lifestyle	Hearing ability	Reflection on CI
Most negative score	-51	-23	-26	-2
Most negative score without outlier	6	0	3	0
Most positive score	55	28	24	10
Maximum score possible	66	30	26	10
Mean score	28)	11	12	5

Figure 5: Illustration of individual participants' total scores for the different factors of the questionnaire



7.3 The existing questionnaires (EQ-5D, SF-36, SSQ)

Out of the 3 questionnaires which participants filled in the last stage of this study (EQ-5D, SF-36 and SSQ), the SSQ was the only questionnaire that was able to show that participants experienced a difference between having one cochlear implant and bilateral implants (p=<0.05). This result is in line with the findings of Sparreboom et al. (2012) where the SSQ was the most sensitive questionnaire used in the study. The different responses on the questionnaire were shown across all three sections of the questionnaire in this study – speech, spatial and quality of hearing. The social functioning section of the SF36 was also able to show a difference between the experiences with one cochlear implant and two (p=<0.05). The responses for the other sections of the SF-36 and EQ-5D did not show a difference in experience with one cochlear implant compared to that with bilateral implants (p=>0.05).

Noble (2010) analysed participant responses when filling in the SSQ questionnaire and referred to a category scheme regarding change in responses over time. Table 38 describes the category scheme that he referred to.

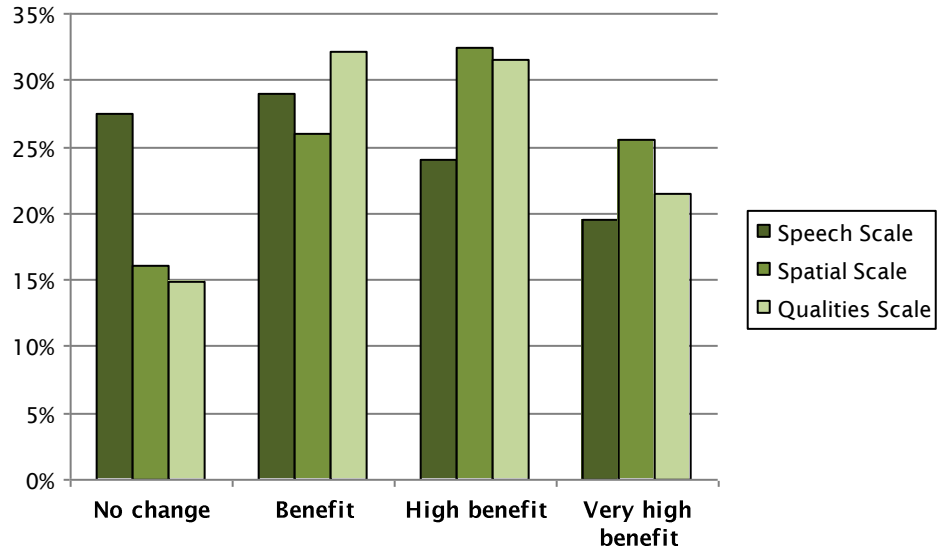
Table 38: Category scheme for results from SSQ (Noble, 2010)

Change in response	Relative meaning to outcome
<±1 scale point	No change
+1-2 points	Benefit
+2-4 points	High benefit
>4 points	Very high benefit

Whilst analysing the data (the SSQ responses from participants in this study), it was noted that there was a variety in responses when participants compared their experiences with one implant to that with two. Figure 6 illustrates the percentage of all the responses from the SSQ questionnaire in relation to the category scheme devised by the Noble (2010). The scale which saw the highest benefit from bilateral cochlear implantation was the qualities scale – only 14.8% of the responses did not show any change as a result of bilateral implantation. Just over a quarter of the responses in the speech scale did not show a positive change as a result of bilateral implantation. Two of the participants in the study did not perceive any change at all in the speech scale but responses from the spatial and qualities scales showed a change (varying from benefit to very high benefit). It was noted that a similar scoring scheme would not be possible to use with the questionnaire being developed in this project due to the number of participants taking part. It would be useful to have such a

scoring system to be able to split the scores in different levels of benefit once more patients are able to fill in the questionnaire.

Figure 6: Participants' responses to the SSQ based on scoring scheme by Noble (2010)



Some comments made by participants in relation to their experiences with bilateral cochlear implants were not expected based on theoretical reasoning. For example, one participant mentioned that the telephone was more difficult to use with two implants when compared with one (using the speakerphone) and similarly for music. Another participant felt that listening in background noise situation made sounds more jumbled with two implants and was experiencing greater difficulty in this situation with two implants. This was not reported by other participants and van Hoesel et al. (2003) were able to show that participants with bilateral implants were able to hear better in background noise situations (more details in section 2.2.2). Three participants found it harder to judge the distance of an object with two implants and they felt that this was easier with one implant.

The responses on the SSQ questionnaire of the participant who reported that the second implant did not improve the quality of life when filling in the Outcome of Bilateral Cochlear Implants (Adults) reflected this experience. The experience with one implant for this participant was not good but it was felt that things were worse with two implants. The participant needs to concentrate more now. As mentioned in Section 7.2, a discussion with this participant could be helpful to both the participant and the cochlear implant team. There might be some specific issue that has led to a

less successful outcome with two implants. This information could be helpful in discussion session with other potential bilateral cochlear implant users.

7.4 Conclusion

Even though the majority of participants (24 out of 25) felt that they had benefitted from bilateral implantation, there was still a variation in their responses on all the questionnaires. The responses from the participants showed that they experienced different levels of improvement when compared to other participants and they felt that there was a greater improvement in some areas when compared to others. The fact that different participants showed improvements (or otherwise) in the different sections illustrates that clinicians also need to look at the specific responses to questions and to the scores obtained. The responses to the questionnaire could lead to discussion in a rehabilitation session, for example, if a patient reports that the benefits of having bilateral cochlear implants do not outweigh any disadvantages, a discussion about this can be held to see if there is a way on how to improve this or if this response was generated by inappropriate expectations It would also be interesting for participants and clinicians to see how the responses to the questions change (or not) as patients progress through their rehabilitation stages.

It was also noted that certain issues which were raised in the questionnaire being developed in this study were not discussed in the other existing questionnaire; for example increase in confidence and independence levels and change in social life experiences. This further justified the need for a specific outcome measure which specifically investigates the experiences of patients who have been implanted bilaterally.

Chapter 8. General discussion and conclusion

8.1 Introduction

Research carried out with patients who have received unilateral cochlear implants has been able to show the benefits of cochlear implantation as can be seen in Section 2.2.1. Benefits to the quality of life have been shown for both the recipient and family members. The focus is now moving to patients who have been implanted bilaterally. The benefits of bilateral implantation can be shown by comparing results and experiences of having one implant to when a patient uses bilateral implants. There is emerging literature covering this topic, and the National Bilateral Audit being carried out in the UK with children who have received bilateral cochlear implants will help increase this information.

The majority of the emerging literature mainly refers to data obtained through clinical tests which does not always show all the benefits (or otherwise) that patients benefit as a result of bilateral implantation. There is some new data related to quality of life and direct patient experience with bilateral implants compared to one implant, for example the studies carried out by Mather et al. (2011a, 2011b) where they looked at experiences of teenagers who had received bilateral implants sequentially and the experiences of their parents. Information about experiences of adults is not fully captured through the outcome measures that are presently available and a questionnaire would be a good way to do this as described in Chapter 3. Section 3.3 reviewed existing questionnaires that are available for clinical use, but none of these were specific to adult bilateral recipients, so such a questionnaire needed to be developed. Section 3.4 described a method how to develop a questionnaire and the work carried out to do this was described in Chapters 4, 5 and 6. Chapter 7 explored the experiences of sequential bilateral cochlear implantation as described by the participants in this study. It is hoped that the information obtained from this project will also add to the knowledge about benefits of bilateral cochlear implantation in adults. The participants in this project all had experience of being unilaterally implanted and could discuss the benefits of bilateral implantation when compared to their experience with just one implant.

8.2 Design and validation of a questionnaire which measures the quality of life of patients with bilateral cochlear implants (received sequentially)

The methodology of this study was based on the Rolls Royce Model as described by Guyatt et al. (1986). Details of this method are found in Section 3.2. Responses to the open-ended questionnaire sent to the participants and interviews with a selection of

them led to the development of items for the closed-ended questionnaire. This needed to go through a refinement process which included face validity, item reduction and factor analysis. This led to the questionnaire having 33 items and three subscales. The reliability and validity of the questionnaire were also investigated and the results are reported in Chapters 5 and 6. The questionnaire was found to be reliable and have good internal consistency.

The responses for the questionnaire being developed in this study were compared to the responses given on three other existing questionnaires (SSQ, SF-36 and EQ-5D). Analysis showed poor correlations between these questionnaires (as seen in section 6.4.2.1). There was a moderate correlation between the Speech scale of the SSQ questionnaire and the Hearing Ability subscale of the questionnaire in this study. The Hearing Ability subscale also showed a moderate correlation with the SF-36 Social Functioning scale. One could argue that the reason why these correlations have become apparent are because the Speech scale of the SSQ covers similar items to the Hearing Ability of the questionnaire under development and a change in this scale would show a change in the social functioning of the individual. The other scales all showed a weak or no correlation with each other. The reason for the need for the development of a questionnaire specific to the needs of patients who received bilateral cochlear implants was because there was no existing measure that already covered these issues. The poor and weak correlations in this analysis show that the existing questionnaires were not sensitive enough to pick up the changes experienced by these participants as a result of them receiving the second implant.

