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Main Article

Cochlear implants: informing commissioning decisions, based on need

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Abstract

Cochlear implantation is a high cost, low volume intervention which is provided to adults and children with profound hearing impairment. Demand is increasing in the UK as a result of improved technology, changes in intervention criteria and the national newborn hearing screening programme. In order to inform commissioning policy for cochlear implantation in five English primary care trusts, we reviewed the evidence and assessed the complexities of developing needs and of service provision assessment and planning. Our results indicated that the current level of provision was well below what would be expected if the majority of people meeting current criteria were given a cochlear implant. Gaps between the clinical intervention thresholds and the level of service commissioned have widened. Long-term cost effectiveness and incidence studies are needed to assess cochlear implantation in the light of these lower clinical intervention thresholds.

Key words: Cochlear Implants; Health Care Administration, Organisation and Administration; Needs Assessment

Introduction

Cochlear implantation is a high cost, low volume intervention which is provided to adults and children with profound hearing impairment. Despite some debate regarding implantation,[1] demand is increasing in the UK as a result of improved technology,[2] changes in intervention criteria[3] and the introduction of the national newborn hearing screening programme.[4] Although the prevalence of profound hearing impairment is evenly distributed across the UK,[5] the level of provision cochlear implantation varies considerably.[6] There are no National Institute of Clinical Excellence guidelines on appropriate provision of cochlear implants.

We have recently reported on the evidence relevant to commissioning future cochlear implantation provision for our area. We present a review of our findings, along with a number of estimates and related costs, which reflect the complexities of developing needs and of service provision assessment and planning.

Background

Our report on evidence relevant to future cochlear implantation commissioning focused on the procedure's effectiveness, cost effectiveness, social costs, risks, acceptability and issues of equity. It highlighted the following.

Effectiveness

Cochlear implants are most effective in adults with post-lingual deafness (i.e. hearing loss occurring after speech has developed), in whom the benefits include improved hearing levels, speech intelligibility and quality of life.[7–9] Specifically, the effectiveness of cochlear implantation is not strongly associated with age at the time of implantation, and it declines with increasing duration of deafness. Cochlear implantation is least effective when the pre-operative audiological status of the better hearing ear is good and the duration of profound deafness in the ear to be implanted is long.[10] In children, cochlear implants are most useful in those with pre-lingual deafness (i.e. hearing loss occurring before speech development) as they allow children to improve their speech reception, language acquisition and reading comprehension,[11–13] to improve their visual attention skills,[14] and to increase their opportunity of receiving mainstream schooling.[14]

The recommended timing of cochlear implantation in children is 'as soon after the loss of hearing as is compatible with definite confirmation of profound deafness and assured compliance with rehabilitation'.[11] More recent evidence suggests

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that intervention before the age of four years avoids irreversible auditory performance losses and that intervention before the age of two years achieves optimal results.[15] Recently, implantation from the age of one year has been proposed.[16]

Thresholds. Potential candidates meet the current selection criteria for cochlear implants if they: achieve a predefined score on a speech recognition test (indicating lack of ability to identify words in spoken sentences, without lip-reading); display a set level of hearing loss (in dB); and, for pre-lingually deaf children, meet appropriate assessment targets for objective audiometry, behavioural techniques and response to hearing trials.

Over time, the actual values used to define these selection criteria have changed. In 1995, the Medical Research Council (MRC) Institute of Hearing Research suggested multiple selection criteria and stated that, typically, adults and young children suitable for implantation should have an average loss of hearing sensitivity exceeding 105 dB. They added that improved technology would reduce this threshold to 100 dB for adults and 95 dB for children.[11]

More recently, this same centre has suggested the following criteria for implantation: severe to profound, bilateral hearing loss exceeding 70 dB; no material benefit gained from hearing aids (i.e. aided threshold >55 dB at 2–4 kHz); no material ability to understand speech using hearing aids (i.e. identifying <50 per cent of key words correctly in a Bamford–Kowal–Bench sentence test presented at 70 dB, without lip-reading).[10]

These revised thresholds reflect a growing trend towards less stringent selection criteria for adults. Adults are now considered suitable when they derive marginal benefit from hearing aids.

