Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology (1979)

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A Study of the Diffusion of Equipment-Embodied Technology

A Report by the
Committee on Technology and Health Care
Assembly of Engineering
National Research Council
and
Institute of Medicine

NATIONAL ACADEMY OF SCIENCES
Washington, D.C. 1979

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

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PREFACE

This report examines the policy and research issues basic to the relationship between new medical technology and the efficiency and effectiveness of the health care system. The National Research Council's Committee on Technology and Health Care, organized jointly in 1976 by the Assembly of Engineering and the Institute of Medicine, has assessed the process by which technology finds its way into the health care system, identifying and analyzing successes and failures in the process of technological change. Ideally, the more effective and efficient technologies should be introduced quickly; others should not. The committee has attempted to determine the extent to which these ideal results actually do occur and, when they don't, why not. In our review of the evidence bearing on this question, we have identified areas where more research is needed.

SCOPE AND LIMITATIONS

The committee limited its inquiry to an examination of "equipment-embodied technology," which is the equipment, procedures, services, or systems that depend primarily upon capital equipment. Fetal monitoring equipment, coronary care units, fiber-optic endoscopic procedures, and medical information systems, diverse though they are, all fall within the study's purview. The study excluded other important technological innovations in health care, such as new therapeutic drugs or new surgical procedures for which particular equipment was not required.

As a first approximation of the issues to be addressed, the committee identified a series of questions:

- What is known about the relationship of equipment-embodied technology to health care costs and social benefits? Are there categories of such technology that are worth their cost and others that are not?
- What factors determine the way decisions are made about the acceptance of new equipment-embodied technology into health care? Are there particular categories of technology that are likely to be adopted too rapidly and uncritically or too slowly? To what extent do current public policies contribute to such problems?
- How is information about the effectiveness and efficiency of new technology developed and used? At what stage in the process of technical change is information generated? To what extent does the development and dissemination of information about medical technology need to be improved?

From the outset the committee decided not to review the state of the art in developing particular kinds of medical technology nor did it attempt to identify significant opportunities for R&D of new technology--although the committee is quite certain such a study could be useful to those federal agencies that are responsible for supporting R&D activities. The committee did not analyze the substantial number of issues associated with biomedical research policy, such as the relative merits of targeted versus untargeted investigations or of large grants over small grants, the continuity of research funding, the peer review of research proposals, and the organizational structure or process most conducive to innovations in medical technology. These were ruled out for two reasons: The issues had just been considered by the President's Biomedical Research Panel, and the time available for the study of medical technology did not allow for expanding the scope of the committee's work.

The committee imposed several additional limitations upon itself in recognition of the constraints of time and the absence of objective studies on certain topics. Thus, it did not deliberate the technical issues associated with developing equipment-embodied technology, including the need for trained technical manpower or for R&D settings in which the collaboration of medicine and engineering can be most productive.* It did not examine fully the influence of the biomedical electronics and equipment industries on the process of technical change in health care; nor did it evaluate the extent to which the industry determines the directions of

*One committee member, William Yamamoto, has taken exception to the limited scope of the study in this connection as well as some of the implications of the conclusions and recommendations. His dissenting view appears as Appendix A.

development and distribution of new medical technology or simply responds to the demands and needs of the health care system, mainly because reliable data about the activities of equipment makers are virtually unattainable. Indeed, the committee assumed in its deliberations that new medical technology results largely from the demand expressed in the "market," which, in the case of the health care system, means physicians, hospitals, other providers, and the public. Consequently, the committee assessed the nature of the market signals in some depth and not the extent to which the biomedical equipment industry may be a powerful force in creating a market for its products.

Finally, the study did not deal with the issues of ethical and social choices now made possible by the availability of medical equipment to prolong life or the financial costs of such technology on either the individual patient and the immediate family or the rest of society. Medical technology raises many fundamental questions about previously uncontrolled aspects of life. It possesses an implicit power to redistribute wealth in the society and to confer benefits upon some of the most underprivileged. It endows health practitioners with new powers over life and death. It creates new jobs and displaces old jobs. While the committee recognizes the differential impacts of technological change on society that medicine now possesses, such ethical and social questions have not been addressed in the study. The committee's main focus has been on the costs and effectiveness of the process of technological change, not on the equity of its consequences.

METHODOLOGY

The committee, consisting of specialists in engineering, medicine, economics, sociology, and health care administration, met four times to deliberate the issues, reach conclusions, and develop a set of recommendations for policy and research that bear on medical technology. In addition, the committee reviewed a series of study papers that it commissioned. Four of the papers were case studies of particular equipment-embodied technology. The other papers included an analysis of property rights policies related to the introduction of new medical technology, an examination of the impact of state and local regulations on medical technology, and an assessment of the economic cost of equipment-embodied technology. While the commissioned papers provided one of its principal sources of information, the committee did not always accept or agree with their findings and conclusions. Some of the papers are included here (Appendixes B-G) so that readers may have access to these otherwise unpublished documents.

The committee held an open meeting to collect the views of concerned citizens on the critical problems of technological change in the health care system. The public's views were the subject of another deliberative meeting by the committee.

ORGANIZATION OF THE REPORT

This report contains an introduction and summary, four subsequent chapters, and appendixes. Chapter 2 reviews what is known about the economic costs of the various types of medical technology. Chapter 3 analyzes the adoption and use of new technology in the health care system, identifying specific factors that may tend to either inhibit or encourage the process. Chapter 4 explores the policy options to deal with the problems in the adoption and use of medical innovations. Chapter 5 discusses the critical question of how evaluative information is generated and disseminated throughout the process of technological change and how that process can be improved.

There are eight appendixes to the report. Appendix A is the dissenting opinion of committee member William S. Yamamoto. Appendixes B through G are six commissioned papers to assist the committee in its analysis of the pertinent issues and to provide case studies of particular technologies. Appendix H is a listing of individuals who attended the open meeting on the process of technological change.

ANOTHER WORD

When this study was undertaken, the committee chairman was Jordan J. Baruch, Professor of Engineering and Business Administration at Dartmouth College. Dr. Baruch and another original member, Karen Davis of the Brookings Institution, left the committee a few months afterward when they were appointed to positions in President Carter's Administration. Three other members left the committee after participating in its initial deliberations. They are Edward Burger, Clinical Assistant Professor at Georgetown University Medical Center; Alain G. Enthoven, the Marriner S. Eccles Professor of Public and Private Management at Stanford University; and Walter A. Rosenblith, Provost of the Massachusetts Institute of Technology.

The committee is grateful to these people for their incisive ideas in the early months of this study.

CONTENTS

1 INTRODUCTION AND SUMMARY

Medical technology has unquestionably advanced at a prodigious pace in the past 20 years, changing both the capability of American medicine to detect and treat disease and the public's expectations of medical care. The continued rapid growth in biomedical and related scientific knowledge is likely to stimulate further significant advances.

Some new technology has reduced the cost of providing health care, some has increased access to health care services, and some has measurably improved the outcome of medical care. In fact, in the recent past, several panels and committees, not unlike our own, were actively deliberating on how the vast potential of the new medical technology could be tapped most effectively. For example, in 1967 the National Academy of Engineering's Committee on the Interplay of Engineering with Biology and Medicine was established to "investigate how technology can contribute to the achievement of health care goals."[83] In 1972, a conference sponsored by the National Institutes of Health explored factors underlying and particularly inhibiting the spread of new medical technology,[41] and the National Center for Health Services Research and Development held a conference to consider priorities for development of health care technology for the 1980's.[17] More recently, the President's Biomedical Research Panel, as part of its major inquiry, investigated how the movement of research findings into practical use could be enhanced.[131] The problem of how to facilitate the transfer of new technology to the practice of medicine remains a major concern today.

In the past 5 years more skeptical voices have been heard. Those who shape and influence national health policy have shown increasing concern over the way in which new technology is

developed and introduced into the health care system. New equipment, procedures, or systems appear to some to be introduced by hospitals and physicians without knowledge of, or concern for, their relative effectiveness or efficiency. Technology purportedly follows its own imperative, eluding effective control by regulatory or financing agencies.[96] Most important, new technology is accused of raising the cost of providing health care. Gaus,[35] for one, has observed that:

> the long-term cumulative effect of adopting new health care technologies is a major cause of the large yearly increases in national health expenditures and in total Medicare and Medicaid benefit levels.

Medical technology has clearly acquired a bad name in some circles. Whereas just 5 years ago it was held out as a major opportunity for improvement in the cost and quality of, and access to, health care, today it represents to many a major cause of problems in these areas. Increasingly, policies to assess, evaluate, or control the introduction of new technology on the federal and state levels have been suggested as cost-containment strategies.[36,96,103,137] Debates have occurred over the nation's continued ability to pay for new technology as it has in the past.[79]

These charges and recommendations merit further investigation. They were the starting point for the study reported here. But, upon reflection, it is clear that the source of the "technology problem," if there is one, is not technology itself, but the behavior of those who make decisions about how, when, and where new health care technology will be introduced. This is, then, a report on the behavior of the health care system with respect to new equipment-embodied technology.

As a guiding principle, new technology should be introduced into the practice of health care when its benefits to society outweigh its costs. We are aware, however, that early knowledge of the benefits or costs of a new technology is often impossible to obtain at the time that decisions regarding its dissemination and use are first made. Such decisions are always made in the face of great uncertainty, and hindsight inevitably reveals mistakes. Our goal has been not to recommend ways to stamp out all such errors. That would be impossible. Rather, the committee has considered the systematic forces that foster appropriate or inappropriate decisions and has assessed the extent to which additional investment in information about the usefulness of new technology is warranted.

Equipment-embodied health care technology can be classified according to the function it performs. In this study we have found it useful to distinguish three major kinds of health care technology:

- *Clinical technology*--that used in the provision of direct patient care, including surgical and medical services.
- *Ancillary technology*--that used directly to support clinical services, such as diagnostic radiology, radiation therapy, clinical laboratory, anesthesiology, and respiratory therapy.
- *Coordinative technology*--that used to facilitate and support the provision of health care services but not directly associated with patient care, including administration, transportation, and communication both within and among health care facilities.

Other health care technology, including educational and research technology, have important functions, but they are not central to our study.

These three major kinds of technology can be applied at any stage in the medical care process--prevention, diagnosis, treatment, or rehabilitation--and in any setting--hospitals, physicians' offices, clinics, or combinations of these.

Figure 1 presents a typology of equipment-embodied technology categorized by function and stage in the medical care process. It includes examples of particular technology for each category. Such examples illustrate the broad range of equipment and equipment-embodied techniques, procedures, and systems that concern the committee. Moreover, the typology serves as a useful tool for analyzing problems in the process of technological change. Technologies in particular categories are likely to be subject to similar problems associated with their development and diffusion. For example, surgical technologies delivered in hospitals are likely to follow paths of development and diffusion that are quite different from diagnostic ancillary services provided in the physician's office. The motivations and objectives of decision makers along the way are likely to be quite different from one another, as are the organizational, financial, and regulatory environments affecting technologies in these categories. Thus, it may be possible to determine which forms of technology require particular policy solutions.

THE PROCESS OF TECHNICAL CHANGE

Technical change is a dynamic process for developing and adopting new methods in health care services. The process of technical change involves decisions that result in the application of new medical technology or new combinations of existing technology. Such decisions are made by many individuals and institutions. Decisions at any point in the process influence the resulting pattern of technical change not only for a particular technology but also for related technologies.

