CoolSim: using industrial modeling techniques to examine the impact of selective head cooling in a model of perinatal regionalization
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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.

CRD summary
This study examined the cost-effectiveness of selective head cooling (SHC) for the treatment of moderate-to-severe hypoxic-ischaemic encephalopathy in term infants, focusing on various deployment strategies across regional systems of care in the USA. The authors concluded that amplitude-integrated electroencephalography and SHC had the potential to be less expensive and more effective in a wide range of deployment scenarios. The study was well conducted, but the sources used were not extensively described. The authors’ conclusions appear to be robust.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of selective head cooling (SHC) for the treatment of moderate-to-severe hypoxic-ischaemic encephalopathy (HIE) in term infants. The analysis focused on various deployment strategies for this technology across regional systems of care in the USA.

Interventions
The two technologies for deployment were SHC and amplitude-integrated electroencephalography (aEEG). A no-intervention scenario was compared with a no-obstacle scenario, and various intermediate alternatives based on different capabilities for neonatal care. In the no-obstacle scenario all infants with a gestational age of 36 weeks or more, with moderate to severe HIE underwent an aEEG and were referred for SHC.

Location/setting
USA/hospital.

Methods
Analytical approach:
A discrete event simulation model was developed to carry out the incremental cost-effectiveness analysis of the various strategies. The time horizon was lifetime. The authors stated that a societal perspective was adopted.

Effectiveness data:
A literature review was undertaken to identify the relevant sources of clinical data. Birth cohort characteristics and the efficacy of SHC were derived from a published, randomised controlled trial (RCT). Most of the data referred to the experience of SHC in Massachusetts. Details on the other sources of data were not provided. The key clinical endpoint was the efficacy of the intervention.

Monetary benefit and utility valuations:
The utility valuations were derived from the literature and the details were not given.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure, which was combined with costs. QALYs were discounted at an annual rate of 3%. Other model outputs such as life-years (LYs), number of deaths, and other disease-related outcomes were reported.
Cost data:
The economic analysis included the costs of post-natal care, aEEG, cooling equipment, neurodevelopmental impairment, and transportation of infants. The costs and quantities were derived from various sources such as a published study, Medicare fee schedules, a systematic review carried out for the Institute of Medicine, and the market price for the aEEG monitor and the cooling equipment. The long-term costs of neurodevelopmental impairment included an estimation of productivity losses attributable to death or inability to work as well as the direct non-medical costs such as out-of-pocket expenses for caregivers and special education. Specific cost-to-charge ratios were applied when required to calculate the true costs of some services. All costs were in US dollars ($) and were discounted at 3% per annum. The price year was 2006.

Analysis of uncertainty:
The issue of uncertainty was addressed by means of a deterministic analysis, which used plausible ranges of values for specific model inputs, and a stochastic approach, based on 1,000 independent replications. The distributions associated with the parameters were reported.

Results
The no-obstacle scenario was the most effective and least costly of all possible options, while the status quo alternative was the most expensive and least effective. Thus, every strategy including deploying both technologies was preferred to the status quo option. However, differences in transfer rates, failure-to-cool rates, and total costs were observed across scenarios.

For example, the movement of both technologies from the transport centres (level four) to level three units was dominant, which means it was less expensive and more effective than the comparator. This result held for all scenarios, except for the movement from level three centres to placement in level two centres, where the combined technologies cost an additional $84,211 per QALY saved. The analysis demonstrated that dramatic reductions in failure rates were observed when a second SHC device was added.

The probabilistic sensitivity analysis showed that the most effective technology placement dominated the status quo in 68.6% of simulations and was cost-effective (less than $50,000 per QALY) in a further 18.9% replications.

These findings were robust to the variations considered in the deterministic sensitivity analyses.

Authors’ conclusions
The authors concluded that the package of aEEG and SHC had the potential to be less expensive and more effective in a wide range of deployment scenarios, compared with the current situation.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear. The authors justified their choice of the alternative strategies, which were appropriate for reflecting the current pattern of care in their own setting as well as the proposed strategies.

Effectiveness/benefits:
The clinical data were derived from published studies. No information on these sources was provided, except for the RCT used for the treatment efficacy, which was partially described. The details of the type of intervention delivered and the patient population enrolled in the trial were not reported. Thus, it is not possible to judge the validity of the clinical inputs, although the sensitivity analysis showed the negligible impact of variations in most of the clinical data. Similarly, no information on the derivation of the utility valuations was provided. QALYs are a validated and appropriate benefit measure.

Costs:
All the appropriate categories of costs appear to have been included. The costs were often presented as macro-categories and were not broken down into individual items. The sources of costs were not described in detail, especially those for multi-costs, such as the long-term management of disease. This reduces the transparency of the economic
approach. The price year and the use of discounting were reported, but no details on the unit costs and quantities of resources used were presented.

Analysis and results:
The costs and benefits were appropriately synthesised using an incremental approach, which showed the dominance of the intervention. The findings were extensively presented for all scenarios. The sensitivity analysis was appropriately carried out to investigate the issue of uncertainty. The model was validated using various approaches. The authors noted some limitations of their analysis. Firstly, the study often used sources that reflected the experience implemented in Massachusetts, which might reduce the external validity of the findings. Secondly, the analysis assumed that all medical centres were capable of providing the wide range of diagnostic, therapeutic, and follow-up services required for this specific group of high-risk infants. Thirdly, the study considered the impact of the disease in terms of severe outcomes, while milder forms of disability were not directly considered. And finally, the analysis did not consider variations in the quality of care between hospitals.

Concluding remarks:
The study was well conducted, but the sources used were not extensively described. In general, the authors’ conclusions appear to be robust.

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