Cost effectiveness

In 2003, it was estimated that cochlear implantation gained a Quality of life year (QALY) at £16 000 in patients with a hearing loss of 85–140 dB. In this patient group, the cost per QALY was less than the £30 000 used by the National Health Service (NHS) to define the upper limit of acceptable cost effectiveness.[17] The estimate is not generalizable to patients with different levels of hearing loss. Cochlear implantation is less cost effective in improving health in the following circumstances: in people obtaining benefit from acoustic hearing aids; in those who have been profoundly deaf for more than 30 years; when selection criteria are relaxed; and when performed bilaterally.[17]

In 2000, in children for whom parental perceptions of quality of life could be obtained, a cost–utility ratio of US$5000–9000 per gain was estimated.[18] Notwithstanding the fact that more than 90 per cent of congenitally deaf children are born to hearing parents,[3] who wish to communicate with their children by speaking rather than signing, the question arises as to whether the benefits of cochlear implantation can be sustained in the long term. There is a lack of research on the long-term outcomes of cochlear implantation in children. This is particularly relevant because cochlear implantation is an intervention for a lifelong condition.

Social costs

People with moderate to profound hearing loss experience high levels of unemployment – one-third rely on government benefits (accounting for 6.2 per cent of total government benefits expenditure).[19] One-third of those employed earn less than £10 000, compared with 11.8 per cent of the general UK population.[19] Cochlear implants are associated with a 20 per cent increase in the implantee's income.[20] The net savings to the community of sending one child to regular school, compared with a special school with an attached hearing unit, for a 12 year period amount to £60 000 at 1999 prices. At university level, the total net savings amount to £8500–10 500 per student at 2000 prices.[20]

Risks

Cochlear implant surgery is considered relatively safe and reliable in terms of subsequent severe complications.[2] These include flap necrosis, wound separation and infection, and intrinsic device failure.

Major complications occur in 10 per cent of implanted adults and 7 per cent of children:[11] 40 per cent report episodes of dizziness;[21] 1.6 per cent experience device failure;[2] and 0.7 per cent experience facial nerve paralysis (often transient rather than permanent).[22]

Around 6 per cent of implanted adults reject their cochlear implant post-surgery.[23] Post-surgical medical and surgical complications are associated with non-use of the implant.

Acceptability

Although cochlear implants are highly valued among the post-lingually deaf, it is important to consider that cochlear implantation is in keeping with the oralist approach, the priorities of which may differ from those of the deaf community. Some deaf people are part of a tight-knit community, reinforced socially, politically and educationally, and share a culture with characteristic customs, values and knowledge.[24] The deaf community has highlighted the ethical dilemmas of cochlear implantation, which, it argues, have largely been ignored by the medical establishment.[25] The deaf community has maintained that cochlear implantation amounts to mental and emotional abuse, ethnocide, and stigmatization of the deaf, and that it undermines the deaf community's achievements in social provision.[24–26]

Equity

Few patients who undergo cochlear implantation are unemployed.[1] For those who are employed, there is no evidence to suggest that the procedure is sought more by patients whose occupation requires a high level of education. However, this may reflect an imbalance in uptake, since it has been shown that

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hearing thresholds climb steadily as a function of social class, with manual workers tending to have the worst hearing.[1] For children, using a proxy measure of affluence, it has been ascertained that significantly more of those in affluent families receive cochlear implants, compared with those in less affluent families.[27]

Based on this evidence, we attempted to estimate the potential need for cochlear implantation for our area of south-west England, on behalf of the operational commissioning college which controls health care delivery within the area. The area is covered by five primary care trusts (PCTs), serving a population of 983 860.

Methods

To ascertain the current level of cochlear implantation, we requested the following data: national rates (from the MRC Hearing Research Institute); regional rates (from the hospital episode statistics database); and local hospital rates (from the local XIOM data warehouse). In addition, all UK cochlear implant centres were contacted to establish their thresholds for cochlear implantation.

To estimate potential future need for cochlear implantation, five different approaches were used, as follows.

