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Medical Technology and The Public Interest

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- Medical technology includes the "drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is delivered." 1/

- Medical technology has been the major force shaping medical care since the 1950's.

- Medical technology, according to government officials, is directly or indirectly responsible for 50% of the increase in costs of hospital care from $13.2 billion in 1965 to $40.9 billion in 1974.

- Medical technology research development is largely financed by government dollars - almost 70%.

- Despite the magnitude and importance of medical technology, there is serious question as to whether the process for the development and introduction of new technology into the mainstream of the health care delivery system best serves the public interest.

Lack of Accountability

Although Research and Development (R & D) is largely funded by the public sector, there is little public involvement in decisions concerning R & D priorities and the dissemination of medical technology. The major source of funding for bio-medical research is from the National Institute of Health (NIH) of the Department of Health, Education, and Welfare (HEW).

The NIH is comprised of eleven semi-autonomous institutes organized around specific disease categories (e.g. cancer), organs (e.g. heart, lung), or age (e.g. aging).

1/ Office of Technology Assessment, "Assessing the Efficacy and Safety of Medical Technologies," U.S. Congress, September 1978, p. XII.

These institutes have formed 52 peer review "study sections" comprised of outside scientists who specialize in these areas. NIH funding priorities and decisions are derived largely from the recommendations of these study sections which assess proposals for funding based on "scientific merit." Grant proposals for funding are also reviewed by the National Advisory Councils (which include some lay members) which are attached to each institute. But their recommendations generally follow those of the study sections.

Scientific merit alone is insufficient for the assessment of medical technology. Most NIH monies are awarded to private institutions (mostly academic) to support research and development activities, initiated and proposed by individual scientists. With "scientific merit" as the major criterion for funding research, there is little room for a coordinated research strategy organized around goals and objectives that would best serve the public interest. Thus, only a portion of NIH funds are targeted towards achieving progress in specific areas, while under the rationale of "scientific merit," most NIH funds are distributed in a random haphazard fashion. Too often the public interest is served by accident, rather than by design.

Lack of Planning and Coordination

Medical technology has brought about many important advances in combating human disease. Such was the case with the introduction of antibiotics in the 1940's and 1950's. Antibiotics proved to be safe, effective and inexpensive. New vaccines have done much to reduce the incidence of measles and the dreaded disease - poliomyelitis. Diseases such as pneumonia and tuberculosis now require shorter hospital stays as a result of new medication.

However, there is another side to medical technology. All new technology does not provide ... miracles. Much of today's new technology is characterized as "half-way technology," which merely palliates the "manifestations of major

diseases whose underlying mechanisms are not yet understood and for which no definitive prevention, control or cure has yet been devised." 2/ Compared with the more definitive technologies, half-way technologies (e.g. organ transplants, renal dialysis) are the most expensive to provide with the least benefit to the individual. New technology is too frequently introduced into the health care delivery system with insufficient evaluation as to its effectiveness, cost, appropriate use, safety and other dimensions of impact. Planning is not done prospectively, before the dissemination of a new technology, but instead retrospectively, after much of the technology has been inappropriately introduced into the system - this is frequently too late! It is easier to prevent errors of dissemination before the fact, rather than trying to erase past errors that have become fixed in large capital investments and medical practice. The National Health Planning and Resource Development Act (P.L. 93-641) specifically prohibits Health Systems Agency (HSA) review of R & D activity. Section 1513 (e) reads that "HSA shall not review and approve or disapprove the proposed use within its health service area of funds appropriated for (research) grants or contracts . . . unless the grants or contracts are to be used to support the development of health resources intended for use in the health service area." Again, this is too late! From the New York City experience, even research activity with health service or delivery implications is rarely, if ever, reviewed.

Coordination is also lacking. In addition to the NIH there are no less than 8 other agencies within HEW and 11 federal agencies outside of HEW that are involved in health research - all unconnected! The development of diagnostic ultrasound involved 19 separate agencies budgeted in their own orbits, is a good illustration of this fragmentation.

