A Cost-Utility Scenario Analysis of Bilateral Cochlear Implantation

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Context: Unilateral cochlear implantation is a cost-effective intervention for profound bilateral hearing loss. There is worldwide interest in providing implants bilaterally.

Objective: To use modeling to estimate the cost of gaining a quality-adjusted life-year by providing implants to both ears of profoundly postlingually deafened adults.

Design: Economic scenario analysis relating the costs of providing implants to estimates of the gain in health-related quality of life (utility) from unilateral and bilateral implantation.

Setting: Fourteen hospitals in the United Kingdom National Health Service and 1 Medical Research Council research unit.

Participants: Normal-hearing adult volunteers with knowledge of implantation (n=70). Adults undergoing unilateral implantation who either did not benefit from acoustic hearing aids preoperatively (type 1, n=87) or benefited marginally (type 2, n=115).

Main Outcome Measures: Changes in utility from unilateral and bilateral implantation estimated with the time trade-off technique (volunteers) and from unilateral implantation measured with the Mark II Health Utilities Index (patients); costs of providing implants and sustaining patients who have undergone implantation (health care perspective).

Results: Gains in utility from unilateral implantation estimated by volunteers did not differ significantly from gains recorded by patients, giving credibility to the volunteers' estimate of the gain from bilateral compared with unilateral implantation. Cost-utility ratios, in pounds sterling per quality-adjusted life-year, based on volunteers' estimates, were £16 774 (type 1: unilateral implantation vs no intervention), £27 401 (type 2: unilateral implantation vs management with hearing aids), £61 734 (simultaneous bilateral implantation vs unilateral implantation), and £68 916 (provision of an additional implant vs no additional intervention).

Conclusion: More quality of life is likely to be gained per unit of expenditure on unilateral implantation than bilateral implantation.

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HEALTH technologies should be reassessed when the technology changes or when criteria of candidature for the technology change.[1] Where radical changes are contemplated, scenario analysis—a technique in which available sources of data are used to predict future outcomes under a range of assumptions—can be a useful tool for exploring the consequences of change.[2,3] Bilateral cochlear implantation is a radical change in relation to the routine practice of providing implants unilaterally because it adds materially to the cost of provision. This article describes a health-economic scenario analysis designed to estimate the cost-effectiveness of bilateral cochlear implantation. Such analysis can inform future research strategy by identifying interventions whose cost-effectiveness is uncertain in relation to current criteria of acceptability. Resources available for research can then be allocated to measuring the cost-effectiveness of those interventions empirically.

Cochlear implants are consistently effective in improving the ability of people with profound-to-total bilateral loss of hearing to understand spoken language and to be understood when speaking.[4,5] Psychosocial benefits include enhanced social and professional participation for adults[6,7] and increased integration in mainstream education for children.[8,9] Outcomes are sufficiently impressive to have prompted the US Food and Drug Administration to expand indications for candi-

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dature to embrace patients who obtain some benefit from acoustic hearing aids (referred to herein as *marginal hearing aid users*) in addition to patients who obtain no benefit (*traditional candidates*).

These improvements have been achieved with one implant. However, now a handful of adults and children internationally have been provided with implants to both ears.[10-12] Bilateral implantation improves the ability to understand speech in noise. It also allows patients to localize sources of sound and hence to establish where to look to see who is talking and where to move to avoid hazards. Adults with bilateral implants contend that these are material benefits. Potentially, the advantages would be of even greater importance to young children.

Advocacy of bilateral implantation poses challenges for health services because implantation is expensive. Despite the high cost, economic analyses have concluded that unilateral implantation (of traditional candidates) represents good value for money in relation to reimbursement rates in the United States[13-15] and acceptable value for money in relation to total health care costs in the United Kingdom.[5] Even so, unilateral implantation is rationed in the publicly funded parts of many health care systems, including those in the United States and United Kingdom.

It is theoretically possible that the cost-effectiveness of a second implant would be more competitive than a first implant. In this instance, better value for money would be obtained by providing 2 implants to 1 patient than 1 implant to 2 patients. This article explores that issue.

