Ethical Problems of Medical Technology

FRANCISCO VILARDELL[1]

♦♦♦

The high cost of new diagnostic and treatment technologies means that they have to be used selectively, and at that point decisions must be made about who should get to use them. In recent years there have been increasing charges of improper use of these new technologies, coupled with increasing discussion of their costs and benefits. Unfortunately, the use of such technology tends to spread indiscriminately and so add indiscriminately to health care costs. Given this situation, there is a need to examine the relevance of new diagnostic and treatment methods, the causes of technological abuse, the ethical aspects of the use of medical technology, and even the relationship between technology and society. Indeed, if there is to be generally effective acquisition and use of health care resources, such examination is essential.

The practice of medicine continually presents dilemmas of an ethical nature. Many conflicting alternatives compel the physician to make value judgments, choosing a path that respects the hopes and wishes of the patient while also respecting the dictates of politicians, who, in heeding the goal of Health for All by the Year 2000, incline more toward investment in society as a whole rather than in the isolated individual. This implies not only greater concern for primary, community, and family medicine, but also restraints—budgetary restrictions—upon the development of tertiary technology.

There is no doubt that these budgetary restrictions on tertiary care, which are the result of decisions taken by health authorities, conflict with the preference of broad segments of the population that have followed the technological advances of modern medicine and consider their proclaimed benefits to be valid and legitimate. Such technological advances range from spectacular forms of treatment—including organ transplants as well as biliary or renal lithotripsy using new and extremely costly equipment prototypes whose use is not yet well-defined—to methodologies used to obtain costly diagnoses, the most visible examples of which are imaging techniques (computerized tomography, magnetic resonance, etc.).

Despite the indisputable successes of these technologies in selected cases, their high cost renders medical care much more expensive, particularly if they are employed in the absence of precise and rigorous indications.

The desires of the patient, who wants to be examined or treated with the most advanced technology, are often in agreement with those of the physician. Indeed, as a matter of principle the physician favors technological development against the wishes of the health authorities, who see medical care costs rising well beyond all forecasts of inflation, without the technology involved appearing to offer compensatory benefits. Moreover, governments often feel powerless to halt a technological onslaught of this

[1]School of Gastroenterology, Hospital de la Santa Cruz y San Pablo, Barcelona, and Council for International Organizations of Medical Sciences. Mailing address: Hospital de la Santa Cruz y San Pablo, 08021 Barcelona, Spain.

kind, whose successes cannot be ignored because of the publicity accompanying them, and which at times even appear to involve national prestige. Generally speaking, all this occurs with respect to any technological advance before proper cost/benefit studies have been conducted.

TECHNOLOGICAL ABUSE

In recent years there have been many protests against the misuse of diagnostic tests by physicians—and not only with regard to advanced technology. A routine test erroneously prescribed for a large number of patients may incur losses as costly as those incurred by a sophisticated diagnostic test erroneously prescribed for a few patients.

A multicenter survey recently performed in the United States that examined the use of a series of preoperative diagnostic tests found that of the 6,200 tests performed on 2,000 patients, more than 60% were not warranted by the patient's clinical history or physical examination (*1*). Another multicenter survey in the same country showed that 17% of the digestive endoscopies performed were not specifically warranted (*2*), while other similar surveys have cited even higher figures (*3*). Perhaps more worrisome is the finding that some 17% of a series of 1,677 angiographies were not clearly warranted (*2*).

It is logical to suppose that if these discrepancies have been found at prestigious hospitals in the United States and other countries, then the discrepancies occurring in the realm of private practice, where much less control is exercised, are even greater. In this regard it is worth noting that both radiologists and analysts complain of the gradual increase in requests for analyses and diagnoses, many of them apparently unwarranted (*4*). And several interhospital meetings on these matters have confirmed that the use of diagnostic tests for the management of patients with the same disease varies greatly from one center to another (*5*).

Obviously, there are several ways in which diagnostic technologies may be used incorrectly (*6*). Tests may be performed when none are warranted; an excessive number may be performed, various of which are superfluous; or those performed may be less informative, less efficient, and more costly than other tests available for the same purpose. At present the available data lead to an inevitable conclusion—that many practitioners are unaware of the true usefulness of the tests they prescribe relative to others, with regard to either cost or possible value in different clinical circumstances (*6*).