FUNCTIONS \ STAGES		Preventive	Diagnostic	Therapeutic	Rehabilitative
CLINICAL SERVICES	*Medical*				
	General	Multiphasic health testing	Computer-aided diagnosis	Computer-aided prognosis and therapy	
	Chest medicine	Screening tests	Cardiac monitoring	Pacemakers Coronary care units Respiratory therapy	
	Gastrointestinal medicine	Sigmoid screening	Fiberoptic scopes		
	Neurology		Diagnostic ultrasound		Paraplegic support
	Nephrology	V.D. screening Prostate CA screening		Renal dialysis	
	Pediatrics	Immunization registries		Neonatal ICU	
	Obstetrics	Genetic screening	Fetal monitoring		
	Gynecology	Cervix smear screening			
	Eye, Ear, Nose, and Throat	Glaucoma screening	Visual tests Hearing tests	Laser beam therapy Internal ear surgery Phakoemulsification	Sensory aids
	Emergency		Telemetering	Emergency dispatching and life support systems Burn units Intensive care units	
	Surgical				
	General				Tissue banks
	Chest surgery		Cardiac catheterization and angiography	Coronary bypass	Artificial organs and parts
	Gastrointestinal surgery			Intestinal shunts	
	Neurosurgery			Brain and spine surgery	
	Urology			Genitourinary surgery	Kidney transplants
	Orthopedics			Hip and spine surgery	Limb prosthetics

ANCILLARY SERVICES	*Ancillary Services* Clinical laboratory EKG X-ray Pharmacy Ultrasound Nuclear medicine	Biochemistry panel Stress (EKG-treadmill) testing Mammography screening Drug reaction monitoring systems Radioassay screens	Automated testing Automated diagnosis Diagnostic mammography Computed tomography Diagnostic ultrasound Diagnostic nuclear medicine	Blood banks Supervoltage therapy Radiation plotting Drug therapy hospital systems	
COORDINATING SERVICES		Telecommunication systems Computerized health care information systems Transportation systems			
EDUCATION		Multimedia and computer-assisted education Broadband communication			
RESEARCH		Epidemiological Health Services	Clinical		

FIGURE 1 Functional classification of equipment-embodied technology for health care (with selected examples).

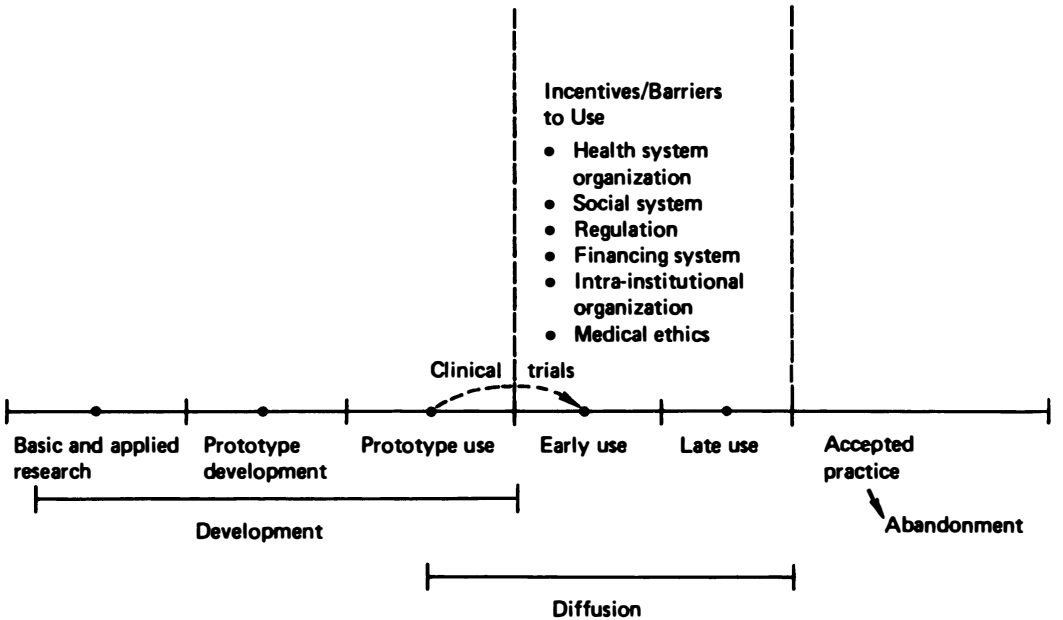

FIGURE 2 The process of technological change in health care. Adapted from U.S. Congress, Office of Technology Assessment, *Development of Medical Technology* (Washington, D.C.: U.S. Government Printing Office).

Although the process of technological change is complicated and iterative, two general stages can be considered separately--development and diffusion. Development refers to activities directly or indirectly intended to produce new capabilities or alter the characteristics of an existing technology. Diffusion is the application of a new technology in the provision of health services. Figure 2 presents a simplified model of development and diffusion as if they occurred in chronological sequence, when in fact the process of diffusion often reveals that a technology needs further development, and diffusion may sometimes parallel the development of a new technology. The two stages in the process are described more fully below.

Development of Equipment-Embodied Technology

The development of equipment-embodied technology refers to creative activities culminating in new technical capabilities. The development of such technology requires a unique blending of clinical, biomedical, and engineering talent in varied proportions, depending upon the particular application. Accordingly, development takes place in a number of settings, including university medical centers, physicians' offices, independent research and development laboratories, and commercial manufacturing firms. It is impossible to generalize, therefore, about who develops new technology and where the ideas come from. Following the typology of such technology presented in Figure 1, the development of clinical technology would follow quite different pathways from the development of ancillary diagnostic technology. For instance, surgical technologies are often developed within the medical care system, most commonly in the academic medical centers. By contrast, new laboratory tests are probably developed more frequently in independent research laboratories, where the need to combine the research and development with direct patient care is not so apparent.

Little is known about the magnitude of R&D efforts in the various settings in which development takes place or about the relative contributions of the government and the private sector to development. Although data are available on government and private funding of research and development as a whole, it is impossible to separate work on equipment-embodied technology from other scientific or biomedical technology. There is also a dearth of information on how much equipment-embodied medical technology emerges from the upgrading or reworking of existing technology that has been developed in other industries. Certainly, the use of digital computers and nuclear medicine, which have wrought a revolution in health care, came in large part from developments wholly outside the field of medicine.

All types of equipment-embodied technology require the development of a prototype at some point to demonstrate the technical feasibility of the concept. Even systems combining existing equipment, such as special care units and computer-based medical information systems, require a field demonstration to determine if certain objectives will be met when the components are brought together in a specific configuration. Once medical equipment moves beyond this experimental stage into more general use, diffusion begins.

The difficulty of tracing the general pattern of development of technology through its several stages is nowhere better illustrated than by the history of automated drug infusion, the use of a computer to administer medications to patients in appropriate doses. The application of this technology has followed a complex and intricate set of events that have been as much influenced by individuals as by forces of the marketplace. In fact, it is difficult to identify any innovative breakthrough as a clear beginning of the use of the technique. No clinical trials to test the value of automated drug infusion have been conducted, and, indeed, the technique has not yet been firmly established in health care delivery.

The concept of automated drug infusion emerged from efforts to deliver cancer chemotherapy at decentralized facilities. Pumps appropriate for this purpose were adapted from science laboratories. Simultaneously, wide interest in the adaptation of digital computers to physiological monitoring and record keeping in intensive care was being fostered by Dr. Homer Warner and his colleagues. In 1969, the National Center for Health Services Research and Development, which had supported Warner's early work, provided funds for four demonstration projects for the application of computerized principles in intensive care. The projects, called "Medlab" demonstrations, were eventually phased out as a result of an unfavorable evaluation. But in one of the demonstrations, at the University of Alabama, the computer aspects of the system had been applied in cardiac surgery. One component of the Alabama system was the use of fluids infusion under closed-loop control. As a result of this experience, the University of North Carolina and the University of Pennsylvania, where similar clinical components had been developed, sought the commercial manufacture of computer-driven infusion systems for postsurgical patients. Roche Bioelectronics undertook to produce such units with the expectation that a much larger market existed for other uses.

The technical concept of the closed-loop control of medication has appeared in other contexts as well, such as automated anesthesiology. The starts have all been fitful, due largely to technical problems, but it seems a durable idea that may someday form the basis of a line of commercial products. Microprocessors may

be the missing element that will provide the standardization and reliability that allow insertion or substitution of one subsystem for another.

In any event, prior to the actual marketing of a developed technology, a long period of custom design sometimes takes place. This period is often influenced by the individuals who work with the technology along the way. Alabama's success with fluids infusion is as much a result of the lead surgeon's ability to associate with cardiologists and to inspire his staff to dedicated performance as it is to the technology itself.

The transition from development to diffusion depends largely upon the successful commercialization of an equipment-embodied technology. Commercialization begins with an organization or individual willing to manufacture and market the equipment. The closer an idea is to the market, and the more certain the market for the technology, the more likely that successful commercialization will take place. As the case of automated drug infusion illustrates, commercial manufacturing firms may enter very late, often after a successful prototype has been developed. By contrast, there are many other instances of technology developed from scratch by commercial firms.

Diffusion of New Equipment-Embodied Technology

The diffusion process for new medical equipment is often expressed as the number of health care providers adopting a new technology as a function of the time or distance from its first availability on the market. Studies of the diffusion of technology usually attempt to explain it on the basis of characteristics of the technology, the adopters, or the environment or conditions facing the adopters.

The decision to adopt a new technology is closely related, but not identical to, the actual use of the new technology. Indeed, for much equipment-embodied technology, the two actions may be independent. Because the adoption of such technology requires capital expenditures, the determination of whether and when a provider has adopted a new technology is generally figured from the time that money has been committed to the acquisition of the equipment. Still, the act of adopting each new piece of equipment does not guarantee its use. The decision to use such technology is made most frequently by health care practitioners. Thus, the acquisition, or adoption, of an automated clinical chemistry analyzer by a hospital laboratory may be the decision of the hospital administrator, but the use is determined by the ordering physicians.

In some instances adoption and use are synonymous, as with medical information or communications systems. Here the installation

implies utilization. The services provided by such technologies cannot be broken down into discrete units of utilization.

The process of diffusion of new medical technology lies at the heart of the process of technological change. The potential adopters of any technology represent its "market." The speed and ultimate level of diffusion among providers of health care dictate the rewards to developers and marketers of the technology. Although developers and marketers can and do influence individual adoption decisions, the ultimate success or failure of a technology to diffuse rapidly and thoroughly to the user community is a function of the health care community's characteristics, including the payment system.

The Management of Technical Change

The development and diffusion of new equipment-embodied technology are everywhere influenced and shaped by public and quasi-public policies, some expressly designed to facilitate or control the process and others with unintended consequences. Taken together, the policies help to form the environment within which development and diffusion occur. The environment provides the setting for the management of technical change. Although the term "management" connotes active intervention in the process of technical change, public management policy also can imply an absence of control.

The management environment in which technical change occurs has an enormous influence on the efficiency of the process. Public management policies that are intended to directly affect the process fall into three general categories: (a) funding policies designed to promote or subsidize particular activities, such as development projects or purchase of new equipment by providers; (b) control policies that are intended to directly intervene or regulate decisions regarding development or diffusion; and (c) facilitating policies that are intended to enhance the efficiency of decisions by providing information relevant to development or diffusion or protective policies such as patents.

Other policies may indirectly and unintentionally affect the process of technical change. These are also part of the management environment. Thus, health care reimbursement policies and facility licensure programs have been developed for reasons wholly unrelated to technical change. Yet they each may have a powerful influence on patterns of development and diffusion.

The term "technology transfer" has been defined and interpreted in various ways.* Within the context of the management of technical change, technology transfer refers to a particular subset of management policies that are intended to facilitate the transition of good ideas and technologies from development stage to diffusion. Technology transfer encompasses the dissemination of information to physicians about promising innovations and patent policies. In later chapters, public management policies that fit within this definition of technology transfer will be evaluated, although the policies will not be identified as such, because technology transfer is a special case within the array of management alternatives that are available to influence the process of technical change.

SUMMARY OF FINDINGS AND RECOMMENDATIONS

Recommendations for additional research are included in the body of the report and are italicized throughout the report for each reference. This section summarizes our major policy findings and recommendations.