METHODS

OVERVIEW

We describe a cost-utility analysis. Cost-utility analysis is a form of cost-effectiveness analysis in which the cumulative cost of an intervention is related to the cumulative improvement in quality of life that results from the intervention. The cumulative improvement in quality of life is usually measured as the number of quality-adjusted life-years (QALYs) that are gained.[14,16] Logically, higher priority in purchasing and providing health care should be given to interventions that gain quality of life (ie, QALYs) at lower cost, that is, interventions with lower cost-utility ratios. The QALYs are calculated as the cumulative number of years for which a health state is occupied weighted by the health-related quality of life of that state.[17] To qualify for inclusion in a cost-utility ratio, health-related quality of life should be measured on a scale ranging from zero corresponding to the state of being dead to unity corresponding to full health. Then, if a person lives for 5 years with a quality of life of 0.5, they can be said to have lived 2.5 QALYs. If, following an intervention, the person would live for 5 years with a quality of life of 0.8, the intervention would gain 1.5 QALYs ($5 \times [0.8-0.5]=1.5$). When measured appropriately,[18] health-related quality of life is referred to as *utility*.

The components of a cost-utility ratio are cumulative incremental cost and cumulative incremental QALYs, that is, the difference in cost between an intervention and the alternative that the intervention might displace and the difference between the QALYs that result from the intervention and the alternative. Four such ratios are relevant to cochlear implantation: (1) unilateral implantation of traditional candidates compared with no intervention, (2) unilateral implantation of marginal hearing aid users compared with management with acoustic hearing aids, (3) simultaneous bilateral implantation (providing 2 implants in 1 surgical session) compared with unilateral implantation, and (4) additional bilateral implantation (providing a second implant to a patient who already has 1 implant) compared with doing nothing beyond sustaining the patient with a single implant. We also report 2 other ratios: simultaneous implantation compared with either (5) no intervention (for traditional candidates) or (6) management with acoustic hearing aids (for marginal hearing aid users). Although these ratios are of theoretical interest, they do not correspond to clinical choices. Neither clinicians nor commissioners of health care have to choose between performing bilateral implantation or not performing implantation at all. Instead, they have to choose between purchasing and providing 2 implants to the same patient or to 2 different patients. This choice is informed by comparing the 2 bilateral ratios defined herein, simultaneous and additional, with the 2 unilateral ratios. Alternatively, commissioners and clinicians have to choose between providing 2 implants to a patient or providing 1 implant and using the surplus resources to provide some other form of health care. That choice is informed by comparing the simultaneous and additional ratios with cost-utility ratios for other interventions.

Trials of bilateral implantation have not yet been undertaken, so measures of costs and benefits are not available. In the absence of empirical data, 4 steps were taken to estimate cost-utility ratios. First, adult volunteers with normal hearing estimated the gain in utility from unilateral and bilateral implantation. Second, their estimates for unilateral implantation were corroborated by comparison with gains demonstrated by patients receiving unilateral implants. Third, the costs of providing implants unilaterally were measured in 5 hospitals. Fourth, clinicians estimated the minimal additional resources required to provide implants bilaterally. Fifth, the robustness of conclusions was tested by sensitivity analysis, that is, by varying the values of key variables within plausible ranges. Finally, to allow extrapolation of the results, a method was devised for bringing cost estimates for the United Kingdom and United States into correspondence. Participation of patients was approved by a multicenter research ethics committee of the National Health Service. Patients gave written consent. Volunteers consented by mailing anonymous questionnaires to the research team.

PARTICIPANTS

Participants were 70 hearing volunteers and 202 profoundly postlingually deafened adult patients. The hearing volunteers included 21 staff members of the Medical Research Council Institute of Hearing Research, Nottingham, England (mean ± SD age, 38 ± 12 years) and 49 clinicians employed in adult cochlear implant programs (mean ± SD age, 39 ± 9 years). Patients were consenting and received unilateral implants from adult implant programs in 14 hospitals between 1997 and 2000. Of a sequential cohort of 316 patients, they were the subset who completed assessments of their health-related quality of life preoperatively and 3 and 9 months postoperatively. Patients were assigned to 2 groups on the basis of their preoperative performance with acoustic hearing aids on 2 tests of speech reception. Bamford-Kowal-Bench (BKB) sentences[19] were presented in a sound-only mode. City University of New York (CUNY) sentences[20] were presented visually and audiovisually. The audio presentation level was 70 dB(A). Traditional candidates (n = 87; mean ± SD age, 54 ± 14 years) were unable to identify any words correctly (BKB sentences) and did not improve scores significantly when lipreading was assisted by acoustic hearing aids (CUNY sentences). Marginal hearing aid users (n = 115; mean ± SD age, 49 ± 15 years) either identified between 1% and 40% of words correctly (BKB sentences) or improved scores significantly when lipreading was assisted by acoustic hearing aids (CUNY sentences). Both groups were included

to provide a double-check on the accuracy with which hearing volunteers estimated the utilities of health states involving hearing loss.

