Commentary

Biomedical Research And Technology Development

by Gerard F. Anderson and Catherine M. Russe

That there is no such thing as a free lunch is one of the maxims of economics. It suggests that competitive forces will require efficient production and that the marketplace will set prices for all goods and services equal to the marginal cost of production. In health care, the cost of producing many of the goods and services is unknown, and some are paid for using an elaborate system of cross-subsidization. As the health care system becomes more competitive, economic theory predicts that cross-subsidized goods and services will be eliminated or substantially reduced unless new sources of financing are found. Much of the recent concern over uncompensated care, graduate medical education, and other services is the result of a belief that the current level of cross-subsidization will be reduced.

An area that has received relatively little public policy attention in recent years is biomedical research and technology development. We anticipate that the new economic environment will influence what biomedical research and technology is conducted, where it is conducted, and the rate of diffusion of new technologies. This has important implications for academic medical centers, health industry manufacturers, and the general public.

The changing environment. One important influence on the scope of biomedical research and technology development is the distribution of funding. While the federal government has been responsible for the rapid growth of biomedical research funding since the early 1950s, during most of the 1980s private spending for biomedical research and technology development increased faster than public spending.[1] Recently, however, manufacturers have also begun to reduce their commitment to research and new product development because of hospital payment reform.[2]

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A second influence on biomedical research and technology development is how payment reform will affect the diffusion of new technologies. It is generally agreed that the diffusion of new technologies and the use of certain high-cost technologies may be discouraged because hospital payment rates may not increase as fast in the future and because hospitals will be encouraged to use less costly technologies whenever possible.[3] Proposed reforms of physician payment systems may have a similar effect.[4]

Clinical research. Medical technology develops in stages, moving from basic research, to laboratory production and testing, to refinement via clinical application, before it is broadly disseminated and incorporated into standard medical practice. The period between the scientific development of a new product and when the product can be widely marketed has not been studied extensively but is probably the most vulnerable in today's economic environment. This is a period of clinical trials, the initial testing of new procedures, and the refinement of new technologies. It is the most expensive period of development for pharmaceutical and health equipment manufacturers.[5] It typically occurs in academic medical centers and could be hindered by today's changing economic environment if adequate financing is not obtained.

There are three areas of concern regarding clinical research. The first is the cost of conducting clinical research. Very little information is available concerning the cost of conducting this research in academic medical centers. The second area of concern is who should finance biomedical research. Traditionally, much of this cost has been cross-subsidized through patient care revenues. New sources of funding will have to be found if clinical research is to continue above a minimal level. A final issue involves the equitable allocation of revenues derived from grants within the academic medical center.

Cost Of Biomedical Research And Technology Development

In the past, most hospital administrators have shown little concern with the costs associated with conducting clinical research, and therefore it has yet to become a major policy issue. This may be due to the fact that clinical research is a major issue to only a small number of institutions. In fiscal year 1985, forty institutions received over half (52.5 percent) of the research grant funds distributed by the National Institutes of Health (NIH). Forty more institutions claimed 19.2 percent of NIH research funds. The remaining 28.3 percent of NIH grant funds were distributed to 859 institutions.[6]

Efforts to modify the Medicare prospective payment system (PPS) and other hospital per case payment systems are beginning to make the cost issue more visible, however. According to a recent report of the

Prospective Payment Assessment Commission (ProPAC), the "third-party cost reimbursement structure concealed a significant amount of subsidization for the patient care component of clinical research. This occurred because the cost of caring for patients being treated with new therapies and treatments is frequently higher than the cost of routine care. Furthermore, it is frequently not possible to separate the costs of research from patient care."[7]

Very little is known about the cost to the hospital of conducting clinical research. These costs can be grouped into four major activities: (1) purchase of new technology; (2) additions to the staff to conduct research projects; (3) additional laboratory tests and ancillary services and procedures; and (4) use of operating rooms and other facilities in developing new procedures. As of May 1987 there were no comprehensive quantitative studies that examined how the presence of clinical research activities contributes to the cost of running a hospital. The National Center for Health Services Research and Health Care Technology Assessment, in conjunction with the National Cancer Institute, is currently conducting a study on the cost differences between cancer patients in an experimental research protocol versus patients with comparable diagnoses who are receiving conventional treatment. Another study, conducted by the Commonwealth Task Force on Academic Health Centers, will attempt to identify the scope of unsponsored research conducted at five major teaching hospitals and to quantify the cost to the hospital of this activity.