Finding

In general, equipment-embodied technology used in hospital, clinical, and ancillary services is subject to strong pressures for adoption and use, whereas coordinative technology, such as medical information systems or emergency medical communications systems, faces pressures against adoption and use. In fact, all equipment-embodied technology that must be applied across institutions suffers from barriers to adoption and use. In addition,

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*Some definitions of technology transfer include:

1. "The process of collection, documentation, and successful dissemination of scientific and technical information to a receiver through a number of mechanisms, both formal and informal, passive and active."[84]
2. "The process through which government research and technology is transformed into processes, products, or services that can be applied to actual or potential public or private needs."[129]
3. "The movement of new product and process ideas from seller (usually an inventor, university, or research institute) to buyer (an industrial organization or company)."[27]

preventive technology, particularly mass screening, whose benefits can be fully realized only when prevention is integrated with treatment and follow-up, is also subject to barriers to adoption and use.

A major factor affecting the adoption and use of new equipment-embodied technology is the prevailing methods of reimbursing providers for health services. The current provider reimbursement methods create improper incentives for the adoption of new technology. Clinical and ancillary technology, particularly that applied in hospitals, is encouraged by the reimbursement system. Coordinative and preventive technology is discouraged.

1. *Recommendation* The prevailing methods of reimbursing providers for health care services should be revised to promote appropriate incentives with respect to the adoption and use of equipment-embodied technology. Because reimbursement policy is central to all aspects of containing health care costs and directly affects the redistribution of wealth and income, the precise avenues of reimbursement reform must be chosen in a larger context. Prospective reimbursement of hospitals and the capitation method of payment are especially promising in altering incentives to adopt and use new equipment-embodied technology.

2. *Recommendation* Public subsidy may well be warranted for the development of coordinative technology, such as medical information systems and emergency medical technology, as well as for preventive technology.

If these recommendations are implemented, health care organizations will have to consider the benefits and costs of adopting new technology and using existing technology in the presence of limited resources. This will undoubtedly result in more effective institutional and regional planning of service delivery.

In addition, the support of development efforts will encourage the further development of coordinative and preventive technology and bring them closer to a point of market viability.

Finding

Current methods for evaluating new equipment-embodied technology are inadequate because they are neither timely nor coordinated. Moreover, they do not consider economic criteria.

3. *Recommendation* A mechanism for evaluating and reporting on the performance, costs, and benefits of equipment-embodied

(and perhaps other) technology should be developed. A national coordinating body should be established to:

- Identify the need for evaluative information on equipment-embodied (and perhaps other) technology.
- Fund planning and evaluation studies where existing funding programs are not adequate.
- Collect and disseminate available information regarding new and existing technology to users.
- Encourage and foster national and international efforts to standardize equipment-embodied technology to achieve economy of equipment design, safety, and comparability of data.
- Conduct and sponsor research into methodologies for evaluating medical technology.
- Coordinate evaluative programs of federal agencies.

If this recommendation is accepted, decisions regarding the adoption and use of new equipment-embodied technology will be based on better information, regardless of the management policies adopted.

Finding

The process by which new equipment-embodied technology is developed and introduced into the health care system is already greatly affected by myriad regulatory programs at federal, state, and local levels. These regulations are costly, administratively burdensome, duplicative, and often conflicting. They affect every point in the process of technical change.

4. *Recommendation* Solutions to the problems of adoption and use of new equipment-embodied technology should be evaluated in terms of their regulatory burden. In the committee's view, policies that alter incentives without the need for detailed regulation are preferable to policies based on new or additional regulation. In addition, the existing regulatory structure could be improved at all levels of government. Regulatory programs influencing the introduction of new medical technology should be reexamined closely with the goal of relieving the system of uncoordinated, duplicative, or conflicting regulatory processes.

2 ECONOMIC COSTS

Questions have been raised about the relationship between medical technology, particularly equipment-embodied technology, and the cost of health care. Technology has been identified as a major cause of increasing health care expenditures,[35] with the implication that controlling new technology is required to contain health care costs. The committee believes that the full economic impact of changes in medical technology can be assessed only by comparing resulting changes in health care costs with net social benefits. Such benefits may be measured in terms of decreasing rates of mortality and morbidity and improving quality of life. Studies of the impact of different classes of medical technology on hospital or health care expenditures alone ignore such benefits, but they do indicate the kinds of technology likely to increase costs (that is, to lead to increases in total per-capita health care outlays) and the need of demonstration of improved patient benefits. Consequently, the committee has assessed the evidence on the relationship between medical technology (particularly equipment-embodied technology) and health care expenditures, as well as the evidence relating these costs to the social benefits that may follow.

CONCEPTS OF ECONOMIC COSTS

The economic cost of new technology can be measured at three levels:

- *Direct costs associated with the operation and use of technology*. These include the capital costs associated with the purchase or lease of equipment and the related facilities necessary

to use the technology, as well as the direct costs of operating the equipment and facilities. Direct cost estimates are often made for a specific technology or class of technology in order to determine the burden on payers. An example is an estimate by Neuhauser and Jonsson that coronary bypass surgery, if performed on 700,000 patients annually, as predicted by some experts, could cost in excess of $5 billion per year.[88]

- *Indirect health care costs or savings*. Pitted against the direct costs of operating a technology are the additional costs or savings (negative costs) resulting from changes or substitution in the delivery of other medical services. The costs of a lengthened hospital stay due to the use of a new procedure would be in this category. Similarly, savings from the substitution of a new technology for more costly technology that previously performed the same tasks would also be considered indirect.
- *Social costs or benefits*. The measurement of all costs associated with a new technology, including direct and indirect health care costs, as well as costs accruing outside of the health care system, represents the highest level of measurement. Increases in productivity, reduction in pain, improvement in the quality of life, and increases in life spans are benefits (or negative costs), although assigning dollar values to such benefits is difficult. Changes in the risk of morbidity or mortality resulting from new technology also need to be included in the social cost or benefit calculation.

Research and development costs are not included here in the measurement of the economic costs of new technology for two reasons: (a) a large part of the research and development of equipment-embodied technology occurs in industrial settings, where, it is assumed, costs will be reflected in the price of the resulting equipment; and (b) it is virtually impossible to assign research and development costs funded by the government to particular classes of technology.

THE DIRECT COSTS OF EQUIPMENT-EMBODIED TECHNOLOGY

There is no question that the use of medical equipment in providing health care services has increased dramatically over the past 5 years alone. Total domestic shipments of x-ray apparatus and electromedical devices increased from $444 million in 1972 to an estimated $1.3 billion in 1977, an annual growth rate of about 24 percent over the past 5 years.[122] Predictions for 1978 are that the industry will sell $1.6 billion of this sophisticated medical equipment, an increase of 20 percent over 1977.[122] Alone, this

trend is not revealing, for the increase in equipment purchases could be substituting for expensive labor and might actually be moderating the rate of increase in health care expenditures. More analysis is needed to determine the total direct costs of all this equipment.

Only one study has attempted to measure the direct contribution of equipment-embodied technology to increases in health care costs. That study, by Cromwell *et al.*,[19] estimated the direct contribution of equipment to changes in the level of hospital costs in 15 Boston hospitals. In a 10-year period (1965-75), Cromwell and his colleagues found, total capital equipment expenditures in these hospitals rose by 23 percent, accounting for 9 percent of the total annual increase in hospital costs in the 10-year study period. Moreover, in a paper commissioned by this committee, Warner extended the estimate by including the costs of complementary inputs associated with the operation of equipment and estimated that "on average the operating (variable) costs associated with capital-embodied technologies at least equal, and probably exceed by a factor of 2 or 3, the capital costs" (see Appendix G). Therefore, equipment may have accounted for 17 to 34 percent of the total increase in hospital costs in recent years. Warner pointed out the problem of using a sample of 15 Boston-area hospitals as a basis for a national estimate, especially because such hospitals have heavy teaching responsibilities and serve as regional referral centers. The estimate would therefore need to be revised downward.

The rising equipment expenditures documented by Warner include not only the costs of new or updated technology, but also the costs of buying additional units of existing equipment in response to increased demand for hospital services and beds during the study period. Furthermore, some of the new or updated technology adopted by the hospitals during the study period may have replaced inputs in other categories (such as labor). Nevertheless, the estimates by Cromwell and Warner are the only reasonable attempts to measure the total direct costs of equipment-embodied technology.

Much of the circumstantial evidence linking equipment-embodied technology to increased hospital and health care costs is based on recent studies of the increased input intensity in the provision of health care services. In 1972, Waldman[133] estimated that increases in real inputs (labor and material) accounted for 50 percent of the annual changes in per diem hospital costs between 1951 and 1970. Similar findings by Worthington[143] and, most recently, Feldstein and Taylor[29] have demonstrated the changing nature of hospital services. Feldstein and Taylor found that about 75 percent of the rise in hospital costs relative to the general economy can be attributed to increases in labor and nonlabor inputs per

patient day.[29] Increasing intensity of care as measured by increasing inputs cannot be assumed to be synonymous with changes in technology. However, Waldman[133] implies that it is, and more recent analysts--such as Gaus and Cooper[36]--have even labeled the increases in input intensity as the "technology factor." This label is misleading; as Warner has observed, "the only conclusions warranted by these data is a tautological restatement of what was calculated: half of hospital cost increases has been due to unit price increases; the other half represents increases in the quantities of inputs" (see Appendix G).

Further evidence about the nature of the increasing intensity of services provided in the hospital has been offered by Redisch,[99] who found that approximately 40 percent of the rise in hospital operating costs per admission results from increased use of nine ancillary services, most under the control of physicians. Such services include pathology tests, nuclear medicine procedures, anesthesiology, pharmacy items, lab tests, radiological procedures, therapeutic x-ray, and blood bank units. More than any other medical care services, these ancillary services are equipment-intensive. Of course, the increasing use of these types of services may be as much a function of increasing demand as it is a function of technological change in the services. Neither Redisch nor any other student of the problem has attempted to analyze the various causes of utilization increases.

THE IMPACT OF MEDICAL TECHNOLOGY ON TOTAL HEALTH CARE COSTS

Several studies have attempted to measure the total impact of medical technology on health care expenditure increases using a residual approach. These studies attempt to account for all other sources of health care expenditure increase, and the unexplained residual of changes over time is assumed to measure the effects of technological change.

In a study of the impact of new technology on the costs of hospital care, Davis[21] used data from approximately 200 nonprofit hospitals for the period 1962-68. She found that when effects of demand and supply variables had been determined, 38 percent of the annual increase in hospital expenses per admission remained unaccounted for. This residual represented a 2 percent annual increase in hospital expenses per admission and was attributed to technological change.

The residual in Davis's study cannot be assumed, however, to represent only the effects of technological change. Other gradual changes in behavior over time, which were not represented by explicit variables in her model, could contribute to the residual increase in costs. Changing attitudes about hospital care and

improved methods of ambulatory care are examples of other possible contributing factors. Davis suggests that at least the residual provides an upper limit for the effects of technological change. This is not the case, however. Unknown factors affecting the residual could decrease costs over time and thus mask some of the effects of technological change. The residual in her model could therefore underestimate cost increases precipitated by technological change. Davis's approach is further limited in its applicability to this study in that it does not differentiate between the effects of equipment-embodied technology and those of other technology.

Several investigators have used the residual approach to estimate the impact of biomedical advances on total medical care costs. Mushkin *et al.*[82] analyzed the total impact of biomedical research and technology on health expenditures between 1930 and 1975. Biomedical research and technological change were estimated to cause annual reductions in total health expenditures of 0.5 percent. This compares favorably with a 20-year study by Fuchs,[32] which found that technological change had a positive residual effect on total health care expenditures of 0.6 percent annually between 1947 and 1967. The difference in these two studies may be attributable to differences in the periods and in the factors examined.