8.3 Limitations and bias in the study

The number of participants in this study was small when compared to other studies which had a similar methodology. The potential consequences of this were that not all the relevant information would be collected in the first stage of the study and relevant themes would be missed from the questionnaire. It was felt that saturation levels were reached as a result of the open-ended questionnaire and interviews held with participants. The number of patients in the study also represented approximately one third of the population in the UK who would have been eligible to participate in the study (as mentioned in section 6.6). In order to increase this number, more implant centres would have needed to participate in the study. However, the other centres in the UK did not have enough adult patients who were sequentially implanted and it was felt that due to time limitations, it was not possible to involve all the implant centres in the UK.

All the participants had implants from the same manufacturer since they got their second implant as a result of a study funded by the manufacturer. One could argue that it is possible that people might have reported different experiences if they also had implants from the other two main manufacturers in the UK. However, one also has to keep in mind that all the devices work in a similar way. Budenz et al. (2009) carried out a study which investigated the results obtained by participants in a clinical setting. Results from 20 participants who were implanted sequentially with different technology on each side were compared to results obtained from 8 participants implanted simultaneously and three participants implanted sequentially. The latter group had the same technology in both ears. All participants underwent testing using the CNC words and results indicated that different technology does not affect results or performance since there were no differences in results between groups and within groups either. This was able to show that the experience of patients with different technology would be similar so their experiences in life would not be affected by the type of implant that they would have received.

Filling in questionnaires which ask you to compare a present state to a past one involve recall and memory. The questionnaire being developed in this study is a change questionnaire so it involved recall. As described in section 3.2.3, memory is a bias in these types of studies since one can never be sure that what participants are recalling is accurate. In order to test whether this would have had an effect, participants would have needed to undergo the 'then-test' as described in section 3.1 – they would have been asked to fill in a state questionnaire before and after their second implant. At the latter stage, they would have been also asked to fill in the questionnaire as they think they would have completed it before they received their second implant and the results from this and the original questionnaire are compared to test reliability (Howard et al., 1979). However, this methodology was not possible in this study since all the participants were already bilaterally implanted at the start of the study and it was not possible to recruit participants who would fit eligibility for participation in the proposed methodology.

Another bias in the study would possibly have been participants filling in the questionnaires in a pleasing manner. It was discussed in section 3.2.3 that there is an element of 'Yea-saying' or acquiescence, where people tend to give positive responses to all questions (Streiner and Norman, 1989, Smith, 2003). However, it has also been shown that only a few people would to do to an extreme manner. Research has shown that the usual way to correct for this bias is to have an equal number of items keyed in the positive and negative directions so this was addressed in the development of the questionnaire.

It was noted that even though there was a variation in the experiences reported by the participants in this study so there is not a ceiling effect, it was not possible to make sure that patients who did not have a positive experience with their second implant participated in this project to make sure that their experiences came through and were included.

8.4 Clinical application of the questionnaire

From personal experience of the researcher, the first few months post implantation in adults involve a number of appointments for audiology reviews and helping the individual go through the rehabilitation process. Assessments in the clinical setting are carried out regularly by the audiologists to assess the progress of the patient through the tuning sessions. The rehabilitation sessions at the initial tuning stage tend to concentrate on helping the patient recognise sounds through the implant as being meaningful. Rehabilitationists tend to start investigating change in quality of life at the first annual review and they do this via a number of questionnaires. The questionnaire developed in this project would be a useful tool for this purpose. In the UK, at the present moment, it is not a very common occurrence that a unilaterally implanted adult patient would go on to receive a second implant sequentially. This tends to happen when either a patient would be able to fund the second implant themselves or a patient experiences a device failure and is offered bilateral implantation as a result of an offer by the manufacturer. There are more situations of the former situation occurring. When patients are implanted bilaterally in a sequential manner, it would be interesting to investigate potential changes as a result of bilateral implantation from an earlier stage than around the first year anniversary which is what happens at the moment. This questionnaire could be filled in by patients early on in the rehabilitation stage post second implant and then again at the annual review. This way perceived change in quality of life is picked up earlier and changes made through the first year of implantation are monitored.

Experience has shown that when patients fill in a questionnaire in a clinical situation, the clinician should also look at answers to specific questions besides the total scores obtained. The same score could be obtained by 2 people filling in the questionnaire but they would have given different answers in their responses. These different answers would possibly require different advice from the clinician. For example, the outcome of a patient indicating that with their second CI, s/he is less aware of everyday sounds than before would be different to if the response indicated that they are less cheerful. The first response would possibly indicate a need to look at the patient's map, whereas the second response would indicate that the clinician needs to

discuss the reasons why the patient is less cheerful. This might be as a direct result of the CI or there might be other influences too which need a different input for example a referral to a counsellor.

The scoring of the questionnaire can be seen as a total but this score can also be split into the different subscales. The information from the 3 subscales would give an indication on whether there is a specific area that is scoring lower than the other areas. This might also help see if any changes in the clinical management of the patient are having the desired effect. For example, if a patient scores low on the Hearing Ability and Psychological and Lifestyle subscales, there might be an assumption that the former subscales is affecting the latter one. Changes might be made to the patient's map parameters which improve the hearing ability score, It would then be useful and helpful to the clinician to see if the second subscale improves too. If this does not improve, further discussion would need to be carried out with the patient to investigate this further.

8.5 Future directions

The population in this study consisted of older participants who were mainly not at work. The national audit being carried out in the UK presently is investigating outcomes for bilateral patients who are up to the age of 18 years. Since this study did not have participants who were still in the workforce or young adults, it would be interesting to carry out interviews with cohorts from this age group to see if any new themes would emerge. These themes might be related to experiences at work and living with young families. It is not known how many participants in this age group exist in the UK since it was not possible to obtain characteristics of non-responders due to data protection. This work would also strengthen the validity of the questionnaire by investigating if any further factors emerge.

Partners and families of the potential participants could also be involved in the study in order to investigate how they perceive the changes brought about by the participants having a second implant. Their views on how their own lives have changed following bilateral implantation of their family member could also be investigated. It is well documented that a hearing loss has an effect on family members of the individual with the hearing loss (Hétu et al., 1993; Stephens, 1991; Donaldson et al., 2004; Scarnici et al., 2009; Manchaiah et al., 2012) so it would be interesting to investigate any changes which result from an intervention to help improve the effects of that hearing loss. This could be done via open-ended questionnaires, interviews or focus groups.

The target population for this measure is adult patients who received bilateral cochlear implants sequentially. However, there are also some other patients who would have been able to receive bilateral implants simultaneously. These would be adults who are dually impaired (hearing and vision) and are therefore eligible for bilateral implants according to NICE guidelines (2009). It would be helpful to investigate any possible differences in the experiences of these two groups of patients by using qualitative outcome measures to see if patients who receive their implants simultaneously have similar experiences in their everyday life as those in this study group.

Information gathered from the questionnaire in clinical use and further investigations could also lead to an adaptation of the questionnaire for adult patients who would be implanted bilaterally simultaneously. The questionnaire would be helpful in identifying the concepts that are important for bilateral implantation. The adapted questionnaire would then need to be validated to its proposed use.

8.5.1 Cost utility analysis for bilateral implantation in adults

The NHS has constrained monetary budgets and decisions need to be made about how the budget is used and split amongst the different interventions that are required by patients across the health service. The purpose of cost utility analysis is to help in this decision making process. It aims to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived in full health by the people who would benefit from the intervention – QALYs (Chorozoglou, 2012). Participants in a study investigating QALYs are given hypothetical examples of impaired health states and asked to score these against a time trade-off. This describes a theoretical remaining life expectancy in a given health state (e.g. 10 years of life remaining in moderate pain and unable to get out of bed) and asks the subject what amount of life expectancy they would be willing to give up to remain in perfect health compared to this alternative (Chorozoglou, 2012).

As mentioned in section 1.3, there is lack of information related to cost-utility analysis of bilateral implantation in adults. The EQ-5D is usually the instrument that is used to help quantify the QALYs but the data for this is not always available or appropriate. In situations like this, a different outcome measure can be used and this is then mapped to the EQ-5D data (Rowen and Brazier, 2011; Longworth and Rowen, 2011). It is proposed that the data from this project has shown that the EQ-5D is not able to pick up the difference between unilateral and bilateral implantation in adults since the questions are not sensitive to the changes experienced by patients. On the other hand, the Outcome for Bilateral Cochlear Implantations (Adults) is sensitive to these changes.

The term mapping is used when an outcome measure is used to predict the utility values instead of using the EQ-5D (Longworth and Rowen, 2011; Chorozoglou, 2012). In order for this method to be accepted by NICE, evidence would need to be submitted to show that the EQ-5D is not appropriate and a different outcome measure should be used instead (Rowen and Brazier, 2011). Rowen and Brazier (2011) also mention that the supporting evidence for an alternative method would also need to show that the outcome measure has good content validity, construct validity, reliability and responsiveness. This project has been able to show that this is in place for the questionnaire that has been developed. In order to strongly claim that the EQ-5D is not appropriate, it would be necessary to administer both questionnaires to a bigger sample of participants than was used in this project.

The outcome measure used in the mapping exercise can be a condition specific questionnaire (such as the questionnaire developed in this project), another generic quality of life questionnaire, such as the SF-36, clinical indicators of disease severity, or a combination of these. The mapping exercise would consist of collecting data from a sample of participants using the EQ-5D and one or a combination of the different sources. From this data, health economists are able to predict utility values for the EQ-5D and use this data for the generation of QALYs. A cost-effectiveness model can then be generated with the data (Longworth and Rowen, 2011; Chorozoglou, 2012).

The process of mapping and working on a cost-effectiveness model is complex in nature and would require the input of a health economist. Developing an outcome measure which would be useful in this exercise is a first step towards being able to inform NICE about guidelines for bilateral implantation in adults in the UK.

