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# COMMENTARY: MEDICAL TECHNOLOGY ASSESSMENT AS SOCIAL RESPONSIBILITY

*Duncan Neuhauser\**

PROFESSOR MEHLMAN HAS done an extraordinary job reviewing the state of the art of medical technology assessment as well as providing a critique of appropriate analytical methods. Doctors Perry and Chu, the other commentators on Professor Mehlman's article, have reviewed the growing number of organizations involved in medical technology assessment in this country. I wish to make the point that data are needed so that these assessments can be implemented.

At the heart of technology assessment in medical care is a conflict between what is good for the individual and what is good for society. There is a social cost that results from our failure to evaluate carefully. But careful evaluation requires a comparison between those who receive a particular treatment with those who do not, and this requires patient involvement.

One of many examples is prefrontal lobotomy, a surgical procedure introduced in 1935 and presumed to benefit mental patients. After tens of thousands of operations, this procedure lost favor in the 1960's.<sup>1</sup> In spite of the lack of evidence of its efficacy, Egas Moniz was awarded the 1949 Nobel Prize in Medicine for pioneering the prefrontal lobotomy. In its heyday in the United States, there were about 5,000 patients per year who had large parts of their brains removed in accordance with this surgical treatment. These patients paid the social price for our failure to rigorously evaluate the efficacy of this technology.

There is another reason why medical technology assessment is desirable. Because I pay for your health care through taxes, social

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1. See E. VALENSTEIN, GREAT AND DESPERATE CURES 280, 284 (1986).

security, and insurance premiums, I want you to have only effective and appropriate medical care—no more and no less.

Evaluation of medical technology is difficult due to at least five obstacles which must be overcome:

*First*, the best methods of evaluation are new. The earliest known Randomized Clinical Trial (RCT) occurred in 1931;<sup>2</sup> RCTs did not become widespread until the 1950's. The first such trial to include a cost analysis was published in 1980. It was not until 1985 that the first trial to measure all benefits, including full costs and patient satisfaction, was published.<sup>3</sup> Old technologies, such as lobotomies, were not evaluated using these new methods.

*Second*, patients differ substantially from each other. The fact that patient *A* with treatment *X* improved, while patient *B* without treatment *X* did not, is not necessarily due to treatment *X*. This reality makes evaluation much more difficult. The accurate comparison between patients with and without treatment *X* requires that the patient populations be defined and uniform.

*Third*, there are the all too human biases of inventors, manufacturers, and users of medical technology. It is desirable that people strive to find a cure for cancer. But, this effort creates the risk that the inventor will become a salesman who, in his own enthusiasm, will convince himself that he has a cure when he, in fact, does not. This problem is greatly exacerbated when the advocate has already, for other reasons, achieved a great reputation. Such was the case with Dr. Wangenstein's advocacy of Gastric Freezing which was eventually shown to be harmful after 1500 machines were sold.<sup>4</sup>

In addition, physicians, in their compassionate desire to help the suffering patient before them, may prescribe a treatment that is demonstratively efficacious for another type of condition but which has not been proven effective in treating the condition at hand. The indiscriminate and inappropriate use of the drug cimetidine provides such an example. The Food and Drug Administration's "yes" or "no" approval system is helpless against this large problem.

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2. See Amberson, McMahon & Pinner, *A Clinical Trial of Sanocrysin in Pulmonary Tuberculosis*, AM. REV. OF TUBERCULOSIS 401 (1931).

3. See Pineault, Contandriopoulos, Valois, Bastian & Lance, *Randomized Clinical Trial of One-Day Surgery: Patient Satisfaction, Clinical Outcomes and Costs*, 23 MED. CARE 171 (1985).

4. See Miao, *Gastric Freezing: An Example of the Evaluation of Medical Therapy by Randomized Clinical Trials*, cited in COSTS, RISKS AND BENEFITS OF SURGERY 198-211 (J. Bunker, B. Barnes & F. Mosteller eds. 1977); Wangenstein, Peter, Nicoloff, Walder, Sosin & Bernstein, *Achieving "Physiological Gastrectomy" by Gastric Freezing: A Preliminary Report on an Experimental and Clinical Study*, 180 J. A.M.A. 439 (1962).

Moreover, human memory is selective. The physician may remember the cures and forget the failures (or vice versa), thus providing a biased view of efficacy. In short, physicians are human beings like the rest of us.

*Fourth*, medical technology, disease, and the environment do not stand still. The decline in tuberculosis from 1850 to 1950 almost certainly had more to do with changing housing conditions than with treatment advances. Comparing coronary bypass surgery with prior and more conservative medical treatment is misleading, because both treatment methods have been improving with time. These changes require concurrent evaluation of the alternatives, necessitating some patients to forego a treatment while a similar group receives it.

*Fifth*, evaluation of medical care technologies establishes the demanding standard that a treatment effect exceed the placebo effect. The placebo effect is created by the patient's belief that a particular treatment will alleviate or cure the medical problem. The placebo effect is very well documented. In 1955, Beecher estimated that a third of the benefits of medical care resulted from the placebo effect.<sup>5</sup> This makes medical care unique among economic markets in that the consumer can maximize benefits of medical care by his or her own ignorance.

To evaluate whether or not the treatment effect exceeds the placebo effect, drug trials may be conducted. These are referred to as "double-blind" trials, because neither the patient nor the physician knows whether any one patient receives the drug or the placebo.

