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Human Experimentation

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HUMAN EXPERIMENTATION

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Since we use patients to ultimately test our drugs, we are naturally faced with moral and ethical values. Medicine has always honored the precept as contained in the Hippocratic Oath, that the doctor works in the close interests of his patient. Indeed, in the American Medical Association's Judicial Committee's principles of medical ethics, it is stated that a single rule governs the entire medical profession. It is crystallized in the word "interest." The interest of the patient. In the Declaration of Geneva in the conclusion of the Nuremberg Trials in 1948, *it is stated that the "health of my patient will be my first consideration and interest."*

Indeed, Pope Pius XII has also, in a discussion of the histopathologists in 1952, *stated that "Man is a personal individual with dignity, and this dignity must not be subordinated to the community."*

In the scientific community there are two types of experiments in terms of objectives and these are challenging. We will have to put them up as challenging questions to Father O'Donnell.

The two types of experiments are: 1) *the experiment designed just to verify a theory or an assumption. How far can we go? What risk can we take? On the other hand, there are the experiments of a therapeutic nature which, indeed may benefit the patient individually at the time the drug is given, and this benefit may actually provide us with further knowledge.*

We must ask ourselves a fundamental question: *Is there ever a time when the desire to advance knowledge alone will coincide with the benefit that an experimental subject might derive in a theoretical sense only?*

The question of consent comes up, whether it should be informed, and to what extent; and lastly the question: *Is there a code to serve the interests of mankind and of science at the same time.*

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VINCENT J. COLLINS, M.D., *Moderator*

Human experimentation is an aspect of medicine which has aroused considerable moral speculation both on the part of the moral theologians and on the part of the medical profession.

Medicine, of course, is an empirical science, and every difficult case is likely to have some aspects of experimentation in its therapy. In a certain sense the very idea of a differential diagnosis implies some degree of experimentation. But it is not in this every day context of medical trial and error that the moral problem arises.

Nor is there any acute moral difficulty in what might be termed the "do or die" experimental procedures which

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can be extremely dangerous in themselves and the outcome of which may often be extremely doubtful, when such experimental procedures are employed as a "last ditch stand" in terminal and rapidly deteriorating types of illness.

Such, for example, would be the case of a very delicate and dangerous brain operation on a patient who is already doomed to proximate death due to a brain tumor. In such a case the patient has really nothing to lose, and everything to gain if the experiment should be successful. Such "one last attempt" procedures, when they hold out some real hope of success, even though it be slim, are obviously acts of wise administration.

The Problem

The real problem arises in the research laboratories, where procedures and remedies which have been tested on experimental animals must finally be tried on human subjects.

When the experimental procedure is fraught with real danger of serious injury or even death, and the experimental subject is a healthy individual in whom disease must sometimes be first induced; or when the subject, even if already afflicted with some illness, is not in any terminal stage; the morality of such an experiment must be tested against our concepts of man's limited dominion over human life, and against the basic concepts of right order.

A Definition of Medical Experiment: By the term "medical experimentation" in the present discussion of its moral implications as applied to human subjects is understood those medical or surgical procedures which are recognized to involve some degree of danger and which are experimentally applied to the individual subject, not so much in his own interest as in the interest of humanity through the advance of medical science.

The moral implications of this sort of experimentation can vary according to the various methods of procedure on various types of human subjects.

With regard to experiments which are performed upon people who are in good health, we must distinguish between those procedures which merely involve testing the reactions of new and potentially dangerous drugs in the normal human being and those which also involve the process of first inducing some disease in the healthy individual as part of the experiment.

With regard to experiments which are performed on people who are already ill with reversible disease, we must distinguish between substituting an experimental remedy in place of proven therapies which are available, and proceeding along experimental lines because there is no proven therapy for the disease.

Finally, with regard to the chronically ill, we must distinguish that type of experimentation which we might call "incidental," in the sense that it is unrelated to the specific illness, or at least not directly concerned with the present malady, but is directed toward some other contribution to medical knowledge.

Moral Aspects of Human Experimentation

The moral aspects of such experimental procedures are primarily concerned with: (1) justifying the concept of a directly intended mutilation for the benefit of medical science in the light of the principle of totality; and (2) justifying the exposure to the danger involved in the experiment in the light of man's limited dominion over his own body. These two moral implications can be pin-pointed as—

the element of danger and the element of consent.

General Principle I: Medical experiment which involves a directly intended suppression of an organic function or the quasi-mutilation of the organ itself is not immoral for that reason, provided that the mutilation is not serious or the organic functional suppression is not of a serious nature—or at least, if it is extensive, is not permanent.

This activity in the service of humanity which inflicts some minor or accidental mutilation, or involves the danger thereof, would seem to be within the concept of man's restricted and useful dominion over his own substance which right order demands. In other words, considering man in himself and in his relations to other men, such an act would seem to come under the concept of "wise administration" and not flow over into the concept of "absolute ownership."*

Moreover, in his address of September 14, 1952, on "The Moral Limits of Medical Research and Treatment," Pius XII, dealing directly with the principle of totality, spoke as follows:

"The patient, then, has no right to violate his physical or psychic integrity in medical experiments or research when they entail serious destruction, mutilation, wounds or perils."

