Cost-effectiveness of cochlear implantation in adults

Report from the Norwegian Knowledge Centre for the Health Services
(Nasjonalt kunnskapssenter for helsetjenesten) No 26–2006
A health economic evaluation

Nasjonalt kunnskapssenter for helsetjenesten

Om rapporten: Vi har gjennomført en kostnadseffektanalyse av ensidig **koklea-implantat** hos tilnærmet døve og helt døve voksne pasienter. **Metode:** Kostnadene i våre anslag inkluderte helsevesenets kostnader ved innsetting av kokleaimplantat og undersøkelser og kontroller knyttet til implantatet. Kostnadseffektiviteten ble målt som merkostnad per vunnet kvalitetsjustert leveår (QALY) med implantat i forhold til ikke å ha implantat. Målet på helseeffekt var sannsynlig forbedring i livskvalitet for voksne behandlet med kokleaimplantat over implantatets forventede levetid. Vi brukte en verdi på 0,2 kvalitetsjusterte leveår per år. Verdien ble hentet fra Kunnskapssenterets rapport "Koklea-implantat hos sterkt tunghørte og døve voksne" (nr 25–2006), og er basert på bare én studie. Kostnadene ved ensidig koklea-implantat ble priset ved hjelp av henholdsvis offisielle nasjonale takster og DRG-baserte refusjonsrater. Både framtidige kostnader og gevinster i form av økt livskvalitet ble diskontert med 4 % per år. **Hovedfunn:** For en gjennomsnittlig voksen pasient som er 58 år gammel ved implantasjon, medførte ensidig koklea-implantat •En merkost-

(fortsetter på baksiden)

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(fortsettelsen fra forsiden) nad på kr 537.100 (diskontert) per tilfelle sammenlignet med ikke å ha implantat • en total livksvalitetsgevinst på 3,12 kvalitetsjusterte leveår per tilfelle • og dermed en årlig merkostnad per vunnet kvalitetsjustert leveår på kr 172. 000. • Resultatene er beheftet med usikkerhet. Vi så derfor på hvor følsomme resultatene var for endringer i sentrale forutsetninger og parameteranslag i vår beregningsmodell. Vi utførte en sensitivitetsanalyse der modellparametre ble variert samtidig og innenfor antatt sannsynlige intervaller. Ved en gjennomsnittlig gevinst i livskvalitet på 0,2 per år var det 97 % sannsynlig at merkostnaden per vunnet kvalitetsjustert leveår lå under kr 400.000. Med et mer konservativt anslag på økning i livskvalitet, på 0,15 per år, var det tilsvarende resultatet 92 %. Om en anser tiltak med en kostnad under kr 400.000 per vunnet kvalitetsjustert leveår som kostnadseffektive, synes ensidig koklea-implantat å være kostnadseffektivt.

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Sammendrag

Introduksjon
Vi har gjennomført en kostnadseffektanalyse av koklea-implantat (KI) i ett øre hos tilnærmet døve og helt døve voksne pasienter.

Metode
Kostnadene i våre anslag inkluderte helsevesenets kostnader ved å sette inn implantatet og undersøkelser og kontroller knyttet til det. Kostnadseffektivitet ble målt som merkostnad per kvalitetsvunnet leveår (QALY) med koklea-implantat sammenlignet med ikke å ha implantat. Vi benyttet en enkel beslutningsmodell der pasienters ferd gjennom systemet gir forskjellige helsegevinster og kostnader.

Målet på helseeffekt var sannsynlig forbedring i livskvalitet for voksne behandlet med koklea-implantat over implantatets forventede levetid, som vi forutsatte å være lik pasientenes forventede gjenværende levetid. Vi brukte en verdi på 0,2 kvalitetsjusterte leveår per år. Verdien ble hentet fra rapporten ” Koklea-implantat hos sterkt tunghørte og døve voksne” fra Kunnskapssenteret (rapport nr 25-2006) som oppsummerer helseeffekten av KI. Anslaget er basert på kun én studie. Kostnadene ved medisinske tjenester forbundet med innleggelse og poliklinisk behandling ved sykehus ble priset ved hjelp av henholdsvis offisielle nasjonale takster og DRG-baserte refusjonsrater (gjeldende for 2005–2006). Både framtidige kostnader og framtidige livskvalitets-gevinster ble diskontert med 4 % per år.

Resultater
Vi har beregnet verdier for kostnad per vunnet kvalitetsvunnet leveår for en gjennomsnittlig voksen pasient, som i norske studier er 58 år gammel ved implantasjon. I hovedanalysen medførte koklea-implantat en merkostnad på kr 537 100 (diskontert) per tilfelle sammenlignet med ikke å ha implantat, en total (diskontert) QALYs-gevinst på 3,12 og dermed en merkostnad per vunnet kvalitetsjustert leveår på kr 172 000.

Resultatene er beheftet med usikkerhet. Vi så derfor på hvor følsomme resultatene var for endringer i sentrale forutsetninger og parameteranslag i vår beregningsmodell. Ved en énveis sensitivitetsanalyse så vi på endringer i én variabel om gangen. Resultatene var spesielt følsomme for endringer i mål på nytten av behandlingen i form av vunnet livskvalitet (QALY) og varigheten av bruken av implantatet. Modellen var rimelig robust i forhold til andre parametre.
Vi utførte også en sensitivitetsanalyse der modellparametre ble variert samtidig og innenfor antatt sannsynlige intervaller. Ved en gjennomsnittlig gevinst i livskvalitet (QALY) på 0,2 per år var det 97 % sannsynlig at merkostnaden per vunnet QALY var under kr 400 000. Med et mer konservativt anslag på økning i livskvalitet, på 0,15 per år, var det tilsvarende resultatet 92 %. Om en anser tiltak med en kostnad under kr 400 000 per vunnet QALY som kostnadseffektive, synes koklea-implantat å være kostnadseffektivt.

Konklusjoner
Resultatene fra denne kostnadseffektanalysen indikerer at:

i) Anslagene for kostnad per vunnet QALY for koklea-implantat (KI) hos voksne i Norge er på linje med resultater rapportert i andre tilsvarende studier.

ii) Anslagene på kostnadseffektiviteten av KI kommer gunstig ut i forhold til andre allment aksepterte helseintervensjoner.

iii) Anslagene er beheftet med usikkerhet. Men sensitivitetsanalyser der vi tok høyde for noe av usikkerheten og blant annet benyttet mer konservative anslag på helsegevinsten ved KI, antydet en stor grad av sannsynlighet for at KI kan være kostnadseffektivt.

Executive summary

Introduction
A cost-utility analysis of unilateral cochlear implantation (CI) in severe to profoundly deaf adults has been undertaken from the primary perspective of the direct medical costs to the Norwegian health care system (all providers) as well as an assessment of those direct medical costs borne by patients (in the form of co-payments).

Methods
Cost-effectiveness was measured as the incremental cost per quality adjusted life year (QALY) gained of CI compared to no intervention and was estimated using a simple patient care pathway decision model (with associated costs and outcomes).
The measure of outcome chosen was the likely improvement in the quality of life (in terms of gain in health utility for adult recipients over the useful life of the implant (assumed to be the implantee's remaining lifetime). A mean value of 0.2 QALYs per year based on a single study included in a systematic review on cochlear implants in severe to profoundly deaf adults from the Norwegian Knowledge Centre for the Health Services' (Report no 25-2006) was used to estimate the "quality weighted health state" gain from CI in the base case analysis. Medical services utilized relating to hospital outpatient and inpatient care were priced using official national tariffs and DRG based reimbursement rates respectively (at 2005/06 levels). Future costs and outcomes were discounted at a rate of 4% per annum.

Results
Values for cost per QALY have been calculated for an average adult aged 58 at time of implantation (based on published Norwegian studies) and results calculated for the lifetime of the implant. In the base case, CI yielded an estimated incremental discounted lifetime cost of kr 537,100 per case, compared to no intervention, a total gain in discounted QALYs of 3.12 and a cost per QALY gained of kr 172,000.
To explore uncertainty in the assumptions used we explored how sensitive the results were to changes in the values of a number of parameter estimates. Univariate sensitivity analysis (varying one parameter at a time) performed on the gain in health utility, resource use, unit costs, discount rate and duration of device use indicated that estimates were particularly sensitive to changes in the gain in health utility and duration of devise use but reasonably robust to the most plausible values for other model parameters. Probabilistic sensitivity analysis (in which model parameters were varied simultaneously) across assumed distributions demonstrated that under a mean utility gain of 0.2, there was a 97% probability that CI in adults would be cost-effective if one was willing to pay kr 400,000. Applying a lower value of 0.15 per year for the mean utility indicated a corresponding 92% probability that CI in adults would be cost effective.

Conclusions
The results from this cost-utility analysis demonstrate that:
i) The estimates of cost per QALY gained for CI in adults in Norway are consistent with other published estimates reported in the adult CI cost-effectiveness literature.
ii) Cost-effectiveness of CI in adults compares favorably relative to other commonly accepted health care interventions.
iii) Analyses undertaken on the uncertainty in parameter estimates, including a more conservative assumption on the gain in health utility, indicated that CI in adults would potentially remain cost-effective across a range of possible acceptability thresholds.

Contents

1. Introduction

Over the past years, unilateral cochlear implantation (CI) has evolved to become an established means of providing auditory perception to profoundly deaf individuals (in adults as well as in children). As experience with the assessment, surgery, and rehabilitation of deaf patients has increased, the selection criteria also have changed. The global experience of bilateral implantation is also beginning to slowly grow, but there are still no prospective studies in the literature discussing the results of CI in terms of patients' own valuations of their health-related quality of life with respect to health utility in becoming the recipient of 2 as opposed to one cochlear implant.

The use of CI has become an established routine treatment option for profoundly deafened adults who gain no benefit from acoustic hearing aids both in Norway and around the world. For such patients, CI generally represents the only other available intervention. CI has also been reported as a treatment alternative for adult patients who derive some benefit from using hearing aids (albeit sometimes only marginal benefit).

CI is a high cost, low volume health care intervention and the treatment must be worthwhile from several perspectives. For individual patients, the long-term benefits should, on average, outweigh the short-term risks. For the health service the clinical benefits gained (in terms of life-years or quality-adjusted life years: QALYs) should justify the costs of treating the relatively few patients that are currently eligible for CI.

The achievement of hearing sensation demonstrated by the enhancement in sound and speech perception after implantation, has been reported to extend to improvements in several aspects of everyday living, such as carrying out usual activities, mental and emotional well-being, and social outcome measures for relationships with others (Carter and Hailey 1999). Relatives of CI recipients have also reported to benefit substantially from patients' improvement in hearing and communication (Mo 2005). In paediatric cochlear implantation, further benefits have been reported in terms of a reduction in the demands associated with special education services (Barton 2006).

In the first part of this study (presented in **Report 25**) a systematic review was performed to assemble the evidence on the efficacy of CI in adults. Some clinicians and patients already regard this evidence as sufficient to justify the use of CI in a small proportion of patients. In addition to evidence of clinical efficacy however, health care decision makers are interested to know the costs associated with CI in adults and whether the surgery and medical device is 'value for money'. Comparison of the additional or commonly referred to in economic terms, the incremental costs to incremental benefits is done by means of a cost-effectiveness analysis resulting in a cost-effectiveness ratio. Cost-effectiveness evidence will offer guidance to stakeholders concerned with health policy, financing and the delivery of hospital services on the efficient use and allocation of limited health care resources, where both clinical and economic evidence is considered together.

