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
Intraoperative facial nerve monitoring (IFNM) in middle ear or mastoid surgeries was under evaluation.

Type of intervention
Other: Monitoring (surgery).

Economic study type
Cost-utility analysis.

Study population
The study population comprised three hypothetical cohorts of patients who received one of the three monitoring strategies.

Setting
The setting was not reported. The economic study was carried out in San Francisco (CA), USA.

Dates to which data relate
The effectiveness data were gathered from studies published between 1982 and 2002. The resource use data were gathered from studies and other sources published between 1997 and 2002. The price year was 2001.

Source of effectiveness data
The effectiveness data were derived from a systematic review of the literature, supplemented by clinic data from the authors' institution.

Modelling
A decision tree model using DATA 4.0 software was created to simulate the costs and effectiveness assigned to each monitoring strategy. The five health states described were permanent complete paralysis, permanent incomplete paralysis, temporary complete paralysis, temporary incomplete paralysis and no paralysis.

Three monitoring strategies were defined. These were IFNM for both primary and revision middle ear or mastoid surgeries (strategy A), facial nerve monitoring for revision surgery only (strategy B) and no monitoring (strategy C).

A lifetime horizon was used.

Outcomes assessed in the review
The outcomes assessed in the review and used as model inputs were:

- the average distribution of primary and revision surgery for middle ear or mastoid procedures;
- the probability of developing iatrogenic facial paralysis with or without monitoring;
- the probability of developing either complete or incomplete facial paralysis with or without monitoring; and
- the probability of developing permanent or temporary facial paralysis with or without monitoring.

A complete paralysis was defined by a House Brackmann grade of VI, whereas an incomplete paralysis was defined by a House Brackmann grade of less than VI (II to V). Permanent paralysis was defined as having some facial functional deficits 12 months after the facial nerve injury (Brackmann grades II-VI).

**Study designs and other criteria for inclusion in the review**
Not reported.

**Sources searched to identify primary studies**
Not reported.

**Criteria used to ensure the validity of primary studies**
Not reported.

**Methods used to judge relevance and validity, and for extracting data**
Not reported.

**Number of primary studies included**
Two primary studies were used to assess the average distribution of primary and revision surgery for middle ear or mastoid procedures. Three primary studies were used to assess the probability of developing iatrogenic facial paralysis. One retrospective study was used to estimate the probabilities of developing either complete or incomplete, and either permanent or temporary, facial paralysis.

**Methods of combining primary studies**
Expert opinion (from specialists) was used to corroborate estimates from the primary studies.

**Investigation of differences between primary studies**
Whenever there were uncertainties or discrepancies in the data, the authors consulted a medical specialist to reconcile the differences.

**Results of the review**
The probability estimates were:

- 0.32 (range: 0.32 - 0.54) for revision surgery in middle ear or mastoid surgery;
- 0.68 (range: 0.46 - 0.68) for primary surgery in middle ear or mastoid surgery;
- 0.0015 (95% confidence interval, CI: 0 - 0.02) for facial paralysis in revision surgery with facial nerve monitoring;
0.9985 (95% CI: 0.98 - 1.0) for no facial paralysis in revision surgery with facial nerve monitoring;
0.00075 (95% CI: 0 - 0.02) for facial paralysis in primary surgery with facial nerve monitoring;
0.9992 (95% CI: 0.98 - 1.0) for no facial paralysis in primary surgery with facial nerve monitoring;
0.04 (range: 0.04 - 0.10) for facial paralysis in revision surgery without facial nerve monitoring;
0.96 (range: 0.90 - 0.96) for no facial paralysis in revision surgery without facial nerve monitoring;
0.017 (range: 0.006 - 0.037) for facial paralysis in primary surgery without facial nerve monitoring; and
0.983 (range: 0.963 - 0.994) for no facial paralysis in primary surgery without facial nerve monitoring.

Methods used to derive estimates of effectiveness
Authors' assumptions were used to derive probabilities, while expert opinion was used to corroborate estimates derived from published literature.

Estimates of effectiveness and key assumptions
The authors assumed that, when a facial nerve injury occurred, the probability of either complete or incomplete facial paralysis was independent of whether IFNM was used.

Two assumptions about patient life expectancy were made. In one, patients who underwent middle ear or mastoid surgery were assumed to have the same life expectancies as the general population. In the other, it was also assumed that the life expectancies of patients with and without facial paralysis were equal.

Measure of benefits used in the economic analysis
The benefit measure used was the number of quality-adjusted life-years (QALYs) saved. The QALYs were derived by multiplying the patient's life expectancy by the utility.

The authors reported that a mathematical model was used to estimate the health utility index (HUI2) from the Short Form-36 questionnaire scores measured in 23 controls and 86 patients with facial paralysis, with an average Brackmann grade of III (Telian et al., see Other Publications of Related Interest).

The benefits were not discounted.