Again, the residual approach employed in these studies has some major limitations. These long-term longitudinal studies include the effects on the cost of medical care of the significant advances in the treatment of communicable diseases during the period under study. They also include the net effect of shifting disease patterns of the population. Thus, the relatively favorable outcome with respect to the role of technology and biomedical research over the entire study period obscures the effects of more recent changes in technology. Moreover, both Mushkin and Fuchs are concerned with technological change in its fullest sense; the impact of equipment-embodied technology cannot be separated from that of drugs, procedures, and other technology in these studies.

Scitovsky and McCall[109] have analyzed the changes in costs of medical care associated with selected illnesses. The net increase in the average cost of treatment of an episode of illness from 1964 to 1971 was calculated for eight conditions--otitis media, forearm fracture, appendicitis, maternity care, cancer of the breast, pneumonia, duodenal ulcer, and myocardial infarction. In almost every instance, there were both cost-raising and cost-saving changes in treatment. However, Scitovsky and McCall note that "the costs of treatment of conditions requiring hospitalization rose at a considerably faster rate than those of conditions treated on an ambulatory basis."[109] Among the factors leading to higher costs were shifts to more expensive drugs, increases in the number of laboratory tests per case, and more miscellaneous inpatient and

output patient services. The most dramatic cost increases occurred in the treatment of myocardial infarction. Such changes were traced principally to the increasing use of intensive care units. Thus, treatment cost increases were found to arise primarily from a shift in the setting of care within the hospital from less specialized to more specialized units. Unfortunately, only a few conditions were studied, and trends detected in this small sample of conditions cannot be assumed representative of all conditions. Therefore, the results of the analysis cannot be used to identify net effects of technological change on total health care expenditures.

THE SOCIAL BENEFITS AND COSTS OF NEW MEDICAL TECHNOLOGY

While the application of benefit-cost analysis to health programs has a long history,[68] the committee is aware of only one study that has attempted to measure the "social" costs of a broad class of technological advances. This study, conducted by the American College of Surgeons,[4] estimated the net contribution of research in surgery to medical and social costs. Using the life-cycle earnings approach to valuing changes in morbidity and mortality, the study found that the most significant research contributions had resulted in a net saving of $2.8 billion for the year 1970, an impressive saving on its face. However, the study deals only with selected successful surgical advances, and the results are therefore biased. The study methodology eliminated from consideration surgical advances that have been considered marginal and even dangerous to the health of patients. It is likely that had these advances been included in the study, their net social costs would have partially or totally offset the net social savings resulting from the successful advances studied.

Study of the economics of equipment-embodied technology ultimately rests on analysis of specific procedures or equipment whose costs have been weighed against their benefits. Even in cases where the benefits are life-saving, as in renal dialysis, program costs can seem staggering from a social perspective. The costs of the End Stage Renal Disease Program have exceeded all expectations.[101] Computed tomographic (CT) scanning is frequently cited as a technology whose direct costs will far outweigh the indirect savings and social benefits that will derive, although this hypothesis is based largely on conjecture at this point.[8] In a case study of gastric freezing (Appendix D), Fineberg has shown that direct costs for the purchase of the freezing equipment amounted to approximately $500,000 over a 2- to 4-year period. This, plus the fees for the surgery that used the new technology were largely wasted, because the procedure was found to be of dubious value to

patients. For additional instances, see Russell and Burke,[105] who have shown large expenditures for uncertain, unproven, or disproved equipment technologies. But other case studies show savings that are attributable to the introduction of specific new equipment-embodied technology. In Appendix B of this report, Collen shows that net savings to the health care system would accrue from a yearly program of mammography screening for breast cancer among women aged 50 and over provided that each test could be performed at a cost of $14 or less. Collen infers that physicians, consumers, and third-party payers should consider this opportunity seriously.

THE DISTRIBUTION OF COSTS AND BENEFITS OF NEW EQUIPMENT-EMBODIED TECHNOLOGY

Who benefits from and who pays for changes in equipment-embodied technology? It is well known and to be expected that health care resources are disproportionately devoted to the seriously ill. For example, in 1975, over 55 percent of spending for acute medical services in the United States was on behalf of just 4 percent of the patient population.[114] Intensive care and coronary care beds totaled 5 percent of all short-stay hospital beds in the United States in 1975, but approximately 15 percent of hospital costs in that year were attributed to intensive care (Appendix G).

More important than this concentration of resources per se is whether it has been intensifying over time. The evidence points to a slow but steady increase in the concentration of resources on those who are most seriously ill. Hospital care expenditures represent an increasing proportion of total personal health care expenditures (up from 39 percent in 1965 to 46 percent in 1976[38]), while patient days per thousand population have remained fairly constant. This trend is only partially accounted for by the aging of the population. Part of the increase must be attributed to changes in prices of hospital inputs and intensity of health services delivered in the hospital setting relative to those delivered in other settings.

Trapnell and McFadden[114] have studied the distribution of annual expenditures for insured health care services between 1965 and 1975 in a large group health insurance plan. They found that "there is a significant but small trend toward increasing concentration of spending on those with the highest expenditures."*

*The trend is probably understated because the spending analysis was based upon hospital charges, which do not accurately reflect the cost of providing individual services. It is often asserted that certain technology-intensive services such as special care units are subsidized by other hospital services. Hellinger[53] has shown that charges are often manipulated to maximize hospital revenue from Medicare.

In a recent study of the benefits of critical care rendered in intensive care units (ICU's), Cullen *et al.*[20] found that 27 percent of the patients in a well-run unit survive only 1 year, resulting in a per-survivor cost of $52,000, and only 12 percent are restored to full function after 1 year. The per-survivor cost is calculated on the assumption that the ICU was a necessary condition for survival. If some patients would have survived without the benefit of intensive care, the cost would have to be adjusted upward. Of course, the application of technology to serious and life-threatening problems provides a measure of hope to all patients, including those who do not survive. By increasing probabilities of survival (if only marginally), this equipment-embodied technology does provide some valuable benefits to all patients.

The question reduces to one of willingness to pay for these benefits. According to Cullen, "Quite properly, those responsible for advancing medical frontiers do not consider the financial impact of providing increasingly costly, high quality intensive care on a large scale. Yet, economically, these costs are becoming intolerable and will be self-limiting in yet undetermined ways."

CONCLUSIONS

As purchases of capital equipment by hospitals have increased, the direct cost of hospital care also has risen. But no evidence exists to compare the increase in hospital costs with the savings to the health care system that come from the increased use of equipment or with the benefits to society. The evidence does show that this application of medical technology as a whole (including drugs and procedures as well as equipment) probably has not increased hospital or total health care costs substantially. But nothing can be said about the contribution of the equipment-embodied component of medical technology to total health care costs. In fact, costs of equipment-embodied technology could be offsetting savings from other technological advances, including new drugs, procedures, or methods for organizing health care delivery.

There is evidence that hospital resources are increasingly concentrated on the care of a smaller proportion of patients--those requiring critical or specialized care. Although critical care implies the intensive application of labor as well as equipment, it is obvious that critical care and specialized care units are equipment-intensive relative to unspecialized hospital beds. Today's increasing allocation of health care resources to the care of fewer patients is a trend whose ultimate benefits are largely unknown.

Health care financing policies have encouraged the increased emphasis on critical care medicine. The Health Insurance Institute[51] recently documented the rapid increase in dollar limitations on group health insurance plans. Today, about 80 percent of all group health insurance benefit packages include a total coverage limit of $100,000 or more, while as recently as 1971 fewer than 1 percent had such a limit. Consumers increasingly demand financial access to services for catastrophic illness even when those services appear to provide only marginal improvements in patient outcomes.

3 PROBLEMS IN ADOPTION AND USE

Significant empirical evidence suggests that the diffusion of new equipment-embodied medical technology often diverges from socially optimal paths. Decisions by health care providers and practitioners to adopt and use equipment and its related procedures in patient care do not appear to be based on a comparison of their benefits and costs to society. Some examples will illustrate this point:

- *Fetal monitors* have diffused widely into the practice of obstetrical care, but the benefits are not yet clear.[49]
- *Computed tomographic scanners* have been adopted by more than 500 hospitals in the past 3 years, well in advance of the collection of information on their effectiveness as diagnostic procedures.[31]
- *Gastric freezing* was diffused widely as a surgical technique used for the treatment of duodenal ulcers and was largely abandoned before definitive evaluation of its benefits could be published (Appendix D).
- *Medical information systems* have followed a fitful process of diffusion, encountering significant barriers except in the few research centers currently funded to demonstrate and develop such systems (Appendix E).
- *Rehabilitative technologies* have not developed in accordance with predictions of their great potential benefits to recipients.[87]

The committee has attempted to analyze the causes of such problems. In particular, it has been interested in identifying systematic tendencies of the health care delivery system to encourage

or inhibit the diffusion of particular classes of equipment-embodied technology. It finds that, in general, equipment-embodied technology in hospital, clinical, and ancillary services is subject to strong pressure for adoption and use with few countervaling forces. Conversely, coordinative equipment-embodied technologies, particularly those relying on coordination among providers within the health care system to achieve full realization of benefits, face strong pressures against adoption and use. In fact, when equipment-embodied technology must be applied across institutions or requires the integration of services to fully realize its potential benefits, it suffers from barriers to its adoption and use. Preventive technology, particularly mass screening, and coordinative technology fall into this category. The remainder of this chapter summarizes the evidence that exists to support these findings.

The committee is acutely aware of the limitations of the available evidence. Although several empirical studies of the diffusion of hospital technology have provided valuable insight into the characteristics of innovative individuals and organizations, the impact on diffusion of the most important policy-related factors--the reimbursement system, the malpractice system, and the organization of medical care delivery--has generally not been studied. Consequently, the committee has had to rely on empirical evidence and its own judgment in assessing the impact that the factors have had on the adoption and use of equipment-embodied technology. In making its analysis, the committee has been sensitive to the need for additional research and has identified areas where opportunities exist for better understanding of the diffusion process. These research recommendations are italicized throughout the text.

THEORIES OF HOSPITAL BEHAVIOR

The decision to adopt equipment-embodied technology is based on resource allocation. It requires the allocation of scarce capital resources to the purchase of equipment, and it further implies an allocation of the productive resources of the health care organization to the provision of certain services. Because the hospital is the major repository of equipment-embodied technology, the way in which hospitals allocate resources is of interest here. Are there definable attributes of hospital behavior that would explain why equipment-embodied technology as a whole, or certain kinds of equipment-embodied technology, would be adopted more or less readily than other productive resources?

There are two sets of theories of hospital decision making that bear on the question of equipment adoption. The first assumes that

the hospital, while organizationally complex, possesses defined institutional objectives on whose basis its behavior can be predicted. The objectives of hospitals have alternatively been postulated as:* maximization of quantity of services produced;[22] maximization of quality of services produced;[28] maximization of a weighted function of the quantity and quality of services produced;[89] maximization of the relative prestige of the hospital in the community;[69] and maximization of the joint incomes of the physician staff.[72] With the exception of the last hypothesis, which is the most divergent and novel articulation of hospital objectives, the alternatives all can be expressed as special cases of the third objective, the maximization of a weighted combination of the quality and quantity of hospital services produced.