2/ Ivan L. Bennett, Jr. "Technology as a Shaping Force" in Doing Better and Feeling Worse by John H. Knowles, W.W. Norton & Co., New York, 1977.

The private sector also funds research and development activity, mostly in applied research. While contributing less than 1/3 of the research dollar, the private sector has the role of introducing technology into the marketplace, directed by the profit motive, not health needs or priorities (e.g. American Home Products, which manufactures Sani-Flush also produces and markets fetal monitors). The lack of public accountability, planning and coordination, has created a number of undesirable effects in the introduction of new technology.

1. Too much technology (too soon) - The premature, inadequately regulated introduction of medical technology into the health care delivery system has resulted in duplication, misuse and overuse. Mammography was widely accepted and used by the medical profession before important questions about its safety were addressed. Fetal monitors are commonplace in obstetric units throughout the United States, yet many of those who use this new technology neither understand when its use is appropriate,nor do they fully understand how to interpret fetal monitor readings. It is said that this misuse and overuse has led to a major increase in Caesarian sections that were not necessary. Coronary bypass surgery is now performed 70,000 times per year, yet studies have shown that for most types of patients, this relatively new and expensive surgical procedure has not resulted in extended lifespan. Some estimates suggest that as little as 10% of all procedures now used in medical practice have been shown to be effective by controlled studies.

2. Problems in Distribution of New Technology - Whether or not the benefit of a new technology is clearly established, there are serious problems associated with the distribution of new technology. In Massachusetts, for example, computerized axial tomography (CAT) scanners were housed in 6 teaching institutions in Boston in the early 1970's. The CAT scanner was widely accepted and desired by other hospitals in Massachusetts even though there was no clear-cut understanding of its effect on health status.

Yet, at that time, it was determined that there were a sufficient number of CAT scanners in Massachusetts, and the certificate of need agency rejected an application for a CAT scanner from a hospital many miles from Boston. It is understandable that the major medical centers and medical schools would have initial access to new technological equipment in the R & D stage, but this also precludes the potential for a rationale regional distribution of new technology. Clearly, there has got to be a better way.

3. Economic Impact - Traditional economics cannot be applied to health care. The basic principles of supply and demand do not work because of the following reasons:

- most of the bills are paid by public and private insurers, not the person who benefits from the services (i.e. the patient);
- the provider (i.e. physician) triggers the demand for services; and
- our social value system places a higher premium on health care than it does on many other social goods and services.

These economic imperfections are most dramatic in medical technology. Lewis Thomas has stated that ". . . in medicine, it is characteristic of technology that we do not count the cost, ever, even when the bills start coming in." 3/ Geiger has observed that "There is no 'effective demand' among American consumers for a barium enema or a heart-valve repair, and there is no 'free market' for hospital rooms as there is for hotel rooms. You don't get them at all without a physician's order: but when a physician orders them, you almost always get them. The suppliers control, even create, the demand." 4/

3/ Lewis Thomas, "Aspects of Biomedical Science Policy: An Occasion Paper" (Institute of Medicine, Washington, D.C., November 1972).

4/ H.J. Geiger in the New York Times Book Review, March 2, 1975.

The economic impact of new technology has two major dimensions:

- new technology is a major contributor to inflation; and
- opportunity costs associated with new technology involve vast expenditures, that if used more efficiently or for other purposes would yield greater public benefit.

a) Inflation - In recent years, fifty percent of the cost of hospital care has been attributed to medical technology. The capital costs receive the most attention, especially the big dollar items such as CAT scanners. However, it is the operating support costs that usually constitute the most expensive component of new technology. Staff must be hired and receive specialized training to operate new equipment. Inorder to justify capital and staff expenditures, the new technology is "marketed" and too frequently overused. New technology is used and public and private insurance pays the bills, without question. One encouraging development is that the Blue Cross Association recently announced that Blue Cross will no longer routinely reimburse hospitals for all diagnostic procedures, unless justified.

b) Forgone Benefits: The Other Cost of New Technology - The disproportionate amount of money used to support new technology has raised serious questions about resource allocation.

