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A PERSPECTIVE FOR CONSIDERING THE MORAL, LEGAL, AND ETHICAL PROBLEMS ARISING FROM ADVANCES IN MEDICAL SCIENCE

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A REVIEW of the manner in which advances in the medical sciences evolve is helpful in appraising the moral, legal, and ethical problems arising from them.

Attainments in medicine usually emerge from basic working hypotheses. These are conceived from realignment of established theory or fact, an extension of conventional thinking or fresh reasoning. However structured, working hypotheses at best remain logical premises until confirmed experimentally.

The cupboards of imaginative medical scientists are filled with working hypotheses. Their fate resides with the results of controlled investigation. Some give rise to a more precise understanding of the fundamental contest between health and disease or to significant improvements in recognizing and treating illness. The majority are destined to be discarded, their false promise laid bare during the testing period. Regrettably, because of defaults in performing or interpreting the inquiry, an occasional one is mistakenly accepted as fact.

A classic example of such an error occurred early in this century and involved the use of digitalis in treating pneumonia when antibiotics were unknown. The working hypothesis proposed that since digitalis increased the vigor of the heart as a pump, it should be useful in supporting the circulation of severely stricken patients. The logic was so disarming, the premise was accepted as fact without further question. In time it became clear that the toxic effects of digitalis offset pharmacological benefits in patients with pneumonia and decreased rather than increased the likelihood of recovery. However, until this was documented a serious clinical misadventure had matured.

Working hypotheses vary in complexity. The premise in organ transplantation is quite unsophisticated. It holds that it should be possible to replace a hopelessly diseased organ with a sound one and in so doing save a threatened life. In a society replete with one type of appliance or another, the philosophy is reasonable. Who would discard an automobile because of fouled spark plugs? However, a number of intricate matters are involved. The surgery of organ transplan-

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tation differs from ordinary procedures. Organs must be removed from donors with major vascular channels and, in some instances, nerve fibers intact. Implantation in the new host must be accomplished within narrow time limits because preservation of tissue is an uncertain science. Anatomic union must be exact. Unless transplants are taken from donors whose blood and tissue types closely resemble those of the recipients, they are rejected as foreign matter. In brief, the simple concept embraces a host of details which extend to and beyond the current frontiers of knowledge.

Regardless of character or complexity, working hypotheses must be submitted to controlled investigation. In many instances, they can be tested satisfactorily with bench laboratory procedures. In the life sciences, however, the majority require animal and human experimentation before they are confirmed or discarded. Although moral, legal, and ethical problems rarely reside in the context of the hypothesis, they do develop during the testing period and pertain, in the main, to the propriety of using living creatures in the pursuit of knowledge and the manner in which this is accomplished.

The problems arising in animal investigation obviously are less significant than those encountered when humans are used as test subjects. They cannot be ignored, however, particularly in a society where prevention of suffering and preservation of life is treasured in most living creatures. Government and private agencies have combined to prevent and minimize these problems by proposing and enacting into law standards of excellence for the custodial care of animals and the conditions under which experiments should be conducted. These regulations vary greatly in different states. In many research communities regulations are stringent enough to require the employment of veterinarians who supervise the health and welfare of the experimental animal. At the very least regulations awaken interest in the prevention of cruelty and needless suffering. Failure to honor standards of excellence may result in forfeit of supporting funds from government agencies or the enactment of punitive measures.

The morality and legality of investigation using human subjects has not been resolved with equal ease. Traditionally, the responsibility for all phases of clinical investigation rests with the life scientist. He is responsible for initiating and setting up the conditions for the inquiry, selecting patient material, making observations, recording results, and defining conclusions. Because he is entrusted with all of these essential details, the life scientist is forced to balance the risks endured by the test subject against the information sought and, on the basis of this appraisal, initiate or abort the investigation.

Although the traditional responsibility of the clinical investigator is grave, he has developed an impressive record of sound and careful judgment. Over the years, morality and ethics have been safeguarded because his effort is structured on a disciplined dedication to the cause of humanity.

Legality, on the other hand, is honored through the ritual of informed consent. An individual qualifies as a test subject when, having been clearly informed of the intent, nature, and inherent risks of the investigation, he voluntarily agrees to participate. Remarkable advances in medicine, penicillin, the Salk vaccine for poliomyelitis, and the heart-lung pumps, for example, have matured under the direction of life scientists who faced the moral, legal, and ethical problems of their projects guided only by conscience and the objective sought.

Again, according to custom, prospective and ongoing human investigation seldom are exposed to public view. A firm code of ethics holds the matter of clinical experimentation inviolate until the purpose is realized or lost. When a working hypothesis evolves into definable fact, it then is revealed through scientific channels first to the profession and then to the general public.

For some time the traditional posture of clinical investigation has been changing. Perhaps more than any other single factor the influence of the mass communications media has been responsible. It has energized public interest in health matters particularly in the prevention, control, and treatment of the major diseases with which modern society is afflicted. In the course of events, the sanctuary of the life scientist has been invaded and he has been placed in open communication with the public. This has not occurred without the subtle and overt cooperation of the investigator who, convinced of the propriety of this new relationship, or for other more obscure reasons, has encouraged an open line to the community. However, as a consequence, his intent, role, privileges, and responsibilities have become available for critical evaluation.

Organ transplantation has progressed only to the point of clinical investigation. Indeed there are those who contend that human experimentation is not warranted as long as the mechanism of tissue rejection is poorly understood and cannot be effectively prevented. Even if this significant difference of opinion is set aside, organ transplantation cannot be regarded a proven form of therapy. With the first experimental ventures the public has been indoctrinated by the news media in the progress of transplantation, first of the kidney, then of the liver and heart. Each attempt has been methodically recorded and the results documented in full public view. Regrettably, this exposure has oc-

curred even though the public had not been trained to recognize the difference between clinical investigation and proven treatment. This inadequacy has led to total confusion regarding the nature of the moral, legal, and ethical problems which are claimed to exist.

At this moment the propriety of human experimentation, the conditions under which it is to be performed, and the safeguards which must be provided for subject and physician alike comprise the only essentials for debate. These matters are complex enough without confusing them with the problems which will arise when organ transplantation is judged fit for general application. Clinical investigation using human subjects is essential for the future development of the life sciences and the health of mankind. Patients may be submitted to experimental procedures when the only expectation is advancement of knowledge. They may be selected when some therapeutic benefit is also expected. Finally, individuals may be chosen in whom the major expectation is therapeutic benefit and advancement of knowledge is but an incidental bonus.

Today renal transplantation is more therapeutic than experimental, reflecting the progress that has been made in developing the science. Liver and heart transplants, however, must be considered more experimental than therapeutic because, aside from the question of tissue rejection, a host of imponderables remain regarding the ability of these organs to continue normal function in a new host.

If the experimental phase of organ transplantation continues, the question arises whether the institution of regulations for human investigation will advance the science and protect the dignity and health of the human being more adequately than the self-discipline of the scientist responsible for the project. Based on the record of transplantation, it appears quite clear that decisions as to life and death, informed consent, and every other pertinent detail regarding clinical investigation can properly reside within the prerogative of the scientist and should not become a matter of public concern and governmental policy until that time in the development of the technique when it is judged fit for mass application.