8.6 General conclusion

This literature review in this project aimed at reviewed the reports of experiences with bilateral cochlear implants from a clinical perspective and also patient perspective. There are indications that clinical tests do not inform clinicians of the full benefits of bilateral cochlear implantation. These types of tests assess the hearing and localisation ability, but they are not able to show how these translate into everyday life for patients. This led to the need of developing an outcome measure that would be able to sensitive and specific to be able to pick up these changes in patients' lives. The responses to the questions of the Outcome of Bilateral Cochlear Implantation (Adults) showed that some participants experienced benefits on the psychological and lifestyle aspects but they did not perceive their hearing ability to have changed from when they were implanted unilaterally. This might be due to various factors, mainly

memory bias or not being aware of improvements in the hearing ability scale. However there is still the possibility that their hearing ability did not improve as much through bilateral implantation. If this is the case, clinical tests would have not been able to target the changes in the psychological and lifestyle areas.

The outcome measure has 2 uses with the first being in a clinical setting. Hickson (2006) argues that successful fittings of hearing aids can be attributed to the right type of rehabilitation that is offered to the hearing aid user. It is mentioned that a number of patients are not successful in wearing their aids as a result of negative attitudes, inability to identify goals and problems with their management. These issues would come to light in discussion with the patient if the right questions are asked. Questionnaires are the a good medium to help start a conversation to see how patients are getting on and if rehabilitation aims need to be changed to accommodate the need of that particular patient. Benefits of bilateral hearing have been shown and it would be a shame if a patient is not able to reach his or her potential with bilateral cochlear implants because their needs would have not been identified correctly. It is hoped that the questionnaire developed in this study, Outcomes of Bilateral Cochlear Implantation (Adults), will be helpful to avoid this in clinical situations.

The second purpose for the questionnaire is to aid investigations in the domain of cost utility analysis of bilateral implantation in adult patients. Presently, adult patients are only eligible to unilateral implantation in the UK unless they are visually impaired too. This situation might not change in the short-term but there is a growing interest in this area and it is hoped that one day a full investigation into the health utility of bilateral implantation is carried out. The Outcomes of Bilateral Cochlear Implantation (Adults) will be able to be useful in the mapping study for this purpose and be able to provide valuable information in this domain.

Appendix 1. Invitation letter to participants for stage one of the study

Dear Sir/Madam,

This study is part of a PhD I am doing at the Institute of Sound and Vibration Research at the University of Southampton. The aim of this multi-centre study is to find out more about the quality of life of patients who have had two cochlear implants. There is more information about this study on the information sheet I have attached to this letter. Once you read the information sheet you will be able to decide if you are willing to collaborate with the study.

If you decide that you are willing to participate in the study, I would be very grateful if you could take some time to fill in the consent form and the attached questionnaire. This questionnaire is the initial part of research study. There are a variety of questions on work, family life, social activities, and your feelings and attitudes. You can send the signed consent form and filled questionnaire to me by using the pre-paid envelope. Please send the questionnaire within a month of it being given to you.

All the information given to me will be kept in strict confidence. ***Confidentiality will not be breeched at any time***. An important aspect of the study is that the individual implant centres will not get any information given by any particular patient. Any responses that may be used for publications will be anonymous so that readers cannot identify any individual.

If you would like further information before you make a decision, please feel free to contact me by either phoning 02380 594939, or emailing me at rb@isvr.soton.ac.uk.

I would like to thank you for your help. Your effort and time are greatly appreciated.

Yours sincerely,

Roberta Buhagiar
Research Student and Audiological Scientist

Appendix 2. Information sheet to participants for stage one of the study

1. Study title

Quality of life of patients with bilateral (2) cochlear implants.

2. Invitation paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

3. What is the purpose of the study?

The aim is to design a questionnaire that measures the quality of life of patients with two cochlear implants when compared to one. The responses from this questionnaire will be used to devise another questionnaire. It is intended that the final questionnaire will be used clinically as a tool for quantifying benefit and guiding patient management.

4. Why have I been chosen?

The main researcher has contacted several cochlear implant centres across the UK asking the clinicians if they were willing to participate in the study. The centres which have agreed to take part were asked to pass on the information pack containing this information sheet, consent form and questionnaire to patients who have had two cochlear implants for at least three months.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you need to sign the enclosed consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. ***A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive***.

6. What do I have to do if I take part?

You will need to sign the consent form (a copy of this will be given to you) and fill in the attached questionnaire. You will be able to take the questionnaire home to fill it in. This questionnaire is the initial part of research study. There are a variety of questions on work, family life, social activities, and your feelings and attitudes. Once

you fill in the questionnaire, please send it together with the signed consent form to the researcher using the pre-paid envelope. Please send the questionnaire within a month of it being given to you.

7. What are the possible disadvantages of taking part?

The questionnaire might set you thinking about any expectations which you had when you got your second cochlear implant and did not achieve.

8. What are the possible advantages of taking part?

The questionnaires will be useful in Cochlear Implant Centres. Better understanding of quality of life after receiving the second implant will aid the professionals dealing with patients in understanding what the practical limitations of these devices are and advising and helping patients accordingly.

9. What if something goes wrong?

It is not envisaged that this study should pose any difficulties to subjects. However, Professional Indemnity Insurance covers the study. Should you need to contact the main researcher or supervisor, the details are as follows:

Roberta Buhagiar (researcher), Profs. Mark Lutman (supervisor)
Institute of Sound and Vibration Research
University of Southampton
Highfield
Southampton SO17 3BJ
Tel. No. 02380 594939
Email: rb@isvr.soton.ac.uk

10. Will my taking part in this study be kept confidential?

All information, which is collected from you during the course of the research, will be kept strictly confidential. Any information, which is used in publications, will have your name removed so that you cannot be recognised from it. The clinicians at your local Implant Centre will not know if you have decided to participate or not and any feedback which is given to them will have your name removed.

11. What will happen to the results of the research study?

The responses will be analysed and the information obtained will be used to devise a further questionnaire that will look at the same issues. It is intended that this questionnaire will be used in Cochlear Implant Centres after validation studies are carried out. Some of the collected information might also be published in Audiology journals. You will not be identified in any report/publication.

12. Who is organising the research?

This research is part of a PhD in Audiology that is being carried out by the researcher at the University of Southampton.

13. Who has reviewed the study?

The Metropolitan MREC, one of the 13 national research ethics committees, has given its approval.

Thank you for taking time to read this information and taking part in the study

Appendix 3. Consent form

Subject Number: .....

This consent form applies to a subject volunteering to undergo a study for research purposes. The form is to be completed before the study commences.

I,.....of.....
(address)

consent to take part in the PhD study 'Quality of life of patients with bilateral cochlear implants' to be conducted by Miss. Roberta Buhagiar.

The purpose and nature of this study have been explained to me. I understand that the investigation is to be carried out solely for the purposes of research. I am willing to act as a volunteer for that purpose on the understanding that I shall be entitled to withdraw this consent at any time, without giving any reasons for withdrawal. I understand that all information will be treated as confidential by the researcher.

Date:.....Signed:.....
(Volunteer subject)

I confirm that I have explained to the subject the purpose and nature of the investigation which has been approved by the Multi-center Research and Ethics Committee.

Date:.....Signed:.....
(Researcher in charge of study)

Appendix 4. Open-ended questionnaire

Cochlear Implant Study Questionnaire

The following questions ask for your views about your second cochlear implant. Please do try and give your initial response to the questions and then add as much detail as you feel appropriate. There is space for additional comments at the end of the questionnaire.

Age: _____

1. How long have you had the first implant for?

2. How long have you had the second implant for?

3. How often do you use your second implant?

4. What do you consider to be the most difficult period since your first implant?

5. What made you consider having a second implant?

6. What made you decide to go ahead with the second implant?

7. What were your expectations for the second implant?

8. Has the second implant met your expectations?

9. Do you feel that the second implant was disadvantageous?

10. How intrusive has the period of the second implantation and follow-up been to
    - you?
    - your family?

11. What does your family think are the effects from you having two implants?

12. Do you feel that having two implants instead of one has affected your personality, mood or attitudes? If so, in what way?

13. Do you think that having two implants had any effect on your relationship with other people? If yes, what was the effect?

14. In your experience, what are the benefits of having two implants instead of one?

15. In your experience, what are the disadvantages of having two implants instead of one?

16. Are there any listening situations that are easier to attend to now that you have two implants compared to when you had one?

17. How would you compare your life overall now with two implants to when you had one?

18. How long did it take to notice any difference in performance (if any) with the second implant from switch on?

19. How would you compare the rehabilitation services provided with the second implant to the first one?

20. How would you compare getting used to having two implants to getting used to having one?

21. Were there differences in the role of the implant centre with the second implant, compared to the first?

22. Did you have any particular concerns before the operation for your second implant?

23. Do you have any particular concerns for the future concerning your implants? If yes, what are they?

24. If you had a chance to reconsider the second implant, would you still go ahead?

25. What advice would you give to someone considering having a second implant (either getting a second one or having two at the same time)?

26. Please add any other comments, especially if you think they are relevant to how your life changed since you had your second cochlear implant.

Appendix 5. Information sheet for interviews

1. Study title

Quality of life of patients with bilateral cochlear implants.

2. Invitation paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

3. What is the purpose of the study?

The aim is to design a questionnaire that measures the quality of life of patients with two cochlear implants when compared to one. Some open-ended questionnaires have already been used in Stage One of this study. These questionnaires have highlighted some issues that need to be discussed in more detail. The responses from the open-ended questionnaire and the interviews will be used to devise another questionnaire. It is intended that the final questionnaire will be used clinically as a tool for quantifying benefit and guiding patient management.

4. Why have I been chosen?

The main researcher has used the details of patients who had already taken part is Stage One.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you need to sign the enclosed consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. ***A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive***.

6. What do I have to do if I take part?

You will need to sign the consent form and return the attached form in the pre-paid envelope. The main researcher will then contact you to arrange a date for the interview to take place.

