Children and Research: A Risk of Double Jeopardy?

LYNN HAGGER
Lecturer in Law, University of Sheffield and Chairperson, Sheffield Children’s NHS Trust

SIMON WOODS*
Senior Lecturer in Bioethics, Policy Ethics and Life Sciences (PEALS) Research Institute, University of Newcastle.

On the one hand there has been significant publicity about the lack of research into drugs used to treat children but, on the other, widespread criticism about unethical research carried out in the past. In addition, some current professional guidelines in relation to research on children unable to consent have been censured for being too permissive. Now, recent legislation in relation to clinical research actually appears to be unduly restrictive. In this paper, we set out to defend the guidelines from an ethical and legal perspective and propose that an even more rigorous approach could be adopted to ensure children are engaged in research. This is not to advocate that the children should be subjected to undue risk nor that those close to them should not be involved in any decision-making process. We hope to demonstrate that a more balanced approach is necessary and timely, in the hope that those working in relevant areas gain sufficient confidence to justify their research proposals robustly rather than avoid them because of fear of castigation at the ethics approval stage. This would ensure children are accorded appropriate recognition of their autonomous interests and that they are afforded the same opportunities to benefit from research as adult subjects.

Introduction

It should be said at the outset that we recognise the vulnerability of the research subject and, in particular, that where the child is involved. It is not difficult to see that the relationship between researcher and participant is unequal in power. It is the researcher who is likely to be seen as imbued with knowledge, status and will be the active partner rather than acquiescent recipient of intervention(s). These factors are exacerbated when considering the subject may well be ill, in unfamiliar surroundings and, if a child, already unequal in
the power stakes outside of the research environment.\textsuperscript{1} The criticism of research carried out in the past on especially vulnerable children such as orphans, the learning disabled and looked-after children i.e. those subject to care proceedings, is entirely legitimate.\textsuperscript{2} These children were given unproven vaccines that were accepted as risky and not approved for general use without parental consent. Some children suffered significant pain and were left with brain damage. Fortunately, now, controls are such that no Research Ethics Committee would approve such a trial.

Some researchers believe the pendulum has swung too far in the other direction so that it is well nigh impossible to carry out appropriate research on children. Recent secondary legislation provides that clinical research may only be carried out on children where there is a ‘direct benefit’ for the group of patients involved in the clinical trial. This apparently rules out non-therapeutic research, unless a very wide reading is taken of the term, so that it may include psychological and other benefits.\textsuperscript{3} This seems unlikely in the current, cautious climate. Some would take the view that this amounts to discrimination against children.\textsuperscript{4} There is some force to this argument in that the UK Government has recognised the paucity of research with children and that up to two thirds of children in hospital may be taking unlicensed drugs. Overall, other estimates suggest that forty per cent of drugs prescribed to children have never been tested on them and that the figure rises to sixty five per cent where newborn babies are concerned.\textsuperscript{5} As will be seen below, some believe even these figures are conservative.

The UK Government is committed to provide additional funding to encourage research in this area. Its position will be bolstered by the European Commission’s intention to draft legislation within the next two years forcing drug companies to undertake appropriate research on children so that their therapeutic needs are more directly addressed. The proposals follow a period of consultation with relevant stakeholders and will be similar to legislation currently enacted within the United States,\textsuperscript{6} that will support and promote studies in children to ensure the safety of medicines, many of which are currently used off-label. As things stand, it is estimated that between fifty and ninety per cent of medicinal products used in the paediatric population have never been specifically evaluated for use in that group. Recent US paediatric studies, conducted in response to US legislation, the Paediatric Exclusivity and the Paediatric Research Equity Act 2002, led to sixty four labels containing new paediatric information for established medicines between July 1998 and February 2004. In forty one cases, the new labels included important new dosing/pharmacokinetic information, lack of efficacy or safety information which had an impact on the safe and effective use of the medicine in children. The Act also established a fund of two hundred million US dollars for the fiscal year of 2002 and such sums as were necessary for each of the succeeding five