Furthermore, beyond the realm of diagnostic tests are a whole host of more serious problems associated with incorrect use of therapeutic intervention. To cite only two examples, one study found that 32% of the endoarterectomies performed at several centers were unnecessary (*6*), while another yielded similar findings with respect to 20% of the pacemaker implantations performed at a Philadelphia hospital (*7*). Clearly, these matters demand attention.

THE RELEVANCE OF TECHNOLOGY

The constant rise in medical service costs will no doubt lead to the development of surveys to investigate the use of both diagnostic and therapeutic techniques and their relevance to patient management. This relevance may differ from one country to another.

Unfortunately, advanced technology is often imported from a more developed

country by a less developed one and used without taking account of local circumstances—including the organization of medical and technical personnel and the economic factors involved in use of the technology. Consequently, it is not surprising that maintenance difficulties arise, that the results are not entirely satisfactory or comparable to those obtained in the country of origin, and that the end result is a squandering of resources.

However, the rapid growth of technology that has led to this misuse, excessive consumption, and diversion of funds assigned to more pressing primary care needs appears to be uncontainable. The sensationalist influence of the mass media, whose information is far from objective, usually impels the public to demand use of "life-saving" technologies in which it has placed its often unfounded hopes. Since all too frequently the results offer nothing more than a precarious and pitiful quality of life, this combination of circumstances makes an already uncontrollable market grow substantially and press for development of costly technologies publicized via sales techniques similar to those usually employed to market everyday consumer goods—development of technologies that often goes unaccompanied by development of the trained personnel needed to make those technologies fulfill their promise.

Any comparison of the year-to-year costs of X-ray machines, ultrasound equipment, fiber-optic endoscopes, pressure monitors, etc. reveals that the prices increase each year far more rapidly than the cost of living. Moreover, high import duties are levied on such items—duties that paradoxically tend to be higher in the countries that need the items most. This constant escalation of prices is not necessarily accompanied by greater equipment yields or by any clear added patient benefit.

The situation is even more serious in countries with significantly aging populations, to which ever-increasing resources must be allocated. This contrasts with the fact that complete periodic examination of asymptomatic individuals requires relatively few tests involving no costly apparatus (*8*).

CAUSES OF TECHNOLOGICAL ABUSE

A serious problem emerges from the fact that technologies of the sort described may invade the health care market without having been subjected to careful scrutiny regarding possible risks, actual benefits, and superiority vis-à-vis other procedures customarily employed. This is evident in the case of heart surgery, whose benefits have been the cause of controversy for years, and in the case of heart and liver transplants, which, after many years of experimentation, only now appear to be providing hopeful results.

This lack of precise data in evaluating results only gives rise to substantial doubts when decisions must be taken regarding the suitability of intervention. A common consequence is overuse of interventions, since, in case of doubt, use rather than nonuse tends to be the rule, particularly if use is accompanied by financial benefit to the user.

John Farrar (*9*) has studied physicians' motivations for using new technologies. He has found the motivations to range from a noble desire to assist the patient all the way to desire for profit, desire for enhanced prestige in an academic or hospital setting, desire to experience the fascination or pleasure associated with performing a new procedure, and the simple desire for self-protection against possible legal action, particularly when facing the legal circumstances found in the United States.

ETHICAL ASPECTS OF MEDICAL TECHNOLOGY

Although it is not possible to subject new medical technology to quantitative analysis with respect to the foregoing concerns (*10*), the following questions must be answered: Is the use of a new technology warranted on the basis of its cost, results, and efficacy? Are the available personnel sufficiently trained to use it properly? Is the new technology superior to those in use, and does it offer economic advantages? Will it improve the quality of life of patients who use it? Will it be available for use by the general population, or will it be reserved for the privileged few? Have its short-term and long-term risks been identified? Have any studies been made of other options that could prove a better investment?

Although the costs and benefits of new technologies have been widely discussed in recent years, much less attention has been paid to the entrance of such technologies into medical practice and the mechanisms that are or should be required for their acceptance. For instance, What kinds of studies are required for their approval? What kind of consent should be obtained from patients before a new technology is applied? Do physicians have a special obligation to inform their patients that the benefits of a new technology are still uncertain? These are questions that demand clear answers (*11*).

During a 1976 symposium held in Budapest on the ethical problems of managing patients with digestive disorders (*12*), participants developed a list of variables for use in assessing the risks of diagnostic techniques. These variables, which are worth recalling when any new diagnostic technology is being considered, are shown in Table 1.

