Comprehensive follow-up care and life-threatening illnesses among high-risk infants: a randomized controlled trial


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 comprehensive follow-up care (CFUC) for high-risk inner-city infants. This comprised care for chronic illness (including availability of health care professionals by telephone or pager at all hours), standard well-baby care, and care for acute illness, provided 5 days per week. A routine home visit was attempted, and a trained foster grandmother (of the same ethnic and socioeconomic status as that of the mother) was offered to those mothers in greatest need. Two paediatric nurses and one physician's assistant, supervised by a paediatrician and a neonatologist who were highly experienced, provided the care.

Type of intervention
Primary prevention and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised infants weighing less than 1,000 g at birth, or weighing between 1,001 and 1,500 g and receiving mechanical ventilation in the first 48 hours after birth.

Setting
The setting was a hospital. The study was performed in Dallas (TX), USA.

Dates to which data relate
The effectiveness data were collected between January 1988 and March 1996. The resource use and cost data were collected between December 1992 and March 1996. The price year was 1997.

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

Link between effectiveness and cost data
The hospital costs were estimated from a sub-sample of the population of infants used in the effectiveness analysis (infants born between January 1993 and March 1996). Personnel time was assessed prospectively during a 6-month period, then extrapolated to a period of one year.

Study sample
A sample size of 760 infants was pre-specified in the planning phase of the study. This assured 80% power in the
assessments of a 50% reduction in mortality associated with the CFUC. Infants born at Parkland Memorial Hospital (Texas) were eligible if they were born to a Dallas county resident and weighed less than 1,000g at birth, or weighed between 1,001 and 1,500g and received mechanical ventilation in the first 48 hours after birth. Moreover, the infants had to survive to nursery discharge, and their parents had to agree to participate in the study. Among 1,004 eligible infants, 887 were randomly assigned to either CFUC or RFUC. The final study sample comprised 783 infants. There were 395 infants in the CFUC group and 388 in the RFUC group. In total, 51 infants in the CFUC group and 53 infants in the RFUC group were excluded after randomisation, either because they died before nursery discharge or because they moved to another location. The authors did not provide any evidence that the final study sample was representative of the study population.

**Study design**

This was a randomised controlled trial (RCT), which appears to have been performed at a single centre (although follow-up care could be given in several sites). The infants were randomly allocated by means of sequentially numbered, sealed opaque envelopes, stratified by birth weight, and using a random table to assign the intervention. The infants were followed up for one year. At the end of the follow-up period, 9 infants in the CFUC group and 28 in the RFUC group were lost to follow-up. The authors stated that the attending physicians and evaluators were generally blind to the study groups to which the infants belonged.

**Analysis of effectiveness**

The basis for the effectiveness analysis was intention to treat. The primary health outcomes assessed for both study groups were:

- the number of and relative risk (RR) associated with known deaths, infants with life-threatening illnesses (i.e. those resulting in death or admission to a paediatric intensive care unit), and infants admitted for intensive care;
- total life-threatening illnesses;
- total admissions for intensive care;
- the total number of days in the paediatric intensive care unit; and
- the number of infants that failed to attend the follow-up clinic one year after birth.

Also assessed was the percentage of children that ceased attending the follow-up clinic by 1 year, and the number-needed-to-treat to prevent one infant from developing a life-threatening illness with CFUC compared with RFUC. The CFUC and RFUC groups were shown to be comparable at analysis in terms of the characteristics of the infants' mothers (age, marital status, education and race), birth weight, disease diagnoses, need for ventilator therapy, need for oxygen therapy at 36 weeks' postmenstrual age, and hospital stay at birth.

**Effectiveness results**

There were no significant differences in the number of infants known to die during the follow-up period between patients receiving CFUC (11) and those receiving RFUC (13). The RR was 0.83 (95% confidence interval, CI: 0.38 - 1.83; p=0.68).

There were 33 infants with life-threatening illnesses in the CFUC group versus 62 in the RFUC. The RR was 0.52 (95% CI: 0.35 - 0.78; p=0.001).

There were 33 life-threatening illnesses in total in the CFUC group versus 63 in the RFUC group, (p<0.001).

The RFUC group had a significantly higher number of infants (52) admitted to a paediatric unit than the CFUC group (23 infants), (p<0.001). The RFUC group also spent, in total, more days in a paediatric intensive care unit (440 versus 254; p=0.003).
Forty-three infants in the CFUC group (10.9%) versus 122 in the RFUC (31.4%) failed to attend the follow-up clinic one year after birth, (p<0.001).

