A controlled trial of nurse practitioners in neonatal intensive care


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 clinical nurse specialist/neonatal practitioner team (CNS/NP) in the delivery of neonatal intensive care in a tertiary care setting.

Type of intervention
Diagnosis; treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Critically-ill neonates of both sexes were the subject of the study.

Setting
A 33-bed tertiary level neonatal intensive care unit in Canada.

Dates to which data relate
Entry to the study took place between September 1991 and September 1992 with follow-up taking place 8 months after the patients were discharged. Resources used were also collected over the same time period. The price year was not stated.

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

Link between effectiveness and cost data
The costing was undertaken on the same sample as that in the effectiveness study and the data were collected concurrently.

Study sample
During the study period (Sept 1991 to Sept 1992), 962 neonates entered the NICU. 82 of these were from multiple births (not the first-born) and were excluded from the study. Of the remaining 880, 58 were not randomised because one of the teams was full to capacity and one case was not randomised at the request of the neonatologist and was assigned to the CNS/NP group. Of 821 infants admitted to the NICU over this one year period, 414 were randomised to care by the CNS/NP team and 407 to the paediatric team. No power calculations appear to have been conducted.

Consent to participate in the study was not sought from parents since both caregiver teams represented standard
practice in the NICU. Consent for data collection for the study was obtained from 97.9% (604/617) of those parents who were approached. Consent was not requested from parents whose babies were discharged before 3 days (124 cases), from 57 parents whose physician advised against it, from 12 parents whose babies died, from 4 parents who could not complete questionnaires on account of poor English and from 7 parents whose infants became wards of the Children's Aid Society. There were no significant differences between the two groups of neonates at baseline.

**Study design**

The study was a single centre, randomised controlled trial. The sample was randomly allocated in blocks of four to one of the two care groups using a predetermined allocation list prepared by means of a table of random numbers. Patients were stratified into four groups according to time of delivery, hospital of delivery, and whether or not admission to the NICU had been anticipated or not. Multiple births were allocated as a unit and only the first-born was included in the analysis. However the stratified randomisation and variation in length of stay created a numerical imbalance between groups. When this was particularly severe, randomisation was suspended for 24-hour periods until the balance was re-established. Such closures occurred on 18 days in the CNS/NP team, and 3 days in the resident team.

The babies were followed up to 8 months after discharge. Of the 604 consenting parents, 450 (74.5%) completed the follow-up questionnaire at 8 months (MIDI - Minnesota Infant Development Inventory) and 357 (59.1%) returned the expense log.

**Analysis of effectiveness**

The primary health outcomes measured were:

- mortality;
- morbidity (neonatal complications);
- process of care (assessed by incidence of indicator conditions which might be expected to be influenced by good medical care);
- parent satisfaction with care (assessed using the Neonatal Index of Parent Satisfaction (NIPS) which was developed by the study authors)
- long term follow-up (using the Minnesota Infant Development Inventory which assesses the infant's development in terms of motor function, language, comprehension and personal-social interaction).

Mortality and morbidity outcomes were based on intention to treat. The other outcomes were based on those babies who exhibited the chosen indicator conditions, and those parents who completed the NIPS and MIDI at 5 days following admission and 8 months follow-up respectively.

**Effectiveness results**

Outcomes for CNS/NP group versus the resident group were:

- Mortality: 19 (4.6%) vs. 24 (5.9%), P=0.40, RR 0.78 (95% CI: 0.43 -1.40);
- Morbidity: 230 (55.6%) vs. 220 (54.1%), P=0.67, RR 1.03 (95% CI: 0.91 - 1.16);
- Long term follow-up (MIDI performance at >30% below age level): 6 (2.6%) vs. 2 (0.9%), P=0.17, RR 2.87 (95% CI: 0.59 - 14.06);
- Parent satisfaction (NIPS mean scores (SD), and difference in means): 140(25.9) vs. 139 (26), difference in means 1.0 (95% CI: -3.6 - 5.6), P=0.67;
- Process of care (indicator conditions). Of the 14 chosen indicator conditions, 7 applied to more than 10% of the study
neonates and were included in the analysis. For only 2 conditions were the differences between the two groups statistically significant, jaundice (P = 0.003) and charting (P = 0.002). The CNS/NP group did better in meeting criteria for both of these conditions, although the differences were unlikely to be clinically significant.

