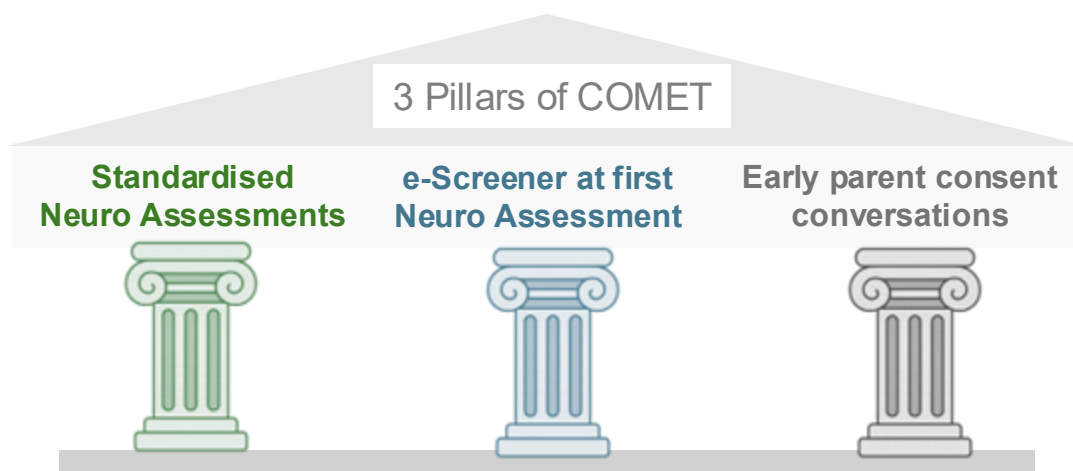


# COMET Conference 2025 – Summary

25–26 September 2025 | Putteridge Bury Conference Centre, Luton

This residential meeting brought together 51 consultant neonatologists from 38 NHS hospitals across the UK, together with the trial team to review progress, share experiences, and strengthen trial delivery. The take-home message was the importance of the Three Pillars of COMET: Neurological Assessment, the e Screener, and Consent Conversations.



## Training & Certification in Neurological Assessment

- Neurological assessments to be performed by trained & certified clinicians to ensure reliability.
- Over 600 clinicians have now completed training; sites should continue to expand certification to all staff involved in assessments.

## Real-time Use of the e-Screener

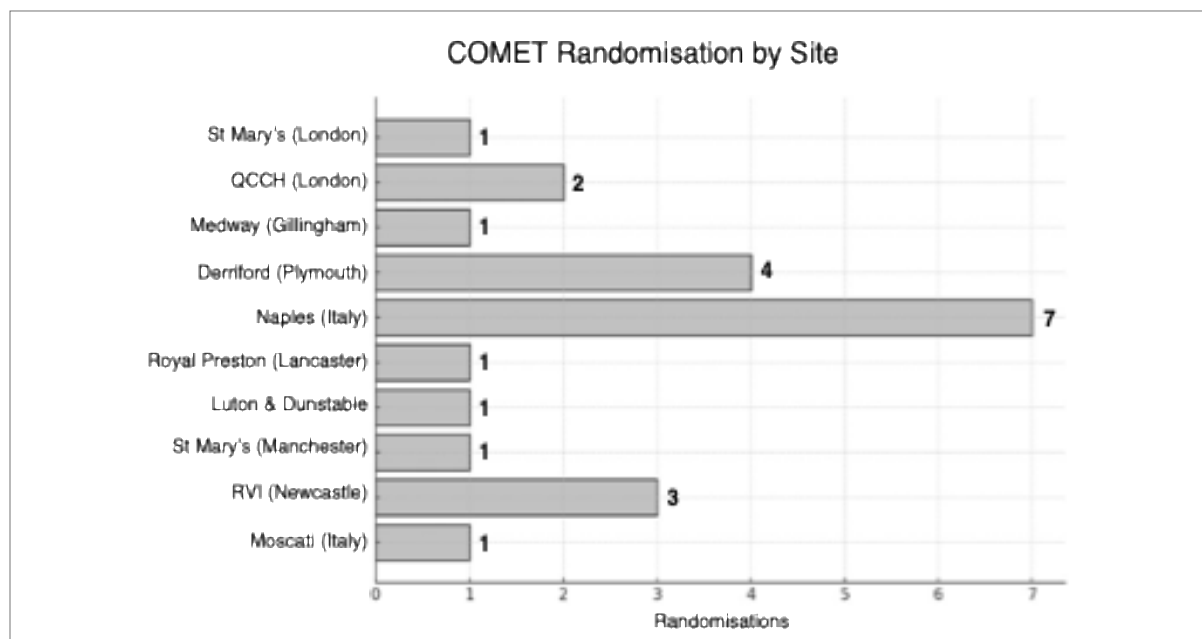
- The e-Screener **MUST** be used during the FIRST neurological exam after admission of a baby meeting Criteria A to the neonatal unit. eScreener minimizes errors in HIE staging and alerts the central trial team to provide real time support.
- Video recording is not mandatory for babies recruited into COMET but is *recommended in babies not recruited to the trial* to reduce therapeutic drift (upgrading severity) and missing (downgrading severity) mild HIE.

