



# **Innovations in Neonatology- Translating Research in Low Resource Settings and Transforming Tiny Lives**

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# Where and Why Newborns die

	Number of neonatal deaths (1000s)	Percentage of global neonatal deaths (n=3.99 million)	NMR (per 1000 livebirths)
India	1098	27%	43
China	416	10%	21
Pakistan	298	7%	57
Nigeria	247	6%	53
Bangladesh	153	4%	36
Ethiopia	147	4%	51
Democratic Republic of the Congo	116	3%	47
Indonesia	82	2%	18
Afghanistan	63	2%	60
United Republic of Tanzania	62	2%	43
Total	2682	67%	

Table 2: Countries with largest numbers of neonatal deaths worldwide<sup>1</sup>

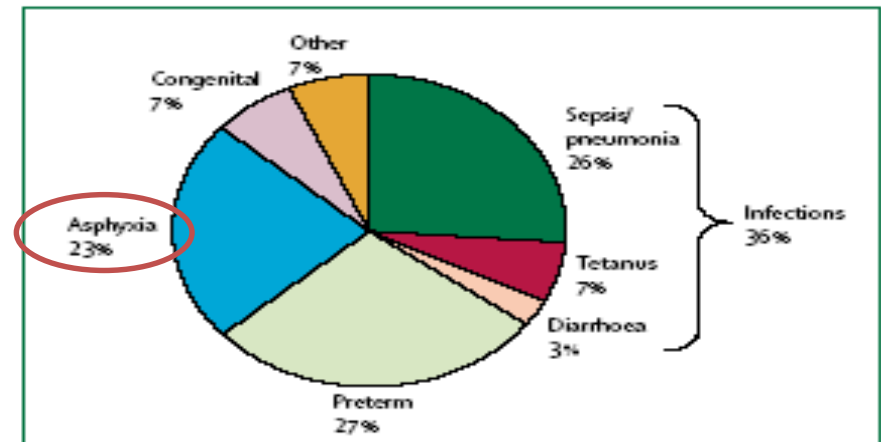


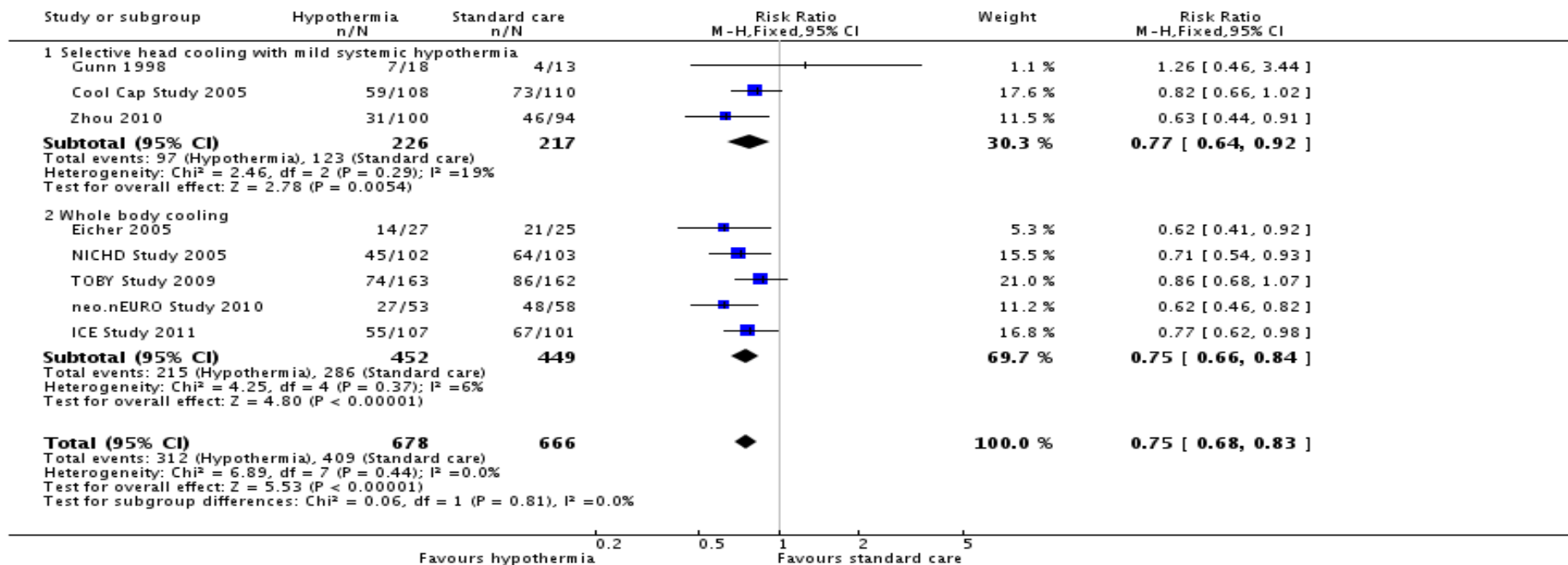
Figure 4: Estimated distribution of direct causes of 4 million neonatal deaths for the year 2000