An opinion that has become increasingly prevalent is that introduction of new technology is akin to research and should consequently be subjected to controls similar to those used for evaluation of new drugs (*11*). In the United States such controls have been precisely defined by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, to the effect that all procedures or their variants—diagnostic, therapeutic, or preventive—that are used with the aim of obtaining a direct benefit for the health of patients and that differ from customary routine practice should be subjected to a research protocol to determine their safety and efficacy (*13*).

The United States has been a pioneer

Table 1. Factors influencing risk in diagnostic techniques.

Factor	Risk
Instrument	Inherent in the instrument (for example, flexible or rigid endoscopes)
	Defective maintenance of instruments
Technique	Preparation of the patient incurs risk (for example, intubation, enema, or allergy to contrast mediums)
	Risk of the technique itself (for example, hemorrhage or perforation)
	Delayed secondary effects (for example, thrombosis or infection)
Operator	Operator with insufficient experience
	Untrained auxiliary personnel
	Careless operator (for example, omission of routine precautions)
Interpretation	Technical defects (for example, defective sampling or poor-quality X-rays)
	Inexperience of the interpreter of the results
Patient	High-risk patient
	Uncooperative patient

Source: F. Vilardell (*12*).

in these evaluations, and several reports relating to them have been published (*14, 15*). Obviously, the basic problem is deciding whether modification of an established technique should be considered research or not, a situation that may differ from one hospital to another. The correct answer depends on careful review of the circumstances in the local environment by an ethics committee organized within the institution where the question arises, one that has been assigned the task of ensuring that no technique will be used in the institution that has not been previously evaluated (*13*).

In this same vein, an ethics seminar sponsored by the World Organization of Gastroenterology some years ago (*16*) prompted a noteworthy discussion, among other things, of the development, selection, and evaluation of new technical procedures. Although these procedures were related to the field of gerontology, the meeting's conclusions appear perfectly valid for any other field of medicine. These conclusions were as follows:

First, an important distinction was made between the advent of previously unproven techniques (that is, techniques being tested for the first time) and the introduction of new techniques at a hospital center. The former clearly involves research and should adhere to the controls defined by the Declaration of Helsinki. All such unproven technology should be subjected to comparative studies with regard to the technology already in use—among other things so as to prevent its rapid introduction into practice, tacit acceptance, and dissemination from interfering with later objective evaluation.

Second, it was proposed that when a recently invented technique is adopted in a hospital, the hospital's ethics committee should evaluate it in order to establish the basis for a study ensuring that appropriate trained personnel will be available to manage it and that the advance consent of patients upon whom the new technique is to be used will be obtained.

Third, particular attention was given to the need for testing a new technique on volunteers (especially on medical, nursing, and other students recruited for this purpose) during the initial phases of its adoption (*16*). The use of coercive recruitment methods or ones involving academic remuneration are clearly to be avoided.

Finally, it was noted that introduction of new technology has commercial implications for industry, making it necessary to ensure that a technology being introduced receives appropriate evaluation by selected medical centers or societies. In no case should industry influence publication of the results of these evaluations.

TECHNOLOGY AND SOCIETY

The President of the Royal College of Surgeons of the United Kingdom has classified technological medical advances into three categories: those that facilitate the prevention of disease and promote health with little expenditure; those that permit the cure of disease at moderate cost; and those that make it possible to maintain health and a reasonable quality of life but whose success depends on the expenditure of substantial material and human resources (*16*). As far as society is concerned, it is obviously the latter that create problems, since over the long run economic factors will decide whether or not the advent of a new technology is to have a direct impact upon a community by facilitating, limiting, or barring use of that technology.

In a certain sense this implies a rationing of health resources, which although indirect is nonetheless real (*17*). The fact that a technique is available does not nec-

essarily mean it should be used, especially if resources are scarce and restrict its use. This is the situation prevailing in the case of heart or liver transplants, for example, because prolific use of these procedures could overwhelm all medical budgets and obstruct programs of more general interest. (In our own hospital we could vaccinate multitudes of employees at risk of contracting hepatitis B for the price of a single heart or liver transplant operation, regardless of its result—*18*).

Despite these objections, advanced technology, including transplant surgery, is a firmly entrenched if debatable medical and social reality. It is very difficult, if not impossible, to accurately determine its costs and benefits because the studies required are extremely complex in view of the extraordinary number of variables involved whose management gives rise to very diverse interpretations (*6*). Therefore, a sound balance between the absolutely necessary promotion of technical advances and the economic drain they may impose is hard to strike, especially in a society accustomed to renovation of what has come to be seen as obsolescence in other commonly used technologies (involving such items as household electrical appliances, sound systems, computers, etc.).