The interview will take place in your home. This will be during daylight hours only and it will not be longer than 1 hour. The purpose of the interview is to discuss the

categories that were developed from the open-ended questionnaires you have answered in Stage One and also to discuss the format of the close-ended questionnaire that will be developed from your responses. The researcher will aim at getting an idea of what is viewed to be important for this subject population and which items should be included in the final questionnaire. The subjects who will be interviewed will also be sent a draft copy of the close-ended questionnaire to determine which questions need to be modified due to inappropriateness, misunderstandings or causing confusion.

The interviews will be recorded and transcribed at a later stage. The recordings will only be available to the main researcher and the project supervisor. Any transcriptions will be anonymous.

7. What are the possible disadvantages of taking part?

The interview might set you thinking about any expectations which you had when you got your second cochlear implant and did not achieve.

8. What are the possible advantages of taking part?

The final questionnaire will be useful in Cochlear Implant Centres. Better understanding of quality of life after receiving the second implant will aid the professionals dealing with patients in understanding what the practical limitations of these devices are and advising and helping patients accordingly.

9. What if something goes wrong?

It is not envisaged that this study should pose any difficulties to subjects. However, Professional Indemnity Insurance covers the study. Should you need to contact the main researcher or supervisor, the details are as follows:

Roberta Buhagiar (researcher), Profs. Mark Lutman (supervisor)
Institute of Sound and Vibration Research
University of Southampton
Highfield
Southampton SO17 3BJ
Tel. No. 02380 594939
Email: rb@isvr.soton.ac.uk

10. Will my taking part in this study be kept confidential?

All information, which is collected from you during the course of the research, will be kept strictly confidential. Any information, which is used in publications, will have your name removed so that you cannot be recognised from it. The clinicians at your

local Implant Centre will not know if you have decided to participate or not and any feedback which is given to them will have your name removed.

11. What will happen to the results of the research study?

The responses will be analysed and the information obtained will be used to devise a further questionnaire that will look at the same issues. It is intended that this questionnaire will be used in Cochlear Implant Centres after validation studies are carried out. Some of the collected information might also be published in Audiology journals. You will not be identified in any report/publication.

12. Who is organising the research?

This research is part of a PhD in Audiology that is being carried out by the researcher at the University of Southampton.

13. Who has reviewed the study?

The ISVR Safety and Ethics Committee of the University of Southampton has given its approval.

Thank you for taking time to read this information and taking part in the study

Appendix 6. Example of data from different participants being combined together in codes

Code: directionality {14-0}

P 1: - 1:1 [direction] (9:9) (Super)
Codes: [direction]

P 1: - 1:8 [I'm sure, definitely, you get ..] (27:27) (Super)
Codes: [direction]

P 3: - 3:2 [Oh goodness yes, it has been a..] (25:25) (Super)
Codes: [direction]

Oh goodness yes, it has been a lot better hearing direction.

P 4: - 4:10 [The directional aspect of it -..] (39:39) (Super)
Codes: [direction]

The directional aspect of it - I went to Southampton for some tests.

P 5: - 5:7 [It is not only to do with spee..] (31:31) (Super)
Codes: [direction]

It is not only to do with speech but also with direction, I don't know.

P 7: - 7:4 [The other thing is range and d..] (28:28) (Super)
Codes: [direction] [easier listening] [improves hearing]

The other thing is range and directional.

P 7: - 7:9 [The directionality gives you m..] (35:35) (Super)
Codes: [direction] [increased confidence]

The directionality gives you more confidence.

P 7: - 7:24 [It is all directional.] (112:112) (Super)
Codes: [direction]

It is all directional.

P 8: - 8:2 [Because with one all the sound..] (11:11) (Super)
Codes: [direction] [more relaxed]

Because with one all the sounds are confusing, I had to look around a lot, whereas now I don't look around as much and it makes things more easy and relaxing.

P 8: - 8:6 [Well yes I think it does, main..] (29:29) (Super)
Codes: [direction]

Well yes I think it does, mainly for sound sidedness - direction if you want.

P 9: - 9:8 [Also, because I know where a s..] (27:27) (Super)
Codes: [direction]

Also, because I know where a sound is coming from I look at the person straight away whereas before I would miss half the conversation.

P 9: - 9:10 [I was always conscience that I..] (31:31) (Super)
Codes: [direction] [easier listening]

I was always conscience that I did not know where a sound was coming from so the location of sound gave me great confidence.

P 9: - 9:13 [I find that now I can tell whe..] (59:59) (Super)
Codes: [direction]

I find that now I can tell whether an ambulance or a police car is in front of me or behind me in traffic.

P10: - 10:2 [It helps in the first instance..] (12:12) (Super)
Codes: [direction]

It helps in the first instance - once you know who the person who is speaking is then it is easier.

Appendix 7. Outcome of Bilateral Cochlear Implantation (Adults) version 1.0

Change in quality of life – two cochlear implants versus one cochlear implant (version 1.0)

These statements ask you to compare your experience with two cochlear implants to when you only had one cochlear implant.

Some of the statements are worded in a negative way (e.g. 'Two implants do not help me understand people more that one implant did') and some are worded in a positive way (e.g. 'I can understand more speech sounds with two implants than with one'). Please read the statements carefully to make sure that you circle the correct response.

Some of the statements might not be applicable to everyone. If you feel that a statement does not apply to you, please circle 'neither agree for disagree'.

Please answer all the questions.

1. Conversations on the telephone are easier with two implants than with just one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

2. Two implants do not help me understand people more than one implant did

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

3. I do not rely on lip-reading as much now that I have two implants compared to when I had one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

4. I can understand more speech sounds with two implants than with one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

5. I am not more confident to initiate conversations with people now that I have two implants to when I had one

Agree	*Agree*	*Neither agree*	*Disagree*	*Disagree*

strongly		*nor disagree*		*strongly*

6. I now join in group discussions more than I did with my first implant alone

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

7. The clarity of my speech has improved since I got my second implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

8. I can listen to the radio since I had my second cochlear implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

9. I can not understand the TV more now that I have two cochlear implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

10. I can distinguish between voices more now that I am using two cochlear implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

11. I can carry out a conversation in background noise more easily with two implants than with just one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

12. Conversations with a passenger in a car are easier with two implants than one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

13. I am not more aware of everyday sounds with two implants than with one implant alone

Agree	*Agree*	*Neither agree*	*Disagree*	*Disagree*

strongly *nor disagree* *strongly*

14. I am not able to discriminate between more everyday sounds with two implants than with just one implant

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

15. I am disappointed that I can not appreciate music as I would like to

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

16. I can hear more warning sounds with two cochlear implants than with just one

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

17. Nature sounds are more enjoyable with two cochlear implants than with one

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

18. I know where sounds are coming from more with two implants than with just one

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

19. Sounds are clearer with two implants than with one

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

20. I am a more cheerful person with two implants than with one

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

21. I am not less lonely now that I have two implants

Agree *Agree* *Neither agree* *Disagree* *Disagree*

strongly		*nor disagree*		*strongly*

22. I feel like I have returned to the person I was before my hearing loss

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

23. Having two cochlear implants has made me more confident than when I just had one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

24. I suffer less depression with two implants than when I just had one implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

25. The second cochlear implant has not increased my self-esteem

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

26. I have a greater desire to join in more social activities now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

27. Since my second cochlear implant I have regained more close relationships

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

28. People are more willing to talk to me now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

29. Others close to me have benefited as much as I have from my second cochlear implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

30. My second cochlear implant has not given me more confidence to approach others

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

31. My independence has increased since I got my second implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

32. Having two cochlear implants has proved to be a great help at work when compared to just having one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

33. I have not become more sociable now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

34. I am more confident driving with two implants than with one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

35. My family and friends have been very supportive throughout the process of getting the second implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

36. Adjusting to the sound of the second implant was initially difficult

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

37. The benefits of having a second implant exceeded any minor problems

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

38. The second implant serves as an insurance in case the first one fails

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

39. My life is much fuller now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

40. My advice to another person going for the second implant would be 'Go for it!'

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

41. My second implant has exceeded my expectations

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

42. My outlook on life is much more positive now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

Thank you for completing the questionnaire.

Appendix 8. Outcome of Bilateral Cochlear Implantation (Adults) version 2.0

Change in quality of life – two cochlear implants versus one cochlear implant (version 2.0)

The statements below ask you to think about your experience with two cochlear implants and how this changed, compared to when you had just one implant. Please only think about your experiences since you had the second implant.

Some of the statements are worded in a negative way (e.g. 'Two implants are no better than one implant in helping me understand people') and some are worded in a positive way (e.g. 'I can understand more speech sounds with two implants than with one'). Please read the statements carefully to make sure that you circle the correct response.

If you feel that a statement does not apply to you, please circle 'neither agree nor disagree'.

Please answer all the questions.