Firstly, estimates were made based on the prevalence of adult hearing loss. These were then adjusted using the MRC's 1995 planning assumption that 10–12 per cent of all adults with profound hearing loss would be suitable and willing to receive a cochlear implant. For children with profound hearing loss, the corresponding percentage was estimated at 75 per cent. These assumptions were based on the current UK intervention threshold, i.e. >95 dB.

Secondly, estimates were made based on the intervention criteria used by the 1995 MRC national evaluation. These intervention criteria took some account of available epidemiological data but were substantially adjusted based on cochlear implant uptake to that date. The emphasis here was on expressed need, i.e. giving weight to observed demand. The intervention threshold used in 1995 was 105 dB in adults and children.[11]

Thirdly, estimates were made based on the MRC's 1995 intervention criteria but also applying their forecast that, should the intervention threshold be relaxed to >100 dB in adults and 95 dB in children, the number of eligible adults would increase fourfold and the number of children by one third.[11]

Fourthly, estimates were made based on the MRC's 1995 intervention criteria (i.e. 105 dB in adults and children)[11] but also applying a Canadian review's forecast of potential need should the intervention threshold be reduced to 95 dB.[28] This review forecast a doubling of adult implantees should the intervention threshold be reduced by 10 dB.

Fifthly, estimates were made based on the current average cochlear implant provision in England (i.e. the benchmark figure), taking into account current commissioning for the future.[29]

Costs

Costs were based on 2004/05 local NHS trust charges, as we considered these to be a more realistic estimate of cost than the proposed national tariff charge. Since April 2005, standard national tariffs have been applied to the designated 48 health care resource group, and these will be extended to cover most medical and surgical hospital activity by April 2008. The national tariff charge for cochlear implantation is currently lower than the local NHS trust charge and only relates to in-patient treatment and not to ongoing rehabilitation and maintenance costs. This national tariff charge also fails to distinguish between adult and paediatric cases, the latter being more expensive. We do not expect an overall reduction in the cost of cochlear implantation once fully cost reflective tariffs are developed.

Results

National cochlear implant commissioning

In 2000–2003, cochlear implantation was provided in the UK at a rate of 7.8 cases per 1 000 000 population, which equates to approximately 400 cases per year (approximately 300 for England alone).[6] In recent years, more children have been implanted than adults. The expected increase for 2004–5 was 5.1 per cent for adults and 7.3 per cent for children, making an annual rate of 8.2 per 1 000 000.[29] Regional variations do occur; for example, in south-west England, the rate of implantation in Devon is threefold that in Avon (Table I). Whilst cochlear implant centres have been recognized to have varying implantation rates, little is known about regional variation in provision rates for defined populations.

National intervention threshold levels

For 14 of the 20 centres which responded to our requests, criteria for intervention were similar, i.e. an aided threshold of >55 dB at 2–4 kHz (with a corresponding unaided hearing threshold of >95 dB at 0.5–4.0 kHz) and an open set speech perception of 20–50 per cent or lower (Table II).

TABLE I

COCHLEAR IMPLANTATION (CI) IN SOUTH WEST ENGLAND, 2000–2002

County	CIs/year (mean *n*)	Population	CIs/million pop/year
Avon	6.7	983 860	6.7
Cornwall	5.7	501 267	11.4
Devon	14.3	704 493	20.3
Dorset	4.6	390 980	11.7
Gloucestershire	4.0	564 559	7.1
Somerset	3.3	498 093	6.7
Wiltshire	4.3	432 972	9.9
Total	43	3 643 252	11.8

Reproduced with permission from the Hospital Episode Statistic Database, 2004. Pop = population

