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Duncan Neuhauser

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Comment

MORE TALES FROM INSTITUTIONAL REVIEW BOARDS

Duncan Neuhauser†

IN 1984, DR. BARRY MARSHALL came to the then outrageous and heretical conclusion that bacteria caused peptic ulcers.¹ Because no one believed him, Dr. Marshall tested his idea by swallowing a glass full of bacteria to see if he would get an ulcer. If he did not get ill, he would prove himself wrong. If he was right, he could become seriously ill.² Dr. Marshall did not consult the hospital's ethics board, violating the established hospital policy, because he thought the board would disapprove of the experiment, calling it "too dangerous."³ After drinking the bacteria, he became ill, recovered and eventually convinced the medical world that he was correct. This discovery led to the publication of 1500 scientific papers worldwide, an effective antibiotic treatment at a much lower cost than existing treatment, the probable future elimination of this disease and a great reduction in stomach cancer mortality.⁴

The institutional review board ("IRB") could have turned Dr. Marshall down, but the world would not have been better off. If denied approval, Dr. Marshall could not appeal the decision. He would have had to move to another hospital and been forced to try again.

† Professor of Epidemiology and Biostatistics at Case Western Reserve University School of Medicine.

1. Terence Monmaney, *Marshall's Hunch*, NEW YORKER, Sept. 20, 1993, at 64, 64 (reviewing the struggle of Dr. Marshall to gain acceptance of his theory by the scientific community and emphasizing the potential loss of innovative research had Dr. Marshall not persevered).

2. *Id.*

3. *Id.*

4. *Id.* at 67.

I wish to applaud the essay *Tales of Informed Consent: Four Years on an Institutional Review Board* by "Bartolo."⁵

IRB committees are required for hospitals receiving federal funds for research. Their role is to review research proposals to determine if informed consent and other safeguards, such as confidentiality, are in place for the research carried out at the institutions.⁶ All this sounds wonderful. However, in reality there are serious problems that can turn these boards into petty tyrannies causing more harm than good. Such problems include no appeal procedure, no due process, negligible public accountability and no agreed upon accumulated body of precedents.⁷

In one hospital, a randomized trial was carried out where some residents were paid money if they ordered fewer laboratory tests.⁸ This trial showed that financial incentives had a modest effect.⁹ Another hospital proposed to replicate this study. However, its IRB vehemently rejected the proposal, stating that it was unacceptable to "bribe doctors not to test."¹⁰ Hence, one board's acceptable study is another IRB's outrage.

It is not uncommon to have studies accepted at one place and not accepted at another. IRB's are established in hospitals in the U.S. which have federal research grants.¹¹ Community hospitals not conducting such research may have no IRB's and

5. "Bartolo," *Tales of Informed Consent: Four Years on an Institutional Review Board*, 2 HEALTH MATRIX 193 (1992) (documenting "Bartolo's" experience as a volunteer attorney on the institutional review board of a hospital for a four-year period).

6. *Id.* at 194.

7. *But cf.* 21 C.F.R. 56.121(a) (1992) (providing that the Food and Drug Administration act as a watchdog over an IRB, removing an IRB's qualifications if it fails to observe federal regulations or acts in a way which is detrimental to the rights of human subjects).

8. Albert R. Martin et al., *A Trial of Two Strategies to Modify the Test-Ordering Behavior of Medical Residents*, 303 NEW ENG J MED 1330, 1331 (1980). First year residents were divided into three groups in order to evaluate the effect of different interventions on test-ordering behavior. One group was the control group, one was offered financial incentives if test-ordering was reduced and the third group was subjected to concurrent chart review. *Id.*

9. *Id.* at 1332-33 (demonstrating reduction in test ordering in both the chart-review and incentive groups with the chart-review having the most significant reduction and long-lasting effect).

10. This information was relayed orally to the author from the President of the IRB in this particular project study. The author requested that the name of the hospital and the IRB President be kept confidential.

11. 21 C.F.R. 56.101(a) (1992) (established to "protect the rights and welfare of human subjects involved in such investigations"); 21 C.F.R. 56.121(d) (1992) (stating that a research grant will not be approved by the FDA if the review is conducted by an IRB or institution which has lost its qualification).

can therefore carry out research not federally funded without the benefit of such review. For instance, regulating physician behavior through finances or other means (as in the above study) will only come before an IRB if it is declared a research project — that is if one wished to learn whether a particular alteration has the effect so desired. Unexamined change occurs all the time in hospitals. A drug is tried on a patient just to see if it works; thus, the line between therapy and experimentation can become blurred.¹²

Today, good management practice calls for empowering employees of an organization by creating ways of improving things, trying out the changes in small experiments, measuring the results and adopting any beneficial change.¹³ This thinking is imbedded in continuous quality improvement concepts which are used in hospitals.¹⁴ So, what constitutes research? A narrow definition of research is a government research grant, while a broad definition is any change examined to determine whether it renders improvements. Apparently, change without the desire to find out what positive effect it has need not be reviewed by an IRB.

The following is an example where one hospital took steps to improve an old practice.¹⁵ At one time, regular nurses and residents managed intravenous fluids ("IV's") for inpatients. It was proposed that a specialized team be organized to manage IV's. If this change had simply been made by management, no

12. Therapeutic experimentation, when used to treat the individual versus when conducted for general research, is becoming more accepted as therapy. See George J. Annas, *Changing The Consent Rules For Desert Storm*, 326 NEW ENG J MED 770, 772 (1993) (discussing the approval of waiving informed consent to use experimental drugs on military personnel during wartime); 21 C.F.R. 50.23(d)(1) (1992).