Clinical conclusions
CFUC appears to have been a more effective strategy than RFUC since it resulted in fewer infants developing life-threatening illnesses and fewer children receiving paediatric intensive care. The CFUC strategy also resulted in fewer total life-threatening illnesses, fewer admissions, fewer total days in a paediatric intensive unit, and higher rates of follow-up one year after birth.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. The study was therefore categorised as a cost-consequences analysis.

Direct costs
Most of the resource quantities were reported separately from the costs. The direct costs in the economic analysis were those of the health service. These included clinic visits and contact with caregivers (including telephone calls and home visits), emergency department visits and hospital care. The authors reported that the costs of physician services outside the follow-up clinic and the costs in the community clinics were not assessed due to difficulties in their estimation. The cost data were obtained from the hospital's annual Medicare Cost Report and hospital charges. Therefore, the costs were estimated from actual data. No discounting appears to have been performed, which was appropriate as the follow-up period was less than 2 years. Adjustments were made by applying cost-to-charge ratios and inflation adjustments (an annual 3% inflation rate was applied). The price year was 1997. The study reported the mean costs per infant for each strategy.

Statistical analysis of costs
Means and standard deviations (SDs) of some health care resources were reported. Uncertainty in the costs was assessed using two-tailed Wilcoxon rank-sum tests, and 95% CIs were given for those health care resources that did not show a skewed distribution.

Indirect Costs
No indirect costs were estimated.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were performed.

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

Cost results
The estimated mean cost per infant was $6,265 (SD=15,424) for the CFUC group versus $9,913 (SD=25,462) for the RFUC group. Both costs exceeded the Medicaid reimbursements, with an estimated shortfall of $1,070 per infant for CFUC versus $2,997 per infant for RFUC.
Synthesis of costs and benefits
The estimated benefits and costs were not combined due to the cost-consequences approach undertaken.

Authors’ conclusions
Comprehensive follow-up care (CFUC), as provided by experienced caregivers, can be highly effective in reducing life-threatening illnesses without increasing the overall costs of care for high-risk inner-city infants.

CRD COMMENTARY - Selection of comparators
RFUC was chosen as the comparator because it was the standard neonatal follow-up care among high-risk infants in the authors’ setting. You should consider whether this type of care is similar to that offered in your own setting.

Validity of estimate of measure of effectiveness
An RCT was performed, which was appropriate for the study question. Stratified randomisation was used, which ensured that the study groups were comparable in terms of the baseline characteristics of the infants in the effectiveness analysis and their mothers. There was uncertainty about whether the infants received additional care outside of the centre were the study was carried out, which could have influenced the effectiveness results obtained. The authors justified the exclusion of this care as it could not be accurately identified. On the other hand, the authors stated that the care given by the RFUC strategy may have exceeded the routine care received by most inner-city infants in the USA. Therefore, these results may be overestimating the effects of the RFUC strategy.

Validity of estimate of measure of benefit
No summary measure of benefit was used in the economic analysis. The study was therefore categorised as a cost-consequences analysis.

Validity of estimate of costs
Although the authors stated that a societal perspective was adopted, the costs included in the economic analysis were those of the hospital. The authors stated that the indirect costs and other relevant costs were excluded because they proved difficult to estimate. However, the authors were confident that this exclusion would not change the results obtained since the estimation of costs was conservative (i.e. it favoured RFUC).

The costing was performed on a sub-sample of the population, according to the availability of cost data. Appropriate adjustments to correct for inflation and charges (in order to reflect the opportunity costs of the interventions) appear to have been performed. No discounting was performed since the follow-up period was one year after birth. The price year was reported. Appropriate statistical analyses appear to have been performed. The fact that infants may have received health care outside the institution where the study was carried out introduces uncertainty into the reliability of the cost results, as the costs considered may not reflect the real care the infants received.

Other issues
The authors compared the cost methodology used and the effectiveness results obtained with those from other studies that analysed alternative high-risk populations. They concluded that there were similarities between them. The reader should be aware that the study population comprised high-risk inner-city infants from a specific location in the USA. Therefore, the results obtained in the current study may not be generalisable to other settings.

Implications of the study
The authors recommended that CFUC should be considered for the follow-up care of high-risk inner-city infants. However, care should be taken when interpreting these results, as there were some caveats in the study that introduced uncertainty in the estimation of effectiveness and costs.
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Other publications of related interest


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