If quality and quantity of services are in fact the attributes of interest to the hospital, then the way in which quality is perceived, not only by the hospitals' decision makers, but also by the patients who will generate demand for services, has a major influence on the behavior of the hospital. Feldstein[28] has theorized that hospital decision makers perceive quality of services as a function of the amount of labor and nonlabor inputs devoted to the production of medical care. A hospital that delivers care with greater service intensity would thus be perceived as a higher quality institution. However, perceived quality may be correlated as much with the level of sophistication of those inputs as with their aggregate amounts.[46] If patients themselves identify hospital quality with the availability of capital-intensive equipment and systems, or specialized labor, then hospitals wishing to maximize the quantity of services provided would respond by emphasizing these inputs relative to others in order to increase the demand for the hospital's services. Thus, the willingness of hospitals to adopt new technology may rest on the degree to which patients and hospital decision makers equate hospital quality with the availability of this technology. Empirical research on perceptions of hospital quality by health professionals and patients is lacking; however, at least one practitioner has observed that

*These objectives have been postulated for private, nonprofit hospitals, which constitute the majority (56 percent) of the approximately 6,000 nonfederal, short-term hospitals in the United States. The remainder are government owned (31 percent) or private, for-profit hospitals (13 percent), which are likely to have different objectives from those of voluntary hospitals. However, of the hospitals with 300 or more beds, 81 percent are private, nonprofit institutions. It is legitimate to concentrate on this ownership form since, to a large extent, standards of hospital care will be dictated by this subset of hospitals.

professionals may be " . . . charmed by blinking lights and cathode-ray tubes into adopting a technology that will decrease the frequency of contact between the human monitor and the patient."[77] This theory would also imply that technology in clinical settings, with its high use and visibility in patient care, would be favored over administrative technology.

A second set of theories of hospital behavior rests on the assumption that hospitals are complex organizations where decisions cannot be predicted from a single objective. Instead, decisions to adopt new technology are assumed to be a function of the structure of the hospital organization and the relative dominance of competing interest groups.[124] Hospital decisions are made on the basis of intra-organizational politics rather than on the basis of a single goal. According to Tushman,[116] the politics of organizations is the "structure and process of the use of power to affect goals, directions, and major parameters." The political view of hospital behavior sees it "not wholly determined by environmental conditions or constrained to cooperative or goal-oriented behavior but as a complex of cross-cutting strategic decisions and exchanges at all levels of the organization."[116] Using this perspective, one is led to seek out the organizational subgroups that affect and are affected by decisions regarding the adoption of new medical technology.

A leading theory of hospital behavior following this line of reasoning has been described as the "physician dominance" theory.[93] According to this argument, the hospital is in effect run by the attending physician staff, because it is physicians who direct the patients to the hospital. Therefore, to understand the behavior of hospitals, it is necessary to examine the goals of different kinds of physicians and to examine the coalition behavior of these groups. The physician dominance theory has been criticized by Greer[44] and others.[93] According to Greer, the hospital administration and hospital boards may have as much or more power than any individual physician or group of physicians. It may also be true that hospital decisions about hospital technology result more often from the coincidence of goals among various groups than the dominance of particular groups. In the absence of a budget constraint, the hospital administrator can meet all demands over time.

What, then, can one infer from this body of theory with respect to hospitals' adoption of new equipment-embodied technology? Although there is little available in the way of deductive inferences, the theories do suggest a number of reasons why clinical equipment-embodied technology is valued in the hospital. It is an input in hospitals' production of both quantity and perceived quality of services; some equipment increases the productivity of attending physicians and some contributes to the prestige of the institution and its affiliated physicians.

EMPIRICAL EVIDENCE ON THE DIFFUSION OF EQUIPMENT-EMBODIED TECHNOLOGY

Because theory provides only broad predictions about factors affecting the adoption of equipment-embodied technology, it is useful to examine empirical studies of diffusion both for corroboration of theory and for a better understanding of the nature of the diffusion process. Three central questions are of interest: (i) What attributes of equipment-embodied technologies influence their rate and pattern of adoption? (ii) What attributes of the potential adopters of equipment-embodied technology influence the process? (iii) What factors in the environment in which potential adopters operate influence the process? Each of the questions is discussed in turn.

Attributes of the Technology

One would expect certain attributes of a technology or innovation to influence the speed of diffusion. Tanon and Rogers[113] have suggested that the following are likely to affect the speed of diffusion:

- Relative advantages over existing technology
- Compatibility with existing values of the institution
- Complexity--the degree to which it is easy or difficult to understand and use
- Relative ease in experimenting or trying out the innovation on a limited basis
- Observability--the degree to which the results of innovation are visible to others.

No systematic study of the impact of these or other attributes on the speed of diffusion of equipment-embodied medical technology has been attempted. However, there is some indirect evidence to suggest that at least some of these characteristics are important determinants. The relative advantages of a new technology, either in improving patient outcomes or reducing patient risks, has been shown to be a strong impetus to diffusion. Greer[44] has documented the reluctance of ophthalmologists in one community to adopt a new equipment-embodied cataract removal procedure, phakoemulsification, because of its added patient risk in the absence of clear therapeutic benefit, in spite of significant savings in patient recovery time and opportunities for physicians to augment their incomes. Fineberg's study of gastric freezing (Appendix D) demonstrates the sensitivity of physicians to the pain and risk of a new procedure in the absence of unequivocal evidence of effectiveness. This

procedure was largely abandoned several years before the first definitive study of its effectiveness in treating duodenal ulcers. Computed tomographic scanning has rapidly replaced more dangerous, painful, and invasive procedures for detecting brain lesions. The more unpleasant the existing alternative procedures, the faster the substitution process has occurred.[120] Warner[136] showed that the diffusion of new drugs for treatment of a desperate condition occurs extremely rapidly compared to drugs used for less serious illness.

Studies of the diffusion of innovations in other industries have demonstrated the importance of certain innovation characteristics. The industrial literature[78,102] shows that the size of the investment required for adoption of the technology (relative to firm size) is important in determining the speed of diffusion. Presumably, the larger the required investment, the more risk the firm faces and the greater the problems of capital availability. Hospitals, too, face capital constraints, but they are likely to be resolved differently from those of industry. In hospitals the risk associated with capital investment is greatly reduced by the predominant cost or charge-based methods of hospital reimbursement.

The ability of an innovation to reduce costs and increase profitability has been shown to be important in studies of agricultural innovation[45] and industrial innovation.[78] In hospitals these financial advantages are likely to be less important than considerations of effectiveness and safety. Indeed, in a study of equipment adoption decisions in 15 Boston hospitals, Cromwell[19] found that criteria such as "improvements in patient care," "life saving capability," and "patient safety" were much more important to hospital administrators than were the financial or cost-saving attributes of equipment.

Characteristics of Adopters

Of course, the potential adopter's perceptions about technology depend upon his own characteristics, and, for this and a variety of other reasons, such characteristics play a role in the diffusion of technology.

A number of studies of the diffusion of hospital clinical technologies have attempted to isolate attributes of the hospital responsible for rapid or slow responses to new technology. Gordon *et al.*[40] showed that the adoption of accepted medical technology (respiratory therapy equipment) is related to the degree of visibility of consequences and the degree of decentralization of resource allocation decisions within the hospital. The study also

revealed that hospitals with highly trained medical staffs tend to be more innovative than others.

As expected, hospital size and medical school affiliation have been shown to be important determinants of early adoption of new clinical equipment-embodied technology.[19,98] In a study of nuclear medicine facilities, Rapoport[98] showed that the existence of a high percentage of hospitals with medical school affiliation in a state slowed down the diffusion of a new technology in unaffiliated hospitals. The leadership role played by teaching hospitals in the adoption of new technology is hypothesized to have had a dampening effect on competition among nonaffiliated hospitals. In a study on the diffusion of innovative health care services in hospitals, Kaluzny *et al.*[66] concluded that larger hospitals, particularly in urban areas, adopt innovations earlier and more quickly than smaller hospitals. Cromwell's study indicates that bed size influences adoption only in nonteaching hospitals.[19]

Other studies suggest that the more comprehensive a hospital's services are, the more likely the hospital is to be highly innovative. Rapoport[98] noted that hospitals that adopted nuclear medicine facilities early tended to be ones already well equipped with specialized services. Similarly, Cromwell[19] found in an intrastate study of hospital diffusion that the range and number of other complex services (for example, intensive care unit, radium therapy, cardiac catheter lab) offered by a hospital is positively correlated with adoption.

The profit or nonprofit status of a hospital should also determine its adoption behavior. Theoretically, profit-making hospitals should be slower in adopting new clinical technology, particularly cost-raising technology. However, Cromwell's study showed no consistent tendency for profit-making hospitals to adopt new equipment more slowly.[19]

The organizational factors responsible for patterns of diffusion of clearly disproven equipment-embodied technology have not been studied in detail. Thus, we have no information on whether the organizational factors identified in the literature as important determinants of adoption of accepted technology are also those that encourage the adoption of poor technology. Perhaps hospitals affiliated with medical schools are better at discriminating between effective and ineffective technologies than unaffiliated hospitals. Unfortunately, there is no information to test this hypothesis. The reason is obvious. The few data sources available to support research on the diffusion of equipment-embodied technology do not compile data on ephemeral technology. Therefore, the study of failed technology would entail retrospective primary data collection, a costly and perhaps even infeasible undertaking.

Environmental Factors

Hospitals encounter various constraints on their operations from numerous external sources. The nature of these constraints can be expected to be a major determinant of the patterns of diffusion for new hospital equipment.

The impact of hospital competition on the adoption of equipment-embodied technology has been studied from several vantage points. In his study of the diffusion of nuclear medical facilities, Rapoport[98] attempted to measure the impact of inter-hospital competition on adoption, using the proportion of a state's population residing in urban areas as the measure of the competitive environment. He hypothesized that more urban environments would experience more competition among hospitals. The variable was found to be significant in explaining statewide rates of adoption of nuclear medicine. Rapoport[98] also hypothesized that states with relatively few physicians might see higher rates of equipment adoption due to competitive forces, because hospitals in these states would have to compete for scarce physician staff. However, physicians also generate demand for services, so the net impact of physician availability is not clear. Indeed, Rapoport found that physician availability is not significantly related to statewide diffusion rates for nuclear medicine. Cromwell[19] also studied the impact of the number of physicians in a state on the number of hospitals possessing an equipment-intensive facility. The total number of physicians per capita was found to be positively related to the number of hospitals adopting a technology, and the ratio of specialists to nonspecialists was also important for most services. In fact, the more specialized the equipment, the stronger was this relationship. Thus, it appears that the demand-generating role that physicians play is more important than competition among hospitals for physician staff in affecting adoption rates.

Certainly, regulation is likely to affect diffusion of equipment-embodied technology. Some inferences can be drawn from related situations. For example, public utilities subject to rate-of-return regulation appear to have little incentive to innovate, although they have a greater incentive to invest heavily in capital assets.[6] Indeed, the major incentive seems to come from the delays inherent in such regulation--that is, the "regulatory lag."[7]

The major regulatory policies directly affecting adoption decisions by hospitals are the state certificate of need (CON) and capital expenditure approval programs. These laws mandate review and approval of large capital expenditures (generally in excess of $100,000) by local and state health planning agencies, with various sanctions applied to a hospital that goes ahead with an

expenditure without this approval. *A priori*, one would expect this law to slow down the diffusion of expensive equipment. However, the evidence suggests just the reverse. The introduction of CON may have increased diffusion of expensive technology, especially in the early years of each state's program.[53] Cromwell *et al.*[19] tested whether the existence of a CON law has a significant effect on the adoption of equipment-intensive clinical services. CON was found to be significantly and negatively related to rates of adoption of x-ray, cobalt, and radium therapy services, but it was not a significant explanatory variable for other services, including intensive care, open-heart surgery, and diagnostic nuclear medicine--three services for which it should have been affected.

