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
Three strategies for the treatment of suspected foetal macrosomia were examined. These were labour induction (LI), elective Caesarean delivery (CD) and expectant management (EM). Elective CD was scheduled at 39 weeks of gestation, as recommended by guidelines from the American College of Obstetricians and Gynecologists. Patients would be scheduled for LI between 38 and 39 weeks of gestation with the method of induction chosen by the provider. With EM, patients went into labour spontaneously or labour was induced according to standard American College of Obstetricians and Gynecologists guidelines.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of pregnant women without pre-gestational or gestational diabetes mellitus, but with suspected foetal macrosomia (foetus suspected to weigh greater than 4,500 g) detected on ultrasound evaluation.

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

Dates to which data relate
The effectiveness data and most resource use data were derived from studies published between 1986 and 2003. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a synthesis of published studies.

Modelling
A decision model was used to assess the costs and benefits of the three treatments for suspected foetal macrosomia in a hypothetical cohort of 100 women without pre-gestational or gestational diabetes mellitus. The structure of the decision tree was reported. The model took the probabilities of BPI, which could be permanent or not, into consideration.

Outcomes assessed in the review
The outcomes estimated from the literature were:
the probability of CD with elective induction and EM;

the probabilities of shoulder dystocia with elective CD, with CD after elective induction, and with vaginal delivery (VD) after elective induction; and

the probabilities of CD, VD, plexus injury, and permanent injury after EM.

**Study designs and other criteria for inclusion in the review**
A systematic review of the literature was undertaken to identify primary studies with which to populate the decision model. The characteristics of the primary studies were not reported.

**Sources searched to identify primary studies**
PubMed was searched for relevant primary studies using the terms "macrosomia", "induction", "delivery", "shoulder dystocia", "brachial plexus injury", "cost analysis" and "caesarean".

**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**
Twelve primary studies were included in the review.

**Methods of combining primary studies**
The primary estimates appear to have been combined using a narrative approach.

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

**Results of the review**
The probability of CD was 0.35 (range: 0.17 - 0.57) with elective induction and 0.33 (range: 0.08 - 0.35) with EM.

The probability of shoulder dystocia was 0.001 (range: 0 - 0.03) with elective CD, 0.003 with CD after elective induction, and 0.145 (range: 0.05 - 0.21) with VD after elective induction.

The probability of CD after EM was 0.003.

The probability of VD after EM was 0.03 (range: 0.01 - 0.14).

The probability of plexus injury after EM was 0.18 (range: 0.1 - 2.6).

The probability of permanent injury after EM was 0.067 (range: 0.011 - 0.194).

**Measure of benefits used in the economic analysis**
The summary benefit measure used was the number of avoided permanent BPIs. This was estimated using the decision model.
Direct costs
The cost analysis was carried out from the perspective of the third-party payer. It included the costs of brachial plexus rehabilitation, VD and CD. The author stated that the long-term costs of BPI were not considered. A breakdown of the cost items was not provided, and the unit costs were not presented separately from the quantities of resources used. Resource use was estimated on the basis of published data and author's assumptions. For example, it was estimated that all patients received the diagnosis of suspected foetal macrosomia through ultrasonic examination with an estimated foetal weight of greater than 4,500 g. The costs were estimated using reimbursement fees rather than charges. Discounting was not relevant as the costs were incurred during a short timeframe. The price year was not reported.

Statistical analysis of costs
Statistical analyses of the costs were not performed.

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

Currency
US dollars ($).

Sensitivity analysis
A sensitivity analysis was carried out to assess the robustness of the cost-effectiveness ratios to variations in the probability of shoulder dystocia, which was varied using the published range.

Estimated benefits used in the economic analysis
The estimated benefits were not reported.

Cost results
The total costs were not reported.

Synthesis of costs and benefits
It was unclear whether average or incremental cost-effectiveness ratios were calculated to combine the costs and benefits of the alternative strategies.

The author stated that EM of labour onset was the most cost-effective strategy at $4,014.33 per permanent BPI avoided, compared with LI (with a cost of $5,165.08 per injury avoided) and elective CD (with a cost of $5,212.06 per injury avoided).

The sensitivity analysis showed that EM continued to be the preferred option as long as the incidence of shoulder dystocia and permanent injury remained below 10%.

Authors' conclusions
Expectant management (EM) was the most-cost-effective approach for the treatment of suspected foetal macrosomia in pregnant women.

CRD COMMENTARY - Selection of comparators
The rationale for the selection of the comparators was clear. The author stated that the three treatment options were
viable strategies for the treatment of pregnant women with suspected foetal macrosomia. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness data were estimated from published studies. A systematic review of the literature was undertaken to identify the primary studies. Some information on the search strategy (source and keywords) was reported, but other details of the methods and conduct of the review were not given. Since there was no information on the design and other characteristics of the primary studies, it is not possible to make an objective assessment of the validity of the primary estimates. A narrative approach appears to have been used to combine the primary estimates. The issue of heterogeneity among the primary studies was not addressed. In general, the information provided on the effectiveness data was limited.

**Validity of estimate of measure of benefit**
The summary benefit measure was specific to the disease considered in the study. It will not be possible to compare it with the benefits of other health care interventions. Nevertheless, it represents an important and relevant end point.

**Validity of estimate of costs**
The cost analysis was restricted to direct medical costs incurred in the short term and strictly related to labour and management of BPI. The author stated that the potential inclusion of some categories of costs that were not considered in the analysis would not have altered the conclusions. The unit costs and quantities of resources used were not given, which limits the possibility of replicating the cost analysis in other settings. There was limited information on the source of the costs, although the author stated that reimbursement costs were used. The cost estimates were specific to the study setting and statistical analyses were not carried out. Sensitivity analyses were not performed on the cost estimates. The price year was not reported, which will make deflation exercises in other time periods difficult.

**Other issues**
The author did not compare the findings of the current study with those from other studies. In addition, the issue of the generalisability of the study results to other settings was not addressed, and few sensitivity analyses were carried out. Therefore, in general, the external validity of the study is limited. The results of the analysis were presented selectively. The total costs and total benefits were not reported. The author noted that, owing to the inaccuracy of ultrasound evaluations, foetal weight might be overestimated, thus some patients with suspected foetal macrosomia would actually deliver smaller infants. This issue lends further support to a strategy of EM.

**Implications of the study**
The study results support a strategy of EM for the treatment of suspected foetal macrosomia.

**Source of funding**
None stated.

**Bibliographic details**

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Other publications of related interest
Sanchez-Ramos L, Bernstein S, Kaunitz A. Expectant management versus labor induction for suspected fetal

Mankuta DD, Leshno MM, Menasche MM, Brezis MM. Vaginal birth after cesarean section: trial of labor or repeat

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