

Editorial

CLINICAL TRIALS

*You needn't ever break the Oath
To study vitamins and growth.
But if you give a man a pill,
Just see it doesn't make him ill.¹*

TO wish to test the efficacy of the remedies that he prescribes is to the doctor one of the most natural things in the world. The family physician has a duty to ensure that what he orders for the treatment of his individual patient is suitable for that patient. There is, and must always be a system of trial and error, based on the clinical condition and investigations of the pathology, biochemistry and bacteriology of the disorder, on the physician's knowledge of the potency of the remedy, and to a large extent on the predilection of the prescriber.

Often, too often maybe, the pathology of the patient can only be incompletely investigated. The patient has come to his doctor for relief of his symptoms and expects to get just that. Frequently the symptoms indicate no major disorder and prolonged investigations are not necessary. The choice of a remedy is then conditioned by the prescriber's knowledge of the action of the drug he uses, and this is based on experience and information acquired from 'write ups' gleaned from the periodical medical press and from the blurbs of the manufacturers. The papers published on the efficacy of remedies—clinical trials—are of varying standards and to the casual reader carry little conviction. The manufacturer's literature suffers from the knowledge that its object is to sell the preparation.

To practise scientific therapeutics today is not easy. The family physician is finding it more and more difficult to trust his own judgement. Yet in the corridors of his memory linger the questions: What clinical trials did the Jesuits make of the bark? What planned assessment did William Withering make of the secret of the foxglove that he learnt from the old dame in the distant Gloucestershire village? What indeed? Would digitalis be used today on such evidence as Withering produced? Are not chance observations as valuable now as they were 200 years ago? Surely, yes. Witness

the discovery of the benefit of ephedrine in the treatment of myasthenia gravis by Harriet Edgeworth.

Having said all this, it must be admitted that the clinical trial is a necessary thing. The purpose of this note is to warn those who are tempted to undertake such an exercise of the dangers with which they are faced. We quote from a paper in the *Clinical Trials Journal*² on "The clinical trials protocol". "The choice of clinical trial designs is wide: Uncontrolled or controlled, what sort of control (active or inert), open, single-blind or double-blind, comparative groups or crossover, matched pairs or matched groups, open ended or close ended sequential. The selection of the appropriate type of trial is dependent on the aims of the study." There it is in a nut-shell. The brave and determined, having made his choice of method, will find his difficulties have not yet been overcome. Is the trial ethical? Should the patient be told that he is the subject of an experiment? Is it proper that the doctor should not know the treatment being administered to his patient? It is just as important to ensure that an ethical rule is not being broken as it is to make perfect the statistical design. So long as the ethical proprieties are strictly observed an imperfect trial will hurt no one though it will damage the reputation of the experimenter. The ethical problems of clinical trials were well described in 1963 by Sir Austin Bradford Hill in his Marc Daniel's lecture to the Royal College of Physicians.³ No one should attempt to undertake a clinical trial, however simple the object may seem without having a very good reason for making the enquiry and without taking the very best advice that he can get. The research committee of Council and the Records and Statistical Unit of the College are always willing to advise on these and similar problems.

REFERENCES

1. Watson, G. I. (1953). *The Practitioner*. 171, 302.
 2. *Clin. trial J.* (1968). 5, 951.
 3. *Brit. med. J.* (1963). 1, 1043.
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