Clinical, psychological, and economic effects of antenatal day care for three medical complications of pregnancy: a randomised controlled trial of 395 women


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 investigated antenatal day care for three medical complications of pregnancy. The day-care facility included a sitting room and dining area, along with two assessment beds, all within a deinstitutionalised environment. Tests were initiated on admission, and the results were processed and reviewed within 2 to 3 hours. Most women were discharged home within a few hours, with no overnight stay.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with three clinical disorders for which there was no clear clinical indication for inpatient admission. Although, ultimately, eligibility for the study was at the clinician's discretion, a protocol for mandatory admission was provided:

- a systolic blood pressure greater than 160 mmHg;
- a diastolic blood pressure greater than 110 mmHg;
- proteinuria of +++ or more on dipstick testing;
- any clinical indication of irritability of the central nervous system or planchnic congestion;
- any biochemical signs of organ dysfunction (such as abnormal results of liver or renal function tests, or evidence of haemolysis or thrombocytopenia); or
- any indication of foetal compromise.

Only women being admitted to the day care-unit as an alternative to hospital admission were eligible for the trial. Therefore, women presenting for cariotocography alone were excluded. Other reasons for exclusion were multiple pregnancy, inability to communicate in English, and prior admission in the current pregnancy for the presenting complication.

Setting
The setting was tertiary care. The economic study was carried out in Australia.

Dates to which data relate
The effectiveness and resource use data were collected between June 1998 and June 2001. The price year was 1999/2000.

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

**Link between effectiveness and cost data**
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

**Study sample**
The authors aimed to recruit about 600 women to the study. A sample size of 576 would allow the detection (power 90%) of a relative reduction of 30% in the average number of admissions after the randomisation visit. When a potentially eligible woman presented with one of the specified complications, the medical officer (in the antenatal clinic, the emergency department, or the antenatal ward) contacted the project coordinator, who checked the woman's eligibility and telephoned the Data Management and Analysis Centre at the University of Adelaide. A total of 731 women were assessed for eligibility, of whom 395 (52.6%) were deemed to be eligible. The main reasons for non-eligibility were medical complications that, in the opinion of medical staff, necessitated immediate admission or delivery (150 of the 356 excluded; 42.1%), and premature rupture of membranes (PROM) occurring more than a week before (72; 20.2%).

Of the 395 women recruited into the study, 263 (66.6%) were assigned day care and 132 (33.4%) assigned ward care. This represented 65.8% of the target sample size. The mean age of the women was 28.9 years (standard deviation, SD=5.3) in the day-care group and 28.1 years (SD=5.7) in the ward group.

**Study design**
The study was a randomised controlled trial (RCT), which was carried out at the Women's and Children's Hospital, Adelaide, South Australia. Allocation to the study group was via a pre-organised computer-generated sequence of variable block randomisation codes. To ensure that the newly established unit was occupied by optimum trial participants, women were randomly assigned in a ratio of two to one between day and antenatal care, and stratified for non-proteinuric hypertension, proteinuric hypertension, and PPROM. To make randomisation practicable and acceptable to women, on the assumption that day care was likely to be a popular option, the authors used the Zelen method by which participants were randomised before consent was sought. Clinical data were gathered through a retrospective review of records. This covered the period from randomisation up to 4 weeks after the woman was discharged from hospital. For infant records it covered the time until discharge or transfer to another hospital. For psychosocial outcomes, follow-up was 7 weeks after delivery. The questionnaire response rate for both groups was 81.0%.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on an intention to treat basis. The outcome measures were maternal outcomes and psychosocial outcomes. Psychosocial outcomes included satisfaction with care and psychological wellbeing. To measure the immediate effect of the two interventions, a self-report questionnaire was sent to each woman's home 4 days after randomisation. The longer-term effect was measured through a second questionnaire sent 7 weeks after delivery, after the authors had checked the outcome of the birth. Nonresponders were reminded by telephone 2 to 3 weeks after the mailing and 2 weeks later, if required. Satisfaction was measured using questions developed and tested for a similar randomised trial of maternity care and using questions designed especially for this study. Psychological wellbeing was measured by the Edinburgh postnatal depression scale. This has been validated for use in pregnancy and postnatally for Australian women. All women with scores above 12 were followed up by telephone by the research midwife, to find out whether support was required from hospital staff. Clinical data were gathered through a retrospective review of records by a research midwife who was not involved in the provision of care.
The maternal outcomes included:

- those in the antenatal period (i.e. the number of women with complications in addition to those for which they were randomised);
- those in the intrapartum period (i.e. the proportion experiencing complications during labour and delivery, high blood pressure, and high blood pressure requiring urgent assessment or consistent with a medical emergency); and
- those in the postnatal period (i.e. women experiencing complications, visiting emergency department after discharge, or requiring readmission after discharge).

The perinatal outcomes included:

- the number of children with Apgar scores less than or equal to seven at both 1 and 5 minutes;
- the number of neonatal deaths;
- the number with neonatal complications;
- the number requiring resuscitation;
- the mean number of days' gestation at delivery;
- the mean weight at delivery;
- the number requiring admission to a neonatal intensive care unit, and length of stay in intensive care; and
- the number discharged home with the mother.

