

Editorial

Research involving children—ethics, the law, and the climate of opinion

The ethical problems of medical research on children continue to cause concern to investigators, ethical committees, and editors. We believe they always will. On p. 443 of this issue Professor Gerald Dworkin gives a lawyer's view on the current state of the law concerning this subject. He argues, like Skegg,¹ that this differs from what a number of weighty authorities have stated, and that it is probably perfectly legal for a parent to consent to a procedure on a child which is not of direct benefit to him, provided the study is approved by an ethical committee and there is no, or minimal, risk to the child.

Does this alter the view of the *Archives* on what is permissible research in children? In no way. In fact, Professor Dworkin's statement of what is legal is almost identical with our view of what is ethical, as stated in our last Editorial on this subject (1973, 48, 751). It is reassuring to know that the attitude we have taken is within the law. However, this statement of the legal view does not mean that we or the profession can be any less rigorous in the ethical standards we apply to clinical research—nor could it mean that. If, to take an improbable example, Professor Dworkin had shown conclusively that the law allowed liver biopsy to be carried out on healthy children, with parental consent, we would still not publish a paper reporting such a study because we should judge it as manifestly unethical, whatever the law said.

Nevertheless we regard Professor Dworkin's article as being of great interest and importance in this continuing debate, and not only because of its reassurance about the legality of our present attitudes. Its wider importance is that it exposes a common medical misconception of the nature of the law itself and of how it can guide us in ethical matters.

In discussing problems of medical ethics there is often an implicit assumption that there is, so to speak, writ in Heaven, an absolute and immutable ethical code, and that all we need do is to discover the relevant parts of this code and apply them to the issue in question. However, absolute moral codes prove to be elusive, and ethical views change with

time and the prevailing climate of opinion. That is presumably why many medical authorities have appealed to the common and statute law as a guide to the ethics and conduct of research. The law must surely be written, definite, and unambiguous. What Professor Dworkin's article chiefly shows is that the law is nothing of the kind, at least in relation to research in children. It is unwritten, untested by any relevant cases, and apparently largely dependent on current medical and public opinion of what is reasonable. If the law does not hinder us in carrying out what we have regarded as reasonable research, it does not help us either in deciding what *is* reasonable. The responsibility is back with us.

We therefore reiterate the position we took in our 1973 Editorial, with its emphasis on the fact that in this area we are always making value judgements rather than absolute ones. We pointed out, too, that editors have a limited role in deciding problems of ethics in research, for they can only review the work after it has been done, whereas ethical committees do so beforehand. However it may be helpful to explain how we try to make our decisions. We ask, in effect, three main questions about a paper reporting a study where investigations not directly to their benefit were made on children, and which therefore raises ethical problems—was it harmful, was it unkind, and was it a worthwhile study? The answer to each of these questions will be a matter of opinion and judgement.*

Harmlessness. We explained in our previous Editorial that virtually any study in which anything is done to a child carries some risk of harm, however remote, and we cited the example of weighing babies. We agree with Professor Dworkin that to be acceptable the risk involved must be either absent or negligible. However it is difficult to give exact and helpful guidance as to what this means. The only instance in which we have made a definite policy decision of this kind is that we will not accept papers

*Where opinions differ, we sometimes ask an author to set out his reasons for considering his research ethical: for an example see *Archives*, 1975, 50, 565, 575.

reporting studies where ionising radiations (*x*-rays or radioisotopes) have been given to normal children for study purposes only. We could, of course, quote other investigations which would be regarded as obviously reasonable, e.g. weighing, or obviously unreasonable, if done for research purposes only, e.g. liver or renal biopsy. However this is not particularly helpful because we imagine no one would expect us to decide otherwise in these situations. We find it much more difficult to give clear guidance about procedures which cause genuine difficulty to investigators, for example blood sampling, and here we would certainly take the answers to our other two questions into account.

Kindness. The need not to be unkind to children in research studies has been discussed much less than the need to avoid harm, but in papers which have caused us difficulty it has often been the more relevant consideration. A study involving repeated venepunctures on young children might be judged to carry some small risk of physical harm, but our major reason for rejecting it would be that we would consider it unkind. However, the evaluation of kindness is very difficult because it depends as much on the spirit and skill of the investigators as on what is actually done. Undressing and weighing a toddler can be very upsetting to him; one skilful venepuncture need not be.

One thing we would mention, in connection both with the need to avoid harm and to be kind, is that we believe the debate on the ethics of research in children has concentrated too much on physical procedures, and too little on the problems which may arise in psychological, social, and educational research. It is equally important that this should not harm the child or treat him with lack of consideration. We would unhesitatingly reject a paper reporting a random controlled study of the effects of maternal separation.

Motivation and worth-whileness. In our previous Editorial we accepted the risk/benefit ratio as a factor which must be considered in deciding whether a research project is ethical, and this seemed to us the most controversial part of that Editorial. The justification of the means by the end is notoriously slippery moral territory. Nevertheless, we have found it both necessary and right to take the purpose and motivation of the research into account. We would certainly allow blood tests on normal children if they were an essential part of the evaluation of a new vaccine for a deadly or maiming disease; we would certainly disallow them if they were done merely to obtain information to satisfy trivial or aimless scientific curiosity. Furthermore, we believe that research studies which are motivated by strong humanitarian considerations or which promise important advances in knowledge are more likely to be carried out carefully, safely, and in a spirit of kindness and consideration to the subjects.

The *Archives* is perhaps more conservative than some journals and some ethical committees in what it regards as acceptable research practice. Nevertheless, we previously explicitly rejected the view that procedures of no benefit to the child can never be carried out even with parental consent, and we are glad of Professor Dworkin's legal support for this view. The great majority of research studies on children which are offered to us are well motivated, valuable, and proper. It must be remembered, too, that there is a real sense in which it is unethical unnecessarily to impede research which advances knowledge of childhood disease and its cure, or which promotes child health.

Reference

- ¹Skegg, P. D. G. (1977). English law relating to experimentation on children. *Lancet*, 2, 754-755.