Part A: This part asks about communication using two cochlear implants versus one

1. I can understand more speech sounds with two implants than with one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

2. I rely less on lip-reading now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

3. Two implants are <u>no</u> better than one implant in helping me understand people

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

4. I can distinguish between voices more, now that I am using two cochlear implants

Agree	*Agree*	*Neither agree*	*Disagree*	*Disagree*

strongly		*nor disagree*		*strongly*

5. I can carry out a conversation in background noise more easily with two implants than with just one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

6. I am more confident in starting conversations with people now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

7. I now join in group discussions more than I did with my first implant alone

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

8. The clarity of my speech has <u>not</u> improved since I got my second implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

9. Conversations on the telephone are easier with two implants than with just one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

10. Conversations in a car are easier with two implants than with one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

Part B: This part asks about your ability to hear everyday sounds with two cochlear implants

11. I am <u>not</u> aware of more everyday sounds with two implants compared to one implant alone

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

12. I am <u>not</u> able to discriminate between more everyday sounds with two implants

compared to one implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

13. Sounds are clearer with two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

14. I enjoy listening to the radio more with two cochlear implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

15. I can <u>not</u> understand the television more now that I have two cochlear implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

16. I am disappointed that I can not appreciate music as I would like to

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

17. I can hear more warning sounds with two cochlear implants compared to one

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

18. The sounds of nature are more enjoyable with two cochlear implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

19. I am better able to tell where sounds are coming from with two implants compared to one

Agree	*Agree*	*Neither agree*	*Disagree*	*Disagree*

strongly *nor disagree* *strongly*

Part C: The part looks at your happiness and well-being now that you have two cochlear implants compared to when you had one implant

20. I am a more cheerful person since having my second cochlear implant

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

21. I do <u>not</u> feel as lonely now that I have two implants

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

22. I now feel like I have returned to the person I was before my hearing loss

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

23. Having two cochlear implants has made me more confident than when I just had one

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

24. I suffer less depression with two implants than when I had just one

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

25. The second cochlear implant has <u>not</u> increased my self-esteem

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

26. Having the second implant as a back up in case the first one fails makes me feel better

Agree strongly *Agree* *Neither agree nor disagree* *Disagree* *Disagree strongly*

27. I feel my life is much fuller now that I have two cochlear implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

28. My outlook on life is much more positive now that I have two cochlear implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

Part D: This part looks at how having two cochlear implants instead of one has affected your lifestyle and social relationships

29. I have a greater desire to join in with social activities now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

30. Since my second cochlear implant I have regained close relationships

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

31. People are more willing to talk to me now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

32. Others close to me have benefited as much as I have from my second cochlear implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

33. My second cochlear implant has <u>not</u> given me more confidence to approach others

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

34. My independence has increased since I got my second cochlear implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

35. Having two cochlear implants has proved to be a great help at work

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

36. I have <u>not</u> become more sociable now that I have two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

37. I am more confident driving with two implants

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

Part E: This part investigates some general issues

38. My family and friends have been very supportive throughout the process of getting my second cochlear implant

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

39. Adjusting to the sound of the second implant was difficult to begin with

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

40. The benefits of having a second implant exceeded any problems

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

41. My second implant has exceeded my expectations

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

42. My advice to another person thinking about a second implant would be to have it

Agree strongly	*Agree*	*Neither agree nor disagree*	*Disagree*	*Disagree strongly*

Thank you for completing the questionnaire.

Appendix 9. Outcome of Bilateral Cochlear Implantation (Adults) version 3.0

Outcomes from Bilateral Cochlear Implantation (Adults) (version 3.0)

The statements below ask you to think about your experience with two cochlear implants and how this changed, compared to when you had just one implant. Please only think about your experiences since receiving the second implant.

Please read the statements carefully to make sure that you circle the correct response and answer all the questions. If the statement is not relevant to your experience, please circle '*same as before*'.

Part A: This part asks about COMMUNICATION using two cochlear implants

1. Compared to when I had one cochlear implant, I can now understand speech sounds

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

2. Compared to when I had one cochlear implant, I now rely on lip-reading

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

3. Compared to when I had one cochlear implant, I now understand people

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

4. Compared to when I had one cochlear implant, I now can distinguish between voices

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

5. Compared to when I had one cochlear implant, I can now carry out a conversation in background noise

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

6. Compared to when I had one cochlear implant, I am now confident in starting conversations with people I don't know well

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

7. Compared to when I had one cochlear implant, I now join in group discussions

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

8. Compared to when I had one cochlear implant, the clarity of my speech is

Much worse than before | *Worse than before* | *Same as before* | *Better than before* | *Much better than before*

9. Compared to when I had one cochlear implant, carrying out a general telephone conversation is

Much worse than before | *Worse than before* | *Same as before* | *Better than before* | *Much better than before*

10. Compared to when I had one cochlear implant, conversations in a car are

Much worse than before | *Worse than before* | *Same as before* | *Better than before* | *Much better than before*

Part B: This part asks about your ability to HEAR everyday sounds with two cochlear implants

11. Compared to when I had one cochlear implant, I am now aware of everyday sounds

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

12. Compared to when I had one cochlear implant, I am now able to discriminate between everyday sounds

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

13. Compared to when I had one cochlear implant, the clarity of sounds has become

Much worse than before | *Worse than before* | *Same as before* | *Better than before* | *Much better than before*

14. Compared to when I had one cochlear implant, I now enjoy listening to speech programmes on the radio

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

15. Compared to when I had one cochlear implant, I can now understand the television

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

16. Compared to when I had one cochlear implant, I now can enjoy music

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

17. Compared to when I had one cochlear implant, I can now hear warning sounds

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

18. Compared to when I had one cochlear implant, I can now enjoy the sounds of nature

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

19. Compared to when I had one cochlear implant, I am now able to tell immediately where sounds are coming from

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

Part C: This part looks at your HAPPINESS AND WELL-BEING with two cochlear implants compared to when you had only one implant

20. Compared to when I had one cochlear implant, I am now cheerful

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

21. Compared to when I had one cochlear implant, I now feel lonely

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

22. Compared to when I had one cochlear implant, I now feel like my old self

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

23. Compared to when I had one cochlear implant, I am now a confident person

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

24. Compared to when I had one cochlear implant, I now feel depressed

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

25. Compared to when I had one cochlear implant, my self-esteem is

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

26. Compared to when I had one cochlear implant, I now worry about having an implant failure

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

27. Compared to when I had one cochlear implant, I now feel my life is fuller

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

28. Compared to when I had one cochlear implant, I now look upon life in a positive manner

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

Part D: This part looks at how having two cochlear implants instead of one has affected your LIFESTYLE AND SOCIAL RELATIONSHIPS

29. Compared to when I had one cochlear implant, I now have a desire to join in with social activities

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

30. Compared to when I had one cochlear implant, I now have close relationships

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

31. Compared to when I had one cochlear implant, people are now willing to talk to me

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

32. Compared to when I had one cochlear implant, I feel that others close to me have benefited from me having cochlear implants

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

33. Compared to when I had one cochlear implant, I am now confident to approach others

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

34. Compared to when I had one cochlear implant, my independence is

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

35. Compared to when I had one cochlear implant, I experience difficulties at work

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

36. Compared to when I had one cochlear implant, I am now sociable

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

37. Compared to when I had one cochlear implant, I am now confident driving a car or another vehicle

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

Part E: This part investigates some GENERAL ISSUES

38. Compared to when I had one cochlear implant, my family and friends need to support me

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

39. Compared to when I had one cochlear implant, the difficulty initially adjusting to the sound of the second cochlear implant was

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

40. Compared to when I had one cochlear implant, I now feel that the benefits of having cochlear implants outweigh any disadvantages

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

41. Compared to when I had one cochlear implant, I now feel that my implants have exceeded my expectations

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

42. Compared to when I had one cochlear implant, the strength of my positive recommendation to another person thinking about a second implant would be

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

Thank you for completing the questionnaire.

Please write any further comments you may have below.

Appendix 10. Invitation letter for face validity

Dear

Re: PhD study 'Quality of life measures in patients with bilateral cochlear implants'

You may remember that you had taken part in the second stage of my PhD study. This involved an interview in your home to discuss how your second cochlear implant had improved your quality of life when compared to the time when you had just one implant.

My research will eventually lead to developing a questionnaire related to quality of life in patients with bilateral cochlear implants. I have devised the first version of this questionnaire based on the responses I had got from the open-ended questionnaire and also the interviews I had conducted. You may remember that at the end of the interview I had mentioned that before I move on to the third stage of my study, I need to ask the patients who participated in the study to review the questionnaire. The review will help me determine which questions need to be modified due to inappropriateness, misunderstandings or causing confusion. You had shown interest in doing this so I am sending you a copy of version 1.0 and a pre-paid envelope. Please do not feel obliged to do this, but should you be happy to review the questionnaire, I would appreciate your comments.

The questionnaire does not need to be filled in at this stage, but I would appreciate it if you could read it through and pass any comments about the wording used and whether this could cause any confusion. Please feel free to pass any comments about the layout of the questionnaire and anything else you can think of. You can put these comments on the questionnaire itself and return it to me in the pre-paid envelope.

Should the questionnaire need major modifications, it might need to be reviewed again before moving on to the next stage. Please let me know if you do not wish to be contacted for a second review should this become necessary.

May I remind you that all your replies will remain confidential and that you will not need to pay any postage.

Should you need to contact me, you can do so either by using the contact details at the top of this letter or by emailing me on rb@isvr.soton.ac.uk.

Once again, thank you for your help and co-operation.

Regards,

Roberta Buhagiar MSc CS
Clinical Scientist (Audiology) and Research Student

Appendix 11. Outcome of Bilateral Cochlear Implantation (Adults) version 4.0

Outcomes from Bilateral Cochlear Implantation (Adults) (version 4.0)

The statements below ask you to think about your experience with two cochlear implants and how this changed, compared to when you had just one implant. Please only think about your experiences since receiving the second implant.

Please read the statements carefully to make sure that you circle the correct response and answer all the questions. If the statement is not relevant to your experience, please circle '*same as before*'.