## Early parental engagement and consent

- Introduce COMET to parents as early as possible.
- Avoid false reassurances ~ “*Don’t worry, it is only mild – they are not going to cool your baby*”. Neuro-disability can occur even after mild HIE – around 10% developing severe, 10% moderate, and 10% mild disability by 2 years of age, and ~ 40% requiring special educational support by school age.
- Describe randomisation as “baby has equal chance of being in normothermia or cooling arm”, not as “computer decides” or “coin toss.”
- Use therapeutic drift positively by explaining that practice varies between hospitals, and COMET will provide the evidence needed to resolve this uncertainty.

## Day 1 – Scientific & Operational Updates

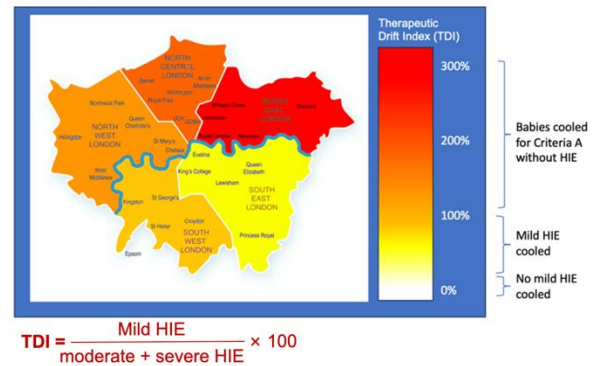
- **Evidence Base (Prof. Shankaran):** Therapeutic hypothermia (33.5 °C for 72 hours) has proven benefit only in babies  $\geq 36$  weeks with moderate or severe HIE in high-income countries. Cooling is harmful in preterm babies ( $< 36$  weeks) and in low- and middle-income countries (LMICs). Recent studies show that mild HIE can lead to adverse outcomes, contrary to earlier pre-cooling era reports. However, the risk-benefit of cooling in mild HIE remains unclear, and COMET is the only randomized controlled trial evaluating this group.
- **Trial Delivery (Prof. Thayyil):** Explained the rationale for 3 COMET Pillars – 1) *Standardisation of neurological exam*, 2) *eScreen* and 3) *Consent*. Mild HIE is a spectrum—with milder end misclassified as normal (**miss**), while the severe end often misclassified as moderate HIE and cooled (**drift**). 22 babies recruited from 10 sites so far. Seven babies recruited in August alone, with 3 babies in one week from Newcastle since the introduction of eScreen. 38 NHS sites are open. Ethics approval is pending for the use of parental videos, posters, and gift vouchers related to the e-screen.



- **Recruitment & Consent (Prof. Woolfall & Dr. Pant):** Contrary to clinician's views, parents are concerned about the risks of cooling, especially if it involves hospital transfer. This suggests therapeutic drift is clinician-driven – cooling without parental consent. Current parental consent rate is around 50%.
- Key challenges include very short recruitment window often in the middle of the night, the use of the term “mild” (which can be falsely reassuring), and the fact that affected babies often appear clinically well. Parents are carefully considering risk – benefit of cooling for their baby before consenting.

## Day 1 (continued)

- **Cooling Practice Variations in London (Dr. Ratnavel):** Over 50% of babies transported for cooling from Local Neonatal Units (LNUs) or Special Care Units (SCUs) in London (2022 & 2023) had mild HIE, reflecting “therapeutic drift.” Neonatal Transport Service (NTS) data shows poor agreement in staging, reinforcing the need for certified training.



- **Site Experience (Principal Investigators):** Use of the eScreener is still variable across sites, and some eligible cases may be missed. The Newcastle site saw a significant improvement, recruiting three babies in one week after introducing the eScreener. International expansion of the trial is now underway.

## Day 2 – Training, Perspectives & Site Experience

- **Workshop (Profs. Thayyil & Shankaran):** Refresher on Expanded Modified Sarnat staging with video review → reinforced consistency in neurological assessments.
- **Obstetric perspective (Prof. Shennan):** Highlighted unpredictability of HIE, issues around association and causality and critical importance of randomisation.
- **Lessons from SurfON trial recruitment (Prof. Boyle):** Target archived (1515 babies) after trial paused during to poor recruitment. Prof Boyle highlighted that *“it is our responsibility to inform parents about research their baby is eligible for, which may benefit their baby or others in the future, but the decision to participate must be theirs — not ours.”* and shared tips for successful recruitment

### A. Site Engagement & Expansion

- Site visits & engagement via CRN
- Newsletters and emails
- Promotion at conferences