MEASUREMENT OF HEALTH-RELATED QUALITY OF LIFE (UTILITY)

To measure utilities, patients completed the Mark II Health Utilities Index.[21] This self-report instrument measures health status in terms of 6 attributes: pain, cognition, emotion, dexterity, ambulation, and sensation. The sensation attribute is determined from subdimensions of hearing, vision, and speech. The instrument establishes the level of function of the respondent on each attribute, ranging in a series of steps from perfect function to no function at all. The utility of the resulting combination of levels can be calculated from a formula imputed from the utilities of a subset of the combinations judged by members of the Canadian public.

There was no difference between utilities measured 3 and 9 months after implantation. The gain in utility from implantation was calculated as the change from the preoperative score to the average of the 2 postoperative scores.

Volunteers undertook the time trade-off technique[18] to estimate the utility of 4 health states that were described in written vignettes. They were as follows: (1) the state of being profoundly, bilaterally, postlingually deaf and receiving no benefit from acoustic hearing aids (ie, being a traditional candidate); (2) as in item 1 but benefiting from acoustic hearing aids to the extent of understanding approximately 25% of the words in prerecorded sentences without lipreading (ie, being a marginal hearing aid user); (3) benefiting from a unilateral cochlear implant; and (4) as in item 3 but benefiting from bilateral implants. The vignettes described likely levels of speech reception and psychosocial function. For each state, informants considered 2 alternatives: living in the state from their current age (x) until death at the age of 75 years and living for a shorter number of years in perfect health with normal hearing. They stated how many (y) of their remaining years they would forgo to achieve the second alternative in preference to the first.

The utility (h_S) of state S was calculated as $(75-x-y)/(75-x)$ for each of the 4 states described herein. The difference between h_3 and h_1 provided an estimate of the gain in utility from unilateral implantation for traditional candidates, as did h_3-h_2 for marginal hearing aid users. The difference (h_4-h_3) provided an estimate of the gain from simultaneous and additional bilateral implantation.

COSTS OF UNILATERAL IMPLANTATION

Cochlear implantation for adults can be partitioned into 4 phases: (1) preoperative assessment, (2) surgical implantation, activation, and tuning of the implanted device, (3) rehabilitation in the year following implantation, and (4) maintenance of patients and their implant systems in the subsequent years. Each phase may involve more than one hospital visit. The number of visits per year in the maintenance phase declines with time. Costs in each phase were estimated in 4 steps. First, total costs incurred by hospitals in providing implants were measured retrospectively in 5 adult implant programs every month from each program's inception until the end of March 1999. Data covered 8 years for 4 programs and 6 years for the fifth program. Costs were inflated to year 2000 cost levels using the UK Treasury Gross Domestic Product Deflator.[22] Costs included staff salaries, occupied space, equipment, and incidentals. Second, the profile of patient care (the number of hours of patient contact with clinical professionals and the time of occurrence of such contact relative to the date of implantation) was combined with the date of implantation of each patient in the program to allow hours of activity in the different phases to be assigned to the month in which they occurred. Third, costs incurred in each month were apportioned among the number of hours of activity that occurred in that month, thus yielding an estimate of the cost of an hour of patient contact. This cost declined with time as the level of activity within programs built up to capacity. Therefore, fourth, an exponential function was fitted to the monthly estimates of the cost per hour of contact. The value of the function in April 1999 was taken as the cost of an hour of contact. Costs of contact hours were aggregated within phases. Specific costs (imaging, surgical session, 72-hour inpatient stay, radiographic examination, implant system, and spares and repairs) were assigned to the phase in which they were incurred. **Table 1** lists median values of the 5 programs.