Using data collected by Arthur Young and Company at forty-five hospitals for a study of the cost of graduate medical education, we analyzed the cost to the hospital of conducting clinical research using research fellows as a proxy for the extent of research conducted in the hospital.[8] Controlling for other factors, our results suggest that each research fellow adds eleven dollars to the operating cost of a hospital discharge.[9] Therefore, a hospital with ten research fellows will have operating costs that are $110 higher per discharge. This is after the direct costs associated with the research are removed from the cost comparison. While research fellows are a crude proxy for the scope of the clinical research activity, it does suggest that research may add to the total cost of the hospital.

Financing Biomedical Research And Technology Development

Generally, the financing of clinical research can be split into two major categories—sponsored and unsponsored research. Sponsored research involves clinical projects that have been explicitly funded by public or private sources or are being explicitly funded by the hospital using internally generated funds. With sponsored research, the investigator is

expected to determine the direct costs associated with clinical research and submit these costs to the funding agency as part of the application. Sponsors generally pay direct costs, including the wages and fringe benefits, materials, supplies, travel, any additional laboratory tests or days of hospital care that may occur as the result of the research protocol, and other expenses associated with conducting the research. Most external sponsors also fund the overhead costs (which they refer to as indirect costs) associated with research. These include expenses such as administration, plant maintenance, utilities, depreciation, and other associated overhead expenses.

Although sponsored projects are theoretically funded to cover all of the research costs, it is unclear whether they pay the entire cost of each project. Some biomedical research may be sponsored but underfunded. For example, in the clinical trial of a new drug, the cost of the drug is likely to be covered under supplies. However, in the event that the standard course of treatment is altered, additional tests or procedures may be required to treat the patient. Researchers may not be able to identify in advance all of the additional services that are necessary. In addition, since total cost is a factor in the evaluation of a grant submission, there is an incentive for the principal investigator to underestimate project costs. The unanticipated costs of these sponsored projects either will be passed on to the patient, the investigator will apply for supplemental funds to the funding source, or the hospital will accept a reduction in its operating margin.

When hospitals develop a procedure or use equipment that is still in an experimental stage, the cost is usually greater than after the technology has diffused and either the marginal cost has declined or the medical practice has become standardized so that tests are not duplicated. These projects add to the hospital's costs with little or no offsetting immediate revenue, but may have long-run payoffs as the hospital becomes known for having the latest technology. The aggregate cost of internally funded projects involving new and experimental technologies is unknown, but could be substantial. As a point of reference, the Johns Hopkins Hospital spends approximately 3 to 4 percent of its operating budget on internally sponsored projects.[10] The University of Utah spent over $200,000 on the care of Barney Clark, the first patient with an artificial heart.[11] A study of cancer patients in New Jersey found that only 3 percent of the patients were involved in clinical trials, but they were responsible for 47 percent of the operating losses incurred by hospitals treating cancer patients.[12]

Unsponsored research involves all of the research conducted in the hospital that is not explicitly funded by internal or external sources. This can involve expensive activities such as surgeons using the operating room an additional fifteen minutes to perfect a new surgical technique, or radiologists requesting both magnetic resonance imaging (MRI) and a

computerized axial tomography (CT) scan for a patient because the physician is unsure of the relative strengths and weaknesses of each technology in a specific instance. It could also involve lower-cost activities such as clinical case studies, which might require review and evaluation of all patients with specific illnesses treated in the institution during a given period of time. These are all funded implicitly by the hospital, usually through patient care revenues.