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TABLE II

COCHLEAR IMPLANTATION INTERVENTION THRESHOLDS USED BY UK CENTRES

Centre no	Threshold	
	Audiometric	Linguistic
2		30% open set speech perception in best aided condition
3	Aided threshold >55 dB from 2.5–4 kHz	
4	Mean aided response >55 dB in high frequency	<30% speech perception in open set material
6	Mean aided response >55 dB in high frequency	
7	Aid thresholds 60–70 dB Unaided pure tone, 100–110 dB in 5–4 kHz	>20% speech discrimination with maximum aid
8	Mean aided response >55 dB, frequency 2–4 kHz	
9	>90 dB at 2 kHz Children: click ABR thresholds >90 dB	
10	Best aided >50 dB at mid-high frequency	30% for BKB sentence material, listening alone
15	Mean aided response >55 dB, frequency 2–4 kHz	0–30% on speech alone, listening alone
16	Unaided hearing loss >95 dB at 2 kHz & higher frequency	Limited open set recognition of words in an audition
17	Children, aided threshold >55 dB at 2–4 kHz	
18	90 dBH at 2 kHz Mean PTA >90 dB	>50% open set sentence discrimination in ear to be implanted. Children, >50% open set sentence discrimination
19	Mean aided response >55 dB, frequency 2–4 kHz	
20	Mean aided response >55 dB across 2–4 kHz	

Responses were not obtained from six cochlear implant centres (centres 1, 5 and 11–14). Centres 3, 8 and 17 provided services for children only. No = number; ABR = audiometric brainstem response; BKB = Bamford–Kowal–Bench sentence test; PTA = pure tone audiometry

This confirms that the selection criteria for adults and children have changed since the national evaluation of cochlear implant services.

Estimating potential need

The five approaches to estimating future need for cochlear implantation (see above) provided widely differing results.

Using the first estimation method, we were unable to calculate relevant estimates of the number of UK adults with hearing impairment. Prevalence data were thus used.[5] Applying this information to a population of 1 000 000, the number of potential candidates was estimated to be: 160–182 adults and 94 children, using an unaided hearing loss threshold of >95 dB at 0.5–4.0 kHz; and 710–852 adults and 149 children, using an unaided hearing loss threshold of >71–94 dB at 0.5–4.0 kHz.

If we adjust the figure and apply a threshold of >95 dB, using the MRC's 1995 planning assumption (i.e. 10–12 per cent of adults and 75 per cent of children with a profound hearing loss of >95 dB would be suitable and willing to receive a cochlear implantation), then 18–20 adults and 63 children per 1 000 000 would require cochlear implantation. Incident cases would add to these figures, but treatment of cases to date and losses due to death or moving out of the area would reduce them. These estimates suggested a required provision at least 10 times higher than the current annual provision. Figures for the lower threshold were even higher; i.e. more than 70 adults and 112 children per 1 000 000 population. There was significant uncertainty about these estimates due to the prevalence data being 15–20 years out of date.

Table III shows the number of cochlear implants and related funds which should be provided per year for a population of 1 000 000, using the remaining methods of estimation. This Table indicates that the current provision in our area did not meet any of the estimates of potential need. The MRC-informed estimates, based on a threshold reduction to 100 dB for adults and 95 dB for children, were the most costly, with an initial projected cost of £413 000–647 000 and recurring annual costs of £32 000–70 000 for maintenance and rehabilitation.

For all the calculated estimates, it is important to stress that there are margins of error. If, for instance, the number of cases requiring cochlear implantation amounted to 30 in a hypothetical population of 1 500 000, one may expect as few as 20 or as many as 42 cases in any one year.[6] As the size of the population increases, the margin of error decreases.

TABLE III

ESTIMATES AND FORECASTS OF COCHLEAR IMPLANTATION AND FUNDING REQUIRED*

Estimate no	Adults (*n*)	Children† (*n*)	Initial cost (£ × 1000)	Maintenance cost (£ × 1000)
1	No incident data available			
2	4	4–12	295–618	23–51
3	6	5–16	413–647	32–70
4	6	4–12	372–696	29–56
5	4	4	279–314	23–25

*Applied to a population of 1 000 000, with related costs in pounds sterling. †Estimates relying on data from the MRC evaluation are in the ranges shown due to distinctions made between younger (<7 years) and older (8–17 years) children. See text for estimation methods.

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Discussion

In England, PCTs have the task of commissioning health services in order to meet the needs of their resident populations. The demand to fund all service developments often exceeds available revenue. Difficult choices have to be made, supported by good quality evidence on need and effectiveness. Decisions can only be 'based on evidence, not made by evidence'.[30] This is illustrated by our demonstration of the differing methods available to assess the need for cochlear implants, reflecting varying reliance on epidemiology, treatment thresholds and service demand.