Cost-effectiveness evidence may take several viewpoints. For example, calculation of cost to a hospital will generally only include costs borne directly by the hospital, but not costs that patients incur or that society incur from long-term morbidity. The choice of a suitable comparator for CI is typically that of no intervention. However it is possible to draw broader comparisons with other healthcare interventions that impact on patients' quality of life that are

generally accepted as being cost-effective, or for which cost-effectiveness ratios have been provided.

The outcomes of CI studies often focus on improvement of speech perception associated with implantation (as documented in **Report 25-2006**). Additionally, a considerable improvement in patients' quality of life (in terms of health utility) following CI is demonstrated by many studies in the literature. In addition, the value of an economic model is then to explore the plausible range of cost-effectiveness of the treatment. This knowledge would inform the decision whether or not to use CI more widely in the health care service or, if not, whether to invest in further research on it.

A number of previous studies (e.g. Palmer 1999, Cheng 1999) have undertaken cost-effectiveness analyses of CI in adults for the US setting. European based studies are also important since resource use, costs and outcomes of healthcare interventions may vary from country to county in important ways and therefore not unexpectedly decision makes are increasingly interested to have data based on their own country's health care situation (Wilke 1998). Against this background then, the objective of the current health economic evaluation was to evaluate the cost-effectiveness of using CI to treat post-lingual deafness in Norwegian adults.

In a prospective cohort study, the UK Cochlear Implant Study Group (UK CISG, 2004) estimated the cost-utility (cost/QALY, price year 2000/01) of CI in adult recipients according to patients' pre-operative ability to identify words in pre-recorded sentences when aided with acoustic hearing aids. Cost-effectiveness ratios in subjects receiving their implantation at a younger age were superior to those of older adult recipients. For example, €17,316 for subjects younger than 30 years of age compared to €44,635 for subjects who were older than 70 years of age. The authors reported that the cost-effectiveness ratios in traditional candidates profoundly deaf for more than 40 years and in marginal hearing aid users profoundly deaf for more 30 years exceeded the inferred (decision-makers') acceptable cost-effectiveness threshold. Therefore CI was considered not to be cost-effective by the authors in this subgroup of patients.

This current report accompanies **Report 25-2006**, and presents the results of a simple model based cost-utility analysis for the use of CI in adults in the Norwegian health care setting. Several key features of the present cost-effectiveness analysis of CI in adult include:

- Primary (base case) estimates of treatment effectiveness (gain in health utility) and safety (e.g. serious complications) come from the systematic review of clinical studies (**Report 25)**
- The impact of uncertainty in current estimates of treatment effectiveness (utility gains) are evaluated in a range of sensitivity analyses and use values derived form all relevant health-utility studies of cochlear implantation in adults.
- The costs used are applicable to the Norwegian health service setting

2. Methods

This economic evaluation has been designed to inform the decision concerning the use of CI for adults in the Norwegian healthcare setting.

2.1 Study perspective

This analysis estimated the cost effectiveness of CI in adults compared with no intervention as judged by the incremental cost per quality adjusted-life year (QALY) gained. The study was conducted from the Norwegian public health care system perspective and, to some degree, also reflects the patients' perspective.

The choice of standpoint regarding "whose" costs were included in the analysis was also to a large part driven by the audience for the analysis (i.e. Eastern Norway Regional Health Authority). In this particular context, the primary costs of interest are related to providing health care, including the consideration of all categories of providers.

The boundary of measurement of resource consequences has been drawn here to concentrate on those resources which are most important to the (study commissioners') objectives and which are subject to the least uncertainty in measurement.

2.2 Costing methodology

In Figure 1 we aimed to present a simple schematic diagram representing some of the main stages in the care pathway of an average adult CI patient. This description of treatment pathways along with the associated identification and measurement of resources utilised was informed both through discussion with clinicians who were involved in the care of adults CI patients in Norway (BM, SH) and based on descriptions and estimates reported in the published literature (Summerfield 2002, UK CISG 2004).

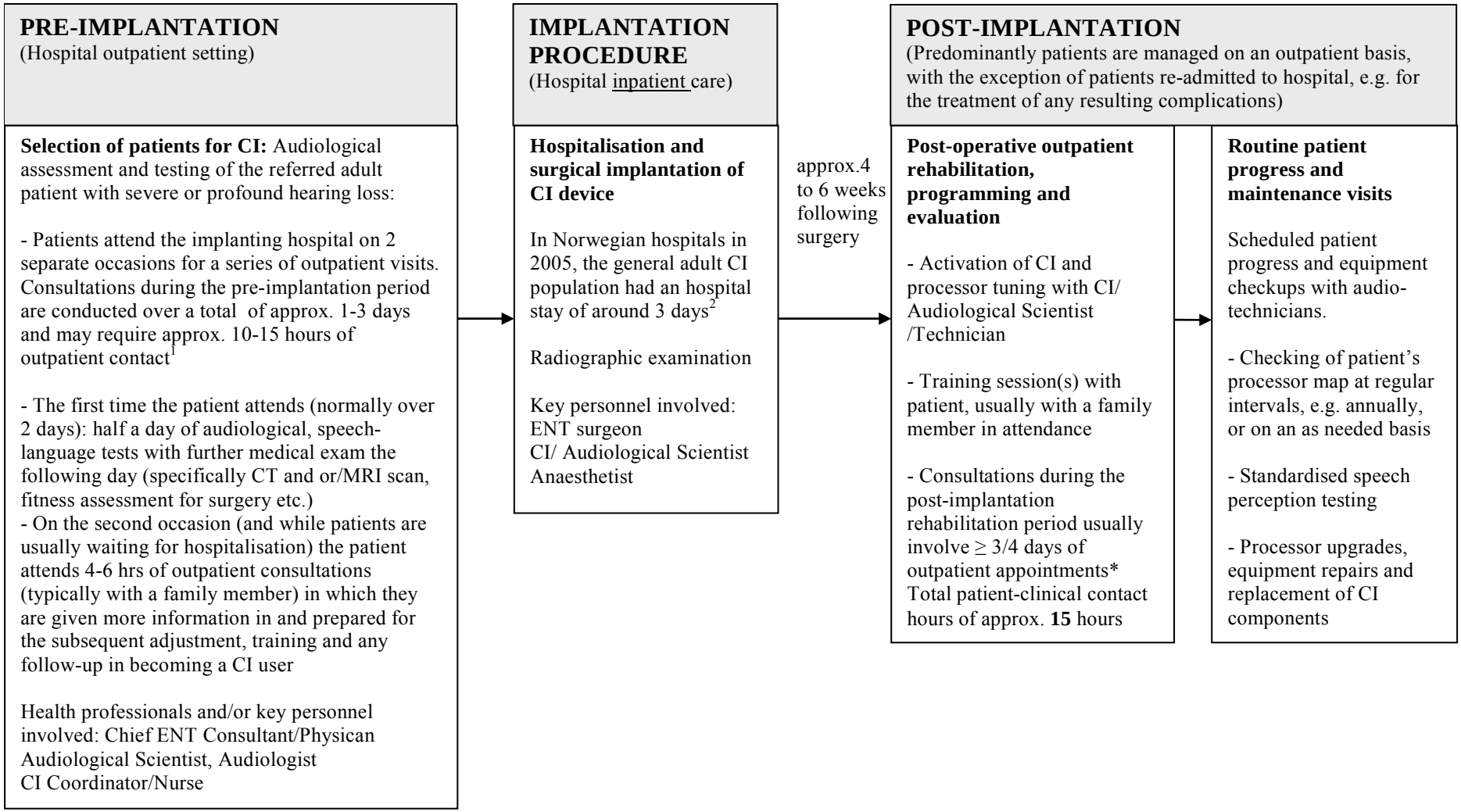
The comparator treatment of no intervention in adults who do not benefit from traditional hearing aids would still probably use some health care resources (e.g. outpatient consultations), even without CI. These resources should typically be subtracted from the CI costs. However, numerically we assumed that these costs would be negligible and therefore we have not included an assessment of them.

The costs of care in the initial phase of managing adult CI patients fall on the hospital sector (through outpatient consultations associated with pre-implant evaluation, followed by, and in those patients eligible for CI, a period of inpatient care associated with surgical implantation).

Post-implantation, costs associated with activating patients' CI, tuning and training of the patient in the use of their CI are incurred in the form of outpatient attendances at their hospital implanting centre. Estimated costs of managing patients with complications (with re-admission) were also included. We have therefore included estimates of the direct costs of hospitalisation, and outpatient care associated with CI selection, post-operative rehabilitation and follow-up.

The study also estimated direct non-medical costs borne by patients in terms of health care co-payments. Resources used by patients in obtaining treatment (e.g. time and travel costs) that might be incurred by a proportion of patients and their relatives (that do not reside locally) whilst receiving hospital outpatient and inpatient care are not included, nor are any

Figure 1. A simplified patient care pathway of some of the main stages in the management of CI in adults in Norway



1. Patients not living locally may be accommodated over night at the "Hospital Hotel" (as may an accompanying family member/person)
2. SINTEF, Norwegian Patient Register Cochlear Implants (DRG4, procedure code DFE00) in Norwegian Hospitals for the year 2005

additional accommodation expenses that may be borne by the patient (e.g. hospital hotel costs). In the latter case, the marginal cost for the inclusion of an overnight stay in the hospital hotel is likely to be very small.

Data regarding indirect costs to society arising from lost productivity in adult CI patients are lacking and we have therefore not included an assessment of any potential indirect economic costs, such as loss of work-related earnings.

Impacts on social productivity, such as increased availability to work, may however be an additional consequence of the health gain resulting from the use of CI. It is desirable that any such monetary benefits should not be subtracted from the estimates of health care resource costs. Such impacts on social productivity are considered sufficiently important in the specific case of paediatric CI and are commonly assessed together with other health and educational program costs. However, data is lacking in regard to CI in adults and the common practice in earlier economic evaluation in adults has assumed these costs would not be significant. Hence we have considered it appropriate to exclude them from the current efficiency calculation.

Available unit cost figures for the most recent price years at the time of the analysis were based on official national tariffs (outpatient care, 2005) and hospital based DRG re-imbursement rates (inpatient care, 2006).

2.3 Economic analysis framework

Study question
From the perspective of the public health service in Norway, is CI (compared with no intervention), cost-effective in the long-term as judged by the incremental cost per quality adjusted-life year gained?

Assessment of alternatives to CI
The only effective treatment for patients with severe and profound hearing loss (not benefiting from traditional hearing aids: traditional candidates) is implantation. However, in clinical practice, marginal hearing aid users could (as a treatment alternative) continue using hearing aids or receive a cochlear implant (so the comparator could be regarded to be different in this case).

We have assumed for the analyses in this report that the alternative interventions being compared are cochlear implantation (unilateral) and no intervention.

Choice of CI device
The most reliable estimate of the efficacy of CI in adults is obtained from a systematic review of all relevant clinical studies (**Report 25**). Most of the evidence in the review comes from studies of the Nucleus and MED-EL implant systems. The comparisons suggested that the systems produced relatively similar results (efficacy). Patients in the studies were from predominantly UK and US centres. So, to produce results that are more relevant to the Norwegian health service setting, we undertook a simple model based analysis, applying primary estimates of treatment effectiveness (health utility gain) based on data from the clinical studies to a population of CI patients treated/managed within the Norwegian hospital setting.

