Pharmacoeconomic impact of factors affecting compliance with antibiotic regimens in the treatment of acute otitis media  
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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
Treatment of otitis media with antibiotics.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness study.

Study population
Children of both sexes aged between 2 months and 7 years old with acute otitis media.

Setting
Primary care. The economic study was conducted in West Virginia, USA.

Dates to which data relate
Dates for effectiveness and cost data relate to 1994. The price year was 1995.

Source of effectiveness data
The source of effectiveness data was a single study.

Link between effectiveness and cost data
The costing was done for the sample used in the effectiveness analysis. Costing for direct costs appears to have been done retrospectively, but the indirect costs were obtained prospectively.

Study sample
380 patients, with 591 episodes of acute otitis media were enrolled. Three subjects dropped out but reasons were not stated. There were no exclusions. The sample was not randomly assigned, and the size of the sample was not determined by power calculations.

Study design
This was a cohort study with data obtained from four clinics. Duration of follow up was not stated.
Analysis of effectiveness
The authors did not state whether the analysis was based on intention to treat or on treatment completers. The health outcomes analyzed were adverse effects, and patient acceptance of the antibiotic (including compliance).

Effectiveness results
Amoxicillin/clavulanate had the highest incidence of adverse effects, with 39.5% of patients experiencing more than 1 adverse effect, and 25% of patients experiencing diarrhea. Cefixime had the lowest incidence of side effects overall. Overall acceptance (a compilation of adverse effects, missed doses, change in medication due to adverse effect, and palatability) was highest for cefixime, and lowest for erythromycin/sulfisoxazole. Although standard deviations were presented, statistical differences (p-values, 95% confidence intervals) were not.

Clinical conclusions
Cefixime had the fewest side effects and was generally more acceptable to patients.

Measure of benefits used in the economic analysis
The health outcomes analyzed were adverse effects, and patient acceptance of the antibiotic (including compliance). Information on these was obtained through a survey of a random sample of 100 caregivers involved in the study. Based on information from the study, valuation was estimated by the authors.

Direct costs
Quantities and costs of resources were reported separately in another article. The costs included: office visit fees, laboratory fees, antibiotic cost and tympanometry/tympanocetesis fees. Direct costs that were fees were obtained from billing records of subjects. Drug costs were derived from wholesale prices. Estimation of all other direct costs was obtained through a telephone survey of a random sample of patients' caregivers. The boundary assumed was the patient/caregiver, except for drug costs as these did not include the cost of the prescription fee. The estimation of quantities and costs was based on data from billing records and survey results between 1 January to 31 December 1994. The price year was 1995. Discounting was not applied due to the period of the study (1 year).

Statistical analysis of costs
The data was treated in a stochastic way, with standard deviations and averages being reported. Statistical testing was not carried out; neither p-values or confidence intervals were reported.

Indirect Costs
Costs and quantities were reported separately in another article. Indirect costs included: value of work time lost and baby sitting fees. The boundary assumed was that of the relatives, or caregivers. The estimation of both quantities and costs was obtained through a telephone survey of a random sample of patients' caregivers. The survey was done within 10 days of the clinic visit. Indirect costs were not discounted due to the period of the study (1 year).

Currency
US dollars ($).

Sensitivity analysis
Not carried out.

Estimated benefits used in the economic analysis
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Cost results
The cost of treating an episode of acute otitis media with these six antibiotics ranged from a low of $78.78 (+/- 31.72) with amoxicillin to a high of $101.31 (+/- 38.45) with amoxicillin/clavulanate. The cost for cefixime was $90.83 (+/- 22.03). These costs include both direct and indirect costs, including the treatment of adverse effects.

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors’ conclusions
The authors concluded that if several antibiotics are appropriate and equally effective, consideration of comparative compliance data may prove helpful. Cefixime was shown to have the most favourable patient acceptance and adverse effects but did not have a lower cost. Ignoring patient preferences may lead to poor compliance and poor therapeutic outcome. The resulting increased morbidity can increase dollar costs and worsen quality of life.

CRD COMMENTARY - Selection of comparators
The reason for choosing these six antibiotics was not clear, and two of the choices (cefixime and cefprozil) made up a small percentage of the total usage. Three other antibiotics that were described in the original article were excluded from the analysis here for unknown reasons.

Validity of estimate of measure of benefit
The measures of benefit were valid.

Validity of estimate of costs
Without a statistical analysis, one cannot know if costs are statistically different. Considering that less than 4% of patients were prescribed cefixime, whereas 59% were prescribed amoxicillin, a statistical analysis would have been helpful. More information on what was included in costs other than drug costs (i.e. what constituted charges for treatment of adverse effects, and where the data came from) would have been helpful.

Other issues
By examining point estimates only, cefixime may look better based on the outcome measures used, however without statistical analysis one cannot tell if there is any statistical difference. Since the wide standard deviations overlap, they may not be different. Costs and benefits should have been combined in some way to make the data useful from a pharmacoeconomic standpoint.

Implications of the study
More research is needed to identify the cost of factors that affect compliance with antibiotic regimens in acute otitis media.

Source of funding
None stated

Bibliographic details

PubMedID
Indexing Status
Subject indexing assigned by NLM

MeSH
Acute Disease; Anti-Bacterial Agents /economics /therapeutic use; Child; Child, Preschool; Cost-Benefit Analysis; Humans; Infant; Otitis Media /drug therapy /economics; Patient Compliance; United States

AccessionNumber
21997000342

Date bibliographic record published
30/09/1998

Date abstract record published
30/09/1998