Domiciliary midwifery support in high-risk pregnancy incorporating telephonic fetal heart rate monitoring: a health technology randomized assessment


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 use of domiciliary care for pregnant women at risk of adverse outcomes. Enhanced domiciliary care comprised home visits from community midwives and domiciliary foetal monitoring, where the results of a cardiotocogram (CTG), recorded in the home, were transmitted to the hospital by telephone using modems. The frequency of surveillance was not specified in the study protocol and the patients were allowed to make hospital or office visits.

Type of intervention
Screening and primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised pregnant women displaying maternal or foetal risk factors. Such factors included poor obstetric history, hypertension, weight loss, a small-for-dates foetus, diminished foetal movements and minor antepartum haemorrhage. Women with complications likely to require acute intervention were excluded.

Setting
The setting was the community and tertiary care. The economic study was conducted in Merthyr Tydfil and Abergavenny, South Wales, UK.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not stated. The price year was also not stated.

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 stated that it was impossible to determine power calculations that would satisfy all the different variables they sought to measure in the study. They stated that their aim was to recruit 120 patients. The woman's consultant obstetrician or deputy decided whether she was suitable for inclusion in the study sample. It would appear that the inclusion criteria of maternal or foetal risk factors were open to subjective interpretation, thus the study sample may not
be representative of a random sample from the same population. However, the study sample appears to have been appropriate for the clinical study question. The study sample consisted of 81 women, of which 38 were randomised to conventional care and 43 to enhanced domiciliary care. The number of patients who refused to participate or were excluded from the study was not reported.

**Study design**
The study design was a multi-centre randomised controlled trial centred on two hospitals. Randomisation was by sealed, numbered envelopes. It was initially to be stratified by whether the patients had given birth before but, in the end, this was not done due to reduced recruitment. The mean duration of follow-up was 65.1 days in the conventional care group and 57.2 days in the enhanced domiciliary care group. The study was not blinded.

**Analysis of effectiveness**
All of the patients included in the study appear to have been accounted for in the analysis. The analysis was conducted on an intention to treat basis. Several psychological questionnaires were used to measure the patient outcomes and clinical outcome factors were also included. However, no single measure was cited as the primary health outcome. The psychological measures were the State-Trait Anxiety Inventory (STAI), the Edinburgh Postnatal Depression Scale (EPDS) and a series of questionnaires to assess maternal satisfaction. Further information on these measures was provided elsewhere (see Other Publications of Related Interest). At analysis, the groups were shown to be comparable in terms of age, gestation, parity (number of children), occupation and environment.

**Effectiveness results**
There were no significant differences between the groups on the STAI measures.

There was little difference between the two groups in the EPDS "not depressed" category. The enhanced domiciliary group showed a higher likelihood of being "possibly depressed", while the conventional care group showed a higher likelihood of being "probably depressed".

There were no differences between the groups in terms of maternal satisfaction.

Mothers in the enhanced domiciliary care group had a higher likelihood of undergoing spontaneous labour (22.2%; 95% confidence interval: 0.8 - 41), but there were no significant differences in the other clinical outcomes measured.

**Clinical conclusions**
The authors concluded that no difference could be demonstrated between the two groups in the study.

**Measure of benefits used in the economic analysis**
No summary measure of health benefit was used in the economic analysis. Hence, a cost-consequences analysis was performed.

**Direct costs**
The resource use quantities were reported separately from the cost comparisons. The study included the direct costs to the patient and health service. The direct costs were for childcare, travel and telephone calls associated with the study, visits to the hospital, general practitioner or midwife, home visits from the community midwife, and the monitoring tests. The source of the unit costs was not stated. Discounting was not relevant since resource use occurred during less than one year. The study attempted to include only marginal costs, and thus did not account for any costs that did not vary by study group. The date to which the price data referred was not stated.

**Statistical analysis of costs**
The costs were treated deterministically. It is likely that the study was very underpowered for detecting a difference in the costs. In addition, any descriptive statistics or statistical tests would be likely to confirm the lack of a significant difference. Resource use was treated stochastically and the only significant differences, (p<0.05), were found in the mean number of community midwife visits and the average time of each community midwife visit. The statistical test used was not specified. The study was not powered to detect a difference in resource use items.

**Indirect Costs**
The authors did not give an explicit rationale for including the indirect costs. The quantities recorded were time off work for the patient, time for home visits and for hospital and other outpatient attendances, and time off work for friends and relatives involved in the patient's care at home, or who visited the patient in hospital. Average earnings were used to cost time off work, but the source of these was not stated. The hours of work lost were reported separately from the cost comparisons. The analysis focused on the costs to the patient and the patient's partner. The quantity of time off work was measured in the clinical effectiveness study, the date of which was not stated. Discounting was not relevant since the costs were incurred during less than one year. The price year was not stated.

**Currency**
UK pounds sterling (%. No conversions were necessary.

**Sensitivity analysis**
No sensitivity analyses were undertaken.

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

**Cost results**
Enhanced domiciliary care cost 223.83 less than conventional care. No statistical tests were performed on the cost data. The costs of adverse events were not relevant.

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors' conclusions**
Enhanced domiciliary care may be a cost-saving alternative to conventional care, with no demonstrable difference in clinical outcome.

**CRD COMMENTARY - Selection of comparators**
The authors chose the comparator on the basis of current practice in their setting. You must decide whether current practice for moderately high-risk pregnancies in your setting is similar to that detailed in this study.

**Validity of estimate of measure of effectiveness**
The basis of the analysis was a randomised controlled trial, which was appropriate for the study question. However, a blinded study would have reduced the possibility of bias. The study sample was subject to selection bias as eligibility for entry was left to the discretion of each patient's doctor, thus it may not have been representative of the study population. The patient groups were shown to be comparable at the time of analysis. The analysis was handled credibly.
Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
All the costs relevant to a societal perspective were included in the analysis. However, the authors were interested only in the marginal costs, and therefore omitted any costs that did not differ by treatment group. These omissions are unlikely to affect the authors’ conclusions due to the similarity between the two study groups. The cost comparisons were reported separately from the quantities. A statistical analysis of resource use quantities was performed. The source of the unit costs used in the analysis was unclear and a statistical analysis of the prices was not undertaken. Discounting was irrelevant since all the costs were incurred during less than one year.

Other issues
The authors compared the results of their study only with earlier pilot studies, and did not compare them with the results from other studies. The issue of generalisability to other settings was addressed. The authors stated that the rural location of the trial may make the results less generalisable to urban settings. The authors do not appear to have presented their results selectively. The authors’ conclusions do not reflect the scope of the analysis since, although it is true that the study did not find any difference in clinical outcomes between the treatment groups, the study was not powered to detect any clinically significant difference that may have been present. To this end, the conclusion that this study may be taken as evidence to support an increase in the provision of domiciliary care may be too strong. The authors admitted that the study was highly underpowered to detect differences between the study groups.

Implications of the study
The authors stated that the results of the study provide evidence to support an increase in the amount of domiciliary care provided to pregnant mothers at moderately high risk of an adverse outcome.

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Other publications of related interest


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MeSH
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