A cost-effectiveness analysis of the intrapartum fetal pulse oximetry multicentre randomised controlled trial (the FOREMOST trial)

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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 study compared the addition of foetal pulse oximetry (FPO) to conventional cardiotocographic (CTG) monitoring with the use of CTG alone in reducing the operative delivery rate for non-reassuring foetal status.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women in labour at 36 weeks’ gestation or more, with a non-reassuring CTG. The inclusion and exclusion criteria were reported elsewhere (East et al. 2006, see ‘Other Publications of Related Interest’ below for bibliographic details).

Setting
The setting was inpatient care at a maternity hospital. The economic study was carried out in Australia.

Dates to which data relate
The effectiveness and resource use data were collected between July 1999 and September 2004. The price year was 2004.

Link between effectiveness and cost data
The costing was carried out prospectively on the same patient sample that provided the effectiveness data.

Study sample
A total of 305 patients were assigned to the intervention group (FPO+CTG) and 295 to the control group (CTG only). Details of the study sample were not provided in this paper but were reported elsewhere (East et al. 2006).

Study design
The study was a multi-centre randomised controlled trial (RCT) that was carried out in four Australian maternity hospitals. For other details of the study design, see East et al. (2006).

Analysis of effectiveness
The primary outcome was the absolute risk of an operative delivery for non-reassuring foetal status.

**Effectiveness results**
The absolute risk was 25% in the intervention group and 32% in the control group.

The absolute risk reduction was 7%.

The relative risk of the intervention over the control was 0.77 (95% confidence interval, CI: 0.599 to 0.999; p=0.048).

**Clinical conclusions**
There was no significant difference in the overall operative delivery rates or neonatal outcomes between groups.

**Measure of benefits used in the economic analysis**
The authors used clinical outcomes (reported in the 'Analysis of Effectiveness' section) as the measure of benefit in the economic analysis.

**Direct costs**
The direct costs to the health service were the treatment-related expenses, the direct medical costs and patient level costs. The direct medical costs covered foetal monitoring procedures, equipment, medications, delivery and postnatal stay. Patient level costs included foetal scalp blood sampling, medications, use of oxygen and/or intravenous hydration fluid, and intervention-related equipment. Resource use related to the treatment expenses and the direct medical costs were derived from clinical records. Relevant costs were estimated by using hospital-assigned diagnosis-related group (DRG) reimbursement rates. Patient level resource use was valued according to local prices. The resource use quantities and the costs were reported separately. Discounting was not relevant as the costs were incurred during a short time. The prices were adjusted to year 2004 using the Consumer Price Index for hospital and medical services.

**Statistical analysis of costs**
The costs and quantities were treated deterministically.

**Indirect Costs**
Inline with the perspective adopted, productivity costs were not included in the analysis.

**Currency**
Australian dollars (AUD).

**Sensitivity analysis**
The authors used a bootstrapping method to investigate the statistical significance of the incremental cost-effectiveness ratios (ICERs). A total of 2,000 replicates were conducted for each sample and the bias-corrected accelerated method was used to estimate 95% CIs. A sensitivity analysis was conducted to investigate the robustness of the results to variability in the level of capacity (i.e. the number of births per week).

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total costs and mean costs (with standard deviation, SD) were reported.

The total costs were AUD 2,251,341 for the intervention group and AUD 2,194,997 for the control group.

The mean costs were AUD 7,381 (SD=2,229) for the intervention group and AUD 7,441 (SD=2,334) for the control group.

The difference in costs per person (intervention minus control) was -AUD 59.25.

**Synthesis of costs and benefits**

In comparison with the control group, the intervention group achieved a negative ICER of AUD 813. This represented a saving of AUD 813 per operative delivery averted for non-reassuring foetal status.

Bootstrapped ICERs were plotted on a cost-effectiveness plane, which was presented in the paper.

The sensitivity analysis demonstrated the robustness of the results to variability in the level of capacity.

**Authors' conclusions**

In comparison with cardiotocographic (CTG) monitoring alone, the addition of foetal pulse oximetry (FPO) to CTG monitoring represented a less costly and more effective use of resources to reduce operative delivery rates for non-reassuring foetal status.

**CRD COMMENTARY - Selection of comparators**

The use of CTG monitoring alone as the comparator was justified as it represented current practice in the authors' settings. You should decide if this represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**

The analysis was based on an RCT. This was appropriate for the study question, as well-conducted RCTs are considered to be the 'gold' standard study design when comparing different health interventions. It is difficult to comment on other aspects of the study design since details of the RCT were given in a previous study. To fully ascertain the internal validity of the effectiveness data the reader should refer to the clinical paper (East et al. 2006).

**Validity of estimate of measure of benefit**

The authors used clinical outcomes as the measure of benefit in the economic analysis. These were derived directly from the multi-centre RCT.

**Validity of estimate of costs**

The perspective adopted in the economic analysis was that of the treatment provider. It appears that all the relevant costs have been included in the analysis. The unit costs and the quantities of resources used were reported separately, which will enable the analysis to be easily reworked for other settings. The costing was performed mainly using the DRG approach from the Australian public sector, although, where necessary, these costs were supplemented using per diem costs from the local hospitals; the data for each were reported, thus enhancing the generalisability of the study. The price year was reported, which will aid future inflation exercises. Discounting was not necessary.

**Other issues**

The authors did not make appropriate comparisons of their findings with those from other studies. However, the issue of generalisability to other settings was addressed in the sensitivity analysis. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors implied a
number of further limitations to their study. A societal perspective was not adopted in the study, and an a priori selection of a less intermediate outcome was not applied.

**Implications of the study**
The authors would appear to recommend the use of the combined FPO and CTG strategy in reducing operative delivery rates for non-reassuring foetal status.

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**Bibliographic details**

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**Other publications of related interest**
Because readers are likely to encounter and assess individual publications, NHS EED abstracts reflect the original publication as it is written, as a stand-alone paper. Where NHS EED abstractors are able to identify positively that a publication is significantly linked to or informed by other publications, these will be referenced in the text of the abstract and their bibliographic details recorded here for information.


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adult; Cardiotocography /economics; Cesarean Section /economics; Cost-Benefit Analysis; Female; Fetal Diseases /diagnosis /economics /physiopathology; Heart Diseases /diagnosis /economics /physiopathology; Heart Rate, Fetal; Humans; Oximetry /economics; Pregnancy; Risk Factors