The CONNECT Study: Summary of findings

What was the CONNECT study?

In the CONNECT study we wanted to find out what families, doctors and nurses thought about research without prior consent (also known as deferred consent) in clinical trials involving children.

Research without prior consent is allowed for trials in emergency situations. This is when children are critically ill and delaying their treatment to discuss research would not be in the child's interests. If research happens in these situations, children are given a treatment as part of the trial and then a doctor or nurse will discuss the trial with parents when the emergency is over.

CONNECT was run by Kerry Woolfall and the CONNECT Advisory Group between March 2012 and June 2015.

Supported by wellcome trust

Who took part in CONNECT?

354 people took part, including 292 parents, 39, nurses, 19 doctors and 4 people who manage trials. This included:

- parents who experienced research without prior consent in a trial called CATCH- this was looking at catheter infections in children;
- bereaved parents;
- parents with experience of their children being admitted to hospital in an emergency.

What did the CONNECT study find?

Parents were often unaware that clinical trials could be conducted without prior consent and many were initially surprised discover that their child had, or could have been, entered into a trial in this way.

Despite their initial concerns, parents were reassured when staff explained why research was conducted without prior consent.

As long as a child's safety was not put at risk, parents supported research being done without prior consent where this research was necessary to improve the treatment of critically ill children.

Parents made suggestions for planning future research without prior consent. They recommended that doctors and nurses should first check that it is an okay time to discuss research with parents. They said that clear written information was important, without using medical terms. Bereaved parents suggested that a doctor known to the family would be the best person to discuss research with parents.

Doctors' and nurses' views on research without prior consent differed depending upon their experience in this method. Those without experience in research without prior consent were concerned that parents would be unhappy to find out that their child had been entered into a trial without being spoken to first. In contrast doctors and nurses who had experience in talking to families about research without prior consent described how families were usually okay with the research, provided staff explained the reasons why research needed to be done without prior consent in emergency situations.

CONNECT findings have been used to produce a set of guidance on the best way to do this type of research in the future.

Where can I find the CONNECT guidance?

Guidance and research papers from the study are on our website: http://www.liv.ac.uk/psychology-health-and-society/research/connect/ If you would like a hard copy please contact Kerry on telephone: 0151 794 4634 or Email: K.Woolfall@liverpool.ac.uk

What will happen next?

Kerry will use CONNECT findings and guidance to help teach the people doing children's emergency research about how and when to explain research without prior consent, so that it is done in a way that is acceptable to families.

We are about to start another study called the VOICES project which is looking at what children think about research without prior consent. For further details please see the VOICES website: http://www.liv.ac.uk/psychology-health-and-society/research/childrens-voices/about/

THANK YOU FOR TAKING PART IN THIS STUDY. YOUR HELP IS ALREADY MAKING A DIFFERENCE TO HOW TRIALS OF CHILDREN'S EMERGENCY MEDICINE ARE DONE.

UNIVERSITY OF LIVERPOOL

MRC Hubs for Trials Methodology Research North West Hub