Our methodology was pragmatic, aiming to inform policy, using existing population estimates of hearing impairment and cochlear implant requirements. Our calculated estimates for cochlear implant requirements may not be exactly accurate. For our estimation methods two, three and four, we relied on evidence that was eight to 10 years out of date,[11,28] and, for estimate method five, we relied on retrospective data from 2000–2003.[29] Therefore, assumptions about patient uptake may have caused over- or under-estimation. Despite this, we noted wide margins of error in estimates of need according to size of population. Whilst our estimates may help commissioners to assess the scale of the average funding increase required, fluctuations in the number of implant candidates assessed each year, against a background trend of rising implant rates, will prevent straightforward annual budgeting. Risks may be reduced through groups of PCTs pooling their resources (and risks) to commission cochlear implantation services. Commissioners need to regularly review their plans, as intervention thresholds and attitudes influencing uptake may change.

Cochlear implantation in children has been funded on the basis of evidence of effectiveness, cost effectiveness and low risk of harm. Clinical indications are changing faster than the evidence base. More research is needed on the optimum age of implantation in the very young and on the long term impact of cochlear implantation on physical, mental and social well-being. This could help parents who are uncertain about whether an implant represents the best solution for their child; it could also assist commissioners trying to prioritize funding requests.

Intervention thresholds were fairly uniform across the UK cochlear implantation centres assessed, but the current level of provision in England was well below what would be expected if the majority of people meeting current criteria were given a cochlear implant. New cost effectiveness studies are needed to guide decisions on the priority that should be given to promoting higher uptake at these thresholds (which are lower than those assessed in the only comprehensive evaluation of cochlear implantation in the UK).[11]

Our estimate of need based on prevalence of hearing loss suggests a level of cochlear implant provision well beyond the current capacity and funding. The backlog of existing cases could not be treated in the immediate future. In the meantime, clinicians and service commissioners need to develop a common understanding of the priorities that will make best use of the resources available to improve hearing. Annual service level agreements should reflect the need to make progress in treating both new cases and backlog cases at an acceptable rate, given competing health needs.

- **The 1995 MRC national evaluation report provided useful information that could be used to estimate the local funding needed for cochlear implant services**
- **Subsequently, demand has exceeded the number of implants funded**
- **Intervention thresholds used by UK cochlear implant centres have changed**
- **Estimated numbers of implants and funding needed are provided, using different planning assumptions**
- **Cost effectiveness studies of implantation at lower thresholds are needed to help guide decisions on priorities for health funding**

Using planning assumptions from national evaluation rather than prevalence studies alone, our estimates of need were much closer to current local demand and higher than the average provision in England.[29] This led us to provide four options for local commissioning policy, based on our estimates (numbers two to five in Table III). We rejected a further option (i.e. continuing the current level of funding, of six implantations per year) on the grounds that it was low compared both with the average implantation provision in England and with all current estimates of need. The selection of one of the preferred options should allow a level of service provision much closer to that currently demanded. Further changes in practice, notably, lower thresholds and bilateral implants, are likely to re-open the gap between demand and funded supply. Good quality evidence on effectiveness and cost effectiveness will be needed to support decision-making.

Conclusions

Alleviating deafness in the community brings benefits to individuals and savings to the community, the government and the NHS. These include reduced social security payments, educational costs, and the costs of the adverse effects of unemployment and low paid employment on health. Cochlear implantation can be effective in improving hearing but poses particular challenges to purchasers and providers of health care. Despite high costs and increasing demand, there is no nationally agreed definition or guideline on who should be offered cochlear implantation.

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The current national trend is towards an increasing number of cochlear implants being provided year on year. A comparison of the selection criteria used by English cochlear implant centres shows that the intervention threshold has already fallen to below the levels envisaged in the 1995 MRC evaluation of cochlear implantation.

The gaps between clinical intervention thresholds and commissioned service provision have widened. This needs to be addressed through agreement between PCTs and providers on the priorities for cochlear implantation, and a new level of service provision needs to be set. New estimates of cost effectiveness are needed which are based on the lower intervention thresholds being used in the UK. Studies of the incidence of hearing loss which meets these intervention thresholds are needed in order to estimate the need for cochlear implantation in the UK population.

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