The baseline characteristics of the two groups were very similar.

**Effectiveness results**

There were no statistically significant or clinically important differences in maternal and perinatal outcomes between the two groups.

General satisfaction was better in the day-care group for two of the five questionnaire items at 4 days after randomisation. These included the questions "I felt I was being well looked after", (p=0.009), and "I am satisfied with the care I received", (p=0.01). Although the direction of this effect was maintained at 7 weeks after delivery, it was no longer significant.

The two groups were very similar in relation to the Edinburgh postnatal depression scale at 4 days after randomisation and 7 weeks after delivery.

**Clinical conclusions**

There were no statistically significant or clinically important differences in maternal and perinatal outcomes between antenatal day care and standard inpatient care in women suffering from complications of pregnancy.

**Measure of benefits used in the economic analysis**

The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences analysis.

**Direct costs**
The direct costs included in the analysis were those of the health care service. These were for antenatal contacts, diagnostic procedures, labour, postnatal contacts, medications, and miscellaneous items such as social-work consultations. The costs of antenatal contacts included the costs associated with all visits to the day-care unit and hospital admissions before labour. The costs of postnatal contacts included the costs related to transfers to other hospitals. Expenditure data were obtained from the hospital's financial system, which provided detailed patient-level information on inpatient contacts for the mother and baby. The costs of medical contact time during the antenatal period, emergency department visits, and transfers to other hospitals during the postnatal period were estimated from a survey of 12 medical staff involved in caring for study patients, standard cost schedules and standardised cost weights. The costs were measured for the mother and baby from entry into the study until 42 days after delivery. Discounting was therefore not applicable and, hence, was not performed. The study reported the average costs. All the costs were adjusted to the base year 1999/2000.

Statistical analysis of costs
Resource use and costs were treated stochastically. The mean values were compared by two-sample t-tests. Probability values of less than 0.05 and 95% confidence intervals that did not bracket zero indicated a significant difference.

Indirect Costs
The indirect costs were not included.

Currency
Australian dollars (Aus$).

Sensitivity analysis
The authors assessed the significance of outliers (i.e. those with costs exceeding Aus$20,000 per episode) by excluding them from the analysis.

Sensitivity analyses were also performed by decreasing hospital transfer costs by 50%, increasing medical staff time spent per antenatal visits by 50%, and increasing the cost of medical staff time during antenatal contacts by 100%.

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

Cost results
On average, the costs were greater by Aus$415.12 per episode for the day-care group. However, this difference was not significant (mean values, day care Aus$6,569.00 versus ward care Aus$6,153.88; p=0.42).

The cost per day difference of Aus$202.21 in favour of the ward group was also not significant (mean values, day care Aus$960.06 versus ward care Aus$757.85).

Synthesis of costs and benefits
The costs and benefits were not combined. The exclusion of outlier cases from the analysis did not affect the overall results. The results were not sensitive to any of the three scenarios examined (decreasing hospital transfer costs, increasing medical staff time spent per antenatal visit, and increasing the cost of medical staff time).

Authors' conclusions
Since the clinical outcomes and costs were similar, the adoption by maternity services of a policy providing specified women with the choice between admission and day-unit care seems to have been appropriate.
CRD COMMENTARY - Selection of comparators
The use of standard ward care 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 since well-conducted RCTs are considered to be the 'gold' standard study design when comparing different health interventions. The study sample appears to have been representative of the study population, and the patient groups were shown to be comparable at analysis. However, the sample size target set a priori was not attained, which resulted in a reduction in power, as only two thirds of the required sample size was recruited. The authors conducted their analysis on an intention to treat basis, and the statistical significance of all differences was tested using appropriate statistical techniques. All these factors enhance the internal validity of the effectiveness analysis.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The reader is thus referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
All the categories relevant to the perspective adopted appear to have been included in the analysis, as were all the relevant costs. However, only certain costs were reported separately from resource use, which will limit the generalisability of the authors' results. The unit costs were derived from the authors' setting. Appropriate statistical and sensitivity analyses of the costs were performed. Discounting was unnecessary, as the costs were incurred during a short time period, and was not performed. The price year was appropriately reported, which will aid any possible inflation exercises.

Other issues
The authors did not make appropriate comparisons of their findings with those from other studies. They reported that a recent systematic review of theirs showed that the published evidence for the efficacy of day-care units was limited to one RCT of 54 women. The issue of generalisability to other settings was partially addressed in the sensitivity analysis. The authors suggested that the results from their trial might be generalisable to other common and slowly progressing medical complications of pregnancy, such as diabetes and hypermesis. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The main limitation of this study, as the authors acknowledged, was the reduction in power because only two thirds of the required sample size was recruited.

Implications of the study
The authors recommended that, against a backdrop of similar clinical outcomes and costs, adoption by maternity services of a policy providing specified women with the choice between admission and day-unit care would appear appropriate.

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