Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Multi-channel cochlear implant in adults aged 18 years or over, with bilateral, postlingual, profound deafness.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
Adults (age 18 years or over) with bilateral, postlingual, profound deafness who were included in studies utilised in the present study. Some studies also assessed hypothetical patients.

Setting
The study was set in hospital and the community. The economic analysis was carried out in the USA.

Dates to which data relate
Effectiveness and cost data were based on studies published between 1995 and 1999. The price year was not explicitly specified.

Source of effectiveness data
The evidence for the effectiveness outcomes was based on a review of the literature.

Outcomes assessed in the review
The review assessed loss in health-utility from profound deafness and gain in health-utility from the cochlear implant.

Study designs and other criteria for inclusion in the review
Included studies had to report the following:

1) data on adults (age 18 years or over) with bilateral, postlingual, profound deafness;
2) a health-utility gain from cochlear implantation on a scale from 0.0 (death) to 1.00 (perfect health);
3) a cost-utility ratio in terms of dollars per quality-adjusted life-year (QALY); and
4) at least 1 conventional statistical parameter (i.e., SD, 95% confidence interval or p value).
The review included theoretical mapping studies, which utilised either the Health Utilities Index (HUI), the Quality of Well-being Scale (QWB), the EuroQol, the Rosser Index, the Rosser-Gudex or the Torrance instrument. For studies included in the meta-analysis, study designs included prospective, cross-section, and retrospective designs, which utilised HUI, Visual Analogue Scales (VAS) or QWB instruments. Control subjects 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.

Sources searched to identify primary studies
A MEDLINE literature search was undertaken, article bibliographies were reviewed, and experts were consulted about unpublished reports.

Criteria used to ensure the validity of primary studies
Studies containing actual patient data were included in the meta-analysis. Retrospective studies were also included in the review since it was deemed that the possibility of recall bias may be mitigated for cochlear implant users as they re-experience profound deafness on a daily basis when their implants are off.

Methods used to judge relevance and validity, and for extracting data
The abstraction process was not blinded to the journal, year of publication, or authors. Health-utility values produced in each individual study, and instruments used to assess the health-utility were reported.

Number of primary studies included
A total of 7 studies with actual patient data were used as the main sources of data. Within the 7 studies, there were 9 reports (n=619) of cases or controls with a loss of health-utility from profound deafness. The health-utility of profoundly deaf adults was based on 7 reports (n=511). A total of 7 studies which did not include actual patient data and performed "theoretical mapping" (i.e., hypothetically estimating how deaf patients would answer a health-utility instrument) were excluded from the meta-analysis.

Methods of combining primary studies
Meta-analysis was used to calculate weighted averages using a statistical weight of 1 per variance. A summary effect size was derived for each outcome using the "fixed-effect model to a continuous measure" method. If a cohort of patients was analysed using 2 different instruments, the meta-analysis weighted each analysis by half (i.e., statistical weight = 0.5 x (1/variance)).

Investigation of differences between primary studies
Differences between studies were appropriately investigated. The studies were reported to differ in terms of being prospective or retrospective (2 studies), sample size, and instrument used to assess health-utility.

Results of the review
The values in 9 reports for loss in health-utility from profound deafness had a range from -0.63 (SD: 0.26; 95% CI: -0.53 - -0.68) in a study with 105 patients to -0.36 (SD: 0.12; 95% CI: -0.27 - -0.45) in a study with 7 patients. The overall estimate was -0.46 (SD: 0.23; 95% CI: -0.44 - -0.48).

The corresponding values in terms of gain in health-utility from the cochlear implant were 0.072 (SD: 0.119; 95% CI: -0.02 - 0.16) in a study with 7 patients and 0.41 (SD: 0.26; 95% CI: 0.36 - 0.46) in a study with 105 patients. The overall estimate was +0.26 (SD: 0.23; 95% CI: 0.24 - 0.28).
Measure of benefits used in the economic analysis
The measure of benefits was quality-adjusted life years (QALYs) gained. A range of health-utility valuation instruments were used (see study designs and other criteria for inclusion in the review). None of the studies reviewed included standard gamble or time trade-off measurement techniques. The methods of calculating QALYs were not reported.

Direct costs
No information was given regarding the cost calculations (it appears that, as one of the outcomes obtained from the primary studies was cost-utility ratio, no direct cost calculation was performed in this study); only the range of costs for the implant device in 1999 was reported and it was not clear whether this was used in the study. No reflation was undertaken to take into account the differing dates for each study. The cost of the cochlear implant was reported (source: The Listening Centre, Johns Hopkins University, Baltimore, Maryland, USA, unpublished data - 1997 prices).

Indirect Costs
Indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
A series of one-way sensitivity analyses was performed to test the robustness of the meta-analysis by varying the inclusion criteria.

Estimated benefits used in the economic analysis
The health-utility of profoundly deaf adults without cochlear implants was 0.54, (95% CI: 0.52 - 0.56).

The health-utility of profoundly deaf adults after cochlear implants was 0.80, (95% CI: 0.78 - 0.82); leading to an improvement of 0.26, (95% CI: 0.24 - 0.28) in health utility.

The corresponding values in terms of QALYs were not separately reported, but are included in the synthesis reported below.

Cost results
Cost results were not given for each strategy; it was only reported that the implant device itself cost from $14,027 to $37,572.

Synthesis of costs and benefits
The summary cost utility ratio of cochlear implantation was calculated to be $12,787 per QALY. Statistical pooling of the 2 prospective studies yielded a cost-utility ratio of $19,999 per QALY. The sensitivity analyses revealed that the base-line meta-analysis results did not change substantially as inclusion criteria were modified.

Authors' conclusions
Profound deafness in adults results in a substantial health-utility loss. Over half of that loss is restored after cochlear implantation, yielding a cost-utility ratio of $12,787 per QALY. This figure compares favourably with medical and surgical interventions that are commonly covered by third-party payers in the United States and the United Kingdom today.
CRD COMMENTARY - Selection of comparators

The 'no treatment' strategy was regarded as the comparator. It allowed the active value of the CRC screening strategies to be evaluated.

Validity of estimate of measure of effectiveness

The study involved no direct effectiveness measures (medical and audiologic outcomes); as a result no judgement can be made regarding the internal validity of the effectiveness results.

Validity of estimate of measure of benefit

Estimation of benefits was obtained from the meta-analysis of the health-utility outcomes derived from the literature based on a systematic literature review. The life expectancy and QALYs were not reported in the study. The heterogeneity of the pooled studies in terms of instruments used to assess health-utilities was acknowledged by the authors to be a limiting factor regarding the meaningfulness of statistical pooling. The VAS has a number of limitations including overestimating health utility losses and the fact that scores are not determined under conditions of uncertainty. Discrepancies were also reported between HUI and VAS scores for health utility gains due to cochlear implants. These issues tend to limit the validity of the results.

Validity of estimate of costs

No objective judgement can be made regarding costs as no information from primary studies was given in this regard other than the cost of an implant in the authors' institution.

Other issues

The authors mentioned the following limitations of the study: one limitation of pooled studies is an inadequate comparison of the health utilities of individuals who have received a cochlear implant and controls who have not; another potential problem is the possibility of recall bias in the retrospective studies. The issue of generalisability to other settings or countries was not addressed. The authors undertook a review and meta-analysis and, as such, the authors compared the results of relevant studies.

Implications of the study

No study thus far directly elicited health utilities from cochlear implant users using the 2 most commonly accepted health-utility methods (standard gamble and time trade-off). This would be a logical next step for future studies. Future studies should also be prospective in nature, evaluating an adequate number of cases and controls longitudinally.

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