

Diabetes research nursing

In this regular column, Shona Brearley discusses diabetes research nursing from a practical perspective, with the aim of sharing best practice ideas and giving readers the chance to ask for advice about their particular study. If you have any queries, or would like to contribute to this column, contact jdn@sbcommunicationsgroup.com.



Involving children and young people with diabetes in clinical research

Shona Brearley
Network Manager for the Scottish
Diabetes Research Network

The Nuffield Council for Bioethics recently published a paper on children's clinical research after conducting an independent investigation into research studies involving children. They have proposed a set of recommendations for researchers to adopt to show good practice (Nuffield Council for Bioethics, 2015).

Many drugs used in the treatment of children have very limited testing in children. They have often been tested in adults and the effective dose is calculated per kilogram of body weight when it comes to being used in children. This is not ideal as children are still growing and developing, so juvenile physiology can be different from that of adults in terms of absorption and excretion rates.

In recent years, there has been a change in attitude so that drugs used in children's medicine should be tested rigorously in children, albeit under very strict medical supervision. The National Institute for Health Research (NIHR), England and the Scottish Children's Network have developed great advances in children's research over the last 10 years by collaboration between experts right across the UK. There has been an emphasis on engaging children and young people to get involved in research and the development of specific protocols.

The Nuffield report recommends that children and young people should be centrally involved in the design of any study. They should be consulted in order to capture data on their priorities, as well as those of the researcher. They should be involved in the creation of Patient Information Sheets, which should be age-specific and should be encouraged to help with any recruitment materials for the study. To facilitate this, the UK clinical research networks have set up children's panels. These children and young people have undergone some training and understand the ethical requirements of a Patient Information Sheet, but can also produce good suggestions as to how to explain

complex procedures in a straightforward manner.

The report goes on to explain the concept of informed consent and assent. Children are often not allowed to sign their own consent form for a study unless the researcher feels that they fully understand their involvement in the study. The Gillick Competencies (British and Irish Legal Information Institute, 1985) are often used to decide whether or not a child can sign the consent form, but even if the child is not able to sign the consent form, the researcher should make every effort to ensure that the child has given assent. The report recommends that the researcher should make every effort to explain the study in a manner that the child can understand and gain assent. Literature for the study should be available in several age groups and reading levels. As technology and communication methods advance, it may be appropriate to use social media for interacting with children and young people, and the best use of this medium to inform or recruit participants may be directed by the children and young people's groups.

The Nuffield report makes it clear that children's research is necessary so that treatment can be advanced, but it should be carried out in conjunction with the priorities of that patient group being taken into consideration. The recommendations of the report also hold true for adults participating in clinical research. All individuals in a study should be well informed of the risks and benefits of a study and we should be involving patient groups in the design of studies, so that questions pertinent to patients, as well as those of researchers, are answered. ■

British and Irish Legal Information Institute (1985) *Gillick v West Norfolk & Wisbech Area Health Authority*

Nuffield Council for Bioethics (2015) *Children and clinical research*. Nuffield Council on Bioethics, London. Available at: <http://bit.ly/1B0FmJJ> (accessed 28.05.15)