COSTS OF MANAGEMENT WITH ACOUSTIC HEARING AIDS

Resources incurred in management with acoustic hearing aids were identified in consultations with audiologists. In the absence of implantation, aids would be upgraded every 3 years, with 50% of patients receiving bilateral fittings. Main costs are the fitting session (£100) and the new hearing aid (£250). Ten percent of patients would receive therapeutic rehabilitation at an annual cost of £300. Costs averted by providing implants to marginal hearing aid users were calculated, taking into account the idea that 25% of marginal hearing aid users would continue to use an acoustic hearing aid in their ear without an implant. Such patients would receive upgrades to the hearing aid but no therapeutic rehabilitation.

COSTS OF BILATERAL IMPLANTATION

The minimal resources likely to be incurred in providing simultaneous and additional implantation were estimated by clinicians. Where opinions differed, the lower estimate of the required resources was used (Table 1).

LIFETIME COSTS

Costs were projected over the 30-year, average expected remaining lifetime of people with the ages and sexes of adult patients undergoing cochlear implantation in the United Kingdom.[23] Costs of assessment, implantation, and rehabilitation were considered to be incurred together. To reflect the advantages of deferring expenditure into the future, subsequent costs were discounted to current cost levels at 6% per annum[24] (ie, a cost of £1000 incurred y years after implantation was valued as £1000/[1.06^y]). The cost of a processor upgrade (£4000) was included every sixth year in line with the marketing policy of the major distributor of implants in the United Kingdom. The QALYs were accumulated from the end of the third month after implantation and were also discounted at 6% per annum. To permit comparison with results from the United States, additional calculations were undertaken with variables set to the values used by Palmer et al[14]; in these analyses, costs and benefits were discounted at 3% per annum and were accumulated during 22 years with no provision for processor upgrades.

RESULTS

Utilities estimated by volunteers were higher than those recorded by patients for nominally identical health states (fourth column of **Table 2**). We tested the idea that this difference arose partly because utilities estimated with the Mark II Health Utilities Index reflect comorbidity in the patient group that was excluded from the consider-

Table 1. Hours of Clinical Contact and Extra Costs Incurred in Providing Unilateral, Simultaneous, and Additional Cochlear Implants in Postlingually Deafened Adult Patients

Variable	Phase: Assessment	Implantation	Year 1 (Rehabilitation)	Year 2 (Maintenance)	Year 3 (Maintenance)	Year 4 (Maintenance)*
Unilateral Cochlear Implantation†						
Hours of contact	15.5	11	19	3.5	3.5	3
Costs, £‡						
Staff	2279	1617	2793	515	515	441
Incidentals	171	121	209	39	39	33
Accommodation and equipment	202	143	247	46	46	39
CT and/or MRI	230	...	...	...	...	...
Surgical session	...	1082	...	...	...	...
Inpatient stay	...	700	...	...	...	...
Radiographic examination	...	30	...	...	...	...
Implant system	...	13 975	...	...	...	...
Spares and repairs	...	...	198	198	198	198
Total	**2881**	**17 668**	**3447**	**798**	**798**	**711**
Simultaneous Bilateral Cochlear Implantation						
Hours of contact	0§	5‖	1 h/y to maintain second device	1 h/y to maintain second device	1 h/y to maintain second device	1 h/y to maintain second device
Costs, £‡						
Staff	...	735¶	147	147	147	147
Incidentals	...	...	...	...	...	...
Accommodation and equipment	...	...	...	...	...	...
CT and/or MRI	...	...	...	...	...	...
Surgical session	...	...	...	...	...	...
Inpatient stay	...	...	...	...	...	...
Radiographic examination	...	...	...	...	...	...
Implant system	...	13 975#	...	...	...	...
Spares and repairs	...	...	198#	198#	198#	198#
Total	**0**	**14 710**	**345**	**345**	**345**	**345**
Additional Bilateral Cochlear Implantation						
Hours of contact	2**	8††	1 h/y to maintain second device	1 h/y to maintain second device	1 h/y to maintain second device	1 h/y to maintain second device
Costs, £‡						
Staff	294	1176	147	147	147	147
Incidentals	22	88	11	11	11	11
Accommodation and equipment	26	104	13	13	13	13
CT and/or MRI	0	...	...	...	...	...
Surgical session	...	1082	...	...	...	...
Inpatient stay	...	700	...	...	...	...
Radiographic examination	...	30	...	...	...	...
Implant system	...	13 975#	...	...	...	...
Spares and repairs	...	...	198#	198#	198#	198#
Total	**342**	**17 155**	**369**	**369**	**369**	**369**