Based on vital registration data for 45 countries and modelled estimates for 147 countries.

Lawn JE, Cousens S, Zupan J. 4 million neonatal deaths: When? Where? Why? Lancet 2005

# The only proven therapy- Cooling

Review: Cooling for newborns with hypoxic ischaemic encephalopathy  
 Comparison: 1 Therapeutic hypothermia versus standard care: subgroup analysis by method of cooling  
 Outcome: 1 Death or major disability in survivors assessed, by method of cooling



11 trials -1505 newborns.

TH- reduction in the risk of death or major disability (risk ratio [RR], 0.75; 95% CI, 0.68-0.83)

Less neurodisability in survivors (0.77; 0.63-0.94) at age 18 months.

# The Burden



- Western data
  - HIE – 1-3/1000 Live births- 700 HIE/year in UK
- Indian data-NNPD
  - 14/1000 live births – 364,000/year
  - with 150,000 asphyxia deaths and 50,000 with CP every year
- Cooling can potentially save 50,000/ year

# Equipment available for cooling



Techotherm/Criticool  
- 16-18 lakhs



- Expensive
- Needs continuous electricity
- Ongoing disposables needed- wrap/balnknet/cap



# Low cost alternative- Cool gel

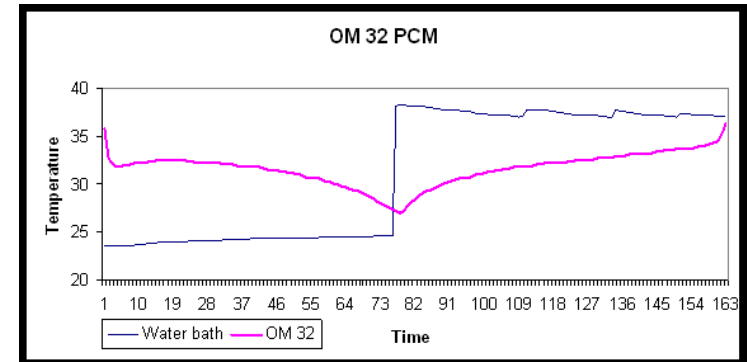


- Frequent changes of packs
- More nursing input
- Constant monitoring
- More shivering
- More swings in temperature

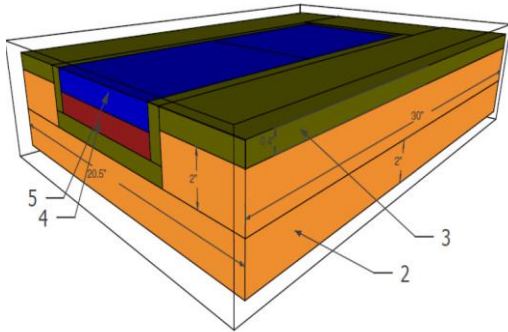


# Phase change material

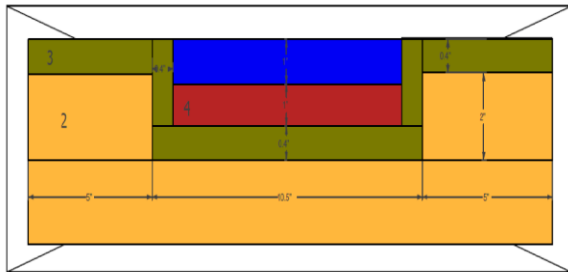
- PCM- made of salt hydride and wax like material
- Properties
  - ✓ stabilizes temp of whatever is in contact
  - ✓ acts as natural servo-controlled devices
  - ✓ Used in industry – refrigeration, buildings to save energy, PCM vest for hot environments etc
- Iwata et al. Arch Dis Child 2009-PCM mattress produced effective cooling in a piglet model of asphyxia
- Thayyil et al, EPAS 2010- Phase II RCT in Calicut- effective cooling is possible using this method



