A randomized trial of nurse specialist home care for women with high-risk pregnancies: outcomes and costs

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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
Home care provided by nurse specialists to women with high-risk pregnancies was examined. The intervention consisted of standard prenatal and postpartum care, but half of the care was substituted with care delivered at home by advanced practice nurses (APNs). The women were also contacted weekly by telephone for 8 weeks postpartum.

Type of intervention
Other: Supportive care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with pre-gestational or gestational diabetes mellitus, chronic hypertension, or diagnosed preterm labour or at high-risk of preterm labour. Women at high-risk of preterm labour included those with uterine fibroids, a prior preterm labour, multiple pregnancy, or a score of 10 or greater on a modified Creasy screening tool.

Setting
The setting was tertiary care. The economic study was conducted in the USA.

Dates to which data relate
The effectiveness and resource use data were gathered from January 1992 to January 1996. The price year was presumably 1995.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was conducted prospectively on the same sample of women as that used in the effectiveness study.

Study sample
Power calculations were not conducted. Of the 188 women initially identified, 15 were excluded because of psychiatric history (1), exclusion criteria (8) and refusal to participate (6). Therefore, the final sample comprised 173 women (and 194 infants). There were 85 women (and 94 infants) in the intervention group and 88 women (and 100 infants) in the control group.
Study design
This was a prospective, randomised, clinical trial that was conducted in a single centre, the Hospital of the University of Pennsylvania, Philadelphia, USA. Randomisation was performed using a sequence of sealed envelopes, prepared in advance by a statistician using a list of random numbers. The women were followed-up for up to 1 year after delivery. No loss to follow-up was reported. The control and intervention women were scheduled to receive the same total number of prenatal visits.

Analysis of effectiveness
The analysis of the clinical study appears to have been conducted on an intention to treat basis. The health outcome measures were:

- a series of infant outcomes (mortality, gestational age and birth weight in both preterm and term infants; length of hospitalisation; number and length of rehospitalisations; number of acute care visits; and number of preterm infants, birth weight and gestational age in twin infants)

- a series of maternal outcomes (number and length of prenatal, delivery and postpartum hospitalisations; number of maternal prenatal and postpartum acute care visits; and biophysical profile tests);

- maternal affect, measured at 3, 6, 9 and 12 months postpartum using the Multiple Affect Adjective Checklist-state form; and

- satisfaction with care, measured 1-month post-discharge using the LaMonica-Oberst Patient Satisfaction Scale.

The study groups were comparable at baseline in terms of their sociodemographic and clinical characteristics.

Effectiveness results
In terms of infant outcomes, there was significantly less mortality in the intervention group (2 losses) than in the control group (9 losses), (p<0.01). The birth weight of preterm babies was higher in intervention infants (2,263.5 +/- 711 g) than in control infants (1,960.4 +/- 748 g), (p<0.05). Significantly fewer intervention infants (1) than control babies (8) had a birth weight lower than 1,000 g, (p<0.05). The number of preterm infants among twin babies was lower in the intervention group, 4 versus 16, (p<0.01). The birth weight of twin babies was higher in the intervention group, 2,351.1 (+/- 484.26) g versus 2,034.8 (+/- 584.38 g), (p<0.05). Finally, the mean gestational age was higher in the intervention group (36.9 +/- 2.05 weeks) than the control group (34.3 +/- 3.82 weeks), (p<0.01). Other infant outcomes were not significantly different.

In terms of maternal outcomes, prenatal length of stay was higher in the intervention group (6.1 +/- 5.1 days) than the control group (5.7 +/- 3.5 days), (p<0.5). Postpartum length of stay was higher in the control group, 1.2 (+/- 1.3) days versus 5.7 (+/- 7.7) days, (p<0.5). The number of women needing prenatal acute care visits was lower in the intervention group, 64 versus 75, (p<0.05). The authors also reported that prenatal visits were more frequent in the intervention group, (mean: 14.6 +/- 5.9) than the control group (mean: 18.3 +/- 5.9), (p<0.001). Differences in other maternal outcomes did not reach statistical significance.

There was no statistically significant difference in maternal affect and satisfaction with care.