According to Warner, if funds expended for Medicare (1967) were used for alternate purposes, the 3.3 million aged poor could be raised above the poverty level, or rent could be paid that would allow the 2.2 million aged living in substandard housing to move into standard housing.[5/]

There are also questions about the amount of the health care dollar used for high technology that might be better used for more basic, less expensive

5/ Kenneth E. Warner, "Effects of Hospital Cost Containment on the Development and Use of Medical Technology," Milbank Memorial Fund Quarterly/ Health and Society, vol. 56, no. 2 (Spring 1978) pp. 187-211

services. In many respects, the health care we receive today is shaped by medical technology, rather than need. It is estimated that the excess supply and use of medical technology in New York State alone costs well over $100 million dollars a year. Overemphasizing sophisticated technology diminishes the importance of basic health care services. As the supply of primary and preventive services is shrinking in New York City, hospitals continue to purchase new equipment and develop new facilities to develop highly specialized services. If these funds could instead be used to provide basic primary care services were needed, it is likely that health status would improve, and it would be possible to eliminate federally designated medically underserved areas in New York State. Indeed, the cost of supporting our fancy for the exotic in medical technology is quite high, in fiscal and human terms.

A Public Interest Approach to Medical Technology

Finite resources require that we make choices on how to best spend the health care dollar. "Scientific merit" should not place the development and dissemination of new technology above public accountability when choices have to be made.

The impact of new medical technology must be evaluated before it is disseminated. A publicly accountable, systematic and comprehensive framework for assessing the broad implications of new technology is needed before it is introducted into the health care delivery system. A comprehensive assessment should go beyond assessing safety and efficacy. The U.S. Congress Office of Technology Assessment (OTA) has suggested that discussions of such assessment should include the following framework:

1. What medical problems is new technology designed to address?

Does it prevent or cure, or does it provide a more limited or halfway remedy?

2. How many people are served and what are potential outcomes (also side effects)?
3. What is anticipated use and potential for its use?
4. What are costs to the individual patient and the economy?
5. What are alternatives for same illness?
6. What are the choices regarding alternative use of funds?
7. What is the impact on the health care delivery system? 6/

An early alert system must be developed at the federal, state, and local levels in order to assess and plan prior to dissemination of new technology.

a) Federal Level - At the federal level there are many agencies that perform technology assessment (from lesser to greater degrees). The most effective assessment machinery is in Food and Drug Administration (FDA)/ DHEW, which has had long standing assessment and regulatory authority over prescription drugs, and in 1976 was given expanded authority over medical devices. Other federal agencies (e.g. NIH, National Center for Health Services Research, Office of Health Practice Assessment, Health Standards and Quality Bureau) perform different aspects of assessment (e.g. safety, efficacy, cost-effectiveness).

Although different government agencies do perform elements of technology assessment, these "elements are not linked together and do not follow each other logically" - a formal or well-coordinated "system" for developing and disseminating needed information for decision-making does not exist.

6/ Office of Technology Assessment, "Development of Medical Technology; Opportunities for Assessment," U.S. Congress, 1976.

The Office of Technology Assessment has identified the following shortcomings in the assessment process:

- Assessment is fragmented, lacking a well coordinated overall system.
- No formal mechanism exists for identifying technologies to be studied.
- Inadequate attention and funding to various steps in assessment.
- The federal government has not given sufficient priority to disseminating information. 7/

A step towards correcting these problems would be establishing a federal authority over all health research activity for identifying, assessing and coordinating the development of new technology. The authority should not be placed in an agency that directly supports research and development activity (e.g. - N.I.H.) because of the potential for conflict of interest.