Other forms of health care regulation have also been posited to affect the diffusion of technology. Institutional licensure, accreditation, and certification programs dictate standards of hospital construction and operation. State licensure programs focus largely on fire and life safety, water sanitation, minimum service standards, and guidelines for staffing and staff qualifications (Appendix E); accreditation by the Joint Commission on the Accreditation of Hospitals (JCAH) also concentrates on these aspects of hospital operation. The net effect of these regulations is unclear, since considerable capital funds can be tied up in meeting licensure and accreditation requirements, thereby reducing availability of capital for equipment and facilities acquisition. Needleman and Lewin (Appendix F) conclude that *the effect of facility licensure and certification programs on hospital adoption decisions is not well understood and should be investigated further.*

Perhaps the most important factor bearing on the adoption behavior of hospitals is unique to the health care industry--the system of third-party payment. That the methods of paying for health care services would influence the patterns of adoption of equipment-embodied technology seems obvious. Yet, there is very little empirical study of the impact of methods of financing and reimbursement on the adoption of new technology by hospitals. This is the result largely of data limitations and the ubiquitous nature of prevailing reimbursement systems, limiting the opportunity for comparative studies.

Only one study has attempted to measure the effect of a change in health care financing on the adoption of equipment. Russell[104] investigated the rates of diffusion of three kinds of equipment-embodied technology--intensive care units, nuclear medicine, and electroencephalography--before and after the inception of Medicare. The results of the study are equivocal. The increase in funding implied by the introduction of Medicare did appear to speed up the adoption of some services in hospitals within specific size

categories, but the result was not uniform across all the technologies studied or across all hospital size categories. A major limitation of this study was the inability to control for changes in technology that independently affect the diffusion process. *Comparative empirical studies in this area are warranted. To what extent does charge- or cost-based retrospective reimbursement of hospitals lead to adoption behavior that is different from such behavior under prospective budgeting or formula rate-setting? How has the diffusion of new technology in other countries with different methods of financing health care differed from experience in the United States? These comparative studies can be augmented by comparison of adoption behavior over time as changes in reimbursement methods are introduced within the United States.*

Lessons from the Empirical Studies

The empirical studies of diffusion, though selective, reveal a pattern to the diffusion process for clinical and ancillary hospital technology. At least for the equipment and equipment-intensive services studied, earlier adopters are large hospitals with decentralized organizations and hospitals affiliated with medical schools. There is strong indirect evidence that competitive factors also play a role in enhancing the diffusion process. Direct regulation of the process of diffusion has not had much effect.

Although there has been little systematic study of the attributes of technology itself that affect diffusion, perceived medical promise appears to dominate financial or cost-saving attributes in hospitals' priority setting. But the studies shed no light on how well hospitals discriminate among different kinds of clinical technology in this regard. If, for example, there is a systematic tendency for hospitals to over- or under-value particular categories of equipment-embodied technology (see Figure 1) relative to one another, studies have not revealed it. Biases against adoption are difficult to detect. Technologies that have not diffused are not highly visible and do not lend themselves to empirical study. Consequently, it is difficult to identify particular procedures or equipment that are fully developed and ready for widespread use that have not been diffused. At best, one can identify instances of promising demonstrations or individual applications that have not been pursued much beyond the development phase.

Little empirical evidence is available on the impact of the system of financing and delivering health services on technology diffusion. In particular, the impact of the system of paying for health care services on the adoption of different kinds of health care technology has not been studied. Nor has there been

a systematic analysis of the impact of the medical injury compensation system (malpractice) on the adoption or use of new equipment-embodied technology. The effect of the organization of health care delivery on the adoption of different kinds of equipment-embodied technology also remains unexplored.

The lack of appropriate control groups and data has hindered this kind of study. Nevertheless, the importance of all three factors in determining the patterns of diffusion of different kinds of technology suggests a closer look at each of them. The remainder of this chapter is devoted to an assessment of the role that these factors play in diffusion based on the indirect and fragmentary evidence that exists and upon the combined judgment of the committee.

THE IMPACT OF THE HEALTH CARE FINANCING SYSTEM ON THE ADOPTION AND USE OF EQUIPMENT-EMBODIED TECHNOLOGY

Four aspects of the present system for financing health care must be analyzed. These are:

- Methods for reimbursing hospitals for routine services
- Methods for reimbursing hospitals for ancillary services
- Methods for reimbursing physicians
- Limits to third-party reimbursement.

Each is discussed below.

Methods for Reimbursing Hospitals for Routine Services

As it is presently structured, the health care financing system provides hospitals with strong positive incentives to adopt and use certain kinds of equipment-embodied technology. Payment for hospital services is almost totally covered by third parties (insurance companies, unions, and governments that reimburse hospitals for the provision of covered services to their members). Typically, these payers reimburse hospitals on the basis of charges or costs and pass the expenses on to consumers through periodic premium payments or taxes. For the most part, reimbursement for routine hospital services is restrospective.*

*Several innovative reimbursement programs have been developed over the past 5 years, some on an experimental and some on a permanent basis. These new programs have been based on a prospective payment concept, where hospital payment rates or budgets are determined in advance for a specified period. Often, these programs contain incentives to the hospital to introduce cost-saving procedures or technologies.

That is, the level of payment is based on actual costs incurred. If hospital costs increase, they are reflected in higher rates of hospital reimbursement. Given this "pass-through" capacity, third-party hospital reimbursement provides incentives to hospitals to push the adoption of equipment-embodied technology to the limit of the availability of capital. If hospitals seek to maximize a combination of quantity and quality, then third-party charges or retrospective cost reimbursements would lead hospitals to increase both the quantity and quality of services beyond a socially efficient level.[89] This tendency would be checked only by limitations on funds available for investment in any period or by limitations on patient demand for hospital care.

Some evidence is available indicating that hospitals do, indeed, tend to push capital expenditures to the limits of capital availability. Ginsburg[39] has shown that the trade-off between capital spending for general bed capacity and specialized equipment depends on how crowded the hospital is. If occupancy rates are low, the money will be spent for capital equipment; if occupancy rates are high, pressures for new additions to the hospital will mount and capital funds will be channelled in that direction. Salkever and Bice[106] have shown that when capital expenditures for new bed capacity have been limited through regulatory action, capital spending has merely shifted to new equipment; in this case, total capital spending is unaffected.

How is capital availability determined? Capital funds for the acquisition of new equipment and facilities come from a variety of sources whose relative importance has been shifting over time in a clear direction. These sources include philanthropy, public bonds, federal subsidies, and debt financing. The proportion of hospital capital spending made possible through debt financing has increased dramatically over the past 10 years, as reflected in the following figures on construction capital:

	1969	1973	1975	1977
Percentage of total construction funds from debt financing	32%*	54.3%†	56.8%†	approx. 67%*

Sources: *Iglehart, John K. "Stemming Hospital Growth--The Flip Side of Carter's Cost Control Plan." *National Journal*, June 4, 1977:850.
†"AHA Research Capsule No. 24: Sources of Funding for Construction." *Hospitals* 51:59.

This increase in the importance of debt is itself a reflection of the retrospective cost-based system of reimbursement. Since

coverage of hospital costs is guaranteed, lenders incur very little risk in making loans to nonprofit voluntary hospitals. Hospitals use debt to augment their sources of capital financing. There are, of course, limits to the absolute dollars available to an institution in any single time period. Hellinger[54] has tested the hypothesis that the hospital follows a gradual adjustment process in its investment plans. This is consistent with the investment behavior of most businesses and with the natural conservatism of lenders.

In an attempt to deal with the problem of insufficient risk associated with hospital capital expenditures, Congress amended the Social Security Act in 1972 to restrict Medicare reimbursement for capital costs to those capital expenditures approved by a designated state health planning agency. P.L. 92-603, Section 1122, was intended to increase the financial risk to the hospital (and therefore to prospective lenders) associated with capital expenditures that are not in the public interest. The law has not been effective to date because it does not restrict funding of the noncapital costs associated with the service, nor does it restrict hospitals from using endowment and philanthropic funds to cover unapproved capital expenses. Most important, however, up to this time few expenditures for capital equipment have been denied by health planning agencies.[70]

Methods for Reimbursing Hospitals for Ancillary Services

Certain hospital services denoted as ancillary services are billed separately from the routine daily rate in hospitals. These commonly include laboratory, radiology, anesthesiology, pharmacy, and certain special therapeutic procedures. Depending upon the particular hospital reimbursement program, these services can generate substantial revenue surpluses for the hospital, which can be applied against losses to other insufficiently reimbursed services. As new ancillary procedures are introduced in a hospital, reimbursement is usually guaranteed. Thus, the incentive to adopt new ancillary technology is even stronger than for other services, because it often expands the pool of funds available for capital or operating expenditures.

Some hospitals are reimbursed by Blue Cross, Medicare, and other payers on the basis of a predetermined per diem rate that includes ancillary services. Although these per diem reimbursement methods differ in their particulars, they all reimburse on the basis of a fixed amount per day rather than on the basis of the volume of services consumed. One would therefore expect these systems to create less incentive for the adoption and use of new equipment in the ancillary services. This hypothesis has not been tested.

Methods for Reimbursing Physicians

As the primary gatekeeper for the use of clinical and ancillary equipment-embodied technology* and as an important participant in the operation of the hospital, the physician is a key determinant of decisions bearing on the adoption and use of medical technology. Consequently, the methods of paying for physicians' services must have a significant effect on the kinds of equipment-embodied technology that will be adopted and used. Several theories of physician behavior have been advanced. The simplest and perhaps the most questionable is that the physician chooses to provide the number and kind of services that will maximize his income subject to legal and moral constraints.[112] A more elaborate theory is that the physician seeks to reach a "target" level of income subject to constraints on leisure and prestige.[26] Income, prestige, and leisure are reasonable and expected goals of any professional; the ethical goal, delivery of quality medical care to patients, must also be considered in an examination of physician behavior.

The third-party fee-for-service system of physician reimbursement, which rewards physicians on the basis of the number of patient visits or procedures performed, should have a significant impact on physicians' decisions to use health care services, especially in the absence of significant perceived financial or medical risks to the patient.† To what extent does this tendency to overuse health services in general translate into a special problem for equipment-embodied technology?

If the ability to perform a procedure depends upon the availability of equipment, then it is incumbent upon the physician desiring to perform the procedure to see that the equipment is adopted by a hospital in which he has staff privileges. The equipment becomes the physician's "tools of the trade." To the extent that the fee-for-service system links the physician's income to his ability to perform the procedure, it strengthens the

*Most diagnostic and therapeutic services must be ordered by the physician or under the physician's direction. The patient may influence use by seeking out a particular service or by refusing services. However, the power of the patient to influence decisions is limited, and it is not clear that the patient should be encouraged to take this role. The more technologically sophisticated a procedure or instrument, the less likely is the patient to be able to adequately assess its relevance to a particular clinical situation.

†The importance of medical risk in affecting physician decisions is described on page 27 above.

imperative that the hospital supply the physicians with these tools. The proliferation of open-heart surgery units in the United States, to the point where the quality of care delivered in these units has been called into question,[63] has allegedly resulted from this phenomenon. As teaching hospitals train cardiovascular surgeons and then close their doors to the graduates of their residency programs, these physicians must find a hospital either with an existing capability or with the willingness to establish such a capability in order to make a living in the field for which they were trained. In the view of this committee, this example illustrates the combined impact that fee-for-service, interhospital competition for prestige and patients, and the system of graduate medical education has on the rate of diffusion of clinical equipment-embodied technology.

Once a physician has access to the equipment necessary to perform a procedure, then the criteria he invokes to determine the necessity or appropriateness of use are likely to be sensitive to the procedure's income-generating potential in some instances (again, taking into account the risk factors). However, the magnitude of this effect on the use of equipment-embodied procedures by physicians is unknown. Other factors, such as defensive medicine, scientific curiosity, and commitment to high-quality care in the absence of financial barriers to patients may be equally or more important than is the fee-for-service system. Indeed, the use of many diagnostic procedures, particularly those performed in hospitals, may not be strongly influenced by the fee-for-service system, since for the most part the physician who orders a test is not paid for performing it. However, the admitting physician does receive a fee for in-hospital visits that might be justified by ordering tests.