Basic decision model
A cost-effectiveness analysis was conducted within a simple decision-analytical framework to assess the direct healthcare costs and benefits (gain in QALYS) of CI in adults compared with no intervention.

The costs and benefits derived from CI occur at different times. A horizon that is too short will underestimate the value of the intervention, and the impact could be life-long. We chose an analytic time horizon of the patient's remaining lifetime. This time horizon is long enough to capture the full costs and effects of CI with an impact that occurs at different times.

Direct costs were estimated over a short-term time horizon (first year of implantation) and also over a longer-term (the duration of time that patients continue to use their device). Basic cost-utility calculations were conducted using Microsoft Excel and supported with additional data analyses (for sensitivity analyses) using in DATA Pro for Health Care (TreeAge Software, Williamstown, Mass).

The health-economic summary measure
The chosen measure of cost per unit of benefit (cost-effectiveness ratio) was expressed as the incremental cost per quality-adjusted life year (cost per QALY) gained and can be defined as follows:

Cost / utility = Costs / Δ (QALYs) = Costs / Δ (Life year × health utility)

Cost effectiveness ratios were calculated for the inclusion of costs and outcomes incurred over the remaining lifetime of the adult CI recipient.

Adjustment for timing of costs and benefits
We calculated the cost and utility for a patient who received a CI. A 4 % discount rate was applied to both cost and utility.

Allowance for parameter uncertainty: Sensitivity analysis
We performed a number of sensitivity analyses to explore the robustness of the study results to changes in the value of key parameter estimates. Because the utility gain varied appreciably between studies we performed simple univariate analysis on the gain in utility following CI. We also considered the impact on cost-effectiveness of varying our base-case estimates on other key following variables. To address shortcomings in performing only univariate sensitivity analysis, we also performed probabilistic sensitivity analysis using Monte Carlo simulation (Briggs and Gray 1999) in which the values of all variables (second-order uncertainty) in the cost-effectiveness analysis were simultaneously varied by replacing parameter estimates with appropriate distributions. Output from this multiway sensitivity analysis can also take into account uncertainty with respect to maximal cost-effectiveness that decision makers would consider acceptable by generating a cost-effectiveness acceptability curve.

For each parameter, an estimated value used for the base analysis, was defined as well as a possible value range, according to which parameter values were varied in one way sensitivity analysis. Values for resource use were estimated from local clinical opinion, and from the literature. Unit costs were based on official national tariffs (outpatient treatment, patient co-payments) and hospital based DRG re-imbursement rates (inpatient care, surgery, implant device). For probabilistic sensitivity analysis, probability distributions were selected based on

appropriate distributions (Claxton et al 2005) of the underlying parameters for gain in utility, hospital costs, rate of major complications, need for re-implantation and duration of device.

For example, parameters with respect to utility gains (and probabilities) are bounded on the interval zero to one, so it would be inappropriate to apply a distribution that gave a non-negligible value outside of that range. In this case, a beta distribution was specified to reflect the normal distribution and restriction to values between zero and one.

With respect to outpatient hospital activity, resource use values were varied according to a log-normal distribution between the upper a lower limits.

Cost estimates were varied by ±50% around base case estimates in univariate sensitivity analysis. This interval was considered to reflect the 95% confidence interval. For Monte Carlo simulation, a gamma distribution was fitted by estimating the standard deviation according to the formulae:

$\bar{x} + Z_{0.975} \times SD$ = upper limit; $\bar{x} + Z_{0.025} \times SD$ = lower limit.

Base case cost estimates for inpatient hospital activity assumed a 100% DRG reimbursement rate (as opposed to a value based on only 40% reimbursement). Since these estimates may still underestimate somewhat actual costs, we varied this assumption ±50% around their base case values.

2.4 Literature search of health utility studies of CI in adults

We conducted a search of the economic literature with respect to the following terms:

- Studies that reported data on the effectiveness of CI in adults measured in terms of the impact on patients' *health utility*
- Economic evaluations that reported on the cost-effectiveness of CI in adults measured as *cost per QALY* gained (compared to no intervention).

Primary sources: Medline 1966 to date; Centre for Reviews and Dissemination Databases, University of York (comprising Databases of Abstracts of Reviews; Health Technology Assessment Database; NHS Economic Evaluation Database). Other published sources including conference abstracts and proceedings were also searched and other grey literature. Key words used for the search included: cochlear implants or cochlear implantation and adults and quality of life or health-related quality of life or quality-adjusted life year or QALY or cost-effectiveness or cost-utility and other variants. We included studies comparing the cost-effectiveness (cost-utility) in adults receiving implants compared with no intervention. Studies which reported on treatment outcomes based on actual patient data were included. We therefore excluded studies in which the estimates of treatment effectiveness were theoretically derived and not based on actual measurements in adult CI recipients. Studies of both a prospective and retrospective design were included in the summary of evidence of the gain in health utility with cochlear implantation.
However, only estimates derived from prospective investigations with a separate control group were used as the basis for the **primary (base case)** cost-utility analysis (that is studies that were included and met the criteria of the systematic clinical review (Report 25).

We searched studies reporting on (QALY) weights that used both direct and indirect methods. With direct measures, the respondent directly assesses and evaluates (the desirability or preference) for a given health state on a scale of 0.00 (death) to 1.00 (perfect health). Direct

methods include the visual analogue scale (VAS), standard gamble (SG) and time-trade-off (TTO) techniques. Health states evaluated can be hypothetical or can be the respondent's own subjectively defined current health state.

Indirect approaches require that respondents provide information regarding their health status by completing a multiattribute health status classification system questionnaire. Indirect instruments include the Health Utilities Index (HUI), the Quality of Well Being (QWB) scale, and the EuroQol (EQ-5D). Preference based assessments, categorised into direct and indirect measures are often used to obtain the desirability or preferences for health states. There is some disagreement in literature on the best approach, though preference-based valuations in which the general public is the source of values have been recommended (Gold 1997). However it is not clear whether community members value a given health state the same as patients who are experiencing that health state. If there are significant differences between these, then the results of economic evaluations could change depending on the preference source.

3. Results

3.1 Health utility studies of CI in adults

A summary of studies reporting on the impact of CI on patients' health utility is presented in table 1 and table 2. Notably, only one study which also measured health utility as a treatment outcome (Palmer 1999), met the inclusion criteria of the systematic review. Palmer 1999 reported a gain in utility of 0.2 in adults receiving CI based on the HUI. This value was used to perform cost-utility analysis calculations for the base case scenario in our analysis. An overall assessment of the agreement between indirectly obtained community preferences and directly obtained patient preferences is difficult. However, differences between utilities derived from e.g. HUI and say VAS, appear to be small.

Specific utility estimates used to undertake cost-effectiveness calculations (cost per QALY gained) from various studies reported in table 2 are summarised and referred to in the discussion section when making comparisons with the results estimated for the Norwegian setting.

3.2 Direct costs

The identification, measurement and valuation of the relevant cost items, data sources together with other key model assumptions are presented in table 3 (detailed descriptions are also given in the appendix section).
The estimated direct health care costs of CI in adults are summarised in table 4. The preoperative cost of outpatient visits associated with audiological assessments and radiological examinations was kr 20,217 (5% of the estimated total cost in the first year). The cost of inpatient care associated with the primary implant procedure (hospitalisation, surgery, implant device) was kr 366,406. Hospital re-admission for the surgical treatment of resulting major complications was kr 19,237 (4% of total first year costs). The postoperative costs associated with device activation, tuning and audiological follow-up during the first year following implantation was kr 23,780 (6% of total costs). The resulting overall total direct cost incurred in the first year was estimated at kr 429,640. Further longer-term costs over the duration of device use and specifically assuming costs associated with an annual routine follow-up of patients and their equipment added a further estimated kr 107,535. Including potential costs over a longer time horizon therefore yielded total net discounted costs of kr 537,175 in adult CI recipients.

3.3 Quality-adjusted life years (QALYs)

Total gain in QALYs calculated over 25 years of device use (or the assumed average remaining life expectancy of the adult implantee) an annual utility gain of 0.2 (e.g. from 0.5 to 0.7 after implantation) and a 4% annual discount rate yielded an estimated total gain of 3.12 QALYs (5.00 QALYs undiscounted) for a 58 year old adult cochlear implant recipient in the base case.

3.4 Cost-utility of CI in adults

A total cost of unilateral implantation (evaluation, surgery, device activation and fitting of the speech processor, first year follow-up visits) of kr 537,175 resulted in a base case estimate of the cost-utility of CI in adults of kr 172,000 per QALY gained (rounded to nearest kr '000).

Table 1. Estimates of the health utility loss from profound deafness in adults

Study	Instrument	QALY weights: preference based method[1]	Country	Study design	Patients	Number	Health utility loss (SD) [95 % confidence interval]
Results from a meta-analysis of published studies by Cheng 1999:							
Palmer 1999[2]	HUI	Indirect/ community	USA	Prospective	Implant	40	-0.42 (0.17) [-0.37 to -0.47]
Palmer 1999[2]	HUI	Indirect/ community	USA	Prospective	No Implant/Controls	14	-0.42 (0.20) [-0.32 to -0.52]
Wyatt 1995	VAS-without	Direct/ patients	USA	retrospective	Implant	229	-0.47 (0.26) [-0.42 to -0.53]
Summerfield 1995	VAS-without	Direct/ patients	UK	retrospective	Implant	105	-0.63 (0.26) [-0.58 to -0.68]
Summerfield 1995	VAS-before	Direct/ patients	UK	retrospective	Implant	103	-0.42 (0.21) [-0.38 to -0.46]
Summerfield 1995	VAS	Direct/ patients	UK	retrospective	No Implant/Controls	52	-0.41 (0.26) [-0.34 to -0.48]
Summerfield 1995	VAS	Direct/ patients	UK	retrospective	No Implant/ Controls	37	-0.38 (0.25) [-0.30 to -0.46]
Harris 1995	QWB	Indirect/ community	USA	prospective	Implant	7	-0.36 (0.12) [0.27 to -0.46]
Wyatt 1996	HUI	Indirect/ community	USA	cross-sectional	No Implant/Controls	32	-0.41 (0.32) [-0.30 to -0.52]
Overall results[3]						**619**	**-0.46 (0.23) [-0.44 to -0.48]**
Additional health utility studies published since Cheng 1999:							
Wong 2000	HRQOL-15D	Indirect/ community	Hong Kong	retrospective	Implant	13	nr
Krabbe 2000	HUI-II	Indirect/ community	Netherlands	retrospective	Implant	45	-0.45 (0.11)
Summerfield 2002	HUI-II	Indirect/ community	UK	prospective	Implant (traditional candidates)	87	-0.281 (nr) [-0.255 to -0.308]
Summerfield 2002	HUI-II	Indirect/ community	UK	prospective	Implant (marginal hearing aid users)	115	-0.145 (-0.123 to -0.167)
Francis 2002	HUI-III	Indirect/ community	USA	retrospective	Implant	47	-0.63 (0.74)
Bichey 2002[4]	HUI-III	Indirect/ community	USA	retrospective	No Implant/ Controls	10	-0.48 (nr)
UK Cochlear Implant Study Group (UKCISG) 2004[5]	HUI-III	Indirect/ community	UK	prospective	Implant, all patients: Traditional candidates: Group 1 Group 2 Marginal hearing aid users Group 3 Group 4	311 227 134 93 84 53 31	-0.567 (-0.589 to -0.545) -0.590 (-0.614 to -0.565) -0.365 (-0.668 to -0.602) -0.525 (-0.557 to -0.492) -0.506 (-0.553 to -0.460) -0.505 (-0.568 to -0.443) -0.508 (-0.578 to -0.438)
Hawthorne 2004	Assessment of Quality of Life (AQoL) scale	Indirect/ community	Australia and New Zealand	prospective	Implant	34	-0.52 (0.15)
Lee 2006	Various: HUI, EQ-5D, QWB, VAS	Indirect/ community	South Korea	cross-sectional retrospective	Implant	11	HUI: -0.71 (-0.58 to -0.84) ; EQ-5D: -0.48 (-0.3 to -0.59); QWB: -0.55 (-0.4 to -0.7)VAS: -0.73 (-0.82 to -0.89)