Direct costs
Although the authors stated that a societal perspective was adopted, only the direct costs were included. The unit costs and the quantities of resources used were presented separately. The categories of costs included in the analysis were intervention, physician services and hospitalisation. The direct costs included were those associated with facial nerve monitoring and diagnosis, physician monitoring associated with facial paralysis (including extra audiologist costs), the treatment of acute facial paralysis, and the treatment of chronic facial paralysis. The unit costs for monitoring equipment were obtained from the Medtronic Xomed 2002 catalogue. The authors assumed 10 years total depreciation for the equipment and estimated that the equipment was used for 100 surgical procedures per year. The hourly salary for an audiologist was derived from a published study. Cost-to-charge ratios were used to estimate the hospital costs and operating room costs calculated from the University of California (San Francisco). The hospital costs were obtained from two national databases. The Medicare Fee schedule for services was used to estimate the costs associated with physician services. All costs were updated to 2001 US dollars using the Consumer Price Index. The costs were discounted at a rate of 3%.

Statistical analysis of costs
No statistical analysis of the costs was performed.

**Indirect Costs**
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
One-way sensitivity analyses were performed on the cost of IFNM, probability of facial paralysis with and without IFNM in primary and revision surgeries, and utility values. Two-way sensitivity analyses were performed on the probabilities of facial paralysis in primary and revision surgeries.

**Estimated benefits used in the economic analysis**
The strategy of monitoring all patients (strategy A) had an average QALY of 45.68. The strategy of monitoring revision patients only (strategy B) had an average QALY of 45.67. The strategy of not monitoring any patients (strategy C) had an average QALY of 45.65.

The strategy of monitoring revision patients only (strategy B) resulted in an average of 0.012 QALY saved compared with no monitoring strategy. The strategy of monitoring all patients (strategy A) resulted in an average of 0.0102 QALY saved compared with facial nerve monitoring in revision patients only (strategy B).

**Cost results**
The average cost was $238 for strategy A, $292.1 for strategy B, and $449.8 for strategy C.

IFNM in all patients saved $54.1 when compared with facial nerve monitoring in revision patients only, and $211.8 when compared with no monitoring.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant as IFNM in all patients dominated the other two monitoring strategies (i.e. it was both more effective and less costly). The sensitivity analyses showed that the results were insensitive to changes in the utility values and cost estimates of IFNM. However, the results were sensitive to changes in the probability of facial paralysis without IFNM in primary surgery and the probability of facial paralysis with IFNM in primary surgery. When the former was less than 0.013 and the latter greater than 0.017, facial nerve monitoring in revision patients only dominated the other strategies. The two-way sensitivity analysis showed that all three strategies would have equal average cost-effectiveness if the probability of paralysis in primary surgeries was 0.0053 and that in revision surgeries was 0.033.

**Authors’ conclusions**
Facial nerve monitoring was cost-effective compared with no monitoring. Intraoperative facial nerve monitoring (IFNM) in all patients undergoing middle ear or mastoid surgeries was cost-effective compared with facial nerve monitoring in revision patients only.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of the comparator (no monitoring) appears to have been clear. You should decide whether it represents a valid comparator in your own setting.
Validity of estimate of measure of effectiveness
The authors reported that a systematic review of the literature was conducted. However, the sources searched to identify the primary studies, the study designs and other criteria for inclusion in the review, and the validity of the studies, were not reported. The authors acknowledged that the incidence of facial paralysis may not have reflected the true incidence in the population because the published rates were variable. Thus, the study might have overestimated the incidence. Most of the estimates were varied in the sensitivity analyses.

Validity of estimate of measure of benefit
The estimation of benefits was modelled. The decision tree appears to have been relevant for the study question. However, some limitations of the study need to be highlighted. First, the utility scores were derived from a study on iatrogenic facial nerve palsy and a mathematical model. A more appropriate approach would have been to derive the utilities directly from the study population's preferences. The approach used in the study limits the relevance of the QALY measurements. Second, the benefits were not discounted although a lifetime horizon was used.

Validity of estimate of costs
The authors reported that they adopted a societal perspective, but they did not include the indirect costs. This might have biased the results in favour of no monitoring care. Consequently, this exclusion might not have affected the conclusions. The costs of middle ear or mastoid surgery were not included in the economic analysis, but it is likely that they did not differ between the groups. The reporting of the costing methods, costs and quantities was very good, which enhances the transferability of the economic analysis to other settings. The costs were treated deterministically in the base-case, and key resource use data were varied in the sensitivity analysis. The ranges of variation were derived from the review of the literature and would appear to be valid. The results of the sensitivity analysis were reported in detail. Since all the costs were incurred during more than 2 years, discounting was relevant and was appropriately performed.

Other issues
The generalisability of the results was not addressed. The authors did not compare their findings with those from other studies. The authors reported a number of further limitations to their study, which have been highlighted already. Sensitivity analyses were performed, using very wide ranges to account for variability and uncertainty in the data. Thus, the external validity of the study should be high.

Implications of the study
The authors recommended that facial nerve monitoring should be routinely adopted to reduce the risk of iatrogenic facial nerve injury during otologic surgery. The authors also stated that prospective studies examining the incidence and associated cost of facial paralysis, and the utility score for iatrogenic facial injury, are needed to confirm the results of this study.

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Other publications of related interest
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MeSH
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