Alcohol versus natural drying for newborn cord care
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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
Alcohol cleaning and natural drying of umbilical cords of newborns.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Mothers and newborns. Mean maternal age was 29.2 years and 89% of mothers had finished high school, 88% gave vaginal birth. The mean gestational age of newborns was 39.7 weeks, 47.5% were male and mean birth weight was 3,500g.

Setting
Tertiary-level university teaching hospital (482 newborns) and level II community hospital (1,329 newborns). The study was carried out at the Hamilton Health Sciences Corporation, McMaster Site, Hamilton, Ontario, Canada, and Grand River Hospital, Kitchener, Ontario, Canada.

Dates to which data relate
From June 1995 to June 1996 mothers were asked, on admission to the postpartum unit, if they wished to participate in the study. Interviews were conducted 2-3 weeks postpartum. The dates of the cost data were not stated, although it is likely that current prices at the time of the study were used.

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

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
A proposed sample size of 613 per group was based on the probability of infection between the treated and untreated groups. Sample size was based on a clinically acceptable difference of an absolute increase of 2.5% for the untreated group. A table of random numbers and opaque envelopes were used to generate group assignment. Approximately 25-35% of eligible newborns were not enrolled in the study, mainly because mothers believed they should use alcohol. 1,876 newborns were randomised, with 1,811 completing the study. 27 dropped out because the newborns were
admitted to the neonatal intensive care unit after randomisation, 25 families could not be reached for telephone interview, 7 families changed their mind about participating in the study, and 6 gave mixed reasons for not participating. Drop-outs were equally divided between the two treatment groups. 902 newborns were assigned to the alcohol group and 909 to the natural drying group.

**Study design**
The study was a randomised controlled trial. Participants were drawn from 2 sites: 482 newborns from a tertiary university teaching hospital (239 alcohol/243 natural drying) and 1,329 from a level II community hospital (663 alcohol/666 natural drying). The period of follow-up was 2-3 weeks postpartum with follow-up being conducted by means of telephone interviews. There was no further follow-up.

**Analysis of effectiveness**
The analysis was based on treatment completers only. Primary health outcomes were: number of umbilical infections (assessed by health care providers following an algorithm to perform a culture for umbilical areas suspicious for infection), cord separation time and maternal comfort (assessed by open-ended telephone interviews with mothers). At analysis both groups were similar for numbers from the 2 sites, mother's educational level, newborn's gestational age, percentage of male newborns, birth weight, intention to breastfeed, maternal infection/use of antibiotic, women with cultural beliefs about cord care and previous experience with cord care. However groups differed in terms of maternal age and percentage of vaginal births.

**Effectiveness results**
No newborn in either group developed a cord infection. Cord separation time was significantly longer in the alcohol group (9.8 days) compared to the natural drying group (8.16 days), (t=8.9; p<.001). Mothers described similar comfort levels with cord care and with cord separation.

**Clinical conclusions**
Evidence does not support continued use of alcohol for newborn cord care.

**Modelling**
No modelling was undertaken.

**Measure of benefits used in the economic analysis**
No summary benefit measure was developed by the authors and as such a cost-consequences analysis was performed. The measures of benefits used were as follows:

1. Number of umbilical infections: assessed by health care providers following an algorithm to perform a culture for umbilical areas suspicious for infection. Culture results were reviewed by the university hospital infection control officer, who was not part of the research team. Routine swabs were not planned because most newborns were expected to be discharged before reaching 48 hours of age, and so before colonisation is normally evident.

2. Cord separation time and maternal comfort: assessed by open-ended telephone interviews with mothers.

**Direct costs**
The direct costs included the costs associated with alcohol provision. It was assumed that alcohol was used at each diaper change, and cost was determined as follows: cost per use times length of stay in days times 8 (nappy or diaper changes per day). Nursing time for health education and cost to families for purchase of alcohol and related supplies varied and was not included. There was no cost for natural drying. Costs would be increased by the expense of cultures obtained because of concerns of health care providers. The natural drying group had 25 cultures taken, versus 7 in the
alcohol group. Prices of cultures were not reported and apparently these costs were not included in the analysis. Costs were not discounted due to the short period of analysis (< 1 year). The price year was not stated.

**Statistical analysis of costs**
Statistical analysis of costs was not reported.

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

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analysis was not carried out.

**Estimated benefits used in the economic analysis**
No newborn in either group developed a cord infection. Cord separation time was significantly (t=8.9; p<.001) longer in the alcohol group (9.8 days) compared to the natural drying group (8.16 days). Mothers described similar comfort with cord care and with cord separation.

**Cost results**
When commercial alcohol-prepared pads and gloves for health care providers were used during a 48-hour length of stay, the cost of alcohol use was approximately $0.52 (US) for each newborn. For caesarean births with a 96-hour length of stay, the cost per newborn was $1.90. If alcohol was applied using individual small bottles of alcohol and cotton-tipped swabs, the cost rose to $1.28 per vaginal birth and $2.74 per caesarean birth. Costs of alcohol drying while in the hospital were greater than those of natural drying. How these costs were calculated was not reported.

**Synthesis of costs and benefits**
Not reported.

**Authors' conclusions**
Costs of alcohol drying while in the hospital were greater than those of natural drying. Evidence does not support continued use of alcohol for newborn cord care. Health care providers should explain the normal process of cord separation, including appearance and possible odour which may not be indicative of infection.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of comparator was clear. The use of alcohol is a traditional means of avoiding infection of the umbilical cord but this has not been previously shown to be the case in clinical trials.

**Validity of estimate of measure of benefit**
The estimate of benefit is likely to be valid. The authors did not, however, develop a summary benefit measure which might have enhanced the strength of the economic evaluation (for example cost per infection avoided) although the results (no infection) did not permit this.

**Validity of estimate of costs**
Not all costs (for example cost of cultures and health professionals) were used in the analysis and none of the calculations were reported.
Other issues
Although the sample size was based on expert estimations these appear to be somewhat unrealistic; for example, there were no infections in either group. In this respect it would appear that the estimation of 0.5% (9 out of 1811) was rather high. Furthermore an estimated increase of 2.5% for the untreated group compared to the treated group, would mean about 22 more infections in the untreated group; this is quite a large number considering that only 4 infections were expected in each group. The issue of generalisability was not specifically addressed, although the results should apply to similar care units.

Implications of the study
Larger studies are necessary, and more details on costs should be provided.

Source of funding
None stated.

Bibliographic details

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Subject indexing assigned by NLM

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