Study	Instrument	QALY weights: preference based method[1]	Country	Study design	Patients	Number	Health utility loss (SD) [95 % confidence interval]
Bilateral implantation							
Summerfield 2002	Time trade-off technique	Direct/ patients	UK	Prospective investigation of unilateral patients only	Adult volunteers with normal hearing asked to value the health state of benefiting from a unilateral CI	70	-0.066 (nr) [-0.046 to -0.085]
Summerfield 2002	Time trade-off technique	Direct/ patients	UK	As above	Adult volunteers with normal hearing asked to value the health state of benefiting from bilateral CI	70	-0.035 (nr) [-0.022 to -0.048]

HUI: Health Utility Index, VAS: Visual Analogue Scale, QWB: Quality of well-being scale, VAS-without: patient rates health utility if the CI were taken away, VAS-before: patient rates health utility recalling back to the time before the CI, nr= not reported

1. Quality weights derived either using direct or indirect methods. Direct methods reflect patients' preferences/values for a given health state. Indirect measures provide general population / community preferences/ values for a given health state

2. Palmer 1999 was the single study meeting the inclusion criteria of the systematic review of studies reported in Report (25)

3. Overall results": This represents a health utility loss of 0.46 from "perfect health" (i.e. 1.00 - 0.46 = 0.54); weight = 1/variance
Cheng and Niparko (1999) pooled results from 9 reports (7 studies, n=619) and estimated a health utility in profoundly deaf adults without CI of 0.54 (95% CI, 0.52-0.56)

4. Postlingually deafened patients with severe to profound hearing loss and a diagnosis of large vestibular aqueduct syndrome: 10 CI patients; 10 patients currently using hearing aids. Seven of the 20 HUIs were scored by proxy (by an audiologist at the centre most familiar with the patient)

5. Group 1: patients with 0% of words correct in pre-recorded sentences without lip-reading and no significant improvement with acoustic hearing aids; Group 2: patients with 0% of words correct without lip-reading but significant improvement when aided with acoustic hearing aids; Group 3: patients with 0% of words correct without lip-reading when the ear to implanted was aided, but between 1-50% of words correct when the other ear was aided; Group 4: patients with 1-50% of words correct without lip-reading when the ear to be given an implant was aided acoustically

Table 2. Estimates of the gain in health utility from cochlear implants (CI) in adults

Study	Instrument	Preference based assessments[1]	Country	Study design	Number	Health Utility Gain (SD) [95% confidence interval]
Results from a meta-analysis of published studies by Cheng 1999:						
Palmer 1999	**HUI**	**Indirect/ community**	**USA**	**prospective**	**37**	**+0.2 (0.17) [+0.15 to +0.25]**
Wyatt 1995	VAS-without	Direct/ patients	USA	retrospective	229	+0.304 (0.239) [+0.27 to +0.34]
Summerfield 1995	VAS-without	Direct/ patients	UK	retrospective	105	+0.41 (0.26) [+0.36 to+ 0.46]
Summerfield 1995	VAS-before	Direct/ patients	UK	retrospective	103	+0.23 (0.26) [+0.18 to +0.28]
Harris 1995	QWB	Indirect/ community	USA	prospective	7	+0.072 (0.119) [-0.02 to +0.16]
Wyatt 1996	HUI	Indirect/ community	USA	cross-sectional	229	+0.204 (0.237) [+0.17 to +0.24]
Fugain 1998	VAS	Direct/ patients	France	retrospective	30	+0.072 (0.25) [-0.13 to + 0.31]
Overall results[2]					**511**	**+0.26 (0.23) [+0.24 to + 0.28]**
Additional studies published since Cheng 1999:						
Wong 2000	HRQOL-15D	Indirect/ community	Hong Kong	retrospective	13	+0.1229 (nr)
Krabbe 2000	HUI-II	Indirect/ community	Netherlands	retrospective	45	+0.28 (0.15)
Francis 2002	HUI-III	Indirect/ community	USA	retrospective	47	+0.24 (0.33)
Bichey 2002[3]	HUI-III	Indirect/ community	USA	retrospective	10	+0.2 (0.13)
Summerfield 2002[4]	HUI-II	Indirect/ community	UK	prospective	87 (traditional candidates)	+0.188 (nr) [+0.150 to +0.226]
Summerfield 2002	HUI-II	Indirect/ community	UK	prospective	115 (marginal hearing aid users)	+0.077 (nr) [+0.045 to +0.110]
UK Cochlear Implant Study Group (UKCISG) 2004	HUI-III	Indirect/ community	UK	prospective	Implant, all patients Traditional candidates: Group 1 Group 2 Marginal hearing aid users Group 3 Group 4	+0.197 [+0.176 to +0.218] +0.214 [+0.189 to +0.239] +0.232 [+0.197 to +0.266] +0.188 [+0.154 to +0.222] +0.151 [+0.113 to +0.190] +0.132 [+0.077 to +0.187] +0.184 [+0.138 to +0.229]
Hawthorne 2004	Assessment of Quality of Life (AQoL) scale	Indirect/ community	Australia and New Zealand	prospective	34	+0.20 (from a health state with a utility valued at 0.48 ± 0.15 to a utility 0.68 ± 0.18)
Lee 2006	Various: HUI, EQ-5D QWB, VAS	Direct/ patients and Indirect/ community	South Korea	cross-sectional, retrospective	11	HUI: 0.36 (0.19 to 0.53); EQ-5D: 0.26 (0.07 to 0.45); QWB: 0.16 (0.04 to 0.28); VAS: 0.33 (0.20 to 0.45)

Study	Instrument	Preference based assessments[1]	Country	Study design	Number	Health Utility Gain (SD) [95% confidence interval]
Bilateral CI						
Summerfield 2002	Time trade-off technique	Direct/ community	UK	Prospective investigation of unilateral patients only	70 volunteers valuation of: 1) simultaneous bilateral implantation compared with unilateral implantation or, 2) additional implantation compared with no additional intervention	+ 0.031 (nr) [+0.042 to +0.18]

HUI: Health Utility Index, VAS: Visual Analogue Scale, QWB: Quality of well-being scale, VAS-without: patient rates health utility if the CI were taken away, VAS-before: patient rates health utility recalling back to the time before the CI

1. Quality weights derived either using direct or indirect methods. Direct methods reflect patients' preferences/values for a given health state. Indirect measures provide general population / community preferences/ values for a given health state

2. The SD was not reported in Fugain et al 1998. Cheng 1999 imputed this value as 0.25, i.e. 0.249, the weighted SD from 3 studies, Wyatt 1995 (n=229), Summerfield 1995 (n=105), Summerfield 1995 (n=103). The authors reported that this value was consistent with other VAS studies. The pooled results of 7 studies showed an overall gain in health utility from cochlear implantation in adults of 0.26 from the "profoundly deaf" score of 0.54 (i.e. 0.54+0.26=0.80); weight=1/variance

3. Postlingually deafened patients with severe to profound hearing loss and a diagnosis of large vestibular aqueduct syndrome. Ten CI patients and 10 patients currently using hearing aids. Seven of the 20 HUIs were scored by proxy (an audiologist at the centre most familiar with the patient)

4. Changes in utility were also estimated by volunteers with values somewhat lower than changes in utility estimated by patients for unilateral implantation compared to no intervention: + 0.169 [+0.143 to +0.195]

Table 3. Summary of key parameters in cost effectiveness model[1]

Parameter	Parameter value			Source/comments
	Base case analysis[2]	**Range applied in one way sensitivity analysis**	**Probabilistic sensitivity analysis distribution[2]**	
Utility gain with CI	0.2	0.1 to 0.3	Beta, parameters conservatively approximated using a mean value 0.2 and SD 0.05	Mean utility gain from Palmer 1999 (study included in Report 25-2006)
Discount rate applied to costs	4.0%	3.0% to 6.0%	base case rate of 4%, not varied	Norwegian Ministry of Finance
Discount rate applied to QALYs	4..0%	0.0% to 4.0%	base case rate of 4%, not varied	Assumed
Duration of device use	25 years	10 to 35	uniform	Assumed
Rate of (major) complications: re-implantation, surgical revision	0.05	0.02 to 0.08	Beta, approximated using a mean value 0.05 and SD 0.015	Range of major complications reported in Report A, UK CISG 2004. Wyatt 1995, Summerfield 1995
Resource use and cost estimates (unit)				
Pre-implant outpatient sessions/ hours	3/ 15	2/ 10 to 4/ 20	Gamma	Assumptions based partially on local clinical opinion and estimates used in the published literature (e.g. Summerfield 2002, 2005)
Outpatient follow-up sessions/ hours	4/ 20	3/ 15 to 5/ 25	Gamma	
Annual outpatient follow-up sessions/ hours	1/ 2	-	Base case estimate, not varied	
Cost per outpatient contact hour	1,136	± 50%	Gamma, approximated using a mean value 1,136 and SD 290	Note. RTV outpatient tariffs include an upward adjustment (50%) to correct hospital costs for outpatient activity SAMDATA Somatikk 1/06 http://www.sintef.no/samdata
CT and /or MRI outpatient attendance	2,382	± 50%	Approximated using a mean value of 2,382 and SD 608	
Hospital inpatient cost	366,406	± 50%	Gamma, approximated using a mean value 366,406 and SD 93,471	DRG 49A reimbursement rates: 40 % = kr 146, 564; **100 % = kr 366,406**
Management of (major) complications: Re-implantation Surgical revision	 366,406 18,336	± 50%	Gamma, approximated using a mean value 366,406 and SD 93,471 Gamma, approximated using a mean value 18,336 and SD 4,678	Re-implantation: 40 % = kr 146, 564; **100 % = kr 366,406** Surgical revisions: 40% DRG reimbursement = 7,334; weight 0.58. **100% = kr 18,336**

1. Detailed description of model input parameters, assumptions and associated calculations are presented in table 3.
2. The distributions from which parameter values were randomly sampled in the probabilistic sensitivity analyses. The ranges for parameters without published variability data followed these assumptions: Costs vary by ±50%; time durations associated with device use varies from 10 to 25 years. Relevant limits were applied to all ranges (e.g. utilities and probabilities must be between 0 and 1 and a beta distribution was applied)

Table 4. Resource use, unit cost and total cost estimates of cochlear implants (CI) in adults (kr)