*Fourth year and subsequent years.
†Medians of values measured in 5 hospitals.
‡Pounds sterling at year 2000 cost levels. CT indicates computed tomography; MRI, magnetic resonance imaging.
§Bilateral audiometry and imaging performed fully for unilateral implantation.
‖One additional hour of surgery. Four additional hours for tuning the second device. No other additional costs for surgical session, in patient stay, or radiographic examination.
¶Variable costs (salaries) included but not semifixed costs (accommodation, equipment, incidentals).
#Additional cost of second implant device and spares and repairs for it.
**Two hours to reassess audiometry, fitness for surgery, and expectations.
††Four hours for surgery plus 4 hours to tune the second device.

ations of the volunteers. Accordingly, we recalculated scores from the Health Utilities Index after placing patients at the highest levels of function on the hearing and speech attributes (ie, only their reported levels on the other attributes were taken into account in calculating their utility). For the volunteers, we assumed a utility of unity in the absence of impairments to hearing and speech. The fifth column of Table 2 lists the results. The last column of Table 2 lists the loss of utility owing to impaired hearing and speech, measured as the difference between the fourth and fifth columns. The losses are similar for the 2 groups. Thus, although there are differences in the absolute utilities recorded by volunteers and patients, the loss of utility owing to impaired hearing and speech was the same for both groups. A second correspondence is shown by the gains in utility for unilateral implantation (**Table 3**) for which the volunteers' values do not differ significantly from the patients'. Taken together, these 2

Table 2. Utilities of Health States Estimated by Patients and Volunteers*

Health State	Informants	Sample Size	Mean Utility (95% CI)†	Mean Utility (95% CI)‡	Loss of Utility (95% CI)§
Profoundly hearing impaired, no benefit from acoustic hearing aids (traditional candidate)	Patients	87	0.562 (0.527-0.596)	0.843 (0.805-0.880)	0.281 (0.255-0.308)
Profoundly hearing impaired, marginal benefit from acoustic hearing aids (marginal hearing aid user)	Patients	115	0.725 (0.693-0.757)	0.870 (0.839-0.900)	0.145 (0.123-0.167)
Traditional candidate benefiting from a unilateral cochlear implant	Patients	87	0.750 (0.705-0.794)	0.813 (0.769-0.857)	0.063 (0.048-0.078)
Marginal hearing aid user benefiting from a unilateral cochlear implant	Patients	115	0.802 (0.767-0.838)	0.851 (0.815-0.887)	0.049 (0.039-0.059)
Profoundly hearing impaired, no benefit from acoustic hearing aids (traditional candidate)	Volunteers	70	0.765 (0.730-0.800)	1‖	0.235 (0.200-0.270)
Severely profoundly hearing impaired, marginal benefit from acoustic hearing aids (marginal hearing aid user)	Volunteers	70	0.836 (0.807-0.865)	1‖	0.164 (0.135-0.193)
Benefiting from a unilateral cochlear implant	Volunteers	70	0.934 (0.915-0.954)	1‖	0.066 (0.046-0.085)
Benefiting from bilateral cochlear implants	Volunteers	70	0.965 (0.952-0.978)	1‖	0.035 (0.022-0.048)

*CI indicates confidence interval.
†Mean utility measured with Mark II Health Utilities Index (patients) and with time trade-off technique (volunteers).
‡Mean utility recalculated with Mark II Health Utilities Index after placing patients at the highest levels of the hearing and speech dimensions.
§Mean loss of utility due to impaired hearing and speech.
‖Assuming a utility of unity in the absence of impairments to hearing and speech.

Table 3. Changes in Utility Estimated by Patients and Volunteers*

Patient Group	Intervention and Alternative	Informants	Increase in Utility (95% CI)
Traditional candidates	Unilateral implantation compared with no intervention	Patients	+0.188 (+0.150 to +0.226)
Marginal hearing aid users	Unilateral implantation compared with management with acoustic hearing aids	Patients	+0.077 (+0.045 to +0.110)
Traditional candidates	Unilateral implantation compared with no intervention	Volunteers	+0.169 (+0.143 to +0.195)
Marginal hearing aid users	Unilateral implantation compared with management with acoustic hearing aids	Volunteers	+0.098 (+0.080 to +0.117)
All candidates	Simultaneous bilateral implantation compared with unilateral implantation	Volunteers	+0.031 (+0.018 to +0.042)
Existing users of 1 implant	Additional implantation compared with no additional intervention	Volunteers	+0.031 (+0.018 to +0.042)

*CI indicates confidence interval.

correspondences give some credence to the volunteers' estimate of the incremental gain in utility from bilateral implantation, which was +0.03.

