Cost-utility analysis of topical intranasal steroids for otitis media with effusion based on evidence from the GNOME trial


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.

CRD summary
This study assessed the cost-effectiveness of topical intranasal steroids for the treatment of otitis media with effusion. The authors concluded that topical steroids were unlikely to be cost-effective in general practice, but the value of information analysis suggested that further research would be cost-effective. The methods were good, and they and the results were sufficiently reported. Given the scope of the analysis, the authors’ conclusions appear to be appropriate.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to assess the cost-effectiveness of topical intranasal steroids for the treatment of otitis media with effusion (OME).

Interventions
Mometasone furoate nasal spray (50 micrograms) was compared with placebo nasal spray (no active treatment). The sprays were administered once daily into each nostril for three months.

Location/setting
UK/primary care.

Methods
Analytical approach:
The effectiveness and cost data were from one randomised controlled trial. The time horizon was nine months (the follow-up period of the trial). The authors stated that the perspective of the UK NHS was adopted.

Effectiveness data:
The effectiveness data were from the General Practice Research Framework Nasal Steroids for Otitis Media with Effusion (GNOME) trial (Williamson, et al. 2009, see ‘Other Publications of Related Interest’ below for bibliographic details). This was a placebo-controlled, double-blind, randomised trial of 217 children aged four to 11 years, with a history of otitis media and tympanometry-confirmed bilateral OME. The patients were recruited from 76 Medical Research Council General Practice Research Framework practices in the UK, with 105 patients randomised to mometasone furoate and 112 to placebo. The primary outcome measure was the proportion of children who were cured of bilateral OME, using tympanometry criteria (at least one ear with an A or C1 type recording) at one month.

Monetary benefit and utility valuations:
The utilities were elicited using the Health Utilities Index (HUI) versions two and three and the European Quality of life (EQ-5D) questionnaire. All questionnaires were completed by parents at baseline, and at three and nine months. The base-case analysis used the HUI3. The utility scores were adjusted to correct for an imbalance in baseline utility values between the study arms, by subtracting the baseline scores from those at three and nine months; each measurement was the increase (or decrease) in utility from baseline.

Measure of benefit:
The measure of benefit was quality-adjusted life-years (QALYs) gained.
Cost data:
The direct costs included consultations with community health-care providers, medications, investigative tests, hospital out-patient care, and hospital in-patient stay. The resource use data were collected in two ways; the research nurses retrospectively extracted information from children's primary care records, and parents completed resource use questionnaires at three and nine months. In the base case, information from primary care records was used. The resource use was valued using NHS Reference Costs, local provider tariffs, the British National Formulary, and other national unit cost sources. All costs were reported at 2006 to 2007 prices, in UK pounds sterling (£).

Analysis of uncertainty:
Missing data were imputed using several methods to avoid bias from complete-case analysis. Bootstrap replications of 1,000 to 5,000 simulations were generated for the imputed datasets and cost-effectiveness acceptability curves were generated for positive incremental net benefits. Independent-sample t-tests were used to test for differences in resource use, costs, utility scores, and QALYs between treatment groups. The expected value of perfect information (EVPI) was estimated to assess the theoretical maximum that society could spend on further research. Sensitivity analyses were conducted: using the resource responses from parents; analysing complete cases; using HUI2 and EQ-5D utilities; and not adjusting for baseline utility. Post-hoc subgroup analyses were undertaken, including by age, gender, and atopy.

Results
In the base case, the mean QALYs gained were 0.036 (95% CI -0.001 to 0.074) with mometasone furoate and 0.053 (95% CI 0.019 to 0.086) with placebo. The mean costs were £454 (95% CI 284 to 623) with mometasone furoate and £442 (95% CI 314 to 571) with placebo. Placebo (no active treatment) was dominant over the topical steroid, as it was less costly and more effective.

There was substantial uncertainty around this result. In 46% of the bootstrap replications, the intervention group was less costly than placebo, and in 24% topical steroids generated more QALYs. At a £20,000 per QALY threshold, the intervention was cost-effective in 24.19% of replications.

Using the utilities from the HUI2 or the EQ-5D, the intervention was cost-effective, with an incremental cost-utility ratio of less than £3,000 per QALY. Topical steroids were cost-effective, compared with placebo, in 63.20% of replications with the HUI2 and 88.66% with the EQ-5D. There were no subgroups in which topical steroids were cost-effective in more than 45% of replications at the £20,000 per QALY threshold.

The EVPI was £65.73 per child or £9.1 million for the 160,000 children in the UK who were potentially eligible for treatment over the next 10 years. This EVPI was higher than the cost of many trials, which suggested that it might be cost-effective to collect further evidence on the efficacy and cost-effectiveness of steroids for OME.

Authors' conclusions
The authors concluded that intranasal topical steroids were unlikely to be cost-effective for OME in general practice. The value of information analysis suggested that further research would be cost-effective.

CRD commentary
Interventions:
The interventions were reported clearly and in detail.

Effectiveness/benefits:
The effectiveness data were from a randomised controlled trial and the details of this trial, including the sample size and duration of follow-up, were reported. The trial appears to have been well conducted and should have good internal validity. The methods used to derive the utilities for the QALYs were well reported. The HUI3, rather than the HUI2 or the EQ-5D, was used in the base case, because it contained separate attributes for hearing and speech, possibly making it more sensitive than the other two instruments. QALYs were an appropriate measure of benefit, given the impact of OME on quality of life. They were appropriately left undiscounted, as the time horizon was less than a year. QALYs also allow broader comparisons to be made with the benefits of other health care interventions.

Costs:
The perspective was explicitly reported and it appears that all the major cost categories and costs for this NHS perspective were analysed. The authors reported the methods used to obtain and value the resource use and this was presented separately from the costs, which enhances the generalisability of the results. The price year, time horizon, and currency were all reported and the costs were appropriately not discounted.

Analysis and results:
The costs and benefits were combined using an incremental cost-utility ratio, where appropriate. The impact of uncertainty on the results was thoroughly tested in a series of sensitivity analyses. The authors imputed missing data, using recommended methods. The methods and results of the study were reported in detail. The authors provided a balanced discussion on the main limitations of their study, such as the method of recruitment into the trial, which was likely to have more accurately identified the population for treatment than is usually the case in primary care.

Concluding remarks:
The methods were good, and they and the results were sufficiently reported. Given the scope of the analysis, the authors' conclusions appear to be appropriate.

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