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Horizon scanning prioritising summary

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**Cool Care System™ : Head cooling device to
prevent/minimise effects of hypoxia
ischaemia in newborn infants.**

May 2004



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PRIORITISING SUMMARY

REGISTER ID: 000100

NAME OF TECHNOLOGY: COOL CARE SYSTEM™

PURPOSE AND TARGET GROUP: HEAD COOLING DEVICE TO PREVENT/MINIMISE EFFECTS OF HYPOXIA ISCHAEMIA IN NEWBORN INFANTS

STAGE OF DEVELOPMENT (IN AUSTRALIA AND/OR NEW ZEALAND):

- | | |
|---|---|
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Nearly established | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Yet to emerge | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|--|---|
| <input type="checkbox"/> Yes | ARTG number |
| <input checked="" type="checkbox"/> No | <input type="checkbox"/> Not applicable |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
New Zealand	✓		
United Kingdom	✓		
United States	✓		

IMPACT SUMMARY:

An international research team has designed and tested a device, the Cool Care System™ to be manufactured by Olympic Medical, to prevent or minimise the damage caused by oxygen deprivation to a newborn around the time of birth.

BACKGROUND

Perinatal data collection in Australia defines the perinatal period as commencing at 20 completed weeks (140 days) of gestation and ending at 28 completed days after birth (AIHW 2003).

The Cool Care System™ also known as the CoolCap is a device that can be fitted onto the head of babies who are starved of oxygen at birth as a consequence of prematurity, birth trauma and/or prolonged labour. The system is designed to remain in contact with the scalp in all areas during the treatment although it does not cover the forehead or ears. It consists of a small thermostatically controlled cooling unit and a pump that circulates water through the Cool Care System™.

Liggins Institute researchers (Auckland, New Zealand) have shown that many brain-injured babies appear to recover in the first few hours after birth, but the cells that initially survive remain

at risk of swelling up and dying many hours afterwards. This condition is called apoptosis, or “cell suicide”. The Cool Care System™’s function is to lower the temperature of the baby’s brain during this critical 72- hour period, thereby protecting against apoptosis and allowing the body’s natural repair mechanisms to work.

CLINICAL NEED AND BURDEN OF DISEASE

It has been suggested that perinatal hypoxic- ischaemic encephalopathy affects approximately 1–4 out of 1000 full-term infants, and nearly 60% of low birthweight infants (Gluckman 2001). While the presence of this syndrome has in the past been debated, with research inhibited by medico-legal issues, studies demonstrate that a significant percentage of infants born with evidence of asphyxia proceed to develop an encephalopathy and later neurodevelopmental outcomes such as intellectual disability and cerebral palsy (Gluckman 2001).

In 2001-02 there were 541 hospital separations in Australian hospitals for principal diagnosis P20 Intrauterine hypoxia including principal diagnoses P20.0 Intrauterine hypoxia first noted before onset of labour, P20.1 Intrauterine hypoxia first noted during labour and delivery and P20.9 Intrauterine hypoxia, unspecified (AIHW 2004). There were 7,545 hospital separations for principal diagnosis P22 Respiratory distress of newborn (AIHW 2004).

DIFFUSION

The technology requires further investigation however; the potential for this technique to be adopted may be significant given that there are limited options for treating or preventing perinatal asphyxia. The technology has been developed in New Zealand and may therefore diffuse rapidly throughout Australia.

COMPARATORS

Few therapeutic interventions are available for perinatal asphyxia and the care of infants with hypoxic-ischaemic encephalopathy is limited to supportive measures and anti-convulsants.

COST IMPACT

A reduction in morbidity as a result of hypoxic-ischemic encephalopathy would translate in reduced costs associated with care and therapeutic interventions. Such data have not been discussed in the sources examined.