Based on that estimate, cost-utility ratios for simultaneous and additional bilateral implantation are 3 to 4 times higher than ratios for unilateral implantation, despite the higher incremental cost of unilateral than bilateral implantation (**Table 4**). Sensitivity analysis demonstrates that this result is insensitive to variation in the duration of use of implants (10, 20, or 30 years) and to the discount rate (0%, 3%, or 6%). It is also insensitive to variation in the incremental gain in utility from bilateral implantation (**Figure 1**). The gain must be increased beyond its upper 95% confidence limit to +0.08 for bilateral implantation to achieve parity with unilateral implantation for marginal hearing aid users. The gain must be increased further, to +0.13, to achieve parity with unilateral implantation for traditional candidates. If the measured gain of +0.03 is incorporated in calculations, parity between additional bilateral implantation and unilateral implantation for marginal hearing aid users would be achieved by reducing the cost of the second implant system and of processor upgrades for it to between 10% and 20% of the cost of the first system (**Figure 2**). Parity with unilateral implantation for traditional candidates would not be achieved, even if there were no charge for the second system.

COMMENT

Scenario analysis uses available data to anticipate the consequences of changes that are under way or that might occur in the future. It is a speculative procedure, not a

Table 4. Modeled Incremental Gain in Quality-Adjusted Life-Years (QALYs), Incremental Cumulative Costs, and Cost-Utility Ratios for 6 Interventions and Their Alternatives*

Intervention and Alternative	Patient Group	Incremental Gain In QALYs for 30 and 22 Years, Respectively, of Use of Implants (Plausible Range)	Incremental Cost Accumulated for 30 (£) and 22 (US $) Years of Use	Cost-Utility Ratio (Cost per QALY) (Plausible Range)†
Unilateral implantation vs no intervention	Traditional candidates	2.45 (2.08-2.83) 2.82 (2.39-3.25)	£41 136 $53 333	£16 774 (£14 452-£19 813) $17 608 ($15 266-$20 799)
Unilateral implantation vs acoustic hearing aids	Marginal hearing aid users	1.42 (1.15-1.70) 1.64 (1.33-1.95)	£39 029 $49 256	£27 401 (£23 014-£33 854) $28 284 ($23 756-$34 946)
Simultaneous bilateral implantation vs unilateral implantation	All candidates	0.44 (0.26-0.62) 0.50 (0.30-0.71)	£27 001 $28 775	£61 734 (£43 908-£103 922) $57 179 ($40 669-$96 253)
Additional implantation vs no additional intervention	Existing users of 1 implant	0.44 (0.26-0.62) 0.50 (0.30-0.71)	£30 142 $33 245	£68 916 (£49 018-£116 012) $66 063 ($46 988-$111 209)
Simultaneous bilateral implantation vs no intervention	Traditional candidates	2.89 (2.45-3.33) 3.32 (2.82-3.83)	£68 137 $83 877	£23 578 (£20 456-£27 825) $23 597 ($20 473-$27 848)
Simultaneous bilateral implantation vs acoustic hearing aids	Marginal hearing aid users	1.86 (1.52-2.21) 2.14 (1.75-2.54)	£65 165 $78 130	£35 002 (£29 529-£42 965) $34 437 ($29 052-$42 272)

*The QALYs were calculated from the changes in utility estimated by volunteers in Table 3. The values for 30 years of use were discounted at 6% per annum and accumulated for 30 years. The values for 22 years of use were discounted at 3% per annum and accumulated for 22 years.

†Plausible ranges were calculated from the 95% confidence intervals of the changes in utility estimated by volunteers in Table 3.