# CMC PCM Mattress- Patent- 3184/DEL/2013



Front View



Top view of mattress with PCM and water packs



Cross section along with outer covering

- 1) Outer Covering Layer-good conductor (only lines)
- 2) Foam Layer (orange-yellow)
- 3) Insulating Layer (green)
- 4) PCM Layer (red)
- 5) Water Pack Layer (blue)





## Phase Changing Material: An Alternative Method for Cooling Babies with Hypoxic Ischaemic Encephalopathy

Niranjan Thomas<sup>a</sup> Yogeshwar Chakrapani<sup>b</sup> Grace Rebekah<sup>c</sup> Kalyani Kareti<sup>a</sup>  
Suresh Devasahayam<sup>b</sup>

Departments of <sup>a</sup>Neonatology, <sup>b</sup>Bioengineering and <sup>c</sup>Biostatistics, Christian Medical College, Vellore, India

41 babies

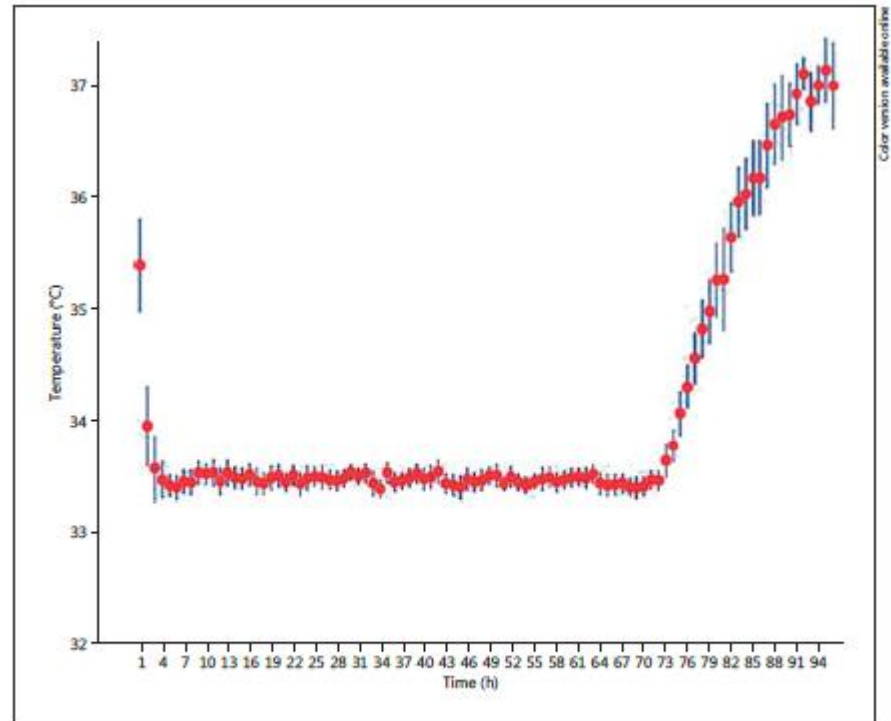
Mean temp  $33.45 \pm 0.26^{\circ}\text{C}$