1. Compared to when I had one cochlear implant, I am now able to discriminate between everyday sounds

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

2. Compared to when I had one cochlear implant, I now can distinguish between voices

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

3. Compared to when I had one cochlear implant, I can now carry out a conversation in background noise

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

4. Compared to when I had one cochlear implant, conversations in a car are

Much worse than before | *Worse than before* | *Same as before* | *Better than before* | *Much better than before*

5. Compared to when I had one cochlear implant, I now enjoy listening to speech programmes on the radio

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

6. Compared to when I had one cochlear implant, I can now understand the television

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

7. Compared to when I had one cochlear implant, I now can enjoy music

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

8. Compared to when I had one cochlear implant, I can now hear warning sounds

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

9. Compared to when I had one cochlear implant, I can now enjoy the sounds of nature

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

10. Compared to when I had one cochlear implant, I am now able to tell immediately where sounds are coming from

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

11. Compared to when I had one cochlear implant, I now look upon life in a positive manner

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

12. Compared to when I had one cochlear implant, I now rely on lip-reading

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

13. Compared to when I had one cochlear implant, I am now aware of everyday sounds

A lot less than before *Less than before* *Same as before* *More than before* *Much more than before*

14. Compared to when I had one cochlear implant, the clarity of my speech is

Much worse than before | *Worse than before* | *Same as before* | *Better than before* | *Much better than before*

15. Compared to when I had one cochlear implant, carrying out a general telephone conversation is

Much worse than before | *Worse than before* | *Same as before* | *Better than before* | *Much better than before*

16. Compared to when I had one cochlear implant, I experience difficulties at work

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

17. Compared to when I had one cochlear implant, I am now cheerful

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

18. Compared to when I had one cochlear implant, my self-esteem is

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

19. Compared to when I had one cochlear implant, people are now willing to talk to me

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

20. Compared to when I had one cochlear implant, I feel that others close to me have benefited from me having cochlear implants

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

21. Compared to when I had one cochlear implant, the strength of my positive recommendation to another person thinking about a second implant would be

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

22. Compared to when I had one cochlear implant, I now join in group discussions

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

23. Compared to when I had one cochlear implant, I now feel lonely

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

24. Compared to when I had one cochlear implant, I now feel like my old self

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

25. Compared to when I had one cochlear implant, I am now a confident person

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

26. Compared to when I had one cochlear implant, I now have a desire to join in with social activities

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

27. Compared to when I had one cochlear implant, I am now confident driving a car or another vehicle

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

28. Compared to when I had one cochlear implant, my independence is

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

29. Compared to when I had one cochlear implant, my family and friends need to support me

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

30. Compared to when I had one cochlear implant, I now worry about having an implant failure

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

31. Compared to when I had one cochlear implant, the difficulty initially adjusting to the sound of the second cochlear implant was

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

32. Compared to when I had one cochlear implant, I now feel that the benefits of having cochlear implants outweigh any disadvantages

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

33. Compared to when I had one cochlear implant, I now feel that my implants have exceeded my expectations

A lot less than before | *Less than before* | *Same as before* | *More than before* | *Much more than before*

Thank you for completing the questionnaire.

Please write any further comments you may have below.

Appendix 12. Invitation and information letter for stage three of the study

Development of a questionnaire investigating the quality of life of patients who have received sequential bilateral cochlear implants

Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent form.

I would like to invite you to take part in a research study. This study is part of a PhD degree I am doing at the Institute of Sound and Vibration Research at the University of Southampton. Before you decide if you would like to take part, you need to understand why the research is being done and what it would involve for you.

1. What is the purpose of the study?

The aims of the research study are to investigate the quality of life in patients with bilateral cochlear implants (an implant in each ear). More specifically, to design a questionnaire which measures the quality of life of these patients. This is a multi-centre study, so the people taking part will be from a number of different cochlear implant centres.

The first and second stages of the study have already been carried out and they involved patients from the UK National Health Service (NHS) who have received two implants. Patients who participated were given an open-ended questionnaire and then some interviews were carried out with them. The results from the open-ended questionnaire and the interviews were compared and added to each other in order to create a final questionnaire. This questionnaire now needs to be refined and compared to existing questionnaires. This is the purpose of this present study.

2. Do I have to take part?

No, it is your choice whether or not to take part. If you do decide to take part, you need to sign the enclosed consent form. You are still free to withdraw at any time and without giving a reason. ***A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive***.

3. What do I have to do if I take part?

You will need to sign the enclosed consent form and return it in the pre-paid envelope. You will also be asked to complete a number of paper-based questionnaires, and return them to me in pre-paid envelopes.

There are two parts to this study:
Part 1 – Enclosed with this letter is the third version of the questionnaire that needs to be refined – "Outcomes from Bilateral Cochlear Implantation (Adults)". You will need to fill this in and return it with the consent form in the pre-paid envelope. Once I receive this I will send you another copy of the same questionnaire to fill in a month after you fill in the first copy. The reason for filling it in again is to check on its reliability (checking that the responses given the first time are similar to those given the second time). Please do not photocopy your first responses, as I need you to fill in each questionnaire independently.

The responses from Part 1 will be analysed using statistics to reduce the number of questions and produce the final questionnaire. The final questionnaire now needs to be compared to existing questionnaires to make sure that it contains valid questions and that it is a reliable source of information for clinicians who will be using it in clinic.

Part 2 – Once the final version of the questionnaire is devised, it will be sent to you together with three standard questionnaires: "Speech, Spatial and Quality of Hearing Scale (SSQ)", "Euro-Qol (EQ-5D)" and "SF-36" questionnaires to fill in. You will be asked to fill in my questionnaire first, and then will be given an order in which to fill in the standard questionnaires. Again, you will be asked to fill in the same questionnaires a month after you filled in the first set. The reason for asking you to fill in these questionnaires twice is to check their reliability.

I realise this is a lot of questionnaires, but it is very important for my research to have the full set.

The questionnaires contain different statements and you are asked to circle or tick the answer for each statement. There are more detailed instructions on how to fill them in on the front page of each questionnaire.

4. What are the possible disadvantages of taking part?
The questionnaires might set you thinking about any disappointments, or expectations which may not have been met, regarding cochlear implantation.

5. What are the possible advantages of taking part?
The questionnaire "Outcomes from Bilateral Cochlear Implantation (Adults)" will be useful in Cochlear Implant Centres. It is intended that the final questionnaire will be used clinically as a tool for quantifying benefit and guiding patient management.

6. What if something goes wrong?

It is not envisaged that this study should pose any difficulties to participants. However, the study is covered by University of Southampton Insurance. Should you need to contact the supervisor of this study, the details are as follows:

Prof Mark Lutman
Hearing and Balance Centre
Institute of Sound and Vibration Research
University of Southampton
Southampton SO17 1BJ

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. The contact details are as follows:
C Level Centre Block
Mailpoint 81
Southampton General Hospital
Tremona Road
Southampton SO16 6YD
Telephone 02380 796325

Will my taking part in this study be kept confidential?

All information, which is collected from you during the course of the research, will be kept strictly confidential. Any information, which is used in publications, will have your name removed so that you cannot be recognised from it.

7. What will happen to the results of the research study?

The responses will be analysed and the information obtained will be used to finalise the questionnaire. It is intended that this questionnaire will be used in Cochlear Implant Centres at the end of this research. Some of the collected information might also be published in academic journals or presented at conferences. You will not be identified in any report/publication.

8. Who has reviewed the study?

Before it can start, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This is to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by Oxfordshire REC B on the 17th September 2009.

If you have any questions please feel free to contact me. My contact details can be found on the first page of this letter or my email address is rb@isvr.soton.ac.uk.

I would like to thank you for your help. Your effort and time are greatly appreciated.

Yours sincerely,

Roberta Buhagiar MSc
Clinical Scientist (Audiology)/ Research Student

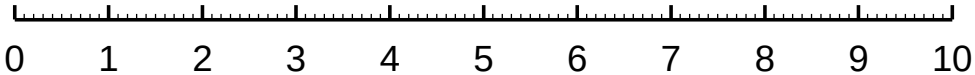
Appendix 13. SSQ

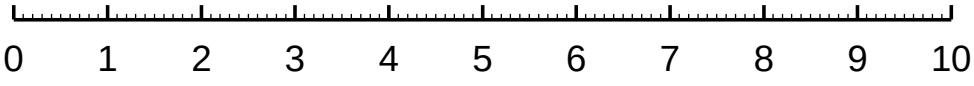
Date: _____

S[peech] S[patial] Q[ualities] version 3.1.1 I.

SPEECH HEARING RATING SCALE

1. You are talking with one other person and there is a TV on in the same room. Without turning the TV down, can you follow what the person you're talking to says?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

2. You are talking with one other person in a quiet, carpeted lounge-room. Can you follow what the other person says?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

3. You are in a group of about five people, sitting round a table. It is an otherwise quiet place. You can see everyone else in the group. Can you follow the conversation?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

4. You are in a group of about five people in a busy restaurant. You can see everyone else in the group. Can you follow the conversation?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

5. You are talking with one other person. There is continuous background noise, such as a fan or running water. Can you follow what the person	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

says?	**With bilateral cochlear implants**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

6. You are in a group of about five people in a busy restaurant. You <u>cannot</u> see everyone else in the group. Can you follow the conversation?	**When you had one cochlear implant**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

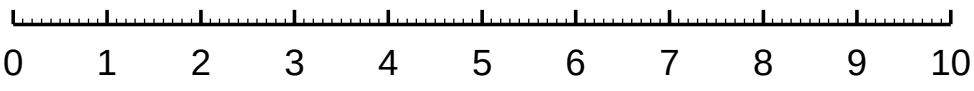
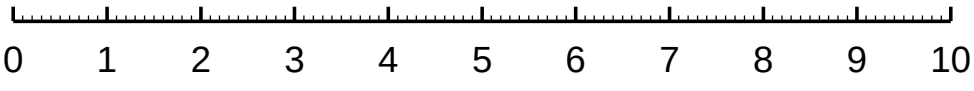
7. You are talking to someone in a place where there are a lot of echoes, such as a church or railway terminus building. Can you follow what the other person says?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

8. Can you have a conversation with someone and ignore another (third) person whose interfering voice is the same pitch as the person you're talking with?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

