



Hypoxic Ischemic Encephalopathy: Opportunities and Challenges August 9-10, 2010

Co-Chairman – Dr. A. David Edwards

NICHD Co-Chairs – Dr. Rosemary D. Higgins, Dr. Tonse Raju

The purpose of this workshop is to review basic and clinical evidence for hypothermia as a treatment for hypoxic ischemic encephalopathy (HIE). Gaps in knowledge, as well as future research directions will be identified by experts in the field. In addition, the impact of implementation of hypothermia therapies for infants with HIE will be discussed, focusing on specific, practical aspects of patient care, follow-up and centralized registries. These discussions and the summation of evidence to date may be used by professional organizations to develop clinical practice guidelines.

Day 1 – August 9, 2010

7:30 a.m. Registration and Breakfast

8:00 a.m.–8:20 a.m. Welcome and Introductions

Session 1: Current Knowledge and Surveillance: Clinical Hypothermic Neural Rescue

8:20 a.m.–8:40 a.m. Dr. Jacobs – Ice Trial

8:40 a.m.–9:00 a.m. Dr. Edwards – Hypothermia and meta analysis

9:00 a.m.–9:20 a.m. Dr. Guillet – CoolCap 6-7 year outcomes

9:20 a.m.–9:40 a.m. Dr. Clark – Diffusion of cooling technology into the NICU and its effect on Outcomes (Pediatrix Medical Group)

9:40 a.m. –10:00 a.m. Dr. Azzopardi – Implementation of cooling following the TOBY trial (TOBY Registry)

10:00 a.m. –10:20 a.m. Dr. Soll – VON Registry and hypothermia for HIE

10:20 a.m.–10:40 a.m. Dr. Pfister – Hypothermia and transport

10:40 a.m. –10:50 a.m. Break

Session 2: Hypothermia Clinical Trials: Clinical Implementation Issues

10:50 a.m.–11:10 a.m. Dr. Rutherford – MRI in neonatal encephalopathy: the effects of hypothermia

11:10 a.m.-11:30 a.m. Dr. Inder – Neuroimaging and encephalopathy

11:30 a.m.–11:50 a.m. Dr. Thoresen – Early outcome markers after perinatal asphyxia, do they change with hypothermia?

11:50 a.m.–12:10 p.m. Dr. Robertson – Cooling in low resource environments
12:10 p.m. –1:00 p.m. Discussion and lunch

Session 3: Areas of Research: Bench-to-Bedside and Translational Investigations

1:00 p.m.-1:20 p.m. Dr. Ferriero – Injury and repair after neonatal hypoxia-
ischemia
1:20 p.m.-1:40 p.m. Dr. Gunn – Laboratory studies and encephalopathy

Session 4: Research: Potential Adjuvant Therapies and New Areas

1:40 p.m.–2:00 p.m. Dr. Laptook – Hypothermia for infants > 6 hours
2:00 p.m.–2:20 p.m. Dr. Shankaran – Optimizing cooling study
2:20 p.m.–2:40 p.m. Dr. Walsh – Hypothermia for premature infants
2:40 p.m.–3:00 p.m. Dr. Thoresen – Improving outcome after perinatal asphyxia
by adding xenon or other drugs to cooling therapy
3:00 p.m.–3:20 p.m. Dr. Maze – Xenon, Argon and Neuroprotection
3:20 p.m.–3:45 p.m. Break/Discussion
3:45 p.m.–4:05 p.m. Dr. Silverstein – Pathophysiology/impact of
seizures/adjunctive treatment with anticonvulsants as
neuroprotective agents
4:05 p.m.–4:25 p.m. Dr. Hagberg – Cooling and infection
4:25 p.m.–4:45 p.m. Dr. Juul – Neonatal Neuroprotection using EPO
4:45 p.m.–5:05 p.m. Dr. Jenkins – Inflammatory mediators of encephalopathy
5:05 p.m.-5:30 p.m. Discussion

Day 2 – August 10, 2010

8:00 a.m. Breakfast
8:20 a.m.–8:40 a.m. Overview of Translating Research Into Practice
Speaker(s) – TBD
9:45 a.m.–11:00 a.m. Breakout Groups

Basic and Translational Research Group – Co-Moderators: Charles Palmer, M.D., and Tonse Raju, M.D.

1. What are the major areas in need of basic and translational research with respect to hypoxia, ischemia and neuronal injury?
2. Are there neuroprotective agents/modalities that can be used for clinical trials in the next 3-5 years?
3. What types of studies can be done with clinical trials to obtain more basic and translational data for HIE (samples, genetic analyses, etc.)?
4. What is the correlation between neuropathology and beneficial effects? Reperfusion injury; neuronal necrosis; global versus regional protection?

Clinical Trial Group – Co-Moderators: David Edwards, M.D., and Rosemary Higgins, M.D.

1. What types of infants can be expected to benefit from hypothermia given that 40-plus percent of infants from trials that received cooling still have death/disability? What is the duration of benefit? How should infants be selected for clinical trials and/or clinical treatment utilizing hypothermia (age, duration of insult, neurologic examination, etc.)? What other neuroprotective modalities can be used?
2. Should hypothermia be offered for any baby with a diagnosis of perinatal depression? What are the patient selection criteria? Mild Cases? Severe Cases?
3. What are the immediate and long-term clinical research questions that can lead to changes in outcomes?

Implementation Group – Co-Moderators: LuAnn Papile, M.D., and Carl Bose, M.D.

1. What hospitals and who in the hospital should be offering hypothermia?
2. What are the training needs? Should there be a process of certification? By whom and how? How is compliance measured?
3. If offered, should hypothermia be total body cooling or selective head cooling?
4. Enrollment into registry issues: Who should be in the registry? How do we facilitate?

11:00 a.m.–11:15 a.m.

Break

11:15 a.m.–11:30 a.m.

Report from **Basic and Translational Research Group**

11:30 a.m.–11:45 a.m.

Report from **Clinical Trial Group**

11:45 a.m.–12:00 p.m.

Report from **Implementation Group**

12:00 p.m.–1:00 p.m.

Lunch and Free Discussion

1:00 p.m. – 3:00 p.m.

Review of the Evidence and Gaps to Formulate Executive Summary:

1:30 p.m. – Basic and translation summary

2:00 p.m. – Clinical summary

2:30 p.m. – Implementation summary

3:00 p.m.

Adjourn