Cost of care item[1]	Resource use	Unit costs (kr)	Source/ reference	Total costs (kr)
Pre-implant outpatient assessment and testing	15 contact hrs/ 3 sessions with patient co-payment per session;	1,136 per contact hr; 265 patient co-payment;	Outpatient resource use based on CI patient care pathway illustrated in Figure 1.Unit costs assumed from RTV official outpatient tariffs. Tariffs further upwardly adjusted based on data from SAMDATA Somatikk 1/06	17,835
CT and/or MRI scan	1 imaging assessment	2,382		2,382
Hospitalisation, surgery and implanted device	1 inpatient hospital admission	366,406		366,406
Post-implant outpatient follow-up and rehabilitation	20 contact hrs/ 4 sessions Patient co-payment per session	22,780 265 patient co-payment	As for pre-implant outpatient care	23,780
Cost of managing (major) complications with re-admissions	Proportion of patients requiring re-implantation: 5%; revision surgery: 5%	366,406; 18,366	Innsatsstyrt finansiering 2006, Helse-Og Omsorgsdepartementet, Oslo, 2006, Rates base on systematic review (Report 25)	19,237
Total cost first year				**429,640**
Ongoing periodic follow-up of patients' progress and equipment maintenance after implantation[2]	Annual visit, 2hrs/1session Patient co-payment per session	1,136 per contact hr, 265 patient co-payment	As for pre-implant outpatient care	107,535
Total cost over duration of device use[3]				**537,175**

1. Detailed assumptions on resource use, unit costs, data sources and calculations relating to specific cost items are presented in the Appendix.
2. Future costs are discounted at a rate of 4% per annum in the base case.
3. Duration of device use in the base case is set at 25 years. The analysis assumed that patients using their device for 10 years = 1 speech processor upgrade; 20 years = 2 upgrades, and so on at a cost of kr 60 000 each time (details in Appendix)

3.5 Sensitivity analysis

The results of univariate sensitivity analysis for duration of device use and utility gain are presented in table 6. Compared to an estimated base case cost effectiveness of kr 172,000 per QALY gained, varying the gain in utility from 0.1 to 0.3 yielded a cost per QALY from kr 115,000 (an increase the cost-effectiveness ratio of 33%) to kr 344,000 (an increase of 100%). Reducing the duration of device use from 25 years to 10 years resulted in a higher (poorer) cost-effectiveness ratio of kr 332,000 per QALY. Varying the cost of inpatient care (hospitalisation, surgery, device) associated with implantation within the range of ± 50% of its base case value (assuming a base case value of 100% DRG reimbursed costs), resulted in a change in the cost per QALY in the range of the same order of magnitude, or approx 44% (kr 117,000 to kr 240,000). Varying the rate of major complications across the range to 2% to 8% had a small impact on cost-effectiveness (168,000 and 176,000 per QALY respectively). Applying the upper ranges for assumptions relating to outpatient resource use and unit costs (table 3) increased the cost-effectiveness ratio to 191,000 kr per QALY gained, an increase of approx 11%.
If the age at implantation is assumed to be younger, then the potential number of years of device use will thus increase (see table 5). For example, an additional 10 years will increase the total number of QALYs to 3.73 (7.00 QALYs undiscounted).The resulting cost-effectiveness ratios also improve. For example 35 years of devise use has a cost per QALY of kr 151,000.

An extreme scenario analysis using the lowest value of 0.1 for the gain in utility with implantation, together with an increase in the cost of inpatient care of + 50% (i.e. increasing hospital inpatient 100% reimbursement base case values by a further 50%) yield a cost per QALY of kr 480 000.

The estimate of cost per QALY was most sensitive to changes in:

- The gain in utility (0.1 to 0.3)
- The number of years over which patients continue to use their device (10 to 35 years),
- The cost of the inpatient care episode (hospitalisation, surgery, implant device) associated with implantation (± 50% around the base case value)
- The annual rate applied to discounting future costs and benefits (QALYs: 0% to 4%; costs: 3% to 6%)

The impact on results to changes in the rate of (major) complications requiring hospitalisation: re-implantation (2% to 8%); other revision surgery (2% to 8%) was small. Varying the assumptions on outpatient treatment had moderate impact on cost-effectiveness results.

Cost-effectiveness acceptability curves for CI in adults representing 2 different annual mean utility gain estimates are presented in Figure 3. Applying the base case mean annual utility gain of 0.2 showed that the cost per QALY was almost always less that kr 400,000 (97% or, 9,666/10 000 iterations of our decision-tree model) with an 88% probability that CI in adults would be cost-effective if a maximum threshold of willingness to pay is set at kr 300,000 per QALY (5^{th}/95^{th} percentiles kr 107,000 to kr 373,000). Applying a lower mean utility gain estimate of 0.15, based on the lower confidence limit from the study by Palmer 1999 (table 2) the probability that CI in adults is cost-effective is 92% assuming a maximum threshold of kr 400,000, 72% if the threshold was 300,000 per QALY and so on (5^{th}/95^{th} percentiles kr 150,000 to kr 445,000).

Table 5. QALYs gained according to duration of device use, utility gain and discount rate

Age at implantation: 58 (years)	Utility gain	Discount rate per annum (QALYS)	QALYs gained: Duration of device use (years)					
			35	30	**25**	20	15	10
	0.1	4%	1.87	1.73	1.56	1.36	1.11	0.81
		3%	2.15	1.92	1.74	1.49	1.19	0.85
		0%	3.50	3.00	2.50	2.00	1.50	1.00
base case	**0.2**	**4%**	3.73	3.46	**3.12**	2.72	2.22	1.62
		3%	4.30	3.92	3.48	2.98	2.39	1.71
		0%	7.00	6.00	5.00	4.00	3.00	2.00
	0.3	4%	5.60	5.19	4.69	4.08	3.34	2.43
		3%	6.45	5.88	5.22	4.46	3.58	2.56
		0%	10.50	9.00	7.50	6.00	4.50	3.00

Results assume a constant annual gain in utility of 0.2 in the base case over the lifetime of an adult aged 58 at time of implantation, e.g. from a baseline utility of 0.5 to 0.7 after cochlear implantation. If the age of implantation is younger, for example an adult aged 40, then the potential number of years of use will be increased, e.g. by a further 10 to 35 years (3.73 QALYs gained, discounted at 4%). On the other hand, if the age at implantation is older, for instance 70 then the potential duration of device use will be reduced: e.g. to a duration of 10 years (1.62 QALYs gained, discounted at 4%)

Table 6. Incremental cost per QALY ratios

Age at time of implant 58 (years)	Utility gain	**Discount rate per annum**		**Cost per QALY gained** (results rounded to the nearest kr 1000)					
		QALYs	Costs	35	30	**25**	20	15	10
	0.1	4	4	257,000	287,000	344,000	395,000	484,000	663,000
		3	3	295,000	310,500	317,000	370,000	464,000	649,000
		0	4	153,000	179,000	215,000	269,000	358,000	537,000
			3	158,000	184,000	221,000	276,000	368,000	552,000
base case	**0.2**	**4**	**4**	144,000	155,256	**172,000**	197,000	242,000	332,000
		3	3	128,000	141,000	159,000	185,000	231,000	323,000
		0	4	77,000	90,000	107,000	134,000	179,000	269,000
			3	79,000	91,944	110,333	138,000	184,000	276,000
	0.3	4	4	97,000	104,000	115,000	132,000	161,000	221,000
		3	3	86,000	94,000	106,000	124,000	154,000	215,000
		0	4	51,000	60,000	72,000	90,000	119,000	179,000
			3	53,000	61,000	74,000	92,000	123,000	184,000

Figure 2. Cost-effectiveness as a function of gain in health utility

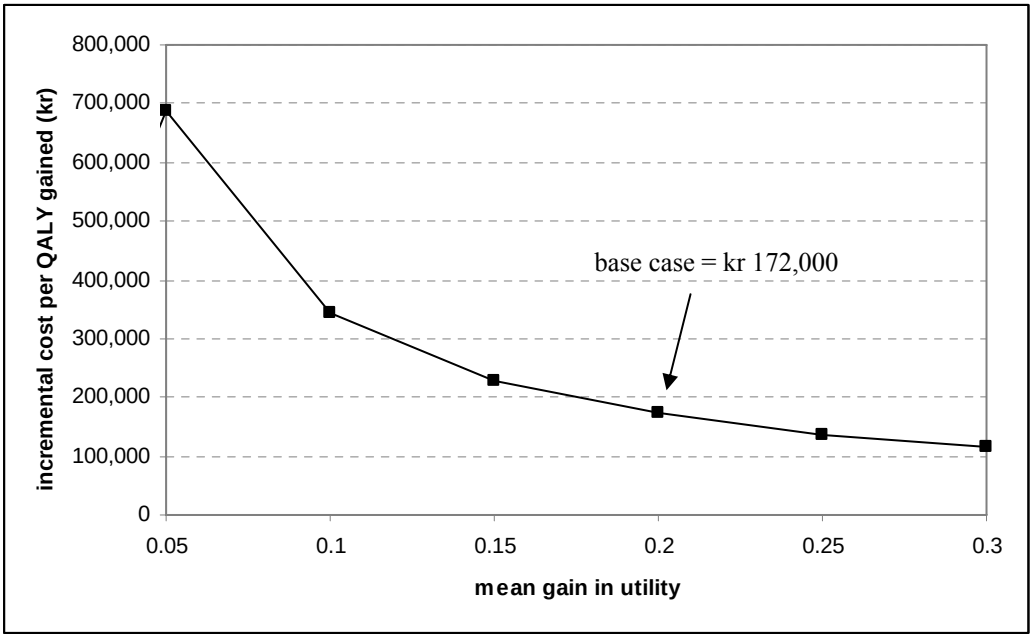
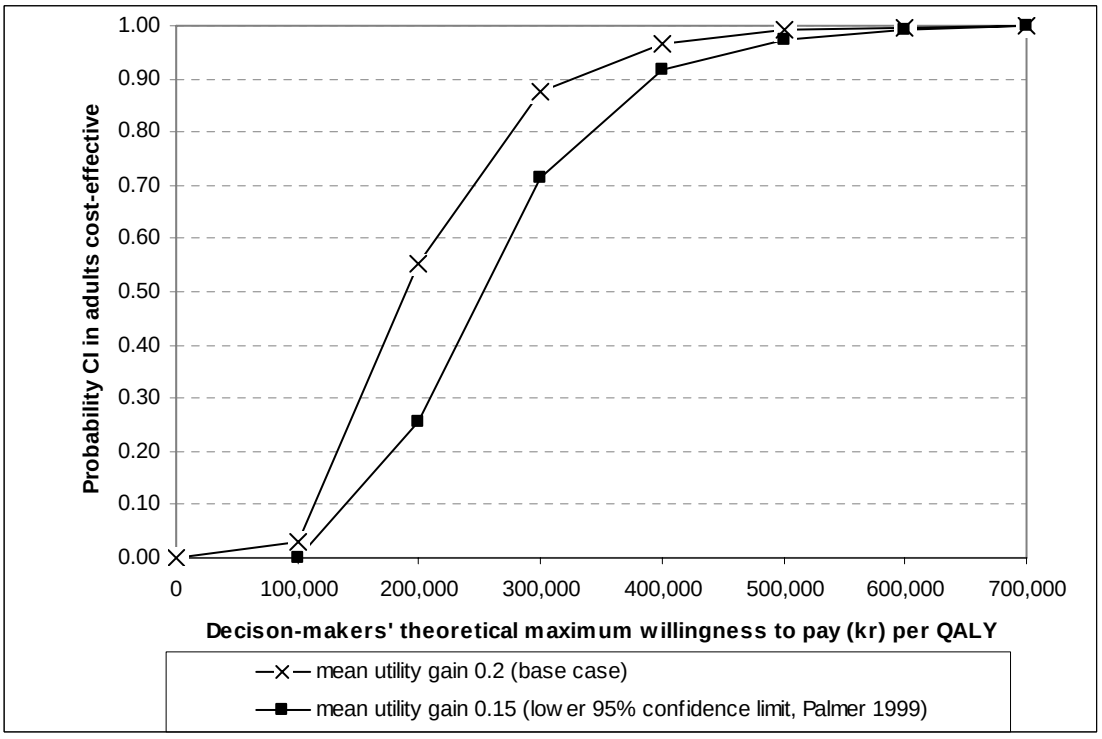


Figure 3. Cost-effectiveness acceptability curves for cochlear implantation in adults:



4. Discussion

Studies have shown that post-lingual and pre-lingual deaf patients have an improved quality of life in comparison with controls (e.g. patients on CI waiting lists, prospective or retrospective investigation of actual CI recipients, hearing aids users), as observed in the studies presented here, and are associated with a significant improvement in the health-related quality of life of adult CI recipients. The summary of studies in the current report adds to the growing body of evidence on the efficacy of CIs in adults, particularly in the area of health-related quality of life.