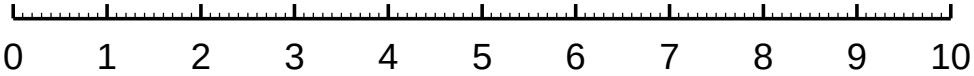
9. Can you have a conversation with someone and ignore another (third) person whose interfering voice is a different pitch from the	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

person you're talking with?	**With bilateral cochlear implants**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

10. You are listening to someone talking to you, while at the same time trying to follow the news on TV. Can you follow what both people are saying?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

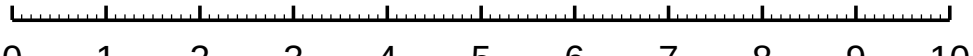
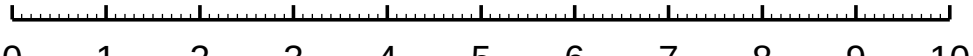
11. You are in conversation with one person in a room where there are many other people talking. Can you follow what the person you are talking to is saying?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

12. You are with a group and the conversation switches from one person to another. Can you easily follow the conversation without missing the start of what each new speaker is saying?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

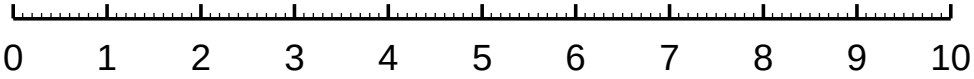
13. Can you easily have a conversation on the telephone?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

14. You are listening to someone on the telephone and someone next to you starts talking. Can you follow what's being said by both speakers?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

SPATIAL RATING SCALE

1. You are outdoors in an unfamiliar place. You hear someone using a lawnmower. You can't see where they are. Can you tell right away where the sound is coming from?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

2. You are sitting around a table or at a meeting with several people. You can't see everyone. Can you tell where any person is as soon as they start speaking?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

3. You are sitting in between two people. One of them starts to speak. Can you tell right away whether it is the person on your left or your right, without having to look?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

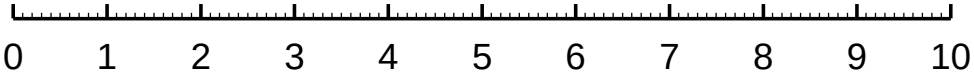
4. You are in an unfamiliar house. It is quiet. You hear a door slam. Can you tell right away where that sound came from?	**When you had one cochlear implant**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

5. You are in the stairwell of a building with floors above and below you. You can hear sounds from another floor. Can you readily tell where the	**When you had one cochlear implant**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

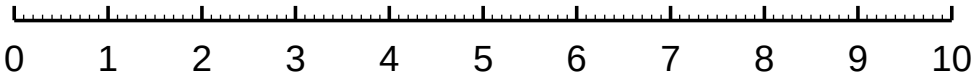
sound is coming from?	**With bilateral cochlear implants**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

6. You are outside. A dog barks loudly. Can you tell immediately where it is, without having to look?	**When you had one cochlear implant**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

7. You are standing on the footpath of a busy street. Can you hear right away which direction a bus or truck is coming from before you see it?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

8. In the street, can you tell how far away someone is, from the sound of their voice or footsteps?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

9. Can you tell how far away a bus or a truck is, from the sound?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

10. Can you tell from the sound which direction a bus or truck is moving, for example, from your left to your right or right to left?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

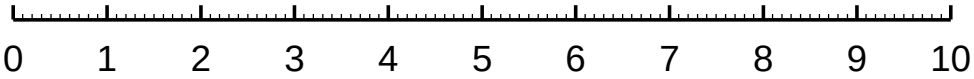
11. Can you tell from the sound of their voice or footsteps which direction a person is moving, for example, from your left to your right or right to left?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

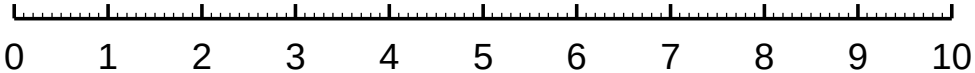
	With bilateral cochlear implants	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

12. Can you tell from their voice or footsteps whether the person is coming towards you or going away?	**When you had one cochlear implant**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

13. Can you tell from the sound whether a bus or truck is coming towards you or going away?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

14. Do the sounds of things you are able to hear seem to be inside your head rather than out there in the world?	**When you had one cochlear implant**	Inside my head Out there  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Inside my head Out there  Min Max	Tick if not applicable or wouldn't hear it [ ]

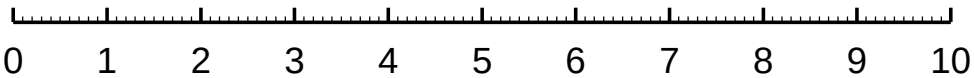
15. Do the sounds of people or things you hear, but cannot see at first, turn out to be closer than expected when you do see them?	**When you had one cochlear implant**	Much closer Not closer  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Much closer Not closer  Min Max	Tick if not applicable or wouldn't hear it [ ]

16. Do the sounds of people or things you hear, but cannot see at first, turn out to be further away than expected when you do see them?	**When you had one cochlear implant**	Much further Not further  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Much further Not further  Min Max	Tick if not applicable or wouldn't hear it [ ]

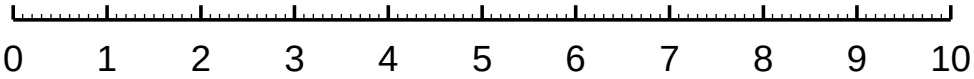
17. Do you have the impression of sounds being exactly where you would expect them to be?	**When you had one cochlear implant**	Not at all them to be Where you expect  Min Max	Tick if not applicable or wouldn't hear it [ ]

	With bilateral cochlear implants	Not at all Where you expect them to be  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

SOUND QUALITIES RATING SCALE

1. Think of when you hear two things at once, for example, water running into a basin[a power-tool being used][a plane flying past] and, at the same time, a radio playing[the sound of hammering][a truck driving past]. Do you have the impression of these as sounding separate from each other?	**When you had one cochlear implant**	Not at all Separate  Min Max	Perfectly Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Separate  Min Max	Perfectly Tick if not applicable or wouldn't hear it [ ]

2. When you hear more than one sound at a time, do you have the impression that it seems like a single jumbled sound? *	**When you had one cochlear implant**	Jumbled jumbled Not  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Jumbled jumbled Not  Min Max	Tick if not applicable or wouldn't hear it [ ]

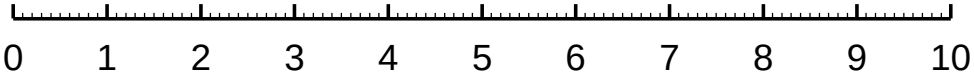
3. You are in a room and there is music on the radio. Someone else in the room is talking. Can you hear the voice as something separate from the music?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

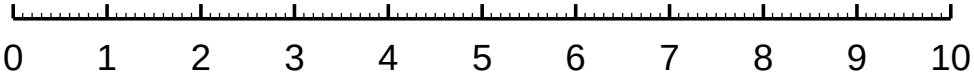
4. Do you find it easy to recognise different people you know by the sound of each one's voice?	**When you had one cochlear implant**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

5. Do you find it easy to distinguish different pieces of music that you are familiar with?	**When you had one cochlear implant**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

	With bilateral cochlear implants	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

6. Can you tell the difference between different sounds, for example, a car versus a bus; water boiling in a pot versus food cooking in a frypan?	**When you had one cochlear implant**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

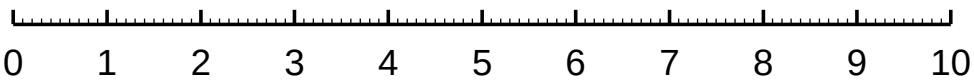
7. When you listen to music, can you make out which instruments are playing?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

8. When you listen to music, does it sound clear and natural?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

9. Do everyday sounds that you can hear easily seem clear to you (not blurred)?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

10. Do other people's voices sound clear and natural?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

11. Do everyday sounds that you hear seem to have an artificial or unnatural quality?	**When you had one cochlear implant**	Very much artificial Natural  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Very much artificial Natural  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

12. Does your own voice sound natural to you?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

13. Can you easily judge another person's mood from the sound of their voice?	**When you had one cochlear implant**	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

14. Do you have to concentrate very much when listening to someone or something?	**When you had one cochlear implant**	Concentrate hard No need to concentrate  0 1 2 3 4 5 6 7 8 9 10 Min Max	Tick if not applicable or wouldn't hear it [ ]

	With bilateral cochlear implants	Concentrate hard concentrate  Min Max No need to	Tick if not applicable or wouldn't hear it [ ]

15. If you turn one implant off, and do not adjust the other, does everything sound unnaturally quiet?	**With bilateral cochlear implants**	Too quiet too quiet  Min Max Not	Tick if not applicable or wouldn't hear it [ ]

16. When you are the driver in a car can you easily hear what someone is saying who is sitting alongside you?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

17. When you are a passenger can you easily hear what the driver is saying sitting alongside you?	**When you had one cochlear implant**	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

	With bilateral cochlear implants	Not at all Perfectly  Min Max	Tick if not applicable or wouldn't hear it [ ]

18. Do you have to put in a lot of effort to hear what is being said in conversation with others?	**When you had one cochlear implant**	A lot of effort No effort  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	A lot of effort No effort  Min Max	Tick if not applicable or wouldn't hear it [ ]

19. Can you easily ignore other sounds when trying to listen to something?	**When you had one cochlear implant**	Not easily ignore Easily ignore  Min Max	Tick if not applicable or wouldn't hear it [ ]
	With bilateral cochlear implants	Not easily ignore Easily ignore  Min Max	Tick if not applicable or wouldn't hear it [ ]

Appendix 14. EQ-5D

Health Questionnaire

English version for the UK

(validated for Ireland)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state **before you had the second cochlear implant**.