Recommendations To Meet The Changing Environment

Hospital-based clinical research supported through internal funds was relatively easy to finance under the cost- and charge-based reimbursement systems. In conjunction with reforms in the hospital financing system, it is necessary to change the method of financing clinical research and technology development to ensure that this research will continue above minimal levels. Because research lends hospitals a comparative advantage by allowing them to differentiate their product, hospitals are likely to continue to use some of their own resources to finance clinical research. However, one would expect to see the extent of internally sponsored clinical research (both explicitly and implicitly funded) decrease as the ability of academic hospitals to cross-subsidize is reduced. This requires policymakers to review the current methods of financing these services and to ask who should pay for clinical research if we want to maintain the current levels of research.

One proposal suggests the creation of a new diagnosis-related group (DRG) for patients engaged in clinical trials sponsored by NIH.[13] In this proposal, hospitals would be paid costs instead of a prospectively determined rate for treating patients involved in a clinical trial. The major difficulty with this proposal is that it suggests that Medicare and other third-party payers should pay for clinical research. While some patients may benefit from a clinical trial, most of the benefit accrues to the pharmaceutical firm, the equipment manufacturer, and the general public. As a result, covering the incremental cost of clinical research from patient care funds is inappropriate.

Most biomedical research and technology development projects are public goods in the traditional welfare economics sense. During the past fifty years the federal government has taken the lead in financing biomedical research. The research conducted in clinical settings is important to the advancement of medical care and often leads to real innovation in clinical practice. Research results are distributed through publication in peer-reviewed journals. As a result, these clinical innovations are incorporated more broadly by practitioners until they become the standard of medical practice.

Because much of the clinical research traditionally funded by hospi-

tals using internal funds is a public good, benefits from these advances accrue to the public collectively. No single individual or hospital captures these benefits to the exclusion of others. Therefore, if as a result of payment reform and competitive forces the actual investment in clinical research falls below the social optimum, it would be appropriate for the federal government to provide some level of funding for these activities to ensure that worthwhile projects are continued.

Use federal grants to support research. An option for maintaining these projects is to use federal grants to support this research. The grant would be made directly to the hospital to continue its program of technology development and clinical research. A prototype for this exists in the Biomedical Research Support Grants from NIH. Currently, institutions that have at least three NIH grants of $200,000 or more are eligible to apply for these grants, which are awarded annually in one lump sum to the institution, free of requirements on how the funds are distributed. Disbursement of these funds is based solely on institutional priorities. In general, the Biomedical Research Support Grant awards are made to universities and schools of medicine but have not been given directly to hospitals.

We propose that the method of financing clinical research in the hospital be changed and that these activities be largely incorporated into the current system of federal funding through the NIH extramural grants program. To make this possible, NIH will need to broaden its definition of appropriate research activity to incorporate more applied biomedical research and technology development. Hospitals would apply to NIH under the current grant-making system for extramural research funding. This would require hospitals to define the programs they currently sponsor through cross-subsidies, particularly the implicitly sponsored clinical research, and to determine the costs of those projects. Applications for these projects would be judged competitively under the peer review process. Hospitals would receive grants based on merit, and renewal of the grant would be based on performance.

This proposal does not suggest that it is necessary for the federal government to fund everything hospitals request or to fund all of the projects that hospitals have funded in the past. It should be left to the political process to determine general research priorities and whether to fund this new group of research projects within the current NIH budget or to increase the budget of NIH. Hospitals that wish to continue to fund research and technology development activities but that did not receive direct funding would be able to continue at their own expense.

This change in financing would allow us to acknowledge the value and importance of the clinical research and to finance it explicitly. It may not be necessary to fund this program at a substantial level now, given the operating surpluses most academic hospitals are experiencing. However,

conditions change, and any change in the mission of NIH will need to be debated for several years.

Pay the full cost of research. Our second recommendation is that the federal government and private corporations pay the full cost of clinical research. On competitive grants, it is in the interest of the principal investigator to underestimate the cost of conducting the research, since grants are decided on the basis of both technical merit and total cost. In the past, hospitals were able to use patient care revenues to cover the unsponsored or partially sponsored research and were therefore unconcerned about research costs.

This change could have important implications for clinical research. Requiring the government to pay the full cost of clinical research may result in fewer research grants being awarded unless the total available funds increase. This is a matter of federal budget priorities. The issue is more serious, however, for private industry.