In some cases, physician income is directly tied to the performance of tests. Some examples are:

- Laboratory tests ordered by physicians in private practice--in some locations and under some third-party payment mechanisms the ordering physician may profit from the test.
- CT brain scans performed by neurologists in private practice. Often a patient is referred to the neurologist for a neurological workup; it is the specialist's decision whether to order a CT examination. If the specialist also performs the examination, the clear incentive to overuse exists.
- Some diagnostic surgery, such as gastroendoscopy.
- Diagnostic x-ray procedures in physicians' offices on a nonreferral basis.

Hospital-based physicians (for example, radiologists, pathologists, and anesthesiologists) are paid by hospitals for services

performed in a number of ways, including salary, fee-for-service, and percentage of gross revenues of their respective departments. Except in the case of salaried physicians, involving approximately 25 percent of pathologists and 10 percent of radiologists,[18] their income varies directly with the number and type of services performed. Therefore, it is in the financial interest of the hospital-based physician to adopt technologies that will maximize volume, regardless of expense incurred. Labor-saving technology will benefit the hospital-based physician when the labor being saved is his own. Thus, technology that standardizes results, improves reliability, increases effectiveness, or shortens the physician's time is clearly in his economic interest.

Administrative hospital technologies, including medical information systems and hospital communication systems, are in a perverse position with respect to physician interests. Often the establishment of a new administrative technology involves significant time and inconvenience for a hospital's medical staff. When the new administrative technologies have been incremental, have not involved major changes in the organization of medical delivery, and have significant benefits clearly demonstrable to the physician, resistance on the part of physician staff has been minimal. Electronic paging systems are an example. By contrast, establishing on-line medical information systems with the capability of processing patient care information and performing certain hospital functions automatically has encountered more resistance from hospital medical staffs. The introduction of these systems involves significant, if temporary, inconvenience to physicians with patient benefits that are difficult to demonstrate (Appendix E).

Limitations on Third-Party Payment Coverage

The prevailing system of third-party coverage does not include all types of health care services. Where coverage is lacking or inadequate, technology is at a particular disadvantage.

One obvious example of the effect of coverage limitation is the exclusion from most insurance plans of coverage for preventive medical care, most notably screening services. This creates a bias against the adoption of technology in this category by health care providers. Mammography screening is a telling example. The screening technology has been largely validated for women 50 years of age and older, yet, outside of the federally funded Breast Cancer Detection and Demonstration Projects (BCDDP's), there is little activity in this area. Fortunately, the technology of mammography has developed in response to a market for its diagnostic uses, so the problem of inadequate technological development following an inadequate market has not occurred.

THE IMPACT OF DEFENSIVE MEDICINE ON ADOPTION AND USE OF NEW TECHNOLOGY

It is often claimed that the medical injury compensation system, which holds hospitals as well as physicians responsible for negligence in cases involving injury to patients, encourages the adoption of equipment-embodied technology. Defensive medicine is virtually always cited as an incentive for physicians to overuse diagnostic services, but there are at present no reliable studies demonstrating the extent of its effect. A recent poll of physicians conducted by the American Medical Association[144] revealed that a majority of physicians believe that unnecessary tests are ordered as a hedge against malpractice. Certainly the evidence is strong regarding the use of particular tests. Routine skull x-rays for all emergency patients with head injury is a frequently cited example.[13] However, the impact of defensive medicine on the overuse of existing and established tests, such as skull x-rays, must be distinguished from the impact of defensive medicine on the overadoption of new technology (new tests or more reliable tests). Defensive medicine may well be a potent force influencing use and adoption in the later stages of diffusion, but its importance in earlier stages is questionable.

Although much is known about the process by which new medical procedures become standards of medical practice, the point in the diffusion process at which the standard becomes an important influence on adoption and use and the impact of that timing on the pattern of diffusion are largely unknown. It is frequently asserted that less than 4 years after its introduction, cranial computed tomographic scanning has become a standard of practice for diagnosing certain brain lesions. What this has meant and what it will mean for the use of CT head scanning and the further diffusion of the technology is largely unknown. *Study of the operational meaning of "standard of care" for the diffusion of new diagnostic technology is certainly in order.*

THE IMPACT OF ORGANIZATION OF HEALTH CARE SERVICES ON ADOPTION AND USE

The delivery of medical care in the United States is characterized by two related attributes: disaggregation and specialization. Together these two factors have an immense, though unmeasured, impact on the kinds of technology that are accepted and diffused throughout the health care system. To the extent that present systems of reimbursing for health care services encourage disaggregation and specialization, the health care financing system can be further implicated in creating systematic biases in pressures for and against technology adoption.

Disaggregation of Care

Disaggregation refers to the delivery of medical care by many small providers who operate essentially independently of and in competition with one another. Disaggregation offers some advantages to patients. It increases geographical access to medical care, and it increases patient choice. However, disaggregation has significant implications for the adoption of equipment-embodied technology.

In particular, two kinds of technology are likely to be affected:

(i) *Technology offering significant economies of scale in relation to the size of providers.* A technology is subject to economies of scale in the production of services if the average cost of producing each unit of service decreases as the volume of service increases. Most equipment-embodied technology, involving as it does high initial capital costs, is subject to economies of scale, at least up to the capacity of each machine or system. The recent revolution in the automation of clinical laboratory procedures, beginning with clinical chemistries in the late 1960's and continuing into microbiology at present,[128] is a dramatic example of the potential for economies of scale in production.

Two separate problems stemming from the phenomenon of economies of scale in the production of medical services must be distinguished. First, there is the problem of a technology whose economies of scale are so great that the entire market for its use is too small to sustain its costs of development, production, and distribution. Second, a technology may be subject to economies of scale that are too large for the markets of individual providers. An example will illustrate the difference. Suppose an automated testing system is developed that is less costly than existing manual methods at volumes above 100,000 per year, based on the assumption that at least 100 machines will be produced and sold. Suppose also that in the entire country only 1 million tests of this type are required in any year. The market for the machine is therefore limited to at most 10 units. The costs of developing, producing, and marketing the device are thus prohibitive, and the concept may never get beyond a prototype stage. This is the problem of an insufficient total market.

Now suppose that a breakthrough in design enables the machine to be less costly than manual methods at volumes in excess of 5,000 tests per year (with at least 100 machines produced). But suppose that each individual provider operates with a market of only 2,000 tests per year. Individual providers would not realize the savings from the economies of scale. This is the problem of a disaggregated market.

The first problem, the lack of a total market, does not always argue for policy intervention. The technology just may not be cost-effective, regardless of its economies of scale in production. Unless the resource costs of developing, producing, and distributing the technology could be significantly reduced through some public policy, the technology is simply not ready for distribution.

Some technologies may suffer, however, from a lack of a total market and yet be very much in need of public assistance. For example, some rehabilitative technology appears to suffer from the problem of an insufficient total market.[87] The diverse nature of the problems faced by the handicapped and the relatively small number of individuals who can benefit from any particular device often renders the cost of developing and distributing new devices prohibitive to those who need the assistance. Yet, from society's standpoint, the development of a rehabilitative technology may be quite justifiable. Public subsidies of development or programs to assist in paying for new devices may be warranted in some cases.

The second problem, disaggregated markets, lends itself to corrective policy since it deals with a market structure that is out of balance with the economic environment.* The only way the technology will diffuse under such circumstances is (a) if each provider can manipulate prices or artifically increase volume to pay for the machine or (b) if providers share the services of a regional technology. The first alternative results in overadoption of the technology relative to its net social benefit. The present system of charge- or cost-based reimbursement, which calculates payment on actual volume, and the freedom of hospitals and physicians to increase the volume of certain procedures, particularly clinical laboratory tests, have encouraged this result. The second alternative, regionalization, may lead to optimal rates of diffusion. No diffusion at all represents a case of underadoption and a loss of the benefits realizable from the technology.

"Regionalization" and "sharing of services" have a long history of proponents who have recognized these problems.[4] Indeed, regionalization has been a major goal of federally mandated health planning programs. But regionalization of services faces strong resistance from hospitals and physicians, and the retrospective reimbursement system in operation today does nothing to discourage that resistance. The regionalization concept also has some natural limitations--for example, when services must be provided on an emergency basis or when considerations of patient access outweigh economies of scale in production.

*Of course, the level of disaggregation of providers may be in response to important access considerations.

(ii) *Technology offering significant benefits realizable only through integration of providers or services.* Coordinative system-wide technology, such as medical information systems and emergency medical services systems technology, is often subject to nonadditive benefits--that is, the benefits accruing from the collaboration of multiple providers outweigh the benefits from individual adoption. For example, the usefulness of the problem-oriented medical information system that records patient data on the basis of medical problems is to a large extent dependent upon the integration of ambulatory care and hospital care data.[134] In the words of Lindberg (in Appendix E):

> To the extent that health care institutions do not work smoothly and sensibly with one another, the medical information system cannot be shared or transplanted. To the extent that health care institutions are balkanized into small administrative parcels, the information systems must of necessity be small as well. It is quite clear why mini-computers are so popular in medicine, and why large data base systems are so rare. The mini-system matches the mini-administrative fiefdom.

Emergency medical services (EMS) systems provide a particularly cogent example of the problems of coordinative technology. Throughout the country, EMS grew up as a network of independent agencies, including police, volunteer and for-profit ambulance services, and hospital emergency rooms. These participants were often linked by informal agreements and sometimes by *ad hoc* arrangements. In most areas of the country, communication technology was rudimentary; few ambulance corps were linked by radio to hospitals, and central dispatching was nonexistent. Indeed, there was generally no single agency, public or private, responsible for the planning and delivery of emergency medical services on a coordinated basis. The Emergency Medical Services Systems (EMSS) Act of 1973 (P.L. 93-154) was developed to combat these serious deficiencies. Not only did the act provide for grants for the purchase of integrative technology, such as simple communications and dispatching systems, but it also provided grants for the establishment of EMSS agencies whose job would be to plan and coordinate the development of system-wide approaches to EMS delivery. However, the EMSS program is based on the assumption that at the termination of the grant programs, EMSS agencies will achieve financial self-sufficiency through state, local, or other federal funding sources. Whether the public and quasi-public EMSS agencies will actually be able to achieve financial independence and maintain their role in the health delivery network remains to be seen. Third-party reimbursement policies,

which at present do not generally recognize system-wide activities and do not provide a level of reimbursement sufficient to cover the costs of operating such a system, could play a major role in this regard.

Specialization

By specialization we mean the tendency of the health care system to function in specialized settings using increasingly specialized physicians and nonphysicians. Physician specialization in particular has a profound influence on the adoption and use of equipment-embodied technology, although it is not clear whether increasing specialization has caused or resulted from the increasing complexity of medical technology. *More study is needed of the relationship between technological change and physician specialization.*

The increasing specialization of physicians in the United States is well documented. The ratio of specialists to general practitioners has increased, and the number of subspecialities has increased. This phenomenon has been observed even within those specialties oriented toward primary care, such as internal and pediatric medicine.[139]

What relationship does this observed trend in specialization have to technological change? It appears that some specialties or subspecialties have developed in response to and around the introduction of new equipment-embodied technology. Many examples of new procedure-oriented subspecialties can be cited: cardiovascular surgeons; nuclear medicine radiologists; ultrasonographers; and, most recently, gastroendoscopists. Although there is no empirical evidence to support the finding, it is possible that the financial rewards inherent in specialization have encouraged the adoption of these technologies. Evans[25] theorizes that increasing specialization is largely the result of an excess supply of physicians, which encourages physicians "to use technologies which enable them to provide more and different services to patients (particularly if the costs of the services are borne in a hospital budget)." Wessen[139] states that:

> the fee-for-service system encourages the use of more and more specific procedures to which charges can be attached. . . . And the tendency of our reimbursement systems to value specific technological procedures more highly than generalized professional consultations confirms the economic bias toward the use of specialty services.