Clinical conclusions
The effectiveness evidence showed that, compared with usual care, the implementation of home care delivered by APNs led to improvements in most infant and maternal outcomes.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic study. In effect, a cost-consequences analysis was performed.
**Direct costs**
Discounting was not relevant since the costs were incurred during less than 2 years. The unit costs were not reported separately from the quantities of resources used, and only the hourly wage of an APN was reported. The health services included in the economic evaluation were related to APN services. For example, time for direct care of mothers, infants and families, telephone time, home visit time, administrative time, and telephone and travel charges. The cost/resource boundary of the study was unclear. Resource use was estimated using data derived from the clinical study. Charges rather than costs were used. The APN salary reflected 1995 APN wages in the geographic area where the study was carried out. Other costs, such as physician services for prenatal, delivery and postpartum care, were assumed to have been similar between the groups and were not considered. The price year was not explicitly reported but it may have been 1995.

**Statistical analysis of costs**
Statistical analyses of the costs were conducted, but the tests used were not described. The costs were presented as mean values plus or minus the standard deviation. Ranges of values were also provided.

**Indirect Costs**
The indirect costs were not considered.

**Currency**
US dollars ($).

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

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

**Cost results**
When hospital and nurse specialist charges were considered, only the mean prenatal hospitalisation charges per patient were significantly different between the groups. These were $6,213 (+/- 9,913) (range: 0 - 50,349) in the intervention group and $10,196 (+/- 19,487) (range: 0 - 116,726) in the control group, (p<0.05).

Delivery and postdelivery hospitalisation charges were not significantly different, but there was a trend towards lower charges in the intervention group.

Similar trends were observed in the sub-groups of twin infants and preterm infants, where big differences in favour of the study intervention were observed.

**Synthesis of costs and benefits**
The costs and benefits were not combined because a cost-consequences analysis was performed.

**Authors' conclusions**
The implementation of nurse specialist home care for women with high-risk pregnancies represented an effective and safe intervention. The intervention led to a substantial reduction in the hospital costs of care for newborns.
CRD COMMENTARY - Selection of comparators
The choice of the comparator (care provided at the hospital) was appropriate as it reflected usual care. The authors provided a detailed description of the standard approach. You should decide whether this is a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis of effectiveness was a randomised trial, which was appropriate for the study question. The methods of randomisation and sample selection were reported. The baseline comparability of the two groups further reduced the potential impact of confounding factors and bias. Some patients refused to participate, and the authors noted that the sample comprised mainly Afro American and poor women. Therefore, the study sample may not have been representative of the study population. The length of follow-up appears to have been appropriate to estimate all relevant outcomes. The major threat to the internal validity of the analysis was the fact that no justification for the choice of the sample size was provided, and it was unclear whether the study had sufficient power to detect statistically significant differences in terms of all outcome measures used in the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used because a cost-consequences analysis was conducted.

Validity of estimate of costs
The perspective adopted in the cost analysis was not stated. Therefore, it is not possible to assess whether all the relevant categories of costs were included in the economic evaluation. Only costs strictly related to the nurse specialist were included, but the role played by hospitalisation costs was not clear. Other resources used were assumed to have been similar and were not included. However, these assumptions were not tested in the sensitivity analysis. Charges rather than costs were used. The authors stated that the estimation of the true costs of the services was beyond the scope of the study. Moreover, they stressed that the use of charges was not a limitation, as the focus of the economic analysis was on whether charges in the intervention group were lower than in the control group. Statistical tests were conducted to compare the costs, which were highly skewed. It would appear that the study had insufficient power to detect statistically significant differences in the total costs per patient.

Other issues
The authors made several comparisons of their findings with those from other studies that reported similar results. All favoured the home intervention of APNs. The authors also stressed the differences between their study and other published evaluations in terms of patient population and type of intervention. However, the issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not conducted. Therefore, the external validity of the analysis was low.

Implications of the study
The authors suggested that models of care, such as that used in the current study, should be implemented to improve both maternal and infant outcomes while reducing health care costs. However, caution is required when interpreting the results of the study due to the limitations of the analysis.

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Bibliographic details
Other publications of related interest

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