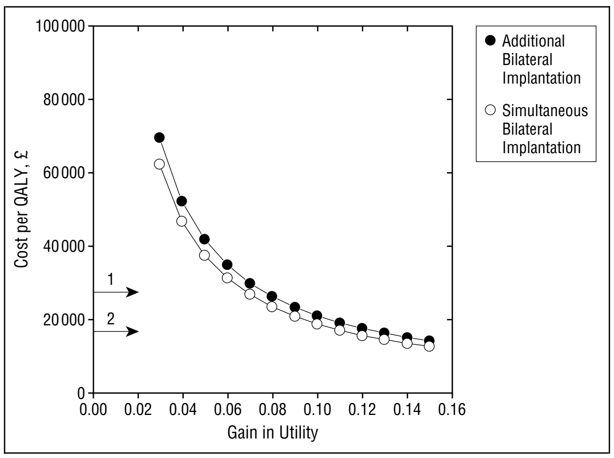

Figure 1. Sensitivity of cost-utility ratios (cost per quality-adjusted life-year [QALY] in pounds sterling at year 2000 cost levels) for simultaneous and additional bilateral implantation to the gain in utility from bilateral implantation compared with unilateral implantation. Arrows mark the base cost-utility ratios for unilateral implantation of marginal hearing aid users (1) and traditional candidates (2).

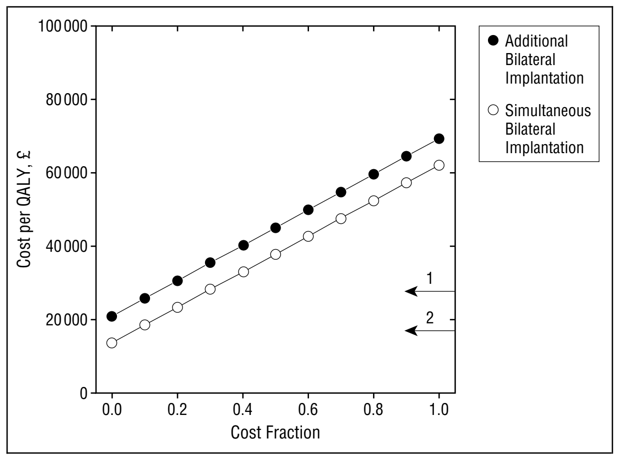

Figure 2. Sensitivity of cost-utility ratios (cost per quality-adjusted life-year [QALY] in pounds sterling at year 2000 cost levels) for simultaneous and additional bilateral implantation to the cost of the hardware of the second implant system and of upgrades to its speech processor. Cost is expressed as a fraction of the cost of the first implant system. Arrows mark the base cost-utility ratios for unilateral implantation of marginal hearing aid users (1) and traditional candidates (2).

definitive one. The following discussion should be read in that light.

There is worldwide interest in bilateral cochlear implantation. Some patients are receiving 2 implants at a time when unilateral implantation is rationed in publicly funded health care systems. Therefore, the aim of the analysis was to give commissioners and providers of otological health care an indication of the cost-effectiveness of a second cochlear implant compared with a first implant. The results indicate that it is likely to cost significantly more to gain a QALY by providing a second implant than it is by providing a first.

LIMITATIONS OF THE PRESENT STUDY

This conclusion stems from a model of health care in the United Kingdom. The model incorporates assumptions about future costs and benefits, together with estimates of benefits of bilateral implantation from volunteers with normal hearing. Although volunteers estimated similar

changes in utility for unilateral implantation to those measured with patients undergoing unilateral implantation, the absolute utilities of health states estimated by volunteers differed from those measured with patients. The differences are likely to have arisen in part from comorbidity in the patients that was not considered by the volunteers. Also, different methods were used with the volunteers and patients to value health states. Therefore, overall, there is no guarantee that the valuations of the volunteers would be replicated by patients undergoing bilateral implantation.

In light of these limitations, 2 steps were taken to minimize the likelihood of drawing an erroneous conclusion. First, the resources assumed for bilateral implantation were the minimum that clinicians consider to be feasible. Second, sensitivity analysis was used to test the robustness of the conclusion. It showed that, for a second implant to be cost competitive with a first implant, the true gain in utility from a second implant would have to be 3 to 4 times higher than was estimated. Alternatively, manufacturers would have to price a second implant at less than 10% of the price of a first implant.

Against this background, 4 issues warrant consideration: the relevance of the present data to the United States, policy implications that would follow if the results were confirmed empirically, implications for implantation in children, and the necessary forms of further research.

