Support for research without prior consent in cases involving critically ill children

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Public health experts at the University of Liverpool have shown that parents and medics support research without prior consent in the emergency treatment of critically ill children.

As children often lack the decision making ability or legal power to provide true informed consent for medical decisions, it often falls on parents or legal guardians to provide informed permission for medical decisions.

In the treatment of adults, health care providers would ask a patient to consent to receive therapy before providing it, or a clinical researcher may ask a research participant before enrolling that person into a clinical trial. Consent is collected according to guidelines from the fields of medical ethics and research ethics.

Much needed research

The process of seeking informed consent for much needed research requires time, but this is severely constrained in emergency situations, such as acute resuscitation and critical care, where even minimal treatment delays are likely to be harmful.

In these situations parents are likely to be highly stressed and struggle to make informed decisions about research in the limited time available. Nevertheless, clinical trials are needed to find out whether critical care interventions are safe and can help to save children's lives.

Life-saving treatments

Many countries now permit variations to informed consent and allow progress in research to develop life-saving treatments. While the details vary, a common feature is that 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.

In 2008, UK legislation was introduced to enable doctors and nurses to

seek consent for research after a child had been given the investigational drug or device in specific circumstances.

Conducting research without prior informed consent has been subject to much debate as there are concerns it limits personal choice. Little was known about the views and experiences of those with first-hand experience of this controversial consent process and how research without prior consent could be conducted in a way that was acceptable to families of very sick children.

First hand experiences

The Consent methods in children's emergency medicine and urgent Care Trials (CONNECT) study, which is the first of its kind in the UK, examined the views and experiences of those with first-hand experience of research being conducted without prior consent.

The study was led by Dr Kerry Woolfall from the Institute of Psychology Health and Society. More than 350 people took part, including 275 parents recruited to the Catheter Infections in Children Trial (CATCH).

Dr Woolfall, said: "The study found that although some parents were initially shocked that their child had been entered into a medical trial without their prior consent they were reassured once the reasons they were not consulted were explained to them at the appropriate time.

"Doctors, nurses and parents supported the use of deferred consent in CATCH and in future trials of interventions already used in clinical care.

"CONNECT provides evidence to support the use of research without prior consent in children's critical care medicine; it also indicates the crucial importance of practitioner communication and appropriate

timing of deferred consent discussions."

More information: Kerry Woolfall et al. How parents and practitioners experience research without prior consent (deferred consent) for emergency research involving children with life threatening conditions: a mixed method study, *BMJ Open* (2015). DOI: 10.1136/bmjopen-2015-008522

Further information is available on the CONNECT website: www.liv.ac.uk/psychology-healt … ty/research/connect/

Provided by University of Liverpool