Editorial

Treatment—Research—Experiment?

How deep is the gulf between the doctor as therapist and the doctor as investigator? In undertaking their separate tasks both seek to induce change and to observe effects. The investigator places great emphasis on prolonged control observations and likes to introduce one variable at a time; the therapist may be forced by his experience and his ethic to prescribe several remedies, bed-rest, operative interference, and a multiplicity of drugs, all at one time. The debating points, therefore, which the investigator may score over the therapist are harsh. The doctor, he says, is willy-nilly doing an experiment when he gives a drug to a patient, but if he gives it without adequate observation and control then he is merely doing a bad experiment, which moreover may perpetuate a useless form of therapy or even be responsible for iatrogenic disease. The doctor, on the other hand, knowing he must prescribe, and feeling that he is at least trying to do good, is liable to accuse the investigator of indulging in idle curiosity and often of undertaking experiments which have no particular value to the patient.

Yet the difficulties of the investigator of the human subject, if his ethics are above reproach and his scientific standards are high, are legion. Compared with the physiologist working with the experimental animal, he is hopelessly handicapped, but may, at the same time, look with envy on the doctor, free as he is to indulge in extensive investigations, providing they can be said to be necessary to establish a diagnosis or to guide treatment.

These general thoughts bear with perhaps special force upon paediatricians who are concerned with the newborn. This period of life being in countless ways unique to itself, it became incumbent upon paediatricians to work out the details of neonatal physiology, immunology, haematology, and so on, and to establish normal ranges for biochemical values under varying conditions, if only to provide themselves with a proper basis for treating the sick infant.

Thus, much valuable research effort in the neonatal field over the past two decades has necessarily come into the category of ‘procedures not of direct benefit to the individual’, to quote from the Medical Research Council’s memorandum on Responsibility in Investigations on Human Subjects (1964). When the clinician and the researcher are different individuals, the issue is clear; the doctor is in charge of the patient and will lean on his medical ethic to decide what is and is not allowable. But one individual may have the ultimate responsibility in both spheres. What then? In the last resort there can be no substitute for the conscience of the individual. The M.R.C. memorandum, while affirming this principle, goes on to add that amongst those who bear a special responsibility for ensuring that irreproachable propriety, which alone suffices where investigations on human beings are concerned, are the editors of medical journals.

When assessing, in this context, the suitability of papers submitted to us for publication, two principles will always be applied. First, when any procedure not in the ordinary course of medical care is contemplated, parental consent should be obtained, and this needs to be clearly stated in any published work. And here the M.R.C. memorandum falls short: with endless possibilities for unconscious, or even conscious, deceit, the protection of the public will admittedly continue to rest upon the maintenance of a collective tradition for honest dealing, and, once again, in the last resort, upon individual conscience.

Secondly, no new therapeutic procedure should be applied to patients until the principles that it involves have, as far as practicable, been tested, and its hazards assessed, by animal experiments. Application of this principle would, for instance, have obviated the humiliating phase of intragastric oxygen.

A final point may be made. The climate of opinion changes, and no set of rules can be considered absolute; the investigator, if challenged, should be prepared to justify his actions before his colleagues, and should gain their agreement in formal conference.