13. PETER M SENGE, *THE FIFTH DISCIPLINE: THE ART AND PRACTICE OF THE LEARNING ORGANIZATION* 139-173 (1990) (emphasizing motivating the individual employees of an organization as the key to corporate growth, since it is the individuals who carry the potential and energy).

14. See generally MARY WALTON, *THE DEMING MANAGEMENT METHOD* 136 (1986) (exploring the concept of continuous quality improvement and focusing on the elements of customer priority, employee involvement and uncompromising integrity); MARY WALTON, *DEMING MANAGEMENT AT WORK* 83-117 (1990) (surveying nine hospitals committed to continued improvement and quality transformation and revealing that the management at these hospitals focused efforts towards teamwork); HARRY V. ROBERT & BERNARD F SERGESKETTER, *QUALITY IS PERSONAL: A FOUNDATION FOR TOTAL QUALITY MANAGEMENT* 112-130 (1993) (identifying specific activities which can be implemented in order to facilitate efficiency and employee satisfaction in health care organizations).

15. Although this example is taken from a published study, for the sake of anonymity the author requests that no citation be provided.

IRB review would have been required. However, the hospital decided to put the IV teams in place in one unit and not in another in order to compare rates of infection. This decision needed IRB review, which was later obtained. The IRB considered the change in the management of IV's an administrative change, and, therefore, individual informed consent was not required. This was because the treatments provided would not change, but rather the change would occur in who was administering the treatments. The study showed that the specialized teams were more effective. The results were published and went unchallenged.¹⁶ Several years later, in a round of budget cuts, management decided to eliminate the IV teams. If they had proposed a study of the elimination to learn the effects of such actions, the IRB might well have declared the study unethical. After all, there was clear evidence available that showed that teams were better. The proposal would thus deny patients demonstrably better care. Would you be willing to have less skilled care? The IRB might well have demanded individualized consent. However, because management selected worse care without labeling the change "research", the change could be carried out without informing any patient or the IRB review.

Thus we have a double standard of acceptable behavior. Recommendations:

- 1) Recognize that the current system of review is seriously flawed. We should be indebted to "Bartolo" for bringing some of these problems forward.
- 2) Recognize that we do not have a good answer for the review of research and allow a variety of alternatives to exist so that they can be examined.¹⁷ (Be assured that any such proposed change, if you wish to see if it works, will be declared unethical by at least some IRB members).
- 3) Require government funded patient-based research to include the cost of insurance against harm. This would not be unlike the flight insurance you can buy at an airport (so

16. For the same reasons stated in *supra* note 15, no cite is provided for this source.

17. See, e.g., A.M. Capron, *Protection of Research Subjects: Do Special Rules Apply in Epidemiology?*, 44 J CLINICAL EPIDEMIOLOGY 815 (1991), reprinted in 19 LAW, MED & HEALTH CARE 184, 186-89 (1992) (proposing alternatives to informed consent, such as peer consultants, after-the-fact debriefing and informed veto, which serve the same functions of minimizing harm, improving research and promoting autonomy and self-determination).

much money if you lose an arm, etc.). The cost of this insurance would vary with the level of risk of the study and would, therefore, place a market based value on the potential sacrifice made by patients. This idea counters the vested interest of the research establishment which appears to want all the money to go to them and not be diverted to patients. (This is not a slur, but a testable hypothesis, if you could get it through an IRB).

4) Recognize that there are market solutions to this problem. This follows Milton Friedman's writings which oppose all forms of professional licensure.¹⁸ One should not take on a trivial example to show how a market alternative might work.

One patient-based research study using sham operations unbeknownst to the patients involved is often cited as one of the worst American examples.¹⁹ It was a trial of internal mammary artery ligation to reduce the pain of angina versus sham operations.²⁰ Without informing the patients in advance that they were part of an experiment, an incision was made and a random choice was taken to tie off the artery or do nothing. The opening was sewed up and the patient woke up not knowing which decision was made.²¹ The result was that both groups of patients felt less pain. The conclusion was drawn that this surgery was ineffective. The blinding of patients and post-operative examiner was essential to providing this convincing result.²² As a result, this procedure is no longer performed, protecting us from receiving this worthless procedure which was once widely performed.

Let me propose that the real horror story here is that these patients were never rewarded after the fact for their contribution to all our welfare. In today's medical care dollars, they

18. MILTON FRIEDMAN, *CAPITALISM AND FREEDOM* 137-160 (2d ed. 1982). Professional licensure acts as a means of limiting the number of professionals in a given field and hence creates a monopoly. *Id.* at 151. Friedman argues that licensure counters an individual's right to voluntarily enter into a contract and further provides no means of quality control. *Id.* at 147.

19. Ernest M. Barsamian, *The Rise and Fall of Internal Mammary Artery Ligation in the Treatment of Angina Pectoris and the Lessons Learned*, in *COSTS, RISKS, AND BENEFITS OF SURGERY* 212, 212-220 (John P. Bunker et al. eds., 1977) (noting that the outcome of this study increased the favorability of controlled studies and in addition has spurred scientists to question the reliability of standard testing procedures).

20. *Id.* at 216.

21. *Id.*

22. *Id.* at 217-18.

might have saved half-a-billion dollars a year for our health care system. Should each of those nine patients (that's all there were in this study) receive say ten percent of the savings. Perhaps they would receive about ten million dollars a year for the rest of their lives.

A market alternative for a research hospital would be to say that twenty percent of all patients will be experimented upon and compensated handsomely for their social contribution. Possible participation is assumed on elective admission to the hospital. Therefore, if the waiting list for admission is long, the compensation may be too high. If the hospital becomes empty, then compensation is too low.

I put this recommendation forward with no expectation that anyone will rush to adopt it. Rather, I want to provoke deeper thoughts about alternatives to the present flawed approach.