Prophylactic antibiotics for non-laboring patients with intact membranes undergoing Cesarean delivery: an economic analysis
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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
The use of prophylactic antibiotics (cefazolin, 1 g intravenous) for the prevention of complications associated with Caesarean delivery in non-labouring women.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of non-labouring women with intact membranes undergoing Caesarean delivery.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data were derived from studies published in 2001 and 2002. The dates to which the cost and resource use data related were not provided. The price year was 2001.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of completed studies.

Modelling
A simple decision tree was constructed to examine the clinical and economic outcomes associated with prophylaxis versus no prophylaxis in a hypothetical cohort of 10,000 pregnant women. The model considered the potential for anaphylaxis and included outcomes of fever and endometritis. The structure of the deterministic model was reported.

Outcomes assessed in the review
The outcomes assessed from the literature were:
the probability of anaphylaxis,
the probability of endometritis without prophylaxis,
the probability of fever without prophylaxis,

the relative risk (RR) of endometritis, and

the RR of fever.

**Study designs and other criteria for inclusion in the review**
It was not stated whether a systematic review of the literature had been undertaken. The primary studies comprised two meta-analyses, and a study of 9,388 patients. Two new clinical trials were included in a meta-analysis. There were no other details on the design of the studies included in the review.

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

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

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

**Number of primary studies included**
Three primary studies provided evidence.

**Methods of combining primary studies**
The primary studies do not appear to have been combined.

**Investigation of differences between primary studies**
Not stated.

**Results of the review**
The probability of anaphylaxis was 0.0002 (range: 0.0001 - 0.005).

The probability of endometritis without prophylaxis was 0.048 (range: 0.009 - 0.43).

The probability of fever without prophylaxis was 0.144 (range: 0.04 - 0.33).

The RR of endometritis (prophylaxis versus no prophylaxis) was 0.18 (range: 0.07 - 0.45).

The RR of fever (prophylaxis versus no prophylaxis) was 0.47 (range: 0.32 - 0.68).

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out. However, some model outputs, such as cases of fever, endometritis and anaphylaxis, were reported.

**Direct costs**
Discounting was not relevant since the costs were incurred during a short timeframe. The unit costs were not reported.
separately from the quantities of resources used since the costs were presented as macro-categories. The health services included in the economic evaluation were anaphylaxis, uncomplicated Caesarean section, the treatment of endometritis, fever workup and prophylaxis. Anaphylaxis covered the cost for 24 hours in the surgical intensive care unit, and costs related to the administration of epinephrine (3 doses), albuterol (4 doses), benadryl (4 doses) and methylprednisilone (1 dose). Fever workup included complete blood cell count, blood cultures, urinalysis and urine cultures. Prophylaxis covered the syringe, needle and drug. Each category of costs included nursing, physician, drugs and materials. The time horizon of the cost analysis included the patient’s initial hospitalisation and any subsequent hospitalisations in relation to the procedure. The cost-resource boundary of the health care system was adopted. The costs and resource use data came from the authors’ hospital accounting system. The price year was 2001.

**Statistical analysis of costs**
The costs were presented as mean values with ranges. No statistical analyses of the costs were carried out.

**Indirect Costs**
The indirect costs were not considered in the economic evaluation.

**Currency**
US dollars ($).

**Sensitivity analysis**
Univariate sensitivity analyses were performed on all model inputs to examine the robustness of the cost estimates. Two- and three-way sensitivity analyses were carried out on key inputs. Ranges of values were derived from published confidence intervals and standard deviations of observed values.

**Estimated benefits used in the economic analysis**
In a hypothetical cohort of 10,000 pregnant women, there were 590 cases of fever, 90 cases of endometritis and one anaphylaxis with prophylaxis. In the absence of prophylaxis, there were 960 cases of fever and 480 cases of endometritis.

**Cost results**
The average cost per case was $1,683.72 without prophylaxis and $1,653.06 with prophylaxis (difference $30.66).

The sensitivity analysis showed that of all the variables varied, only antibiotic cost had a threshold value. This suggested that if the antibiotic cost more than $31.70 (a far higher estimate than the base-case value), then no prophylaxis was cost-saving. Two- and three-way sensitivity analyses suggested that the base-case conclusions were robust to plausible variations in clinical and economic inputs.

**Synthesis of costs and benefits**
The costs and benefits were not synthesised since a cost-consequences analysis was carried out.

**Authors’ conclusions**
Antibiotic prophylaxis in non-labouring women undergoing Caesarean delivery led to fewer complications and lower costs in comparison with no prophylaxis. The conclusion of the analysis was unchanged over the wide ranges of values investigated in the sensitivity analyses.
The selection of the comparator (no prophylaxis) was appropriate as it reflected standard care for non-labouring women undergoing Caesarean delivery. You should decide whether this is a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**

The effectiveness analysis was based on published studies. It was not stated whether a systematic review of the literature was undertaken to identify the primary studies, but the effectiveness parameters were mainly obtained from meta-analyses. Some details of the designs of the primary studies were reported. However, methodological differences between the studies were not discussed and the primary estimates were combined in a narrative. All of the clinical inputs were varied in the sensitivity analysis.

**Validity of estimate of measure of benefit**

No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**

The authors stated explicitly which perspective was adopted in the study. The majority of the cost categories relevant to the health care system were included in the analysis. However, the authors did not include outpatient costs in their analysis. Also, there was limited information on the unit costs and quantities of resources used, which restricts the possibility of replicating the analysis in other settings. The costs were specific to the study setting but were varied in the sensitivity analysis. The source of the data was reported. The price year was reported, which aids reflation exercises in other settings.

**Other issues**

The authors did not compare their findings with those from other studies. They also did not explicitly address the issue of the generalisability of the study results to other settings. However, extensive sensitivity analyses were carried out, which enhanced the external validity of the analysis. The study referred to non-labouring women undergoing Caesarean delivery and this was reflected in the authors' conclusions. The authors reported some limitations of their analysis. For example, the exclusion of some cost categories from the analysis and the fact that potential emergence of resistant organisms was not addressed in the model. However, the inclusion of most costs would have further favoured the prophylaxis option.

**Implications of the study**

The study results supported the use of routine prophylaxis in non-labouring women undergoing Caesarean delivery. The authors stated that currently unquantifiable issues, such as antibiotic-resistant organisms or medical liability costs, could ultimately alter the results of the model.

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None stated.

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MeSH
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