Clinical conclusions
The two methods of care can be seen as equivalent. There were no statistical differences between the groups on these key measures.

Measure of benefits used in the economic analysis
Since the interventions were shown to be equivalent in terms of effectiveness, a cost consequence analysis was performed and no specific measure of benefit was used in the economic analysis.

Direct costs
A societal point of view was used for the cost analysis. The cost data were collected whilst the neonate was in the NICU and a fully allocated hospital cost model was used to determine the per unit cost of resources used. The direct cost of neonate care was calculated based on the severity of the infant's condition and the length of stay in the NICU. Hospital costs included salaries for NICU staff (Nurses, CNSs, pharmacists), diagnostic tests, radiological tests, medications, depreciation and overheads. Professional fees included salaries for CNS/NPs, residents, neonatologists and trainees, specialty consults and follow-ups, surgical fees and fees for interpretation of tests. A research nurse reviewed each patient's charts to collect data on resource use per patient. Expenses incurred whilst the infant was in the NICU, by families whose babies remained there for 3 days or more, were recorded on an expense log. These included time lost from work which resulted in lost income, travel, parking, accommodation expenses and other out-of-pocket expenses such as telephone calls. Mean family expenses were imputed when the expense log was not completed. Costs were estimated over the course of the study period (Sept 1991 to Sept 1992), but the actual price year used was not reported. No discounting was reported.

Statistical analysis of costs
Confidence intervals and p values are provided for cost data.

Currency
Canadian Dollars (Can$).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
No specific benefits were included since intervention and comparator were shown to be equivalent and a cost consequence analysis was performed.

Cost results
There were no significant differences in average health care use or costs per infant between the two groups. Average health care use included length of stay, number of diagnostic tests employed, number of surgical procedures, physician consultations and follow-up visits from other specialities.

Average medical costs (Can$) for CNS/NP group (n=414) vs. the resident group (n=407) were:

Hospital: Can$11,826 vs. Can$10,970, difference=856, (95% CI: -1,111 - 2,823), P=0.39;
Professional fees: Can$1,806 vs. Can$1,703, difference=103, (95% CI: -196 - 401), P=0.50.

Average family expenses (Can$) for CNS/NP group (n=183) vs. resident group (n=176):
Productivity losses: Can$305 vs. Can$304, difference=1, (95% CI: -82 - 84), P=0.98;
Expenses: Can$306 vs. Can$289, difference=17, (95% CI: -61 - 96), P=0.67.
Total cost: Can$14,245 vs. Can$13,267, difference=978, (95% CI: -1,303 - 3,259), P=0.40.

Synthesis of costs and benefits
No synthesis was performed.

Authors' conclusions
Care provided by CNS/NP teams has, in this study, been shown to offer comparable health care to paediatric resident teams at comparable cost.

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator is clear and a justification was provided. The selection of comparators reflects real world practice where the implementation and role of nurse practitioners is widening.

Validity of estimate of measure of benefit
The estimate of benefit was based on a single relatively large randomised controlled trial. Several outcome measures were used in order to assess the impact on the neonates' health status. However, no power calculations were performed and there were significant problems with the randomisation procedure used (randomisation was actually suspended on 21 days), which could have led to bias in the outcomes. Although some of the analyses were based on intention to treat, other data were collected from only a subgroup of participants.

Validity of estimate of costs
More detail of the derivation of the costs and the prices which were used would have been beneficial, especially on the individual cost component level which would have allowed readers to compare cost data with their own setting. The authors investigated the impact on the costs on the families involved although data were collected for only a subgroup of the total and mean family costs were used for those who did not complete an expense log.

Other issues
Despite the methodological limitations and lack of detail provided in the study, the authors' conclusions do appear to be justified, although whether or not the results would be generalisable to other settings is not clear.

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Bibliographic details
Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
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