

## Project R42 End of grant report

Summary/list of the original objectives:

Run a one-day meeting to:

- 1) Bring together experts and PPI representatives to develop CONNECT study guidance on approaches to consent in children's critical care trials;
- 2) Engage key stakeholders to help raise awareness of the study and outputs as part of the CONNECT dissemination strategy.

What was achieved (on the day)

- 32 key stakeholders attended the meeting including parents; recruiters; ethicists; philosophers; researchers and clinical trialists.
- Dr Paul Baines (Alder Hey Children's Hospital) and Professor Angus Dawson (University of Birmingham) gave opening presentations which provided delegates with a background to the practical and ethical challenges of conducting trials in this challenging setting. Kerry Woolfall then presented the CONNECT study findings, which was the first opportunity for many of those present to hear about the study and its findings. Presentation slides, podcasts and a description of the event are available on the CONNECT study website: <http://www.liv.ac.uk/psychology-health-and-society/research/connect/>
- We used facilitated focus groups to assist delegates in their critical appraisal of each recommendation in the draft CONNECT guidance. This format provided extremely valuable information on the usefulness and feasibility of draft guidance. We audio recorded group discussions.
- KW analysed transcripts of audio recordings and drew on them in developing the guidance. Key issues arising from the focus groups: the need to consider providing parents with some form of brief information about the trial as soon as possible after randomization, rather than deferring all information until after their child's condition has stabilized (as previously recommended); the use of the term 'critical care' rather than 'emergency care' to more accurately describe the setting for recommendations; the need for doctors to speak to bereaved parents before leaving hospital to seek deferred consent; and how the scope of the guidance should be widened to apply to all trials rather than only to 'low risk' trials, which was considered more appropriate given the difficulties in defining risk within trials.
- Delegates identified areas for further research, which were added to the guidance. This included the need for research to explore child assent in this setting.
- We used a questionnaire to evaluate the meeting, potential impact of the CONNECT guidance and to identify avenues to inform CONNECT dissemination activities. Many (90%) of stakeholders indicated that the meeting had influenced their views on seeking consent in children's emergency care trials. The majority (85%) stated that guidance would have a positive impact on children's EC research, whilst 75% stated that they (or their group/organisation) would use the CONNECT guidance. In their responses delegates indicated that the guidance would inform future practice in the field: "I feel the guidance has influenced my view as it will be a standard (gold) that everyone should work to" (Research Nurse).

What has been achieved (since the event)

- CONNECT guidance is now in final draft. Dissemination will begin in March 2015 using key contact information and dissemination suggestions provided by delegates in evaluation questionnaire. [tinyurl.com/CONNECTguideline](http://tinyurl.com/CONNECTguideline)

- KW has used CONNECT guidance to inform the development of trial protocol, patient information and recruiter training for a Health Technology Assessment (HTA) trial called 'EcliPSE': Emergency treatment with Levetiracetam or Phenytoin in Status Epilepticus. Start date March 2015.
- One reviewer of a HTA trial application (Fever trial) referred to the CONNECT study as evidence when considering the ethics of the trial, given its use of deferred consent. A second reviewer stated "the involvement of Kerry Woolfall in this is key given her previous experience in this field" when describing the actions that need to be taken if trial should be funded.
- CONNECT findings and guidelines have been fed into the development of five NIHR HTA and one RfPB clinical trial applications (One successful pending response to reviewers (Fish Trial), two pending (CPAP or HF02 trial [RfPB] and SAINT trial) and three unsuccessful (AMIPROM trial, Bronchiolitis Endotracheal Surfactant Trial and CPAP or HF02 trial [HTA]).
- Since the meeting KW received an invitation to present CONNECT guidance at the Annual Scientific Conference of Clinical Excellence in Emergency Medicine, Exeter University, 9th-11th September 2014 and at the Women's and Children's Health Clinical Trials Group, University of Liverpool, 13th October 2014. In response to presentations senior paediatric consultants have described the research as "much needed" and "a game changer".
- KW used CONNECT guidance to inform a paper written by the STaR Child health group (<http://ifsrc.org/>) entitled: Decisions in difficult circumstances: parental consent for a trial under time pressure. The paper has been favourably reviewed by the journal Paediatrics and a revision invited.

#### Next steps for the following 12 months

- KW will submit CONNECT study findings and guidelines to:
  - Wellcome Trust in April 2015 as part of an end of grant report
  - a leading peer reviewed journal (e.g. BMJ, Critical Care Research, BMC Paediatrics or Trials).
- Publications will be sent to delegates as part of the dissemination strategy.
- KW will continue to develop links and networks through presentations and use of social media to assist in the 'adoption' of guidelines by a leading body (e.g. RCPCH, PERUKI).
- KW will present guidelines at two medical conferences. An abstract has been accepted by the RCPCH annual conference in Birmingham (April 2015) and an abstract has been submitted to the European Society of Paediatric and Neonatal Intensive Care (ESPNIC) in Lithuania (June 2015).
- CONNECT guidelines will be evaluated through interviews with patients and clinicians who experience the 'CONNECT model' of deferred consent used in the EcliPSE trial (2015-2017).