What this really means is that society or its representatives must demand that the introduction of new medical technologies be accompanied from the outset by systematic evaluation of their correct application and their benefits. If this were done, many of the current problems would be at least partially avoided—especially in the developing countries, which see themselves as being forced to adopt advanced technologies in order to dissuade numerous patients within their populations from going to other countries, often unnecessarily, to seek medical relief (*19*).

REFERENCES

1. Kaplan, E. B., L. B. Sheiner, A. J. Boeckmann, et al. The usefulness of preoperative laboratory screening. *JAMA* 253:3576–3581, 1985.
2. Chassin, M., J. Kosecoff, R. E. Park, et al. Does inappropriate use explain geographic variations in the use of health care services? *JAMA* 258:2533–2537, 1987.
3. Kahn, K. L., J. Kosecoff, M. R. Chassin, et al. Use and misuse of upper gastrointestinal endoscopy. *Ann Intern Med* 109:664–670, 1988.
4. Fowkes, F. G. R. Containing the use of diagnostic tests. *Br Med J* 290:488–489, 1985.
5. Ashley, J. S. A., P. Pasker, and J. C. Beresford. How much clinical investigation? *Lancet* 1:890–892, 1972.
6. Jennet, B. *High Technology Medicine: Benefits and Burdens*. Oxford University Press, Oxford, 1986, pp. 53–74.
7. Greenspan, A. M., H. R. Day, B. C. Berger, et al. Incidence of unwarranted pacemaker implantation in a large medical population. *N Engl J Med* 318:158–163, 1988.
8. Oboler, S. K., and F. M. La Force. The periodic physical examination in asymptomatic adults. *Ann Intern Med* 110:214–226, 1989.
9. Farrar, J. Gastroenterology and the impact of the rise of technology in the United States. *Ital J Gastroenterol* 21:49–52, 1989.
10. Institute of Medicine, Committee for Evaluation of Medical Technologies in Clinical Use. *Assessing Medical Technologies*. National Academy Press, Washington, D.C., 1985, pp. 154–160.
11. McMahon, L. F., D. Fleischer, and R. Levine. Emerging technology: Patient protection versus proliferation. *J Clin Gastroenterol* 9:258–273, 1987.
12. Vilardell, F. (ed.). Ethical problems in the management of gastroenterological patients. *Scand J Gastroenterol* 12(suppl):47, 1977.
13. United States, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of*

Research. DHEW Publication (OS) 78–0012, 1978. U.S. Government Printing Office, Washington, D.C., 1978.
14. Kessler, D. A., S. M. Pape, and D. N. Sundwall. The federal regulation of medical devices. *N Engl J Med* 317:357–365, 1987.
15. Perry, S. Technology assessment: Continuing uncertainty. *N Engl J Med* 314:240–243, 1986.
16. Black, D. The paradox of medical care. *J R Coll Physicians Lond* 13:57–65, 1979.
17. Churchill, L. R. *Rationing Health Care in America: Perceptions and Principles of Justice.* University of Notre Dame Press, Notre Dame, Indiana, 1987.
18. Vilardell, F. Organ transplantations: Are they ethical? *World Health*, June 1988, pp. 20–21.
19. Woolhandler, S., D. U. Himmelstein, B. Labar, et al. Transplanted technology: Third World options and First World science. *N Engl J Med* 317:504–506, 1987.

♦♦♦

Liver Transplantation

The transplant procedure that presents the most notable technical difficulties is liver transplantation. This operation, done for the first time 25 years ago in the United States, is now performed throughout the world. Although it is a feasible treatment for certain patients, problems still exist in identifying the most appropriate candidates and the best timing for this intervention. In addition, the long-term quality of life of the recipients and the cost of the operation, which now ranges from US$65,000 to $450,000, are subjects of continuing controversy. A report of the U.S. Agency for Health Care Policy and Research (AHCPR) emphasized the necessity that these operations be performed in centers of recognized excellence and experience and with adequate infrastructure to sustain a transplant program.

Source: U.S. Department of Health and Human Services—AHCPR, *Assessment of Liver Transplantation*, Health Technology Assessment Reports No. 1, 1990.