

useful only for preliminary screening of potentially valuable antimalarials. . . . The decisive evaluation of drugs for the prevention and treatment of human malaria can be done only on man. For a number of years studies of antimalarial drugs were based upon the results of treatment of cases of malaria seen in hospitals. These observations were useful but the variability of the clinical response to natural malaria infections limited their scientific value and much difficulty has been experienced in the interpretation of data from different countries.

In 1942-43 when the acute shortage of quinine showed the vital need to develop new synthetic drugs, a number of experimental studies were carried out on human volunteers in Britain and the United States. The most famous of these experiments were those by Fairley in Australia on approximately 1000 army volunteers deliberately infected with malaria. This work was taken up in the United States by two outstanding malaria research projects that started in 1944 and still continue. One was set up at the Federal Penitentiary at Atlanta (1), the other in the Illinois State Penitentiary near Chicago (2). The stated objective of both projects was to assess the value of promising drugs for the prevention of sporozoite-induced malaria and for the clinical and radical cure of established infections. Those who are acquainted not only with the rules governing the acceptance of the service of volunteers in these two research units, but also with the way the medical and ethical principles are adhered to, can bear testimony to the fact that the health, the dignity, and the freedom of choice of these subjects are protected.

The World Health Organization expressed its appreciation of these studies in terms that are not often used in sober scientific reports (3):

. . . At the present time, human malaria research centres employing non-immune volunteers exist only in the U.S.A. The amount and quality of scientific data obtained in these centres on the characteristics of drug-resistant strains of malaria parasites and on their response to drugs is invaluable, and . . . medical science owes an immense debt of gratitude to the administrators of these institutions, to the research workers concerned, and above all to the courage and devotion of the volunteers.

. . . It seems that straightforward, well-planned and perfectly executed investigations such as those at Atlanta and Stateville on fully informed, healthy

human volunteers are ethically and professionally more justifiable than some trials done on hospital patients without their knowledge or consent.

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References

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2. A. S. Alving, B. Craigie, Jr., T. N. Pullman, C. M. Whorton, R. Jones, Jr., L. Eichelberger, *J. Clin. Invest.* 27, part 2, p. 2 (1948).
3. *World Health Organ. Tech. Rep. Ser.* 296 (1965).

In response to Webb's comments, I have come to the conclusion that no meaningful distinction can be drawn between the experimenter's volunteering for risky research (self-experimentation), and the use of well-informed and highly willing volunteers in general. The crucial issue is not whether the volunteer is the researcher, his research assistant, or a man off the street. The crucial question (and this also applies to Bruce-Chwatt's comments) is: Are there ethical or moral limits of risky research even with fully informed and highly willing subjects? Our Judeo-Christian value system condemns suicide as well as certain types of self-mutilation and risk-taking, and our society has embodied some of these moral precepts into law. I am not sure at what point volunteer research would cross a line into legally or morally proscribed territory, but I feel that in our society, with the values that prevail, there is such a line. If this premise is accepted, it then follows that use of volunteers (no matter who they are, or how well-informed or willing), does not *ipso facto* provide license for risky experimentation. While insurance protection for both researcher and subject is a good idea, I cannot see how incentives such as hazardous duty pay affect the issue of limits to ethically permissible research with volunteers.

There are two minor points on which Webb apparently misread my paper: I fully intended to equate considerations of physical and psychological risk; and I specifically and strongly argued against the notion that informing should include all details or full understanding of the experiment. Only essential elements, such as the types of rights and risks involved, were proposed as indispensable to an informed consent.

The issue raised by Stucki can probably be resolved by drawing a clear distinction between (i) experimentation

designed primarily for the benefit of an individual in a human management situation, whether generalizable knowledge does or does not result from such an experiment; and (ii) experimentation not designed for the benefit of the subject, even though some advantages may (or may not) accrue to him. For the latter type of research on level 1, consent may be meaningless, as no rights may be involved; infeasible, as in studies of traffic flow; or outright undesirable, as in research use of national census data which U.S. residents must provide by law, whether they like it or not. However, I have the impression that Stucki is mostly concerned with the former (clinical management) experimentation. Here, I would agree that those playing human management roles need to learn to better recognize the tentative or unvalidated elements of their practice. They should make greater efforts to inform their clients, or clients' responsible agents, of the risks of treatment or management alternatives, and of the degree to which such alternatives are believed to be valid. An informed consent to submit to such treatments should, indeed, be obtained, but such a treatment consent should be clearly distinguished from a research consent where subject benefits are not primary.

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Military and Academe

Nelson's article on the new chancellor at Pitt has caused me some wonder (News and Comment, 3 Feb., p. 540). Would the same people who were "aghast" at the prospect of having a military officer as chancellor have considered a petition against a lawyer, a Negro, or a New Frontiersman *before* determining his academic qualifications? As a friend and colleague for some 5 years, I know that Posvar and his wife will be a welcome addition to the Pitt scene. I am very sure that if the stigma of serving one's country in uniform for 20 years proves too much for the Pitt faculty, there are other universities who can find a place for him, and for a few more like him who are approaching eligibility for retirement.

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