Mobility

I had no problems in walking about ❑

I had some problems in walking about ❑

I was confined to bed ❑

Self-Care

I had no problems with self-care ❑

I had some problems washing or dressing myself ❑

I was unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I had no problems with performing my usual activities ❑

I had some problems with performing my usual activities ❑

I was unable to perform my usual activities ❑

Pain/Discomfort

I had no pain or discomfort ❑

I had moderate pain or discomfort ❑

I had extreme pain or discomfort ❑

Anxiety/Depression

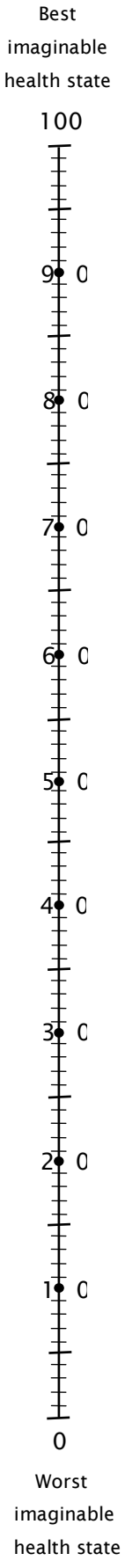
I was not anxious or depressed ❑

I was moderately anxious or depressed ❑

I was extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health was before you had the second cochlear implant, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state was.



By placing a tick in one box in each group below, please indicate which statements best describe your own health state **today**.

Mobility

I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care

I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

Pain/Discomfort

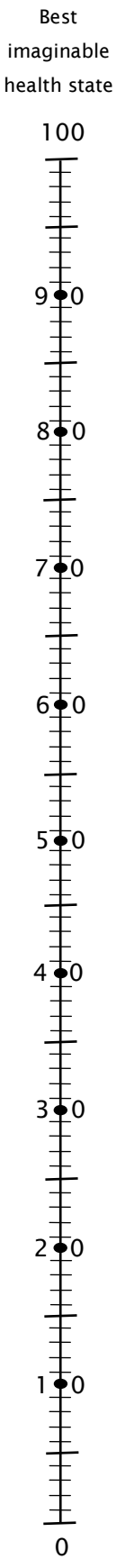
I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.



Appendix 15. SF-36

The Short Form 36 Health Survey Questionnaire (SF-36) –
Part one (life with one cochlear implant)

The following questions ask for your views about your health when you had one cochlear implant, how you felt and how well you were able to do your usual activities. If you are unsure about how to answer any questions, please give the best answer you can and make any of your own comments if you like. Do not spend too much time in answering as your immediate response is likely to be the most accurate.

1. **In general**, would you say your health was:

(*Please tick **one** box*)

Excellent	□
Very good	□
Good	□
Fair	□
Poor	□

2. The following questions are about activities you might have done during a typical day. Did your health limit you in these activities? If so, how much?

(*Please tick **one** box on each line*)

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	□	□	□
b) **Moderate activities**, such as moving a table, pushing a vacuum, bowling or playing golf	□	□	□
c) Lifting or carrying groceries	□	□	□
d) Climbing **several** flights of stairs	□	□	□
e) Climbing **one** flight of stairs	□	□	□
f) Bending, kneeling or stooping	□	□	□
g) Walking **more than a mile**	□	□	□
h) Walking **half a mile**	□	□	□
i) Walking **100 yards**	□	□	□
j) Bathing and dressing yourself	□	□	□

3. When you had **one cochlear implant**, did you have any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(*Please tick **one** box on each line*)

	Yes	**No**
a) Cut down on the **amount of time** you spent on work or other activities	□	□
b) **Accomplished less** than you would have liked	□	□
c) Were limited in the **kind** of work or other activities	□	□
d) Had **difficulty** performing the work or other activities (eg. it took more effort)	□	□

4. When you had **one cochlear implant**, did you have any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(*Please tick **one** box on each line*)

	Yes	**No**
a) Cut down on the **amount of time** you spent on work or other activities	□	□
b) **Accomplished less** than you would have liked	□	□
c) Didn't do work or other activities as **carefully** as usual	□	□

5. When you had **one cochlear implant**, to what extent did your physical health or emotional problems interfere with your normal social activities with family, friends, neighbours or groups?

(*Please tick **one** box*)

Not at all □
Slightly □
Moderately □
Quite a bit □
Extremely □

6. How much **bodily pain** did you have when you had **one cochlear implant?**

(*Please tick **one** box*)

None □
Very mild □
Mild □
Moderate □
Severe □
Very severe □

7. When you had **one cochlear implant** how much did **pain** interfere with your normal work (including work both outside the home and housework)?

(*Please tick **one** box*)

Not at all □
A little bit □
Moderately □
Quite a bit □
Extremely □

8. These questions are about how you felt and how things were with you when you had **one cochlear implant.** How much time when you had **one cochlear implant:**

(*Please tick **one** box on each line*)

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Did you feel full of life	□	□	□	□	□
b) Were you a very nervous person?	□	□	□	□	□
c) Did you feel so down in the dumps that nothing could cheer you up?	□	□	□	□	□
d) Did you feel calm and peaceful?	□	□	□	□	□
e) Did you have a lot of energy?	□	□	□	□	□
f) Did you feel downhearted and low?	□	□	□	□	□

g) Did you feel worn out?	□	□	□	□	□
h) Were you a happy person?	□	□	□	□	□
i) Did you feel tired?	□	□	□	□	□

9. When you had **one cochlear implant**, how much of the time did your **physical health or emotional problems** interfere with your social activities (like visiting friends or close relatives, etc)?

(*Please tick **one** box*)

All of the time □
Most of the time □
Some of the time □
A little of the time □
None of the time □

10. Please choose the answer that best describes how **true** or **false** each of the following statements was for you when you had **one cochlear implant**.

(*Please tick **one** box on each line*)

	Definitely true	**Mostly true**	**Not sure**	**Mostly false**	**Definitely false**
a) I seemed to get ill more easily than other people	□	□	□	□	□
b) I was as healthy as anybody I know	□	□	□	□	□
c) I expected my health to get worse	□	□	□	□	□
d) My health was excellent	□	□	□	□	□

The Short Form 36 Health Survey Questionnaire (SF-36) –
Part two (life with two cochlear implants)

The following questions ask for your views about your health, how you feel and how well you are able to do your usual activities. If you are unsure about how to answer any questions, please give the best answer you can and make any of your own comments if you like. Do not spend too much time in answering as your immediate response is likely to be the most accurate.

1. **In general**, would you say your health is:

(*Please tick **one** box*)

- Excellent ☐
- Very good ☐
- Good ☐
- Fair ☐
- Poor ☐

2. **Compared to one year ago**, how would you rate your health in general now?

(*Please tick **one** box*)

- Much better than one year ago ☐
- Somewhat better than one year ago ☐
- About the same ☐
- Somewhat worse now than one year ago ☐
- Much worse now than one year ago ☐

3. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

(*Please tick **one** box on each line*)

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a) **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	□	□	□
b) **Moderate activities**, such as moving a table, pushing a vacuum, bowling or playing golf	□	□	□
c) Lifting or carrying groceries	□	□	□
d) Climbing **several** flights of stairs	□	□	□
e) Climbing **one** flight of stairs	□	□	□
f) Bending, kneeling or stooping	□	□	□
g) Walking **more than a mile**	□	□	□
h) Walking **half a mile**	□	□	□
i) Walking **100 yards**	□	□	□
j) Bathing and dressing yourself	□	□	□

4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(*Please tick **one** box on each line*)

	Yes	**No**
a) Cut down on the **amount of time** you spent on work or other activities	□	□
b) **Accomplished less** than you would have liked	□	□
c) Were limited in the **kind** of work or other activities	□	□
d) Had **difficulty** performing the work or other activities (eg. it took more effort)	□	□

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(*Please tick **one** box on each line*)

	Yes	**No**
a) Cut down on the **amount of time** you spent on work or other activities	□	□
b) **Accomplished less** than you would have liked	□	□
c) Didn't do work or other activities as **carefully** as usual	□	□

6. During the **past 4 weeks**, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

(*Please tick **one** box*)

- Not at all □
- Slightly □
- Moderately □
- Quite a bit □
- Extremely □

7. How much **bodily pain** have you had during the **past 4 weeks**?

(*Please tick **one** box*)

- None □
- Very mild □
- Mild □
- Moderate □
- Severe □
- Very severe □

8. During the **past 4 weeks** how much did **pain** interfere with your normal work (including work both outside the home and housework)?

(*Please tick **one** box*)

Not at all □
A little bit □
Moderately □
Quite a bit □
Extremely □

9. These questions are about how you feel and how things have been with you in the **past 4 weeks.** How much time during **the past 4 weeks:**

(*Please tick **one** box on each line*)

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) Did you feel full of life	□	□	□	□	□
b) Have you been a very nervous person?	□	□	□	□	□
c) Have you felt so down in the dumps that nothing could cheer you up?	□	□	□	□	□
d) Have you felt calm and peaceful?	□	□	□	□	□
e) Did you have a lot of energy?	□	□	□	□	□
f) Have you felt downhearted and low?	□	□	□	□	□
g) Did you feel worn out?	□	□	□	□	□
h) Have you been a happy person?	□	□	□	□	□
i) Did you feel tired?	□	□	□	□	□

10. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends or close relatives, etc)?

(*Please tick **one** box*)

- All of the time □
- Most of the time □
- Some of the time □
- A little of the time □
- None of the time □

	Definitely true	**Mostly true**	**Not sure**	**Mostly false**	**Definitely false**
a) I seemed to get ill more easily than other people	□	□	□	□	□
b) I was as healthy as anybody I know	□	□	□	□	□
c) I expected my health to get worse	□	□	□	□	□
d) My health was excellent	□	□	□	□	□

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