Rate of rewarming  $0.25 \pm 0.09^{\circ}\text{C}$

Target temp 96.2%

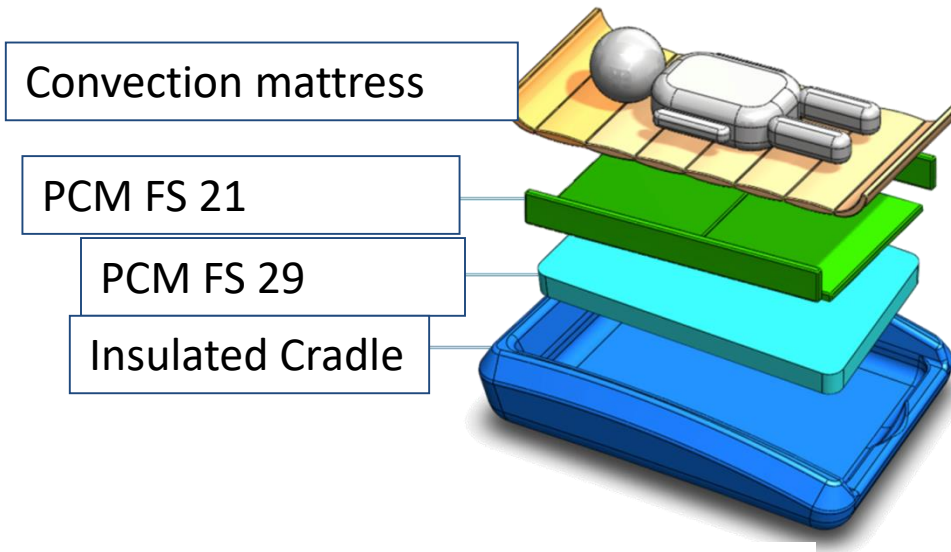
<  $33^{\circ}\text{C}$  – 2.4%

>  $34^{\circ}\text{C}$  – 1.4%



**Fig. 2.** Means and 95% confidence intervals of hourly temperatures during induction, maintenance and rewarming phases of cooling.

# Miracradle- Design

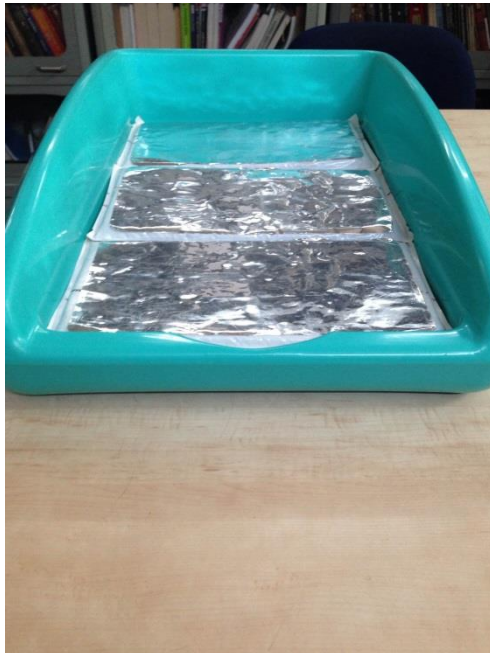
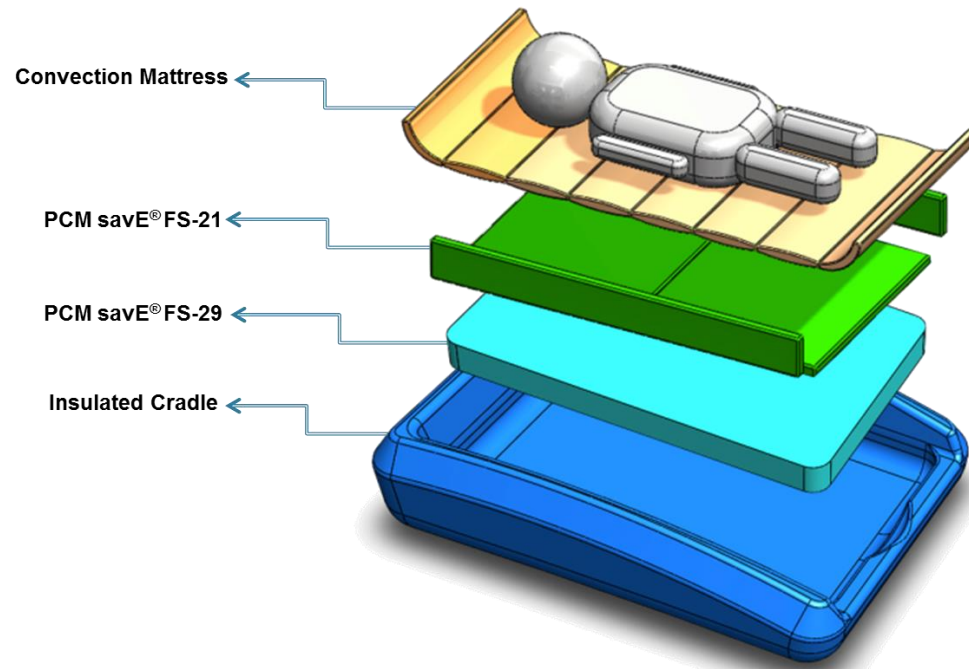


