Cost-effectiveness of rapid tests and other existing strategies for screening and management of early-onset group B streptococcus during labour


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 examined the cost-effectiveness of screening and prevention strategies, including rapid testing during labour and delivery, for neonatal early-onset group B Streptococcus infection. The rapid tests did not provide value for money, while routine antibiotic prophylaxis during labour for all women was the most cost-effective strategy, followed by treatment based on a culture test at 35 to 37 weeks gestation. The methods were valid and the authors’ conclusions appear to be robust, despite limited reporting of the data sources.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This study examined the cost-effectiveness of screening and prevention strategies, including rapid testing during labour and delivery, for neonatal early-onset group B Streptococcus (EOGBS) infection.

Interventions
There were two rapid tests: a polymerase chain reaction (PCR) test and optical immunoassay. The 10 strategies were:

- Antibiotic prevention given during labour and delivery for all women.
- No screening and no antibiotic prophylaxis.
- Treatment based on the microbiological culture of vaginal and rectal swabs that were taken from women at 35 to 37 weeks gestation.
- Treatment based on rapid testing during labour using the PCR test.
- Treatment based on rapid testing during labour using optical immunoassay.
- Treatment for infants with one or more of five risk factors.
- PCR testing for women who possess one risk factor or more, with treatment based on the results of the test.
- Treatment for all who have one risk factor or more and PCR test for those who do not, with treatment based on the results.
- Optical immunoassay for women who possess one risk factor or more, with treatment based on the results of this test.
- Treatment for all who have one risk factor or more and optical immunoassay for those who do not, with treatment based on the results.

The risk factors were: a previous baby with EOGBS, bacteria identified during pregnancy, pre-term labour, prolonged rupture of the membranes, and fever during labour.

Location/setting
UK obstetric unit.

Methods
Analytical approach:
The analysis was based on a decision tree, with a short time horizon. The authors stated that the perspective of the UK NHS was adopted. Two analyses were carried out, one included all 10 strategies and the other excluded the strategy of antibiotics for all patients.
Effectiveness data:
The clinical evidence was mainly from one study, which was supplemented with data from other sources, where required. The main study was prospective and involved 1,400 pregnant women who were booked for delivery at one of two large UK obstetric departments (Daniels, et al. 2009, see ‘Other Publications of Related Interest’ below for bibliographic details). Vaginal and rectal swabs, taken from these women, were tested using enriched microbiological culture, the PCR test, and optical immunoassay. The diagnostic accuracy of these tests was the key input to the model and was calculated for each strategy.

Monetary benefit and utility valuations:
The authors assumed that newborns who survived the disease returned to full health, with no effect on their quality of life.

Measure of benefit:
The benefit measures were the number of deaths from EOGBS and the number of EOGBS infections avoided. Quality-adjusted life-years (QALYs) were calculated, based on the expected survival of newborns, and these were discounted at an annual rate of 3.5%.

Cost data:
The economic analysis included the costs of the tests (PCR, optical immunoassay, and culture), antibiotics (penicillin and clindamycin), delivery (normal and caesarean), treatment of disease (in mothers and babies), and identification of risk factors. The costs and resource quantities were from one of the collaborating obstetric departments, a time and motion study, NHS official tariffs, the British National Formulary, the Department of Health, and a published study. They were in UK pounds sterling (£) and referred to 2005 to 2006 prices. A 3.5% annual discount rate was applied, when required.

Analysis of uncertainty:
A one-way sensitivity analysis was undertaken on the following inputs: the cost associated with death from EOGBS, the cost of the culture test, the effect of antibiotics on EOGBS infections and death, the accuracy of the PCR rapid test based on a vaginal swab only or on rectal and vaginal swabs combined, the gold standard for determining the accuracy of the optical immunoassay and PCR rapid tests, the cost of the rapid PCR test, removal of the assumption that all women who delivered before the culture test at 35 to 37 weeks gestation were given antibiotics, and the cost of the antibiotics. Alternative assumptions were based on authors' opinions or published estimates. A probabilistic analysis was undertaken.

Results
After excluding the dominated strategies, the mean cost per woman was £1,058.53 with no treatment, £1,063.80 with risk-factor screening, £1,069.78 with culture test screening, and £1,069.93 with treatment for all. The percentages of EOGBS infections avoided were 99.9524 with no treatment, 99.9631 with treatment for all. The percentages of EOGBS deaths avoided were 99.9964 with no treatment, 99.9972 with treatment for all.

The incremental cost per EOGBS infection avoided was £50,000 with risk factors, £42,000 with culture, and £24,000 with treatment for all. The incremental cost per EOGBS death avoided was £660,000 with risk factors, £612,000 with culture, and £330,000 with treatment for all. The incremental cost per QALY gained with treatment for all was £15,815 and this was the most cost-effective strategy. When treatment for all was removed from the analysis, the most cost-effective strategy was the culture test, with an incremental cost of £23,444 per QALY gained.

These results were generally stable, with two main exceptions: when the assumption that all women who delivered before the culture test were treated was removed and when the cost of the culture test increased by a small amount, screening based on risk factors was most cost-effective. The cost of the rapid tests had to decrease substantially for them to be cost-effective. The probabilistic analysis confirmed these findings.

Authors' conclusions
The authors concluded that the PCR and optical immunoassay rapid tests did not provide value for money. Routine
antibiotic treatment for all women was the most cost-effective strategy, followed by treatment based on a culture test at 35 to 37 weeks gestation.

**CRD commentary**

**Interventions:**
The authors justified their selection of the comparators as the two proposed rapid tests were compared against existing and hypothetical strategies for the prevention of EOGBS infection. The results of the enriched culture test of both vaginal and rectal swabs were considered to be the reference standard.

**Effectiveness/benefits:**
The authors provided limited information on the sources of data for the clinical analysis. More details were presented in another paper, based on a Health Technology Assessment (HTA), and this design should have ensured the validity of the effectiveness data. Most of these data were from a large study, conducted in two UK hospitals, and these should be representative of the authors’ context. The primary benefit measures were disease specific and, to improve the generalisability of these results, the authors calculated the QALYs associated with the infant outcomes. An assessment of maternal preferences for the strategies would have been interesting.

**Costs:**
The cost categories were appropriate for the viewpoint stated. A few details of the unit costs and resource use were reported, with a reference to the HTA report for more information. The sources used for the resource use and unit costs were representative of the UK setting. Some costs were varied in the sensitivity analysis, particularly to assess the impact of changes in the costs of the tests on the results. The costs of possible complications of antibiotic treatment were not considered.

**Analysis and results:**
The results were extensively presented and the costs and benefits were appropriately analysed, using an incremental approach, which allowed the identification of the most cost-effective strategy. The uncertainty was satisfactorily investigated and discussed, but the detailed results of the probabilistic analysis were not reported. Conventional discounting was applied, when required. The authors stated that the strategy of antibiotics for all women might be difficult to implement, and the costs associated with this strategy might have been underestimated. The results of other studies were reported and some differed from those of this analysis.

**Concluding remarks:**
The methods were valid and the authors’ conclusions appear to be robust, despite limited reporting of the data sources.

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