As previously mentioned a number of earlier cost-utility studies have been performed for CI in adults, mainly in the UK and US healthcare setting. The majority of these studies have concluded that CI compares favourably with other accepted healthcare interventions, but the range of results was considerable: a health gain of 0.07 to 0.41 QALY per year and a cost-utility of $7,405 to $31,711 per QALY (Cheng 1999).

Studies reporting actual patient data are desirable. Prospective measurements of the values and utilities of the health states in which patients find themselves before and after CI are generally considered preferable to retrospective studies (Summerfield 1995). However, as noted by Cheng 1999, some studies have obtained virtually the same results using the HUI, whether patient data was collected prospectively or retrospectively (Wyatt 1996, Palmer 1999). Cheng 1999 argue that there may be a lack of recall bias for CI user, since they turn off their implants on a daily basis at bedtime and when bathing (and lose their use when the batteries run out).

In the meta-analysis of the cost-utility of CI in adults by Cheng 1999 the authors pooled the results of retrospective CI data with prospective data, though do perform sensitivity analysis stratifying by study type. The authors identified 14 unique studies on the cost-utility of the cochlear implant in adults of which 7 presented actual patient data. Reports of cases or controls with a loss of health-utility from profound deafness were defined as adults with profound deafness who had not received cochlear implantation. These patients were on the waiting list to receive an implant, were rejected as an implant candidate for medical or insurance reasons, or did not wish to receive an implant. The pooled results (N=619) showed a combined health utility of profoundly deaf adults without cochlear implantation of 0.54 (95% confidence interval, 0.52-0.56). Pooling data on the change in health utility reported by CI users (n=511) showed that health utility improved to 0.8 (95% confidence interval, 0.78-0.82), an improvement of 0.26.

As Cheng 1999 have already argued, one limitation of their meta-analysis is the inadequate comparison of the health utilities of individuals who have received a CI and controls that have not. The studies included few or no controls, or where the CI patient served as their own control, and some cohorts of patients were used in multiple analyses. At the time of their analysis, only 1 study had incorporated the use of longitudinal controls. Palmer 1999 evaluated 37 cases and 14 controls prospectively for 1 year. Whereas there was an overall 0.2 (95% confidence interval 0.15-0.25) increase in health-utility in the implanted group, the control group reported no change in the same baseline health utility with time (from 0.58 to 0.58). Two cross sectional studies (Wyatt 1996, Summerfield 1995) asked “controls” to determine their health-utility loss from profound deafness but did not evaluate their health utility over time.

Also, between the studies, results differed according to which health utility instrument was used. To some extent, as Cheng 1999 have already noted, this heterogeneity in the instruments used, limits the meaningfulness of statistical pooling. The summary health-utility gain of 0.26 was approximately halfway between those values found in studies using the HUI and those using the Visual Analogue Scale (VAS). Of the 7 studies, 4 used the VAS, 2 used the HUI, and 1 used the Quality of Well-being Scale.

The HUI incorporates into its scale a health utility loss for "complete deafness" of -0.40 (i.e. 1.00 – 0.40 = 0.60), a value derived by the standard gamble method from 532 individuals of the general population in Ontario. The visual analogue scale (VAS) is essentially a "feeling thermometer" rating scale in which patients simply rate their own quality of life on a scale from 0.00 (0%) to 100 (100%). It is noteworthy that 2 disparate health utility methods, the HUI (-0.42) and the VAS (-0.47), derived similar utilities for profound deafness. However, the corresponding health utility gain from CI was less similar for the HUI (+0.20) and the VAS (+0.31). The VAS has been criticised for overestimating losses in health utility from mild disease because the respondent is not forced to make a choice under conditions of uncertainty (Torrance et al 1995). Also the linearity of the VAS has been questioned (Torrance et al 1995). On the otherhand, the HUI can be faulted for attaching a value to profound deafness based on responses of people who have never experienced deafness. The direct elicitation of utilities from individuals who have experienced profound deafness and normal hearing may provide more meaningful results.

Given the potential heterogeneity within these studies it is not clear if this type of methodology to arrive at an overall measure of cost-effectiveness (or overall measure of effect size, i.e. in this case gain in health utility) is without some pitfalls. Since Cheng's meta-analysis of health utility studies in CI, a number of additional studies measuring health utility loss from profound deafness together with the gain in utility with CI have been published. These studies are summarised in table 1 and table 2 along with the original studies included in Cheng 1999.

At the time of the meta-analysis by Cheng 1999, there had been no studies of directly elicited health utilities from CI users using the 2 most commonly accepted health methods (standard gamble and time trade-off). They recommended that future studies might use these health utility methods, that studies should be prospective in nature, evaluating an adequate number of cases and controls longitudinally. In the additional studies we identified (table 1 and 2), none had used direct measures to asses gain in health utility from unilateral CI. One study (Summerfield 2002) did however provide an assessment for bilateral CI, based on the time trade-off. Health states were valued by adult volunteers with normal hearing. This is an important area for future research.

This improvement of 0.26 in health utility resulted in a cost-utility ratio of $12,787 ($6,848 to $31,711) per QALY. Sensitivity analysis on the type of health utility instrument used and excluding studies of less that 20 patients demonstrated that the base case meta-analysis results did not change substantially as inclusion criteria were modified. Statistical pooling of the 2 prospective studies only (Harris 1995, Palmer 1999) yielded a cost utility ratio of $19,999 per QALY.

Gain in health utility has also been reported to vary with age at implant and duration of device used. The UK Cochlear Implant Group (2004) reported a higher gain in utility in patients who at the time of implantation were of a younger age and also in patients with a shorter duration

of profound deafness. For example, in traditional candidates aged between 30 to <40 years the utility gain was 0.26 compared to a utility gain of 0.17 in patients aged over 70 years. Additionally, in patients profoundly deaf for 10 to < 20 years the gain in utility was 0.20 compared to a gain of 0.1 in patients who had been profoundly deaf for more that 40 years. The resulting cost-effectiveness of cochlear implantation in younger adults was consequently superior to older adults (older subjects having fewer remaining years of life over which to accumulate QALYs). The results of the present analysis also support this trend.
In the same study, the authors also reported that cost-effectiveness was higher (poorer) in traditional candidates profoundly deaf for more than 40 years and in marginal hearing aid users profoundly deaf for more than 30 years (due to a generally lower gain in utility following implantation). The value assigned to the gain in health utility following CI in adults does seem have a large (if not the largest) impact on the resulting cost-effectiveness estimates computed (as clearly is apparent by figure 2)
In the present study, cost-effectiveness calculations were undertaken for the inclusion of direct health care costs incurred over the longer-term (over the expected duration of time that patients continue to use their device: often equivalent to patients' remaining life expectancy) and associated with the ongoing periodic follow-up of patients' progress and equipment maintenance after implantation.

From an economic perspective, how much society is willing to pay for health improvements (in this case of CI, as measured by the gain in health utility) is uncertain. In the US, $50 000 per QALY (approx. NOK 311,000 rate 1US $ = NOK 6.22) is a threshold commonly used to delineate cost-effectiveness. Theoretical cost-effectiveness thresholds for health care interventions in the UK, by the National Institute for Health and Clinical Excellence (NICE) 'stated ranged of acceptable cost effectiveness' of £20,000 to £30,000 per QALY (approx. NOK 230,000 to NOK 345,000, rate £1 = NOK 11.49). Technologies with incremental cost-effectiveness ratios above this level seem more likely, but not certain, to be rejected (Towse 2002), although others have suggest an implicit threshold somewhat higher (Devlin 2004). Rawlins 2004 observed that, on the grounds of cost-effectiveness, the National Institute of Health and Clinical Excellence (NICE) would be unlikely to reject a technology with a ratio in the range £5,000-£15,000 per QALY but would need special reasons for accepting technologies with ratios over £25,000-£35,000 per QALY.

Our estimates of cost per QALY are generally lower than the latter quoted upper mid-range. For example, there was an 88% probability that CI in adults would be cost-effective if one was willing to pay kr 300,000 per QALY gained, assuming a mean annual utility gain of 0.2. Also, the results from the sensitivity analyses lie within the ranges of earlier published cost-effectiveness studies of CI in adults (table 7) and within published cost-effectiveness ranges of some other health care interventions for Norway that are either life-saving and/or improve the patients' quality of life (table 8).

In terms of the long-term impact of CI on quality of life, effects are generally stable over time. For example, the beneficial effect of CI was reported to be sustained over an additional six years after implantation (Damen 2006). However, there was somewhat of a downward trend in quality of life scores over time – though the magnitude of change (decrease) was comparable to that of non-implanted controls.

Adults may be classified as "non-users". For example adults may stop using their CI after implantation due to psychological issues or lack of enjoyable stimulation (Raine 2006).

Initial costs are high and are associated with surgery and implant costs. In the longer term costs incurred are typically due to programming and maintenance of the CI device. In general, the average costs of managing a user compared to a non-user are quite similar. Raine 2006 reported that by 13 years of implantation, non-use had added 7% to the average costs of implanting and maintenance.

Recall bias remains still a concern with retrospective investigations. However, the extent of recall bias in cochlear implant patients may be minimal, given that the patients are not cured of their deafness and re-experience their impairment whenever they remove their speech processor. Both retrospective and prospective studies have come to similar conclusions about the quality of life outcome of cochlear implantation in groups of younger adult patients (Cheng et al 1999).

In Norway, the total number of CI procedures performed in adults at the National Implanting Centre at Rikshospitalet over the period 1st January to 19 May 2005 was 23 or, approximately 60 for the entire year. Applying an estimated net cost associated with cochlear implantation in adults yields an approx kr 429,640 per case in the first year, and results in an estimated annual cost in the order of kr 26 million. However, it should be noted that on top of these (annual costs) assuming a long-term programme strategy of periodic follow-up is in place, there are accumulating costs of follow-up etc. over 25 years for an increasing patient population.

The primary analysis has been conducted for adult patients receiving cochlear implants considered to be "traditional candidates". Such patients do not receive any benefit from acoustic hearing aids. This assumption implies that there is no alternative management to cochlear implantation for patients judged to be "traditional candidates" and thus the choice of comparator, "no intervention" by definition assumes no assignment of costs. On the other hand candidates for cochlear implants considered to be "marginal hearing aid users" would be expected to incur resources associated with managing patients who continue to use hearing aids in the absence of implantation. However, Summerfield 2004 recently reported that the extra costs of maintaining marginal hearing aid users for additional years (who continue to use hearing aids) is more or less offset by any cost savings that are expected to result from the reduced need to provide this group with hearing aids and lower complication costs associated with marginal hearing aid users.