**PLUSS<sup>®</sup>**  
TECHNOLOGY FOR  
A BETTER WORLD

- Initial results of the CMC PCM mattress presented at the NNF national conference -won the best innovation poster award in Dec 2012
- PLUSS advanced technologies- Gurgaon had supplied the PCM
- Slow induction with initial prototype- hence in collaboration with PLUSS designed the MIRACRADLE with two layers of PCM with different melting points for better cooling

<http://www.miracradle.com/>







## Phase Changing Material for Therapeutic Hypothermia in Neonates with Hypoxic Ischemic Encephalopathy – A Multi-centric Study

NIRANJAN THOMAS<sup>1</sup>, THANGARAJ ABIRAMALATHA<sup>1</sup>, VISHNU BHAT<sup>2</sup>, MANOJ VARANATTU<sup>3</sup>, SUMAN RAO<sup>4</sup>, SANJAY WAZIR<sup>5</sup>, LESLIE LEWIS<sup>6</sup>, UMAMAHESWARI BALAKRISHNAN<sup>7</sup>, SRINIVAS MURKT<sup>8</sup>, JAIKRISHNAN MITTAL<sup>9</sup>, ASHISH DONGARA<sup>10</sup>, PRASHANTHA YN<sup>4</sup> AND SOMASHEKHAR NIMBALKAR<sup>11</sup>

103 babies

Mean temp  $33.5 \pm 0.39^{\circ}\text{C}$

Rate of rewarming  $0.28 \pm 0.14^{\circ}\text{C}$

Target temp 85%

<  $33^{\circ}\text{C}$  – 10.6%

>  $34^{\circ}\text{C}$  – 4.9%

THOMAS, *et al.*

PHASE CHANGING MATERIAL FOR THERAPEUTIC HYPOTHERMIA

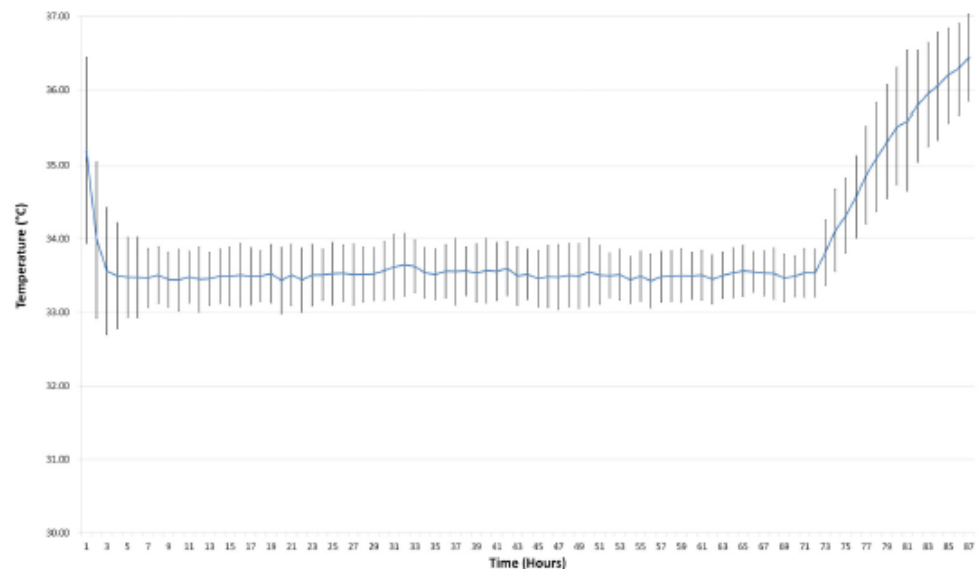


Fig. 1 Temperature (mean $\pm$ SD) of cooled babies.



# Scaling up and Impact of Miracradle

- > 300 Miracradles currently in use in India-  
impact on hundreds of babies' lives and future
- 15 Miracradles sold in South Africa, Kenya and
- 1 Miracradle being trialled in Turkey
- Grand challenges Canada grant to trial the  
Miracradle in Kenya
- Drager Germany has taken distribution rights  
worldwide



Thank you