A randomized trial of early discharge and nurse specialist transitional follow-up care of high-risk childbearing 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
A model of transitional care (in-hospital education combined with home visits and telephone contacts) provided by perinatal nurse specialists in two groups of high-risk childbearing women (groups of women diagnosed with diabetes or hypertension during pregnancy). The protocols used for the intervention group during pregnancy and after delivery were as follows: during pregnancy, women in the intervention group were discharged earlier than routine institutional length of stay when the women (a) had fasting blood glucose lower than 125 mg/dl and preprandial lower than 140 mg/dl over 2 consecutive days; (b) understood how to prevent, identify, and treat hypoglycemia and hyperglycemia; (c) understood nutritional requirements; (d) demonstrated testing blood glucose levels using an Accuchek II monitor; (e) demonstrated the ability to administer insulin and change dosage appropriately and knew the difference in peak time and action of long- and short-acting insulin; (f) knew warning signs of pregnancy complications; and (g) could take their temperature and read the thermometer. The nurse specialist assessed the subjects and co-ordinated discharge planning; after discharge, women received a minimum of five home visits, and thereafter three weekly telephone or clinic contacts until delivery. After delivery, all the subjects in the intervention group were discharged when the following criteria were met: (a) they had demonstrated knowledge of discharge information; (b) demonstrated ability to take own and infant’s temperatures and read thermometer; (c) ability to identify signs and symptoms of infection in self and infant; (d) ability to identify signs and symptoms of hyperbilirubinemia; (e) stable blood pressure; (f) haemoglobin equal or greater than 8 g% or hematocrit equal or greater than 32%. Additionally for women with diabetes, blood glucose levels lower than 200 mg/dl for four readings daily on 2 consecutive days were maintained. The nurse specialist assessed the subjects and co-ordinated discharge planning. Women and infants in the intervention group received a minimum of two scheduled home visits and 10 telephone calls during an 8-week follow-up period. Medical follow-up care was provided by the hospital's high-risk obstetric clinic or by private physicians. Obstetricians and pediatricians at the hospital provided medical backup.

Type of intervention
Treatment and educational programmes.

Economic study type
Cost-effectiveness analysis.

Study population
The study included women who were diagnosed with either diabetes or with hypertension in pregnancy. All candidates had to use the English language in daily living and had to have access to a telephone service. Private and clinic patients were invited to participate in the study.

Setting
The study setting was community and hospital. The economic analysis was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data appear to correspond to patients treated between 1988 and 1991 (dates reported only in the discussion section of the original paper). The price year was not explicitly specified.

**Source of effectiveness data**
The evidence for the final outcomes was based on a single study.

**Link between effectiveness and cost data**
Costing was mainly performed on the same patient sample as that used in the effectiveness analysis but it was not entirely clear whether it was conducted retrospectively or prospectively. It appears that the hospital costing was carried out retrospectively while the nurse specialist costing was conducted prospectively.

**Study sample**
Power calculations were not used to determine the sample size. Of 103 women enrolled in the study, 7 were excluded from the analysis for different reasons. The final sample consisted of 96 women and 93 infants with two intrauterine deaths at term (1 in each group) and one spontaneous abortion at 16 weeks (intervention group). The intervention group included 44 women (with a mean (SD) age of 28 (7) years) and 42 infants, and the control group included 52 women (with a mean (SD) age of 27 (7) years) and 51 infants. From the group of 96 women, 55 were initially hospitalised before delivery and received follow-up for 8 weeks postpartum (24 intervention and 31 control); 41 women were initially hospitalised for delivery and also received follow-up for 8 weeks postpartum (20 intervention and 21 control). The mean gestation at enrollment during pregnancy was 26 weeks (SD=9.07) for the intervention group and 24 weeks (SD=9.05) for the control group.

**Study design**
The study was a randomised, controlled trial, carried out in a single centre. The duration of the follow-up was 8 weeks postpartum. The number of patients who were lost to follow-up was 3 patients (out of 7 who were excluded from the analysis). The two study groups were divided into subgroups according to diagnosis and timing of initial hospitalisation. The subjects were randomised using the sealed envelope technique. The clinical specialist worked with the women in the intervention group only, research assistants who were blinded to the routine or intervention groups collected all demographic and questionnaire data.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness appears to have been treatment completers only (due to the exclusion of 7 patients from the analysis). The clinical outcomes were maternal outcomes (acute care visits, rehospitalisations, return to normal activities, and satisfaction with care), and infant outcomes (birth weight, glucose level postbirth, acute care visits, and rehospitalisations). Functional status (return to normal activities) was measured with the Enforced Social Dependency Scale. Functional status was measured 2, 4, and 8 weeks postpartum. Patient satisfaction with care (measured at the end of the study, 8 weeks postpartum) was measured with La Monica-Oberst Patient Satisfaction Scale. The study groups were comparable in terms of demographic and clinical characteristics.

**Effectiveness results**
The maternal outcomes were as follows:

Of the 24 patients in the intervention group enrolled before delivery, 20.8% (5 subjects) were rehospitalised once and 8.3% (2 women) were rehospitalised twice. The corresponding values in the control group were 16.1% (5 subjects) and 25.8% (8 women), respectively.