### B. Staff Involvement & Roles

- NIHR Associate PI scheme
- Launched SurfON Champion scheme
- Enabled ANNs to confirm eligibility
- Broad inclusion on delegation logs

### C. Training & Support

- Bite-size online drop-in training sessions
- Recruitment example video
- Recorded debate about the study
- Shared site feedback, tips, and suggestions

### D. Recruitment Strategies

- Approach parents as early as possible
- Use reminders and available resources
- Discuss the study at unit meetings
- Review eligible but non-recruited babies

### E. Insights & Publications

- Published in *Infant* journal – read by nursing staff.
- Gained insight into recruitment challenges and trial equipoise concerns

- **Publication policy and sub-studies (Prof Shankaran and Prof Thayyil):** The lead PI at each site will be listed as a co-author on the main publication. Site team members will be acknowledged in the manuscript and indexed in PubMed. PIs are expected to support recruitment, contribute to trial conduct, and present data at monthly meetings. Sub-study proposals should be submitted to the Trial Steering Committee and include a research question, methodology, and analysis plan.

## Proposed Topics for Sub studies/Publications:

- *Evolution of HIE in Mild Encephalopathy*
- *Predictors of Outcomes in Mild HIE*
- *Association Between APGAR Scores and Outcomes in Mild HIE Babies*
- *Parental Perceptions Regarding Diagnosis, Treatment, and Outcomes of Mild HIE*
- *Effect of Delayed vs Early Cord Clamping on Outcomes After Mild HIE*
- *Exploring Reasons for Wide Variation in CC&C Across NHS Trusts*
- *Standardisation of Neuro-Certification for the Expanded Modified Samat Staging*
- *EEG in Mild HIE as a Predictor of Outcomes and Disease Progression*
- *Role of MRI Imaging in Prognostication of Mild HIE*
- *Inter-Rater Variability in Neurological Assessments*
- *Utility of Cord/Blood Lactate Within 6 Hours for Outcome Prediction*
- *Systemic Effects of Cooling in Mild HIE*
- *Supportive Care Strategies in Mild HIE*
- *Prospective Policy Implementation and Engagement With Policy Teams*
- *Use of AI for Video-Based Detection and Classification of HIE Severity*
- *Parental Perceptions Regarding Cuddling During Cooling or MRI*
- *Qualitative Studies on Informed Consent for Research in HIE*
- *Drugs levels during cooling in mild HIE*
- *Impact of Training and e-Screener Use on Reducing Therapeutic Drift*
- *Cooling in Borderline Preterm Infants With Mild HIE*



**Standing (left to right):** Sudhin Thayyil, Seetha Shankaran, Krzysztof Zieba, Elaine Boyle, Azaz Khalil, Edit Molnar, Simisola Williams, Emma Strogen, Toria Klutse, Silke Häusler, Imdad Ali, Archana Mishra, Ambalika Das, Jenna Gillone, Shaveta Mulla, Santosh Patnayak, Aung Soe, John Ho, Varun Meena, Mallinath Chakraborty, Ajay Sinha, Narendra Aladangady, Nandiran Ratnavel, Anshuman Paria, Dilip Vasudeva, Sundeep Harigopal, Bharat Vakharia, Palaniappan Sashikumar, Melanie Philipps, Vidya, Hemant Ambulkar, Robin Miralles, Shilpa Ambulkar, Ragamalika Pinnamaneni, Elizabeth Lek, Mia Kahvo, Rosaline Garr, Claudia Ganado, Mohamed Elboraee, Balamurugan Palanisami, Ajit Mahaveer, Thilipan Thaventhiran. **Sitting (left to right):** Stuti Pant, Preetam Meena, Anchal Dhawan, Kudzai Mugweni, Jogesh Kapadia, Prakash Satodia, Syed Mohinuddin, Santa Masila, Dulip Jayasinghe, Ravindra Bhat, Mia Cunliffe.

## Please complete the Conference feedback survey:

[https://imperial.eu.qualtrics.com/jfe/form/SV\\_6zM97SFa1Bfu5jU](https://imperial.eu.qualtrics.com/jfe/form/SV_6zM97SFa1Bfu5jU)

## Upcoming Opportunities – COMET Neurology Nurse Champions!

We're inviting clinical neonatal nurses and ANNPs at every COMET site to become Nurse Champions. You'll lead by example, support colleagues in certified neurological assessments, promote eScreener use, and help ensure clear, balanced consent conversations with families. Champions will join a recognised national and international network, gain structured neurology training, resources, and peer support, contribute to monthly meetings, and have the opportunity to work closely with world leaders in hypothermic neuroprotection, with access to an annual study and training bursary. A formal Champion's Charter and one-year tenure programme are currently in development—offering an exciting opportunity to shape COMET's success, strengthen your research leadership, and contribute to delivering the highest standard of care for babies