EFFECTIVENESS AND SAFETY ISSUES

A study presented (level II evidence) recently at the 2004 Pediatric Academy Society Annual Meeting reported the use of the CoolCap on 234 term infants with clinically defined moderate to severe neonatal encephalopathy and with abnormal amplitude integrated electroencephalography (aEEG). The study aimed to test whether selective head cooling with mild systemic hypothermia, initiated within 6 hours of birth to infants with evidence of hypoxic-ischaemic encephalopathy, could reduce the combined rate of death or severe disability on blinded neuro-developmental assessment at 18 months (Gluckman et al 2004).

116 infants were assigned to head cooling for 72 h starting within 6 hours of birth, with rectal temperature maintained at 34.5 ± 0.5 C. the remaining 118 infants were assigned to conventional care. In 218 infants (93%) for whom follow-up was available 66% of control and 55% of cooled infants had an adverse primary outcome ($p=0.1$).

The key findings included a significant reduction (58%) in severe neuromotor disability, with 17.8% affected infants in the control group compared to 11.7% in the CoolCap (p=0.03). The effect of the hypothermia was highly related to the pre-randomisation aEEG, with no effect in the infants with the most abnormal aEEG changes, defined *a priori* as a combination of severely suppressed amplitude and seizures (n=46, p=0.51). In the remaining infants (intermediate aEEG abnormality), adverse outcomes were reduced from 65.9% in controls (n=88) to 47.6% in cooled infants (n=84, p=0.01, OR 0.42 (0.22, 0.80). In the most severely affected infants, the CoolCap showed no benefit.

The study above was the latest in a series of trials (level II evidence). Earlier versions of the device have been trialled and results indicated that head cooling with mild systemic hypothermia was a well-tolerated method of reducing cerebral temperature in term infants after perinatal asphyxia (Battin et al 2001 and Battin et al 2003).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were raised in any of the sources examined other than the requirements for gaining consent to participate in the studies.

CONCLUSION:

There is currently limited, although good quality, evidence available on the safety and effectiveness of the Cool Care System™.

HEALTHPACT ACTION:

It is therefore recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

AIHW NPSU 2003. Australia's mothers and babies 2000. AIHW Cat. No. PER 21. Canberra: AIHW National Perinatal Statistics Unit (Perinatal Statistics Series no. 12).

AIHW 2004 [Internet] Available from: <http://www.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/AHS/principaldiagnosis0102> [Accessed May 20, 2004].

Battin, M. R., Dezoete, J. A. et al (2001). 'Neurodevelopmental outcome of infants treated with head cooling and mild hypothermia after perinatal asphyxia', *Pediatrics*, 107 (3), 480-484.

Battin, M. R., Penrice, J. et al (2003). 'Treatment of term infants with head cooling and mild systemic hypothermia (35.0 degrees C and 34.5 degrees C) after perinatal asphyxia', *Pediatrics*, 111 (2), 244-251.

Gluckman, P. D., Pinal, C. S. & Gunn, A. J. (2004). 'Hypoxic-ischemic brain injury in the newborn: pathophysiology and potential strategies for intervention', *Semin Neonatol*, 6 (2), 109-120.

Liggins Institute [Internet] Available from: <http://www.scoop.co.nz/mason/stories/ED0405/S00029.htm> [Accessed May 18, 2004].

Gluckman P D, Wyatt J S, Azzopardi D, Ballard R, Edwards D, Ferriero D M, Polin R A, Roberston C, Thoresen M, Whitelaw A, Gunn A J, the CoolCap Study Group.

'Selective Head Cooling with Mild Systemic Hypothermia To Improve Neurodevelopmental Outcome Following Neonatal Encephalopathy: The Cool Cap Study' abstract (3305) presented at Pediatric Academic Society Annual Meeting 2004

(<http://www.abstracts2view.com/pas/search.php?search=do&intMaxHits=10&where%5B%5D=&andnot%5B%5D=&query=CoolCap> [Accessed May 13, 2004].

SEARCH CRITERIA TO BE USED:

Asphyxia Neonatorum/complications

Developmental Disabilities/ etiology/prevention & control

Hypothermia, Induced

Hypoxia-Ischemia, Brain/complications/etiology/ therapy