COMPARISON WITH RESULTS FROM THE UNITED STATES

Differences between the funding of health care in the United States and United Kingdom are reflected in economic analysis as an emphasis on charges in the United States and on costs in the United Kingdom. Fortuitously, the costs measured in the present study correspond closely to the charges reported by Palmer et al[14] for adult patients undergoing unilateral implantation in the United States when translated at the current exchange rate (£1=US $1.4). For example, the mean total charge for unilateral implantation measured by Palmer et al[14] from the time of implantation through 12-month follow-up was $36837. The corresponding median cost measured in the present study was £23996 ($33594). Palmer et al[14] measured changes in utility using the same version of the Health Utilities Index as the present study. Their participants did not differ significantly from the traditional candidates in preoperative or postoperative utility. If key variables in the present cost-utility model are given the values incorporated in the analysis by Palmer et al[14] (no processor upgrades, 22-year follow-up, 3% discount rates, gain in utility of +0.20), the resulting cost per QALY for traditional candidates receiving unilateral implantation is £10641 ($14898) and is close to the estimate of Palmer et al[14] ($14670). We conclude from these correspondences that the current cost-utility model can make indicative predictions for the United States. Those predictions are listed in US dollars in Table 4. Comparisons among the ratios lead to the same prediction of the greater competitiveness of unilateral implantation over bilateral implantation, as was drawn directly from the UK data.

POLICY IMPLICATIONS UNDER 3 SCENARIOS

Scenario 1

In scenario 1, unilateral implantation is rationed. The analysis predicts that QALYs would be gained at lower cost by providing 1 implant to each of 2 new patients than either 2 implants simultaneously to the same patient or a second implant to each of 2 patients who already use 1 implant. If so, then in circumstances in which unilateral implantation is rationed, as it is in many publicly funded health care systems, it would be logical to address needs for unilateral implantation before considering bilateral implantation.

Scenario 2

In scenario 2, unilateral implantation is not rationed. In this circumstance, it would be logical to compare the cost utility of simultaneous and additional implantation with the cost-utility ratios of other interventions that are competing for the same funding. Palmer et al[14] identified ratios for other interventions routinely provided within the US health care system, which ranged up to $83688 per QALY. The cost-utility ratios for simultaneous and additional implantation calculated in US dollars (Table 4) both fall below this value. Thus, the present analysis suggests that additional and simultaneous implantation could gain QALYs at a lower cost than some interventions that are routinely provided in the United States.

Scenario 3

Scenario 3 is a binaural implant system. To date, most patients who have undergone bilateral implantation have received 2 speech processors and 2 electrode arrays, 1 for each ear. Preservation of binaural differences in spectral amplitude and timing, which provide the basis for normal spatial hearing, would require that sounds from 2 microphones be processed by the same speech processor before being delivered to 2 electrode arrays.[10] Some commissioners of health care might judge the priority for provision of a binaural implant system from its incremental cost utility in relation to a do-nothing alternative (ratios 5 and 6 in Table 4). Others, however, would note that the greater part (approximately 85%) of the gain in utility predicted to be achieved by bilateral implantation is achieved by unilateral implantation. In considering whether to commission a binaural implant system or a conventional monaural system, they would examine the cost utility of achieving the additional 15% of utility and would rely on the simultaneous and additional ratios to guide the allocation of resources.

CHILDREN

The foregoing conclusions apply to adults. For children, judgments of priorities for expenditure on bilateral implantation might take into account additional considerations, including the requirement for bilateral input to drive normal central auditory development and the possibility of paying for bilateral implantation by averting costs in other domains.[9]

FURTHER RESEARCH

The cost utility of bilateral cochlear implantation should be measured empirically in randomized trials that are powered to detect small gains in utility. To define the range of the results, several methods should be used for measuring changes in utility,[25] in addition to the Health Utilities Index. Care should be taken in specifying recruitment criteria to ensure that results can be generalized appropriately, given that benefit from a second implant can arise in more than one way: binaurally through bilateral stimulation conferring abilities in spatial hearing or monaurally through patients receiving the second implant in their physiologically more responsive ear.

In conclusion, this scenario analysis indicates that a second implant is likely to be less cost-effective than a first but that a second implant could be cost competitive compared with some other interventions routinely provided in the United States. To guide priorities in commissioning health care, resources available for providing implants bilaterally should be concentrated in randomized controlled trials designed to test these conclusions empirically.

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