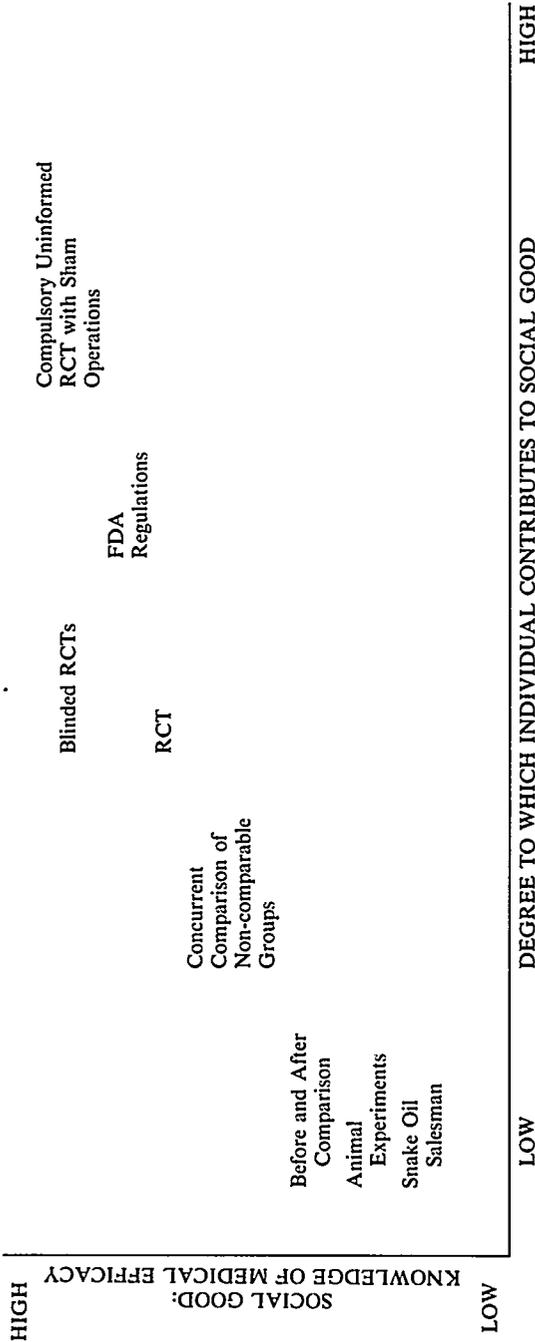
This is not an exhaustive list of the problems inherent in technology assessment. In addition to these is the problem of long-term effects. For example, diethylstilbesterol's harmful effects were not found until the daughters of the patients became teenagers and developed vaginal cancer. Another problem is establishing causation. Some diseases can be self limiting; yet the "cure" may be inappropriately attributed to treatment. Finally, the results of animal testing are not completely transferable to humans; because a treatment cures mice does not necessarily mean it will cure men.

Obtaining better information about the efficacy of medical care requires the individual patient's willingness to participate in clinical

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5. See Beecher, *The Powerful Placebo*, 159 J. A.M.A. 1602 (1955). For a more recent listing of the studies undertaken which have verified this effect, see J. FRANK, *PERSUASION AND HEALING* 136-51 (1973).

DIAGRAM 1  
INDIVIDUAL CONTRIBUTION AND SOCIAL GOOD FOR MEDICAL TECHNOLOGY ASSESSMENT



trials. Thus, to some degree, an individual contribution is required in order to achieve the social good of better knowledge about medical care efficacy. An attempt to show this tradeoff is presented in Diagram 1.

Various methods of evaluation are placed on this graph according to both their accuracy (vertical axis) and the individual commitment to the social good required (horizontal axis). Readers may not agree with the location of these methods and should feel free to create their own diagram. For example, a Hindu believing in reincarnation may equate animals and human beings and, therefore, place animal experiments to the far right of this diagram.

The worst form of evidence is the proverbial snake oil salesman. The individual is free to purchase, and negligible evidence of efficacy results. This has long been criticized by the courts. In 1630 in Boston, the very first year of settlement, the court convicted Nicholas Knopp for selling a cure for scurvy "of no worth or value."<sup>6</sup>

The best evidence would be obtained by compulsory, uniform, double-blind, randomized, clinical trials. However, proper evaluation of surgical procedures using this method would require sham operations, where an incision is made but nothing done beyond that.<sup>7</sup> It is generally accepted that such evaluations demand too great an individual sacrifice in the name of social good. Yet, if any one of this method's characteristics is deleted, accuracy and knowledge are sacrificed. If one eliminates the compulsion, representativeness is sacrificed; if patients are informed and blinding is eliminated, one loses control of the placebo effect; if randomization is eliminated, one loses assurance that the experimental and control groups are comparable; if one studies animals rather than humans, one is not sure that the results will be similar in humans. Thus, there are trade-offs between patient participation, informed consent, choice, and the quality of evidence obtained.

The fiduciary relationship between physician and patient implies that the physician can only recommend participation in a trial if he or she believes that both treatments are equally beneficial. If pushed hard, it would be exceedingly rare for a physician to be truly indifferent. As the true indifference point is more sharply defined,

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6. See J. YOUNG, *THE TOADSTOOL MILLIONAIRES* 16-17 (1961).

7. See, e.g., Cobb, Thomas, Dillard, Merendino & Bruce, *An Evaluation of Internal-Mammary-Artery Ligation by a Double-Blind Technique*, 260 *NEW ENG. J. MED.* 1115 (1959).

the number of physicians who could ethically recommend randomization becomes exceedingly small.

Lawyers, physicians, and all of us who are absolutist in our belief in the fiduciary relationship between physician and patient (and absolutist in our belief of the individual good over social good) should be willing to accept the consequences of these beliefs and, as a result, be willing to receive unnecessary or harmful treatments for ourselves and our families.