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# Informed Guinea Pigs

By Joshua Lederberg

MODERN, scientific medicine rests on controlled observations of human beings. Every person whose health and life has been improved by medical care is indebted to a previous patient who undertook some risk in an experiment for the benefit of his fellows.

Science  
and  
Man

Clinical experimentation poses some of the most poignant dilemmas of the scientist's responsibility to society, but the responsibility is shared by everyone who benefits from modern drugs and advanced surgery.

Intemperate attacks have lately been leveled against clinical research, since we do not yet have workable norms. Nevertheless, for every patient who may have been abused by some insufficiently regulated clinical trial, a thousand patients suffer by being untreated or maltreated with scientifically unsound or less than ideal drugs and procedures.

In a society dedicated to personal liberties, no one should be subjected to arbitrary risks against his will. Hence, every responsible physician and clinical investigator would support the principle of knowing consent as the basis for recruiting subjects into research studies which involve significant new risks.

THE CRITERION of "informed consent" is, however, still controversial. Its application to situations involving trivial risks may frustrate the experimental design for a trivial advantage of personal security. Equally important, informed consent requires an understanding of experimental medical science that goes far beyond the training of most laymen, and sometimes of the investigators.

Will it be necessary for every patient to have the advice of counsel before a physician uses any technique unknown to Hippocrates? Some criticisms of sophisticated medicine could be answered only by such an absurdity.

The ethical issue rests in part on the vagueness of the patient's moral responsibility for participating in medical progress, in contrast to the reality of his motives and legal rights to protect his body.

How much information must a person have before he could "prudently" risk his life? To take an unhappy example, it is plain that astronauts have volunteered to undertake one of the most hazardous of occupations, but did their informed consent reach to the perception that trial runs on the ground might be more hazardous than spaceflight?

Yet far more detailed criteria of informed consent are being proposed for medical research, with grave penalties for physicians and institutions who would substitute their own moral judgments for legally airtight forms.

RISK IS PART of life, but the purpose of medicine is to mitigate hazards. No subject should be asked to make any sacrifice that could be avoided, and especially so if the essential aims of clinical investigation can still be achieved. The very expression "risk" brings to mind "insurance," and there is an important step that we could take to rationalize the participation of human subjects.

Besides giving their knowing consent, they should be insured against the potential hazards, the cost of premiums being accepted as a plausible charge to the re-

search projects. A subject who has possibly suffered damages in an experiment should not have to sue for redress on a claim of culpable negligence or fraudulent misinformation, no more than should an industrial employe in a potentially hazardous occupation.

The registration of subjects for appropriate levels of insurance would become a self-enforcing system of control, particularly if the patient were required to endorse the registration. It would then be a cause of action if a patient were enticed into an experiment without being insured at a level appropriate to his risks.

The cumulative costs of the premiums would discourage the overexposure of patients to risks beyond the significance of the expected results. Above all, the insurance concept would provide a basis of evaluating the rights of the patient-subject, for which informed consent might be an ideal but practically unworkable alternative.

Research-risk insurance might be attacked as adding to the costs of research. However, these costs are already paid, in the currency of the risks taken by the subjects, and this is an unfair burden that should be accepted by the whole community.

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