The intervention group had fewer antepartum rehospitalisations for glucose control (3) than the control group (8) (p=0.048).
The number of acute care visits during pregnancy was 8 (n=6) in the intervention group and 11 (n=9) in the control group.

After delivery, there was no significant difference between the two study groups in terms of the number of rehospitalisations or acute care visits.

There was no difference in functional status between the intervention and control groups at 2, 4, and 8 weeks postpartum.

With regard to satisfaction with care, the mean (SD) for the intervention group was 189.8 (24.5) versus 180.8 (28.6) for the control group (p=0.06).

The infant outcomes were as follows:

For the women enrolled before delivery, there was no statistically significant difference in terms of birth weight between the two study groups.

The intervention group weighed an average of 339 g more (p=0.09).

For the infants of women enrolled after delivery, the difference in birth weight was not significant. There were no significant differences between the two groups in the number of infant rehospitalisations, acute care visits, or mean glucose levels postbirth. For women enrolled before delivery, low-birth-weight infants were more than three times more prevalent in the control group (n=9 or 29%) than the intervention group (n=2 or 8%) (p=0.056).

Clinical conclusions
The similar numbers of rehospitalisations and acute care visits for mothers and infants in the intervention and control groups support the safety of early discharge using this approach.

Modelling
The conceptual framework represented a modification of a three-variable framework of quality of care, including outcome, patient satisfaction, and cost proposed by Doessel and Marshal (1985). The health service portion was derived from the Quality-Cost Model of Clinical Specialist Transitional Care (Brooten et al., 1988).

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only individual clinical outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Some quantities were reported separately from the costs. The cost breakdown was reported. The cost analysis covered the costs of hospital (including room and board charges (per diem), ancillary charges (including laboratory testing, labour and delivery, pharmacy, and supplies)), and nurse specialist time (including in-hospital visits, home visits, travel time, telephone, charting, office visits, and other). The hospital charges were divided into 4 categories: antepartum hospitalisation, antepartum rehospitalisation for glucose control, postpartum hospitalisation, and infant hospitalisation. The patient charting time was calculated on a subset of patients (15% of the total sample) all reported items except patient charting being based on the actual minutes for each patient. The perspective adopted in the cost analysis was not explicitly specified. Data on actual charges were used for hospital fees and data on costs were used to determine the expenses related to the services provided by the nurse specialists. A subgroup analysis of charges was performed for the subset of 11 low-birth-weight infants (9 in the control group and 2 in the intervention group). The price year was not given.

Statistical analysis of costs
Statistical analysis was performed on length of stay, hospital charges using t test; if the distribution was very skewed, then the Mann-Whitney test was used.

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

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The mean total charge in the control group was $30,351, compared with $17,024 in the intervention group; resulting in cost savings of $13,327. The mean total nurse specialist cost per subject was $772.

**Synthesis of costs and benefits**
Costs and benefits were not combined since the use of specialist nurse appears to be the dominant strategy (better overall efficacy and cost savings).

**Authors' conclusions**
Early discharge of high-risk childbearing women with transitional home follow-up care provided by master's-prepared perinatal nurse specialist is safe, feasible, cost-effective, and well received by women.

**CRD COMMENTARY - Selection of comparators**
The strategy of using routine care was explicitly regarded as the comparator. It allowed the active value of the intervention to be evaluated.

**Validity of estimate of measure of effectiveness**
The internal validity of the effectiveness results is likely to be high due to the randomised nature of the study design, the comparability of the study groups, and the blinding of the investigators involved in the data collection. However, power calculations were not performed to justify the sample size and the effectiveness analysis was not conducted on an intention to treat basis. The study sample appears to have been representative of the study population.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit in the economic analysis. The analysis was therefore of cost consequences design.

**Validity of estimate of costs**
Positive aspects of the cost analysis, likely to enhance its validity, were as follows: some resource use quantities were reported separately from the costs; the cost profile was dis-aggregated; the costing for the nurse specialist time was
mainly based on the actual minutes for each patient; statistical analysis was performed on some resource use data and cost data. However, the price year and the perspective adopted in the cost analysis were not specified; the cost analysis did not pursue a consistent method as hospital costs were based on charges and specialist nurse costs were based on actual costs; the effects of the alternative procedures on indirect costs (productivity loss) were not addressed; the subgroup analysis was based on too few patients, lacking statistical power to detect meaningful differences between the groups. As a result, the cost results may not be generalisable outside the study setting.

Other issues
Overall, the study conclusion appears to be justifiable despite the uncertainties in the data, and the weakness of the cost analysis (due to large differences in costs). The issue of generalisability to other settings or countries was not addressed, but appropriate comparisons were made with other studies. No comments were made regarding the issue of whether the study sample was representative of the study population.

Implications of the study
If the intervention approach is instituted on a broad basis, it is likely that, with a higher volume of visits, the home visits could be scheduled more efficiently. This would substantially decrease the travel portion of the nurse specialist costs. Additionally, although the research protocol dictated that nurse specialist make five antepartum home visits, the nurse specialists believed that three visits would have sufficed in many cases.

For a hospital, the value of such a service lies in the improved and extended service it can provide to high-risk women and their families. Society also stands to benefit in many ways that cannot be quantified, such as in the support provided to families through pregnancy and the difficult period after delivery, the potential reduction in the incidence of low-birth weight, as well as decreased health care costs.

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Other publications of related interest


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