General Principle II: Where there is question of a procedure which carries with it considerable danger of serious mutilation it is evident from the principle of totality that to directly intend such a mutilation or such a procedure, in the interests of medical experimentation, is outside of man's restricted and useful dominion over his own body and is contrary to the immanent teleology of the parts thereof.

Such an act must be looked upon as one of absolute ownership rather than one of wise administration.

The distinction between administration and ownership here is as difficult to describe as it is important. As the danger connected with the experiment increases we reach a point where the entire moral object of the act changes, and an act which could have been classified as one of wise administration, and therefore permitted, becomes a completely different act—an act which would be proper only for an absolute owner, and therefore an immoral usurpation of an exclusively divine prerogative.

Administration or Ownership?: Danger can be defined as the objective probability of incurring some evil, and in the realm of medical experimentation we would say that the objective probability of so compromising the patient's physical or mental well-being and integrity that ordinary men would judge the probable risk to be a considerable one, and would consider the probable result as a serious affliction, would take the experimental act out of the realm of administration and put it into the category of ownership.

Danger can be more or less serious according to the seriousness of the evil which might be incurred as well as according to the greater or lesser probability of incurring the evil at all.

Rules for Human Experimentation

With these two basic principles in mind we may lay down certain definite rules for the guidance of medical experimentation on human subjects:

1. The human subject must be made aware of the full extent of the risks involved in the experiment and he must freely consent to the entire procedure.

The preliminary is explicitly de-

*Blood transfusing and skin grafting, voluntary exposure to the common cold, procedures involving excessive diuresis or temporary frontal cortex suppression would be examples of such minor mutilations or quasi-mutilations.

manded by the American Medical Association in its directives regarding proper procedures relating to human experimentation and is likewise stressed by Pius XII in the following words:

"In the first place it must be assumed that, as a private person, the doctor can take no measure or try no course of action without the consent of the patient. The doctor has no other rights or powers over the patient than those which the latter gives him, explicitly or implicitly and tacitly. On his side, the patient cannot confer rights he does not possess. . . ."

2. All safeguards must be employed to protect the patient from injury.

This rule includes the supposition that the experiments have been first tested on animals, that the experimenters are qualified scientists, and that all accessory precautions are at hand to avert danger, counteract harmful effects, or terminate the experiment should the need to do so arise.

The Judicial Committee of the American Medical Association include this second rule under their requirements as follows:

". . . (2) the danger of each experiment must be previously investigated by animal experimentation, and (3) the experiment must be performed under proper medical protection and management."

3. A dangerous experiment is not to be undertaken unless the results cannot be obtained by other methods of study and no experiment should be undertaken when there is real reason to believe that death or serious injury will result.

The reasoning behind this third rule is based on the fact that the danger connected with a legitimate experiment is not intended by the experimenters. Precisely as danger, it in no way contributes to the good accomplished by the experiment and thus, in its moral aspect, it can be approached under the principle of double effect. And under this principle one cannot reasonably permit an evil effect if the intended good can be reasonably obtained in some other way.

Moreover, in the application of the principle of double effect in medical experimentation, there must be a special emphasis on the need to evaluate the proper proportion between the good intended and the evil permitted.

Certainly some experiment-connected danger may be permitted, but it must be remembered that the proportion here is between the good accruing to the commonweal in general, through the advance of medical science, and the evil of the danger of injury to an individual member of society.

In estimating the proportion between the good thus intended and the evil permitted, the scale is already heavily weighted in favor of the individual subject of the experiment; and a possible contribution to the common good, though not without its importance, weighs lightly against serious harm to a given individual. This is so because society in general, or the common good, exists for the individual, not vice versa. It is true that in the event of impending common catastrophe the common good prevails over the individual good; but this is only because the common good must be preserved in the interest of many individuals, and not because the common good is an end in itself.

Moreover, once the danger has reached that degree of seriousness which makes the experimental act cease to be one of administration and begin to be one of absolute ownership, there can be no question of applying the principle of double effect at all,

since the moral object of the act itself has become evil. Danger should not exceed the meaning of moderate. There are several variables in the analysis of moderate danger. There is a qualitative variable and a quantitative variable. If you will, these are coefficients.

An Invalid Distinction: The various secular codes of morality regarding medical experimentation, such as the directives of the American Medical Association and the decisions of the Nuremberg Medical Trial, agree substantially with the three basic rules listed above. Some of these secular codes, however, while condemning the type of experiment wherein there is reason to believe that death or disabling injury will result, strongly imply that even these might be permitted provided that the experimenting physicians themselves also serve as subjects. This distinction is completely illogical, as Pius XII has pointed out in the following words:

"What pertains to the doctor with regard to his patient is equally applicable to the doctor with regard to himself. He is subject to the same broad moral and juridical principles as govern other men. He has no right, consequently to permit scientific or practical experiments which entail serious injury or which threaten to impair his health to be performed on his person; and to an even lesser extent is he authorized to attempt an operation of experimental nature which, according to authoritative opinion, could conceivably result in mutilation or suicide. This also applies, moreover, to male and female nurses, and to anyone who feels himself disposed to offer his person as a subject for therapeutic research. . ."

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