A recent report in Sweden estimated the cost of a single cochlear implant (device cost only) at approximately 220 000 Swedish kroner (SEK) in children. The total cost for unilateral implantation is estimated to be around 350 000 SEK (approx. 301,036 NOK) including evaluation, surgery, fitting of the speech processor, and followup visits for the first year. Insertion of two implants during a simultaneous operation would add the cost of the second device, but the associated costs would not increase substantially. Hence the total cost for bilateral implantation would be approximately 600 000 SEK. If the two devices were implanted sequentially, with an interval of several months, the cost would be higher (at least 700 000 SEK). Few studies have yet been conducted to evaluate the cost effectiveness of bilateral CI in adults. The main reason for this is due to the lack of actual patient data on health utilities following a second CI.

Published studies on the weights assigned to value the improvements in the quality of life of adult CI recipients are based on a variety of different instruments and use both direct and indirect methods.

We excluded studies which reflected the perspective of experts in the field of cochlear implantation (e.g. Carter) or those which were based on theoretical mapping investigations (i.e. included only those reporting actual patient data).

The impact on the families of adult implantees could extend to further improvements in every day living.

The weights assigned to the gain in utility were based largely on the findings of one key study Palmer 1999. Studies comparing quality of life of implantees with that of a control population of profoundly deaf persons are still relatively rare. More prospective studies with such a control group would be a worthwhile area for future research, as would assessments of QALY weights using preference-based valuation methods in which the general public is the source of values.

Table 7. Comparison of cost/ QALY with some other recent cost-effectiveness studies of CI in adults

Study	Age at time of implantation (years)	Duration of devise use (years)	Utility Gain	Discount rate[7]	Estimated average total incremental cost per patient treated[4]	Incremental cost per QALY gained[1]
Present analysis (Norway)[2]	58	25	0.2	4%	Duration of device use: Kr 537,000	Base case: kr 172,000 results from probabilistic sensitivity analysis: kr 208,000 (107,000 to 373, 000)
Summerfield 2002 (UK) Ranges calculated from 95% confidence intervals of the changes in utility estimated by volunteers	54	30	0.188	6% Costs 3% QALYs	£41 136	Traditional candidates: £16,774 (£14,452 to £19,813) kr 239,629 (206,45 to 283,043)
	49	30	0.077		£39,029	Marginal hearing aid users: £27,401 (£23,014 to £33,854) kr 391,443 (328,77 to 483,629)
Simultaneous bilateral implantation vs. unilateral implantation (all candidates, i.e., traditional candidates plus marginal hearing aid users)[6]		30	0.031		£27,001	£61,734 (£43,908 to £103,922) kr 962,164 (684, 334 to1 619,692)
		30	0.031		£30,142	£68,916 (£49,018 to £116,012) kr 1,171,838 (833 495 to 1,972, 653)
Additional implantation in existing users of 1 implant vs. no additional intervention						
Summerfield 2004[3] (UK)	50.8	29.8	0.197	6%	€67,017	All patients: €27,142 (€24,532 to €30,323) kr 275,452 (248,057 to 306,608)
	52.5	28.3			€67,076	Traditional candidates: €35,336 (€22,720 to € 28,647) kr 256 186 (229,730 to 289,666) Group 1: €24,032 (€21,052 to €28,209) kr 242, 997 (212, 865 to 285,243) Group 2: €27,062 (€22,772 to €32,852) kr 273,642 (230,259 to 332,176)
	47.9	33.8			€66,854	Marginal hearing aid users: €33,512 (€26,697 to €44,449) kr 338,841 (269 951 to 449 447) Group 3: €39,009 (€27,474 to €64,471)

Study	Age at time of implantation (years)	Duration of devise use (years)	Utility Gain	Discount rate[7]	Estimated average total incremental cost per patient treated[4]	Incremental cost per QALY gained[1]
						kr 394,447 (277,800 to 651,895) Group 4: €27,092 (€21,519 to €37,807) kr 273,938 (217,583 to 382,286)
					€72,522	**Age at time of implantation** (for traditional candidates), yrs: < 30: € 17,316 (€13,761 to €23,514) 30 to < 40: € 19,176 (€14,833 to €26,227) 40 to < 50: € 21,531 (€17,855 to €27,672) 50 to < 60: € 30,991 (23,982 to 43,638) 60 to <70: € 29,815 (24,334 to 38,497) 70+: € 45,448 (30,582 to 86,980)
					€58,566	**Duration of profound deafness** (for traditional candidates), yrs: 0 to <10: € 22,891 (20,058 to €26,727) 10 to< 20: € 26,891 (22,336 to € 34,053) 20 to <30: € 24,044 (17,375 to €37,333) 30 to <40: € 27,246 (17,560 to €56,285) 40+: € 52,985 (€29,584 to € 212,190)
					67,679	**Years of use** 20 yrs All: € 31,028 (€28,115 to €34,022) Traditional candidates: €28,850 (€25,927 to €31,878) Marginal hearing aid users: €28,239 (€24,613 to € 32,318)
					€63,963 nr nr	10 yrs of use All: €42,746 (€38,694 to €47,786) Traditional candidates: €39,643 (€5,580 to €44,698) Marginal hearing aid users: €56,441 (€45,237 to €74,889)

Study	Age at time of implantation (years)	Duration of devise use (years)	Utility Gain	Discount rate[7]	Estimated average total incremental cost per patient treated[4]	Incremental cost per QALY gained[1]
Palmer 1999 (USA)	56.0	22	0.20	3%	$37,405[5]	$14,670 (11,645 to 19,718) kr 158,195 (153,677 to 212,632)
Francis 2002 (USA)	63.4	21	0.24	3%	$36,025	$9,530[8] Approx. kr 98,371
Wong 2000 (Hong Kong)	41.2	33.8	0.1229	6%	HK$224,225	$HK 133,087[8] Approx. kr 177,182
Lee 2006 (South Korea)	44	5.6	0.16 to 0.36	3%	$22,320	VAS: $19,223; HUI: $17,387 EQ-5D: $24,604; QWB: $40,474

1. The base case incremental cost-effectiveness ratio. In the main, studies included only direct health care costs (i.e. costs of outpatient and inpatient treatment). The reported range or lower and upper 95% confidence limits are in parentheses. All original currency figures are reported and also standardised to reflect their approximate Norwegian kr 2005 prices in line with the year of this analysis. Where necessary values were inflated to kr 2005/06 using the Norwegian consumer price index at http://www.ssb.no/emner/08/02/10/kpi/tab-01.html
2. Assuming unilateral implantation compared to no implantation and discounting future benefits at a rate of 4% per annum. Range of cost-effectiveness calculated for changes in utility gain over the range 0.2 in the base case and over the range 0.1 to 0.3 in the sensitivity analyses.
3. Group 1: patients with 0% of words correct in pre-recorded sentences without lip-reading and no significant improvement with acoustic hearing aids; Group 2: patients with 0% of words correct without lip-reading but significant improvement when aided with acoustic hearing aids; Group 3: patients with 0% of words correct without lip-reading when the ear to implanted was aided, but between 1-50% of words correct when the other ear was aided; Group 4: patients with 1-50% of words correct without lip-reading when the ear to be given an implant was aided acoustically
4. Estimated direct health care costs with long-term and/or lifetime devise use
5. Palmer 1999 (table 3, without imputation of missing charges). Mean total charges to 1-year follow-up
6. Estimates of the benefits of bilateral implantation are derived from volunteers with normal hearing. There is currently no data available on valuations provided by actual patients undergoing bilateral implantation. The valuation of volunteers may not represent those of patients – even though the estimate of the gain in utility from unilateral implantation was similar between patients and "controls" (Summerfield 2002). New studies e.g. Buhagiar 2006 aim to assess patients' quality of life when two implants are delivered sequentially
7. Unless otherwise stated the same annual discount rate was applied to both future costs and benefits
8. The actual cost year was not reported though usually these figures might be expected to be based on price levels 2 or 3 years prior to the actual date of study publication: 1999/2000 levels (Francis); 1997/1998 levels (Wong)

Table 8. Comparison of cost /QALY provided for some other health care interventions in Norway

Intervention	medical or surgical	Incremental cost per QALY gained (kr)[1]
Present analysis for CI in adults[2]	surgical	Base case: kr 172,000 results from probabilistic sensitivity analysis: kr 208,000 (107,000 to 373, 000)
Periodic surveillance in patients after surgical resection of CRC (with CEA monitoring, ultrasound of the liver, chest radiograph and colonoscopy (Norum et al 1997a)	medical	114,760 to 195,080
Alendronate to prevent hip fractures in elderly women compared with no intervention (Kristiansen et al 1997)	medical	291,000 (range 109,000 to 489,000)
Replacement of diclofenac alone with a fixed misoprostol-dicolfenac combination in patients with rheumatoid arthritis (at increased risk of serious gastrointestinal events)(Kristiansen et al 1999)	medical	High risk M: 126,700; F: 105,700 No-risk factors M: 671,300; F: 508,900
Intensive treatment with the high-dose melphalan (HDM) combined with autologous blood stem support in patients under 60 years of age compared to conventional therapy based on a simple cyclic oral treatment with melphalan and prednisone (Gulbrandsen et al 2001)[2]	medical	249,000 (range 186,850 to 370,000)
Adjuvant chemotherapy (cyclophosphamide, methotrexate, fluorouracil) for the treatment of breast cancer in women aged 50 years, compared to no treatment (Norum 2000)	medical	35,676 to 94,320
Use of drug eluting stents instead of bare metal stents for patients with stable angina (Kristiansen 2005)	surgical	$46,000 (kr 286,990) 64% probability < $50,000 per QALY
Aromatase inhibitor as a monotherapy for 5 years compared to treatment with tamoxifen for 2-3 years followed by an aromatase inhibitor (in different age groups) as adjuvant treatment for postmenopausal breast cancer (Lønning 2006)	medical	Patients aged: 55 years: 226,587 to 297,112; 65 years: 301,682 to 297,539; 75 years: 478, 836 to 640,453
Breast conserving surgery (BCS) compared to modified radical mastectomy (MRM) in the surgical management of breast cancer (Norum 1997a)	surgical	$20,509 ($6,153 to $20,508) Approx kr 67,731 to 225,749
Adjuvant chemotherapy with fluorouracil and levamisole compared to surgery alone in patients with Dukes' B or C colorectal cancer under 75 years of age (Norum 1997b)	medical/surgical	48,000 to 336,000

1. Base case values (reported range of cost-effectiveness or 95% confidence interval around the base case value). All figures standardised to reflect their approximate 2005/06 prices in line with the year of this analysis. Where necessary values were inflated to kr 2005/06 using the Norwegian consumer price index at http://www.ssb.no/emner/08/02/10/kpi/tab-01.html
2. Ranges include estimated indirect as well as direct costs. 3. Based on projected two-year costs and health benefit

5. Conclusion

The cost per quality adjusted life year (QALY) values calculated for CI in adults in Norway in this evaluation confirms published cost effectiveness studies in other countries. With a mean annual utility gain of 0.2, the cost effectiveness of unilateral CI in adults compared to no implantation was estimated to be kr 172,000 per QALY in the base case. Analyses undertaken to explore the uncertainty in model parameter estimates resulted in a 95% confidence interval of kr 107,000 to kr373,000 per QALY in probabilistic sensitivity analysis. Compared to the cost-effectiveness of other health care interventions which might be considered to be acceptable value for money, the cost-effectiveness profile of CI in adults falls within these reported ranges (table 8). CI in adults remains relatively cost-effective across a wide range of possible decision-makers' cost-effectiveness acceptability thresholds.
Estimates of the cost-effectiveness of performing bilateral implantation in adults remain uncertain. To a large extent, this is due to a present lack of published studies of patients own valuations of their quality of life receiving two cochlear implants, either simultaneously or in addition to one CI.

