Correspondence

Patient Consent

To the Editor: The statement concerning patient consent attached to the paper "Measurement of Anti-Arrhythmic Potency of Drugs in Man: Effects of Dehydrobenzperidol" (ANESTHESIOLOGY 28: 318, 1967) presents a remarkable new interpretation of an investigator's responsibilities. It departs so sharply from the traditional view that I beg leave to quote the statement in its entirety:

"The problem of obtaining valid consent always exists in an experiment performed on human beings. Despite the fact that all of our subjects were interviewed before the study and the procedure explained, we believe that an informed consent cannot be obtained for a study of this type, because of the impossibility of transmitting to a patient both the relevant information and the *background* needed to analyze and evaluate such information. Instead, *we have accepted the role of guarantor of the patient's rights and safety:* (1) only physical status I is acceptable; (2) inhaled cyclopropane concentration must not range beyond 20–30 per cent; (3) respiratory acidosis must be prevented; (4) starting dose and rate of administration of epinephrine must be the minimal one, 3.6 μg./minute in these experiments; (5) the infusion is terminated when an arrhythmia appears."

In my opinion, the problem of obtaining a patient's valid consent for experiments on his or her person is not solved by an investigator who side-steps the problem and, instead, assumes "the role of guarantor of the patient's rights." To begin with, there is an obvious inconsistency between the claim to guarantee the patient's rights and the failure to honor the foremost of those rights, the right to exercise informed consent or dissent. A guarantee of this sort is nugatory. Further, the role itself implies infallibility, as if the investigator can always guess correctly whether the patient would consent to the procedure if she fully understood the nature of the experiment.

Neither is it possible for an investigator to guarantee the patient's safety. A physician cannot guarantee the outcome of an experiment he performs on a patient; he can reduce the risks or render them negligible, but he cannot eliminate them. Indeed, this is one of the reasons for the common rule that at the start of a new study the experimenter himself goes first, followed by his colleagues. But the question at issue is not really whether the experiment is safe, the question is, does the patient want to have it done?

Investigators, however conscientious, do not have the right to infringe the prerogative of the subject to exercise informed consent. The patient, it is universally held, is entitled to make his or her own decision and, if an informed decision demands rather a lot of information, the investigator is in duty bound to take the trouble to impart it.

I have deliberately refrained from commenting on other ethical aspects of the experiments performed by Long, Dripps and Price. I contend that what is at issue is not the opinion of the investigator or reader about the merits of an experiment. What is at stake is the ordinary patient's right to her own considered decision concerning projected experiments on her person, and to the information necessary to make such a decision. If the information cannot be given, the experiment should not be carried out.

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To the Editor: Thank you for the opportunity to reply to Dr. Fink.

The ethics of "human experimentation" is receiving much attention. We have been involved in this for almost three decades and think that we have developed a responsible, but practical approach.

Informed Consent. Dr. Fink seems not to have understood the second sentence in the quotation. The patients were given every opportunity, and had of course, every right to refuse consent. The majority acquiesced to the proposed study.

Dr. Fink admits that it is difficult—we believe it impossible—to conduct an interview so that consent can be granted on the basis of complete knowledge. He suggests that one offer "rather a lot of information." With this we agree. But where does one begin and end? Does Dr. Fink believe, for example, that one should inform patients about to receive fluids by vein that thrombophlebitis may result, a thrombus form, and that an embolus may lodge in the lung and prove fatal? Or must he warn that one patient in every 45,000 may die from an anaphylactic reaction to an aspirin tablet?

Being concerned that patients may grant consent either because they trust their physicians completely, or because they are fearful of offending those who care for them, we have turned increasingly to volunteers. The disadvantages of this is that studies are limited to essentially normal, usually young and almost always male individuals.

Guarantor. We believe it essential, that insofar as it is humanly possible, the clinical investigator be *responsible.* This means to us establishment of the safest possible protocol, interruption of a study should an untoward event occur, and constant awareness of a plan of resuscitation (with tested equipment and competent personnel available at all times) should a catastrophe develop. All this we do. Furthermore, studies conducted on individuals receiving general anesthesia require a guarantor. The patient himself cannot request that the study be stopped, for he is unconscious.

The best guarantor might be a third party acting in the role of friend of the subject (amicus curiae). It is difficult, however, to find individuals able to devote the time and possessing the degree of knowledge of the investigators in the area under study.

If Dr. Fink is wondering whether I would have conducted this modest, and in my opinion completely safe study on one of my children, the answer is "yes." Many anesthesiologists are unaware of the relationships in *man* between epinephrine, cyclopropane and ventricular fibrillation, and assume that the latter is always a possibility, the likelihood varying with the bias of the particular anesthesiologist. It is our judgment based upon years of experience that the protocol could not have *caused* ventricular fibrillation in any of the patients selected for study.

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Metabolic Effects of Blood Transfusion: Acid-Base Balance

To the Editor: I am writing in response to Dr. G. G. Nahas' letter (ANESTHESIOLOGY 28: 787, 1967) in which he takes me to task for alleged deviations from fact in my review article, "Metabolic Effects of Blood Transfusion" (ANESTHESIOLOGY 27: 446, 1966).

Dr. Nahas presumes to lecture on the elementary physical chemistry of acid-base balance but is himself either ill-informed or deliberately chooses to distort. At *p*H 6.8, more than 95% of citric acid occurs as fully ionized citrate, and more than 99.9% of lactic acid as lactate. Virtually all of the equivalent hydrogen ions, approximately 14 mM/L, are buffered by plasma bicarbonate and by hemoglobin and other protein within the donor red cells, as clearly stated in my review. The rapid transfusion of such blood in which the buffers have been sharply reduced causes acidosis by dilution, again as stated. The data from Foote, Trede, and Maloney, my simplification of which Dr. Nahas criticizes, is introduced as an excellent example of such an acute dilutional acidosis (and not to advocate the use of ACD blood for cardiopulmonary bypass. My personal view that fresh heparinized blood is the preparation of choice for this procedure is stated both at the beginning and at the end of my review).