Children's views should shape how research is conducted, says ethics body

May 14 2015

A new report by the Nuffield Council on Bioethics calls for a change in culture across all areas of children's health research, so that children's and young people's views and opinions can help to shape how research is prioritised, designed and reviewed. Unless ethical concerns about asking children to take part in research are addressed, our understanding of childhood disorders and ability to provide evidence based care will remain limited.

"It will always be easier to say 'no' to research with children on the grounds that it's too difficult, but we should challenge the idea that it is acceptable to continue to offer healthcare to children without seeking to improve the evidence base for many of the treatments provided," says Professor Bobbie Farsides, Chair of the Nuffield Council on Bioethics Working Party and Professor of Bioethics at Brighton and Sussex Medical School.

The report is the result of a two-year inquiry, which has heard from over 500 professionals, parents, children and young people, in the UK and internationally.

In many areas of child health, evidence on childhood diseases and treatments remains limited because of a lack of research specifically with children. For instance, many medicines prescribed to children have not been developed specifically for children, meaning that doctors must use their expertise to adapt adult doses.

Research in areas such as childhood leukaemia, where survival rates are now over 80%, demonstrate the crucial role of research in improving healthcare. The Council argues that research with children should become a core part of the NHS.

"Being invited to take part in research can come at very difficult times in children's and parents' lives", said Professor Farsides, "but children told us time and time again that it was important they should be asked to take part in research, particularly as it may help other children in future."

Children should have a say in the whole research process

The starting point for most health research is adult needs, leaving children's research lagging behind. But there are examples where children and parents help set research priorities, and the Council supports these initiatives. For example, the James Lind Alliance has worked with parents, researchers and health professionals to set out the 15 most pressing research priorities in preterm birth.

The role of research ethics committees (RECs) is to assess the value, risks and benefits of all research proposals. However, members of RECs told the Working Party that they can feel anxious about approving research with children. The Council concludes that to make properly informed decisions, RECs should have access to experts in child health who can advise on the risks or burdens of normal practice, and areas where there is a lack of evidence. The Council recommends that registers of experts in different areas of child health should be set up and that employers should ensure that doctors' time to serve on ethics committees is protected.

Additionally, RECs should require researchers to have listened to

children and parents when developing their studies. An example of this is the UK network of Young Persons' Advisory Groups (YPAGs). These are groups of 8-18 year olds who advise researchers on whether their proposed studies and information materials are acceptable to children - for example, by commenting on language, the number of blood tests or days off school required. The Council recommends that industry should help fund YPAGs, for example through a central fund to protect the groups' independence.

"Research should always be subject to robust scientific and ethical review, but by speaking to children and their families, researchers can design studies which are more suited to their needs, and ultimately more acceptable," says Hugh Whittall, Director of the Nuffield Council on Bioethics. "Throughout our project, we've heard from children with strong opinions on complex ethical and scientific issues. We shouldn't underestimate them. Alongside appropriate regulation, we need a change in culture to ensure that children have a say in the whole research process."

Children should be actively involved in decisions to take part in research

Under UK law, young people aged 16 or above can give their own consent if they want to take part in research. Under 16, parents consent on behalf of their children. While there is usually a requirement to provide information to children, there is little agreement on how children should be involved in decisions to take part in research under the age of 16.

The Council concludes that, where possible, decisions to take part in research should be a partnership between researchers, children and their parents; and that children should be as involved in decision making as

they are able, and wish to be.

"As soon as children are able to express their opinions, or give their views, we should respect them as individuals by listening to them. Parents will always be concerned with their child's well-being, and there may be times when those concerns override a child's wishes," says Dr Helen Sammons, member of the Working Party, and general paediatrician at the Derbyshire Children's Hospital. "However, in most cases, researchers should seek to get the agreement of both children and their parents to take part in research. Children don't suddenly become adults overnight at the age of 18, but develop their ability to make decisions with their parents' support."

Smarter regulation of clinical trials is required

Some incentives do exist to help encourage research with children. The 2006 EU Regulation on Paediatric Medicine requires that any trial of a new medicine should also include research with children, unless the medicine would treat a disorder that occurs only in adults. In these cases waivers may be granted. In its first five years, the regulation has led to 132 new medicines, or new uses for existing medicines, being licensed for children.

Although there has been progress, the Council concludes that the waiver system is not working as intended. Many adult disorders, such as some cancers, do not have direct equivalents in children, but this does not mean that the medicine being developed won't be effective in treating related disorders in children.

The Council recommends that EU regulation should be amended so that if the medicine has a possible related use in children, then waivers should not apply. Furthermore, the Council recommends that smarter regulation is needed to encourage companies to adapt off-patent

medicines for children, including in age-appropriate formulations like syrups.

More information: nuffieldbioethics.org/wp-conte … arch-full-report.pdf

Provided by Nuffield Council on Bioethics