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Appendix. Cost utility analysis of cochlear implants (CI) in adults: Detailed model assumptions, base case values and range of plausible values

Parameter	Base-case value and assumptions	Plausible range (used for S/A)	Source/comments
Utility gain	0.2	0.1 to 0.3	Based on table 2
Age at implantation	58 years old	40 to 70 years old	Average age from study of Norwegian adult CI recipients (Mo 2005)
Duration of device use	25 years (remaining lifetime)	10 to 35 years	Over the approximate average remaining life expectancy based on Norwegian life tables[1]
Discount rate for (future) costs	4%	3% to 6%	Range of commonly reported discount rates and/ or used in the international literature[2]
Discount rate for (future) outcomes (QALYs)	4%	0% to 6%	As above
COST ESTIMATES			
Cost of hospital outpatient assessment and testing Patients undergo a series of assessments and tests (including audiology (e.g. accuracy of speech perception) and imaging to determine eligibility for CI that may require a full morning to afternoon session (or even equivalent in some instances to a day care attendance)	Approximately **3** days of outpatient sessions with the CI Team at the implanting hospital centre (or up to an equivalent of 10-15 hours of outpatient contact time) Each "session" is assumed to consist of a morning to afternoon of outpatient attendances (or up to approx 5 hrs?). In most cases, Takstgruppe tariffs apply to a single outpatient consultation of less than 1 hr. The sessions associated with cochlear implantation patients are likely to last considerably longer. A crude estimate of total outpatient contact time of **approx 15 hours** is assumed (or as a proxy to the equivalent costs of 15 > 1 hour long consultations) the highest tariff from group G. Øre-nese-halssykdommer takstgruppe 5 of kr **757 per consultation hour** Outpatient cost estimates (based on RTV tariffs) included a further upward **adjustment (50%)** to correct hospital costs for outpatient activity a value of a SAMDATA Somatikk 1/06 http://www.sintef.no/samdata **=1,136 per contact hour** **15 hrs= kr 17,040** **Plus patient co-payments** limited to **3 = kr 795** **=kr 17,835**	2-4 sessions (or equivalent to a range of 10-20 hours of contact) Assume ± 50% around base case cost estimates	An estimate of the plausible number of days/ number of hospital outpatient consultations/ total contact time was informed in part by clinical opinion and also from the published literature[3] Outpatient Reimbursement Fees, National Health Insurance Administration Scheme, Rikstrygdeverket (RTV)[4]. Section G. Øre-nese-halssykdommer. **Use of an appropriate tariff representative of a long consultation > 1 hour, kr 757** *PLUS* patient co-payment, takstnummer 201b = (**kr 265**)

Parameter	Base-case value and assumptions	Plausible range (used for S/A)	Source/comments
CT and or/ MRI scan	Cost of pre-implant imaging assessment (including a 50% upward adjustment): **=kr 2,382**		RTV[4], Primærkategori(s) PK001 Granskning CT MR og angio = **kr 64.914** Takstnummer PK302CT kontrast flere bilder = **kr 477** Takstnummer PK402 MR kontrast region/rekonstr. = **kr 671**, insentivsats 15? Patient co-payment, takstnummer 202 = **kr 200**, 201b = **kr 265**
Cost of inpatient care (associated with surgery, CI device, hospitalization)	Inpatient care (DRG based costs) **= kr 366,406**	Assume ± 50% around base case cost estimates	DRG 49 B[5] 40% DRG reimbursement = kr 146 563; corresponding weight = 11,59: 100% = **kr 366,406** (bilateral implant weight = 9,07: 100% = kr 286,739)
Cost of outpatient follow-up post-implantation Routine post-operative outpatient follow-up and rehabilitation during the *first year* following implantation (e.g. CI fitting, activations and optimising tuning/programming of the device/ revision of CI programming, therapy and training sessions for patients in the use of their device)	An estimate of approx. 20 hours of hospital outpatient contact is assumed in the base case or equiv. 4 sessions (**1,136 per contact hour)** **= kr 22,720** Plus patient co-payments, assumed 4 = kr 1060 =**Total kr 23,780**	≥3/4 days in total following surgical implantation base case 4 days **(range 3-5)** Assume ± 50% around base case cost estimates	The number of days/ number of hospital outpatient consultations/ total contact time is informed in part by clinical opinion and also from the published literature[3] RTV Reimbursement Tariffs[4] **Use of an appropriate tariff to represent a long consultation > 1 hour, kr 757**
Cost of managing complications	Major technical/medical/surgical complications (caused by failure of an internal component of the CI) **An overall re-admission rate of 10% for treatment of complications is assumed in the basecase[8]** **i) 5% involving re-implantation** **ii) 5% requiring other revision surgery** **(Device failure responsible for approx <1-2% ? in first year)** **i) Cost apportioned (averaged) over all patients** **= kr 18,320**	2% to 8% 2% to 8%	An estimate of the overall complication rate is informed by the present clinical review, with an approximate reported range of 3% to 26%. In general, the rate lies between 10% and 12%. These latter estimates are in general agreement with clinical experience, suggesting that around 10% of patients experience problems post-implantation The rate of major complications (e.g. device failure, flap break down, extrusion of electrode) requiring hospitalisation for re-implantation or revision surgery was reported in the range 5-8% (over 7 to 10 years of follow-up). The UK Cochlear Implant Group (2004) recently

Parameter	Base-case value and assumptions	Plausible range (used for S/A)	Source/comments
	ii) Cost apportioned over all patients **= kr =917**		reported a rate of 8.7% of patients with re-admissions requiring revision surgery (37 adverse events in 27 subject out of a total 311). Device failure approx. responsible for <1-2%. Some previous economic studies have used a lower base case rate of around 2-3% for their cost-utility calculations (e.g. Wyatt 1995, Summerfield 1995) i) DRG 49 B[5] 40% DRG reimbursement = kr 146 563; weight 11,59. 100% = **kr 366,406** (bilateral implant weight = 9,07. 100% = kr 286,739) ii) ? DRG 53 B[5] for complications in which patients' require to be hospitalized for revision surgery (but not reimplantation) "Operasjoner på temporalben, masteoideus og indre øore": 40% DRG reimbursement = 7,334; weight 0.58. 100% **= kr 18,336**
Cost of routine follow-up and maintenance of patient and equipment post 1 year implantation Speech processor upgrades, internal/ external implant hardware repairs (e.g. failure of the microphone, the processor, the transmitter coil, the cables that link the processor to the transmitter coil or to the microphone), implant hardware replacement parts, e.g. batteries and electrode arrays	Assumed **one *annual*** hospital progress visit/check-up, including audiological tests and any revision of CI programming (or about 2 hours of outpatient contact time per visit), with a further upward adjustment of 50% (SAMDATA) **= kr 2,271** = Total annual outpatient cost with patient co-payment **kr 2,536** Speech processor upgrades: for example, a processor upgrade every 10 years at a cost of €8079 (UK Cochlear Implant Group, 2004), or every 6 years at a cost of £4,000 based on an implant device manufacturer's recommendation (Summerfield 2002). Assume in the base case an estimate of approx **kr 60, 000** for processor upgrades every 10 years Existence of maintenance services contract with various CI device suppliers to cover the costs of repairs to externals hardware such as processors and replacement of items such as connecting leads?	1-3 hrs per session Assume ± 50% around unit cost estimates	The number of hospital outpatient consultations/ contact time is informed in part by clinical opinion and also from the published literature Outpatient Reimbursement Fees (RTV)[4] Section G. Øre-nese-halssykdommer **Use of an appropriate tariff representative of a long consultation > 1 hour, kr 757** *plus* patient co-payment, takstnummer 201b (**kr 265**) The total outpatient cost estimates (based on RTV tariffs) further include an upward adjustment (50%) to correct hospital costs for outpatient activity a value of a SAMDATA Somatikk 1/06 http://www.sintef.no/samdata

Parameter	Base-case value and assumptions	Plausible range (used for S/A)	Source/comments
TOTAL estimated costs: **1st Year** **Lifetime**	 **kr 429,640** **kr 537,175**[7]		

1. Life tables, 2005. Statistics Norway http://www.ssb.no/emner/02/02/10/dode/tab-2006-04-27-05.html
2. Veileder I samfunnsøkonomise analyzer. Finansdepartementet, Finansavdelingen p 42, section 5.11 Oppsummering, note 2 (effective as of September 2005)
Discounting of future costs is applied only to those costs occurring after the first year (post-implantation). That is, to any costs which may be incurred during routine follow-up and maintenance of patients and their equipment
3. B Mo (Consultant, ENT Centre, Drammen. Personal communication, June 2006). S Harris (National CI Team Leader, Rikshospitalet, Oslo. Personal communication, July 2006).
The UK Cochlear Implant Study Group (2004) assumed an average of 19.8 hours (range: 14-28) of outpatient contact with pre-implant selection, assessment and testing at a cost of €253 per contact hour *(approx £1741EUR 1=0.688 £. Total outpatient costs €4,880 (€3,923 to €5,403)*
Summerfield 2002 assumed an average of 15.5 outpatient hours of contact during the assessment and testing stage at a cost of £147 hour of outpatient contact. In a recent Spanish study, Manrique 2005 estimated the total costs of outpatient care (excluding cranial CT) to be €1,821
4. Norwegian National Insurance Administration Reimbursement Fees (effective from July 1, 2006) http://rundskriv.trygdeetaten.no/rtv/lpext.dll/Infobase9/f20001201nr1389?fn=main-j.htm&f=templates
5. Enhetsrefusjonen for 2006 er fastsatt til 31 614 kroner (Innsatsstyrt finansiering 2006, Helse-Og Omsorgsdepartementet, Oslo, 2006). Hovediagnosegruppe 3: Øre-Nese-Og Halssykdommer
6. Summerfield 2002 reported 19 hours of outpatient contact associated with rehabilitation post-implantation. The UK Cochlear Implant Study Group 2004 reported 26.6 hours (range: 21-35 hours) associated with rehabilitation, and 3-3.5 hours associated with annual maintenance visits for routine checking of patients and their device
7. Estimated longer-term costs associated with routine follow-up of patient and equipment. It was assumed that patients using their device for 10 years = 1 speech processor upgrade; 20 years = 2 upgrades, and so on.
8. Patients may also receive treatment for the management of minor medical/surgical complications (e.g. infection, tinnitus, for stimulation of the facial nerve). Outpatient care may include ambulatory cures, pharmacological treatment or revisions of the programming of the CI). However, the costs of treating major complications requiring hospitalisation are likely to have the largest impact on resource use. Potential costs incurred in treating minor complications not included in the present analysis.
9. It is feasible that after a few years of using their device, not all patients will continue to receive an annual follow-up for the entire duration of time that they continue to use their device. However, we have assumed that patients continue to receive routine follow-up on an annual basis. Consequently, this will tend to bias the results against cochlear implantation (i.e. to over, rather than underestimate the true costs of long-term follow-up)