The National Center for Health Care Technology, created by the Health Services Research, Health Statistics and Health Care Technology Act of 1978, would appear to be suitable locus for carrying out these assessment and coordination functions.

The National Center for Health Care Technology has two major missions.

1. It should stimulate increased scrutiny of new and existing health care technologies to ensure that their safety, efficacy, cost effectiveness, social, ethical and economic impacts are more completely explored.

Direct quote

7/ Office of Technology Assessment, "Assessing the Efficacy and Safety of Medical Technologies," U.S. Congress, September 1978.

2. Encourage the rapid dissemination of newly developed health care technologies which have proved their worth in terms of safety, efficacy and cost-effectiveness. 8/

Direct Quote

In addition to the creation of the National Center for Health Care Technology, the new law also provides for the following:

- Creation of a National Council for the Evaluation of Medical Technology to develop and disseminate standards, norms and criteria concerning the utilization of specific technologies. (The "Council" would be strengthened if it were in some fashion formally connected with the National Council on Health Planning and Development and the National Professional Standards Review Council);
- Funding support for the creation of public and private non-profit centers to assess health care technology; and
- Authorizes the "Center" to make recommendations concerning administration and reimbursement policies in Medicaid and Medicare in regard to new technology. 9/

At the time of this writing, it would be premature to attempt to assess the extent to which HEW has fulfilled its responsibilities under this new law.

b) State and Local Level - The Health Planning Law (P.L. 93-641) requires that state and local planning agencies determine that "need" exists prior to approval of new captial expense projects. "Appropriateness review," (which, to date, has not been adequately defined for implementation) holds out the potential for planning agencies to review existing

8/ U.S. House of Representatives, "Conference Report: Health Services Research, Health Statistics and Health Care Technology Act of 1978" (Report No. 95-1783), 95th Congress, 2nd Session, October 13, 1978.

9/ IBID

programs/services, with similar criteria, and the potential for approving or denying the continuation of existing programs.

The National Council for the Evaluation of Medical Technology should issue guidelines (based on standards, norms, and criteria) that would in turn be adopted by state and local planning agencies for regional application.

The State/Health Planning and Development Agency (SHPDA) and the local Health System Agency (HSA) have specific decision making responsibilities. In the past, the decisions were not made, or made too late, or made in a vacuum without sufficient data. With adequate information, the SHPDA, in consultation with the HSA's should be responsible for developing a plan for dissemination of new technologies based on the needs assessment framework suggested by OTA (see pp 7-8). Given the high cost that is often associated with new technology and the usual pressure of all 300,000 physicians and 7,000 hospitals in the nation desiring to "acquire" the latest technology, SHPDA's and HSA's should place special emphasis on avoiding duplication, understanding the costs involved, with particular attention to alternative needs (e.g. primary care) to which limited health care dollars may be applied.

Special attention should be given to ensure a fair distribution of new technology that would improve population access - this is particularly important at the initial stages of dissemination.

These plans should be developed in formal consultation with Professional Standards Review Organizations (PSRO). PSRO linkage not only

actively involves the participation of informed provider group concerned with the effects of different types of medical intervention, but it offers the potential of acquiring future data on the effects of certain new technologies that would be useful for future decision-making.

Once a state plan is established, state certificate-of-need regulations should be issued for the dissemination of the new technology, and should include reimbursement penalties for unapproved use of new technology.

The HSA's local Health Systems Plan (HSP) should include a plan for local distribution of new technology, based on state criteria. If this can be achieved on the basis of need with adequate information, new technology can be used to serve the public interest by fulfilling the priority goals and objectives of the HSP.

To succeed, a coordinated federal, state and local early identification, assessment and dissemination strategy must begin at the earliest stage of r and d - before the fact. If it begins during the dissemination stage, it is after the fact, and too late.

The choice is simple and complex - will new technology be shaped to meet the public interest, or will the public interest be shaped to accommodate new technology?