Consequences of nonindicated preterm delivery in singleton gestations

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
This study considered the clinical and financial implications of delaying pre-term delivery that is classified as "elective", from 34 to 35 weeks and from 35 to 36 weeks. Elective pre-term delivery was defined as induced labour, or a scheduled Caesarean delivery, at less than 37 weeks' gestation for reasons other than pre-term labour, premature rupture of membranes, or medical induction for complicating maternal or foetal circumstances (i.e. at the discretion of the patient and her primary physician).

Type of intervention
Treatment and management.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised singleton births after labour was induced, or a Caesarean section, for reasons other than premature rupture of membranes or other medical indications for early delivery (e.g. maternal hypertension or foetal health). All women were considered to have a high-risk condition, but there was no evidence of an acute condition requiring immediate delivery.

Setting
The setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data related to births that took place between October 1995 and February 2000. No price year was stated.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The resource use data were collected retrospectively from the same patient sample that provided the clinical effectiveness evidence.

Study sample
The patient sample was taken from a clinical database that holds details of outpatient perinatal care, and subsequent birth and neonatal care. All births that met the inclusion criteria were included in the patient sample. Of the 1,538 births
included in the sample, 193 were born at 34 weeks' gestation, 398 at 35 weeks' gestation, and 947 at 36 weeks' gestation. No sample size or power calculations were reported.

**Study design**
The study was of a retrospective multi-centre cohort design. The clinical database that provided the clinical data covered all pregnant women who received perinatal outpatient care, and therefore covered a range of settings from small hospitals to large teaching institutions. The babies were followed up until they were discharged from hospital. The data were stratified by gestational week at delivery. The fact that the data were taken retrospectively from a clinical database means that there was no loss to follow-up. The nature of the study means that there was no blinding.

**Analysis of effectiveness**
The health outcomes measured were:

- admission to the neonatal intensive care unit (NICU) and length of stay;
- the length of stay in the regular nursery;
- whether the baby was ventilated;
- whether the baby was diagnosed with respiratory distress syndrome; and
- the mortality rate.

The three patient groups were shown to be comparable in terms of maternal age, marital status of the mother, tobacco use, cerclage, previous pre-term delivery, or gestational age at the start of outpatient care.

**Effectiveness results**
The proportion of babies admitted to the NICU was 53.4% of those born at 34 weeks' gestation, 32.2% at 35 weeks' gestation, and 17.4% at 36 weeks' gestation. The decrease in admissions between 34 and 35 weeks and between 35 and 36 weeks was statistically significant, (risk of admission declined by >50% with each week gained, p<0.05).

The mean length of stay in the nursery was 1.7 days (standard deviation, SD=2.3) for babies born at 34 weeks, 2.3 days (SD=2.5) at 35 weeks, and 2.4 days (SD=1.5) at 36 weeks. These differences were statistically significant, (p<0.05).

The mean length of stay in the NICU was 5.0 days (SD=6.9) for babies born at 34 weeks, 2.6 days (SD=5.1) at 35 weeks, and 1.1 days (SD=3.3) at 36 weeks. These differences were statistically significant, (p<0.05).

The mean total length of stay in the nursery was 6.8 days (SD=6.1) for babies born at 34 weeks, 4.9 days (SD=4.6) at 35 weeks, and 3.5 days (SD=2.9) at 36 weeks. These differences were statistically significant, (p<0.05).

Ventilation was required in 5.7% of babies born at 34 weeks, 6.8% of those born at 35 weeks, and 4.1% of those born at 36 weeks. The difference between 34 and 35 weeks was statistically significant, (p<0.05), but the change between 35 and 36 weeks was not significant.

Respiratory distress syndrome was diagnosed in 9.3% of babies born at 34 weeks, 7.0% of those born at 35 weeks, and 3.6% of those born at 36 weeks. The difference between 35 and 36 weeks was statistically significant, (a decrease of 49%, p<0.05).

There was no perinatal mortality in either group.

**Clinical conclusions**
The authors concluded that delaying pre-term delivery by one week to either 35 or 36 weeks' gestation results in better
neonatal outcomes in this study population.

Measure of benefits used in the economic analysis
No measure of health benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.

Direct costs
This study considered the hospital costs of neonatal care (i.e. regular nursery costs and NICU costs). The resource use data related to October 1995 to February 2000, and were obtained from the clinical database that provided the clinical effectiveness data. The unit cost data were derived from the Healthcare Utilization Project Nationwide Inpatient Sample 1997, Agency for Healthcare Research and Quality. No exact price year was reported. Discounting was not undertaken since the costs were incurred during less than one year.

Statistical analysis of costs
The statistical significance of differences between the costs was tested using the Mann-Whitney U-test.

Indirect Costs
No indirect costs were included in this study.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was undertaken.

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

Cost results
The estimated mean nursery costs (including NICU) were $10,792 (SD=12,335) for babies born at 34 weeks’ gestation and $6,923 (SD=10,229) for those born at 35 weeks. Babies born at 36 weeks had mean nursery costs (including NICU) of $3,785 (SD=6,859).

The decreases in costs between those born at 34 and 35 weeks and those born at 35 and 36 weeks were statistically significant, (p<0.05).

Synthesis of costs and benefits
The costs and benefits were not combined since the study was, in effect, a cost-consequences analysis.

Authors' conclusions
Delaying pre-term delivery from 34 to 35 weeks gestational age, and from 35 to 36 weeks gestational age, results in better neonatal outcomes and is cost-saving.

CRD COMMENTARY - Selection of comparators
No explicit justification for the choice of the comparator was given. You should consider how the three patient groups
Validity of estimate of measure of effectiveness
This study used clinical effectiveness data from a retrospective cohort study. This was appropriate to the study question, although a randomised controlled trial would have provided a more robust estimate of effectiveness. The maternal characteristics of the three patient groups were shown to be comparable. The authors did not compare their sample with their study population. However, the patient sample was taken from a national clinical database and all patients who met the inclusion criteria were included. Thus, the patient sample is likely to be representative of the patient population. An appropriate statistical analysis was undertaken.

Validity of estimate of measure of benefit
No measure of health benefit was used in the economic analysis. The study was therefore classified as a cost-consequences study.

Validity of estimate of costs
The paper did not explicitly state the economic perspective of the study, although a hospital view appears to have been used. The study assessed resource use in terms of length of stay in the NICU and the general nursery, and allocated a unit cost for stays associated with various diagnoses. However, it was not entirely clear what items the unit costs included. Thus, it is possible that some costs, such as laboratory tests and pharmacy costs, have not been included. The mean lengths of stay and their unit costs were reported separately, which increases the generalisability of the paper's results. The generalisability of the study's findings is further increased through the use of a national framework to derive the unit costs. On the other hand, the lack of a clear price year introduces ambiguity and prevents future reflation exercises. An appropriate statistical analysis of the mean total costs, which identified the degree of certainty around the differences in costs between the three patient groups, was undertaken. Discounting was appropriately not undertaken since as all the costs were incurred during less than one year.

Other issues
The authors made appropriate comparisons of their findings with other published studies and commented on the slight differences observed. They did not directly consider the scope to generalise their results to other settings. The authors did not report any limitations of their study. The authors presented their results clearly and comprehensively, and their conclusions accurately reflected their data.

Implications of the study
The authors suggested that anticipated neonatal morbidity at a particular gestational age is an important consideration when planning pre-term induction of labour, or when scheduling Caesarean delivery.

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