Editorial

Archives of Disease in Childhood, 1973, 48, 751.

The ethics of research involving children as controls

The editors of medical journals have been strictly enjoined to ensure ‘that their journals contribute to the maintenance of high ethical standards in research and treatment in man’ (Statement of European Association of Editors of Biological Journals, 1972), and more specifically ‘that no paper should be accepted for publication if there are any doubts’ that ethical requirements have been fulfilled (Statement by Medical Research Council, 1962). Some 6 years ago, under the title ‘Treatment-Research-Experiment?’¹, we discussed the peculiarly difficult ethical issues which may be raised by research involving infants and young children. In the intervening years we have continued to be faced with decisions of great difficulty when offered a paper judged to be scientifically acceptable but ethically at least debatable. It seems worth while, therefore, to try again to clarify some of the issues, of which none perhaps are more controversial than those which relate to ‘investigations that are of no direct benefit to the individual’, to quote the M.R.C. Statement. In this category a special case is the investigation involving children as ‘controls’, as the understanding of a disease process so often demands comparative observations on individuals who are either normal or who are receiving medical attention for some unrelated condition.

This sensitive problem the M.R.C. Statement manifestly failed to face, leaving the matter in the air by merely setting out a purely legalistic view. In effect the conclusion was reached that in this country no parent has any legal right to give permission for any procedure to be carried out on a young child which is of no benefit to that child. Disagreement with that interpretation of the law has been voiced by some who have looked at the matter critically², but in any case the question still remains, What constitutes a procedure in this context?

A research might involve twice-daily weighing of babies in a maternity unit where this was normally done less frequently. It might be argued that this procedure both caused the baby some discomfort by interfering with his sleep, and marginally increased the hazard of the nurse slipping and injuring the baby she was carrying, so that the procedure could not be ethically countenanced. Nevertheless, if the research seemed likely to point to ways of ultimately improving the ability of the mothers of other babies to breast feed them successfully, nearly everyone would no doubt accept the research as proper, even laudable. We have taken, perhaps, a far-fetched example, but the point is made that a value judgement has been involved. If weighing a baby is a procedure causing trivial discomfort and negligible risk and is therefore acceptable, what about a single skin prick? or a venepuncture? or two venepunctures? and so on.

Whether or not these procedures are acceptable must depend, it seems to us, on whether the potential gain to others is commensurate with the discomfort caused to the individual. The freedom of today’s children from being killed or maimed by infection with poliomyelitis, to take only one example of many, has been gained by past research that involved taking blood samples from many normal children. The small but not negligible pain or distress to those children, though of no direct benefit to them, was never at the time a matter of question because of the clearly immense potential benefit to others—in short, the risk/benefit ratio was low.

Despite all the difficulties then, it seems ineluctable that the ethics of paediatric research must, in many cases, continue to involve a value judgement. Value judgements are not absolute, but depend on the prevailing climate of opinion. During the past decade or so two shifts of opinion in this field have been discernible. The first was a move towards a more restrictive ethical code typified by the M.R.C. Statement quoted, which, if it had been strictly observed, would have totally ruled out large areas of important research involving children. Perhaps this should now be seen as an understandable, though exaggerated, response to the shocking disclosures after the war of the inhuman experiments that had been carried out during the Nazi period.
More recently many have come to see this extreme position, like most extreme attitudes, as running counter to common sense, and liable to do real harm, by preventing studies which are both ethical in spirit and likely to benefit humanity in general without real risk to the individual. As a result, it is easier today to take a compromise attitude (which we do not believe compromises important principles), an attitude which we can see reflected in such recent discussions of the matter as those in the British Medical Journal\(^3\) and the New England Journal of Medicine.\(^4\) But having accepted that there are no absolute values, and that a value judgement has to be made, who is to be the arbiter of that judgement?

The fairly wide adoption of the idea of each medical centre having its own ethical committee goes far towards providing an answer; and we believe that few of the reports of research we have had to refuse on ethical grounds had been scrutinized by such a committee.

While the Editors of the Archives take most seriously the responsibilities outlined in the quotations at the beginning of this Editorial, our influence is necessarily limited. When we refuse a paper on ethical grounds, the work has already taken place, and though the authors may now have a clearer idea of what we regard as acceptable, no one else will, and this includes other potential research workers who might be contemplating a similar study. The hospital ethical committees, who review studies before they are started, are in a far better position than we to influence the conduct of research. We have occasionally asked an author to excise the unethical component of a piece of work, but again the resulting emasculated report, gravely weakened as it usually has been by the exclusion of the essential ‘controls’, has served merely to display the inadequacy of this compromise. Alternatively, we have sometimes invited an author to agree to our adding an editorial note to his paper, pointing out that there has been a difference of opinion on the ethical propriety of the publication. Not unexpectedly the authors have usually declined.

Curran and Beecher\(^2\) in their closely reasoned article on ‘Experimentation in Children—a Reexamination of Legal Ethical Principles’ (in the United States and England) finally concluded, ‘children under 14 may participate in clinical investigation which is not for their benefit where the studies are sound, promise important new knowledge for mankind, and there is no discernible risk’. With this view we concur, adding only the necessity for informed parental consent.

References