In the United States, hospitals and medical schools generally require pharmaceutical firms and equipment manufacturers conducting clinical trials to pay the cost of the clinical trial. In addition to the cost of the drug or equipment, the corporations theoretically fund any tests or days of care beyond the standard medical procedures necessitated by the clinical trial. Since most of the benefits of the clinical trial are captured by the firm directly, it is important for the academic medical center to recover all of the costs associated with a clinical trial.

This proposal could have profound implications for where clinical trials are conducted. In many foreign countries, most of the cost of the clinical trial is paid for by the government through national health insurance. This creates an economic incentive for manufacturers to conduct clinical trials outside the United States. Because other countries' policies are generally not as stringent as those of the U.S., many of the trials had to be repeated in the U.S. to receive Food and Drug Administration (FDA) approval. Recently, however, the FDA has become increasingly willing to accept clinical trials conducted in foreign countries as long as they meet specified regulations.[14] Following the change, pharmaceutical companies and biotechnological equipment manufacturers increased their use of foreign sites for final testing of their products. If private corporations were required to pay the full cost of these clinical trials in U.S. hospitals, the exodus may accelerate. If this process continues, it is possible that the United States will lose scientists to foreign countries where an increasing number of corporations are building plants and have corporate headquarters.

Share overhead payments with hospitals. Our third recommendation concerns the allocation of revenues within the academic health center. Generally, a research grant is awarded to the medical school, which may allocate resources to the hospital on a project-specific basis to cover

direct and overhead costs of the project. In most academic medical centers, the overhead costs are largely retained by the medical school. Medical schools and universities receiving NIH and other grants should be encouraged to ensure that hospitals receive a fair share of the overhead costs paid under the grant. The magnitude of overhead costs may become important enough that other hospitals follow New England Medical Center's lead in positioning themselves to capture all of overhead reimbursement from external grants. The New England Medical Center has built a research building where all of the medical school faculty's basic science research is conducted, and the hospital receives overhead on sponsored projects that exceeds $20 million per year. Academic medical centers may want to begin discussing how to allocate resources among the various components to ensure an equitable distribution of payments for overhead.

NOTES

1. See M.R. Pollard and G.S. Persinger, "Investment in Health Care Innovation," *Health Affairs* (Summer 1987).
2. Walter Robb, Vice President for Research and Development, General Electric Corporation, speech given to the National Committee for Quality Health Care, 17 July 1986.
3. G. Anderson and E. Steinberg, "To Buy or Not to Buy, Technology Acquisition Under Prospective Payment," *The New England Journal of Medicine* (19 July 1984):182–185; and L. Garrison and G. Wilensky, "Cost Containment and Technology," *Health Affairs* (Summer 1986).
4. "Medicare Physician Payment: An Agenda for Reform," Annual Report to Congress" (1 March 1987).
5. See Pollard and Persinger, "Investment in Health Care Innovation."
6. National Institutes of Health, special analysis done for this article.
7. Prospective Payment Assessment Commission, "Medicare Prospective Payment and the American Health Care System," Report to Congress (February 1987):99.
8. "Study of the Financing of Graduate Medical Education," Report II, Hospital Cost Analysis, Arthur Young and Company (October 1986).
9. G. Anderson, J. Lave, C. Russe, and P. Neuman, "No Free Lunch: Analyzing the Effect of Payment Reform on Hospital Services," A Report for the Commonwealth Task Force on Academic Medical Centers (Summer 1987).
10. Irwin Kues, senior vice-president, The Johns Hopkins Health Care System, personal communication.
11. Bruce Steinwald, "Reimbursement Schemes on Clinical Research in Hospitals: The Case of the Prospective Payment System," *Journal of General Internal Medicine*, supplement (July/August 1986):S56–S59.
12. L.E. Mortenson and R. Winn, "The Potential Negative Impact of Prospective Reimbursement on Cancer Treatment and Clinical Research Progress," *Cancer Program Bulletin* (September 1983):7–9.
13. J.W. Yarbro and L.E. Mortenson, "The Need for Diagnosis-Related Group 471," *Journal of the American Medical Association* (1 February 1985):684–685.
14. Title 21, Code of Federal Regulations, 312 and 314.