As the demand for specialists has increased, so has the supply of residencies offered by graduate teaching hospitals. Hadley and Reinhardt[48] hypothesize that hospitals provide residency spaces in order to assist in the production of patient care, and that the demand for residents in a specialty service of a hospital is responsive and secondary to the demand for the medical services that residents supply. And, because graduate medical education is financed largely through third-party reimbursement,[62] the ability of hospitals to provide financial support for residents is also a function of patient demand for the specialty services. Sloan[111] has tested a similar hypothesis for ophthalmology residency positions and has found that the number of positions offered is negatively related to the stipends hospitals must pay residents. Thus, the introduction of new clinical or ancillary procedures sets in motion a chain of events leading to continued training and production of specialty physicians and, to the extent that physicians can influence the demand for such procedures, continued increases in their frequency of use.

CONCLUSIONS

This chapter has attempted to bring together our knowledge, both formal and informal, regarding the impact of different factors on the adoption of equipment-embodied medical technology by health care providers, particularly hospitals. Although there is significant research on the diffusion of health care technology, with notable emphasis on hospital technology, this research has not measured the impact of factors that affect all providers and the general environment in which technology diffusion takes place. We are left with anecdotal experience, logical analysis, and judgment to ascertain the impact of policy-related factors on adoption and diffusion. The major factors include: (i) the system of reimbursing health care providers for medical services; (ii) the medical injury compensation system; and (iii) the organization of medical services, including disaggregation of providers and specialization of manpower. *More study is needed to determine the true impact of each of these factors on the development, adoption, and diffusion of various kinds of equipment-embodied technology.*

In the judgment of this committee, the present system of third-party reimbursement is the primary factor creating systematic biases for and against adoption and use of particular kinds of equipment-embodied technology. The reimbursement system encourages the use of clinical and ancillary hospital technology and discourages the use of coordinative, system-wide

technology. The reimbursement system further encourages specialization of manpower and facilities, which in turn has a distorting effect on the adoption and use of new technology.

On balance, the hospital reimbursement system probably creates incentives to overadopt new technology with significant economies of scale relative to the size of individual providers. However, this kind of technology could also be subject to an underadoption problem in the absence of such a lenient cost-based reimbursement system, due to the disaggregation of providers. Were the reimbursement system to be changed from a cost-based system, regionalization and sharing of services would have to be encouraged in order to induce providers to adopt new high-volume technology whose cost-saving potential lies in its economies of scale.

4 ALTERNATIVE APPROACHES TO TECHNOLOGY MANAGEMENT

The previous chapter contends that the prevailing system for reimbursing health care providers is singularly responsible for persistent biases in the adoption and use of equipment-embodied medical technology. The reimbursement system discourages application of economic criteria in adoption and use decisions. Third-party payers virtually underwrite hospital capital investments; institutions bear little or no risk for poor decisions. Moreover, the system provides no incentives for regionalization of services and does not discourage wasteful competition among hospitals for patients or prestige. The reimbursement system also hinders the introduction of system-wide coordinative technology. To some extent, the reimbursement system creates incentives for physician specialization, and the system for reimbursing physicians encourages overutilization of equipment-embodied procedures.

Solutions to the problems of technology adoption and use need not include reimbursement reform. Other policies--for example, direct regulation of the use of medical services--could conceivably redress the imbalance. But as long as reimbursement policies provide incentives (or at least no disincentives) to overadopt hospital clinical and ancillary technology and provide inadequate incentives to adopt coordinative technology, all other policies to manage the introduction of new technology must counteract these effects of the reimbursement system. Even with reform of the reimbursement system, regulatory or enabling policies designed specifically to improve adoption and use decisions might be desirable. Consequently, this chapter reviews some policies that this committee or others have identified as possible avenues for dealing with the technology problem. It analyzes the

expected direction, and, in some cases, magnitude of impact that these policies would have on the adoption and use of new equipment-embodied technology.

Policies to influence decisions to adopt and use new technology involve different costs and problems of practicality. Perhaps the most important problem is the level of detail at which a policy must be implemented. Policies requiring knowledge of many individual transactions are more costly and difficult to administer than those providing a structure of incentives which individual transactions follow. But direct regulation is often the only politically feasible alternative, because changes in incentives often result in fundamental changes in the organization and delivery of services. Regulations often impose a layer of control over a system that remains essentially intact. The participants in the system will adjust to the controls. If incentives are radically restructured, the entire system can be seriously disrupted, a prospect that most affected parties would vigorously oppose. Arguments against regulation have been eloquently stated elsewhere (see, for example, Noll[90] and Schultze[108]). This committee remains committed to seeking out policy solutions that minimize the need for detailed knowledge of many transactions on the part of regulatory bodies.

The committee also recognizes that the technology problem is part of a larger problem of health resources allocation. Many of the policy alternatives reviewed in this chapter have been widely suggested as more general cost-containment strategies. We have analyzed the impact of such alternatives only on the problem at hand--the adoption and use of equipment-embodied technology--and have not attempted to enumerate the many administrative, ethical, and political aspects of each strategy.

The policy options fall into six categories: (i) funding of development; (ii) direct regulation of sellers of technology; (iii) direct regulation of adoption and use; (iv) payment or reimbursement policies; (v) health manpower policies; and (vi) information strategies. Particular policy options within each area are discussed below.

FUNDING OF DEVELOPMENTAL EFFORTS

As Galbraith[34] has emphasized, the development of large-scale technological systems requires extraordinarily large capital investments, usually over a period of up to 10 years, before a return can be expected. If, as in the case of coordinative technology such as computerized medical information systems, the ultimate market for the technology is highly uncertain, venture capital certainly will not be forthcoming. The development of

the technology may need a boost, either through the creation of a more certain market environment or through subsidization of development costs, or both. The relative advantages of developmental subsidies versus creation of a ready market must be judged in terms of the present state of development of the technology (the earlier in development, the more likely are subsidies to be relatively advantageous) and the degree to which private development funds could be reasonably expected to respond to market signals. Little is known about where private firms place their research and development efforts. *The need for more information on the extent to which public support of research and development augments or merely substitutes for private sector commitments* has been recognized by others.[132]

In the view of this committee, funding of large-scale technological development projects by the federal government is a reasonable approach, particularly for coordinative technologies. In the past, the National Center for Health Services Research funded large-scale demonstration projects for development of medical information systems and telemedicine. Currently, the National Center funds a special-emphasis Center for Technology at the University of Missouri, but decreases in federal funding and a shift in emphasis from development to evaluation have left a void in this area. Lindberg's paper on medical information systems (Appendix E) documents the catastrophic effects of on-again off-again federal commitments to development in that area.

DIRECT REGULATION OF INTRODUCTION OF NEW EQUIPMENT-EMBODIED TECHNOLOGY

It has been suggested that new medical technology should be constrained from diffusing until adequate evaluation takes place.[103] A technology would be allowed to diffuse only upon meeting defined evaluative criteria in experimental or demonstration settings.

Such controls already exist for new "medical devices" in the form of premarket clearance requirements pursuant to the Medical Devices Amendments of 1976 (P.L. 94-295). Third-party payers who refuse to pay for new procedures unless they have been approved are also engaged in this kind of control process. Nonpayment policies lack the force of law, however, and can merely inhibit, not stop, diffusion; a new procedure can always be performed at direct patient expense. The medical devices law requires manufacturers to demonstrate the safety and effectiveness of substantially new medical devices prior to commercial distribution.*

*This law is presently in its earliest stages of implementation; consequently, procedures outlined do not represent actual operation.

P.L. 94-295 specifies that:

> Safety and effectiveness of a device are to be determined (1) with respect to the persons for whose use the device is represented or intended; (2) with respect to the conditions of use prescribed, recommended, or suggested in the device's labeling; and (3) weighing any probable benefit to health from the use of the device against any probable risk of illness or injury from such use.

The amendments provide for classification of devices by the Food and Drug Administration (FDA) into three categories: Class I devices need only comply with the general regulatory controls of the law; Class II devices are additionally subject to performance standards promulgated by FDA; and Class III devices are subject to premarket approval requirements, including demonstration of effectiveness by well-controlled investigations, including clinical investigation "where appropriate."[9]

The regulatory scope of the medical devices law is wide. The federal government holds the authority to prevent introduction of virtually any new technology that depends on a new medical device. This power is somewhat limited with respect to equipment-embodied technology, however, by two factors: the legal definition of "medical device" is not entirely coincident with equipment-embodied technology; and the interpretation by FDA of "effectiveness" is likely to be narrow.

- *Limited coverage.* The law defines "medical device" as:

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory which is
>
> (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which does not depend on being metabolized for the achievement of any of its principal intended purposes.

This definition includes most clinical and ancillary equipment-embodied technology, but it does not cover new configurations of existing equipment (for example, intensive care units) and coordinative technology (for example, medical information systems).

- *Limited definition of effectiveness*. Although the law reads broadly, its major concern is with issues of safety. Consequently, the FDA is likely to interpret effectiveness in the narrowest sense possible consistent with patient safety. Where a device poses negligible safety hazards to patient and user, it is unlikely that the FDA will require evidence of improved patient outcomes as a condition for premarket clearance. Moreover, the law includes no provisions for considerations of economic or societal criteria in evaluating new devices. The cost-effectiveness of a new device cannot be considered by the FDA under the terms of the law.

Policies to control the introduction of new technology suffer from inherent limitations. The most important is the "all-or-nothing" nature of their effect. Although approval of a new technology can be limited to specified conditions of use (as in the medical devices law), it is difficult to enforce such limits. Indeed, malpractice litigation is the only available sanction against inappropriate use of technology short of direct utilization controls, and it is applicable only if significant injury has been sustained.

A hypothetical example illustrates the weakness of preintroduction regulations in affecting health care costs. A new, convenient, and relatively inexpensive test could be proven cost-effective when used in diagnosis for a particular set of presenting symptoms. It would therefore be allowed to diffuse. If it subsequently became overused, its introduction could actually have precipitated an increase in total diagnostic expenditures. Therefore, even if cost-effectiveness were a criterion for premarket approval, decreased health care costs could not be assured in the absence of utilization controls.

Premarket testing cannot always detect rarely occurring but serious hazards. It is also difficult to anticipate adverse reactions that appear only after a long time interval. Such effects can be more consistently detected by long-term postmarket monitoring of technology usage.

Premarket control of the introduction of new technology may have unintended side effects, the costs of which outweigh the intended benefits. Studies of the regulation of new drugs in the United States have identified and attempted to measure the magnitude of such effects, particularly since the enactment of amendments in 1962 requiring drug manufacturers to demonstrate efficacy as well as safety. Although it is invalid to draw direct

inferences about the effects of controlling the introduction of new equipment-embodied technology from studies of drug regulation, the drug studies do provide insights into relevant areas of concern.

Major findings of studies of the impact of premarket drug regulation are set forth below:

- *Impact on new product development time and cost.* Several studies of the drug industry document an increase in development time and cost following enactment in 1962 of amendments adding efficacy requirements to the 1938 Food, Drug, and Cosmetic Act. Grabowski and Thomas,[42] using cross-national data, attribute half of the postamendment decline of productivity of the U.S. drug research dollar to the premarket approval process; the other half is attributed to a worldwide "depletion of research opportunities."
- *Impact on the producing industry.* The increased cost and time duration of new drug development following the 1962 amendments led to the hypothesis that regulation induces a shift in the composition of the industry favoring large, multinational companies. These companies can afford and compensate for increased costs and risks of product development that might cripple smaller domestic firms. New drugs introduced in the postamendment era were developed by fewer and larger companies than were drugs developed prior to 1962.[43]
- *Impact on innovation.* Several critics of the premarket approval process for drugs contend that it forces manufacturers to divert technical and financial resources to the generation of large amounts of preintroductory evidence while foregoing research that might lead to significant new discoveries.[107] Increased development cost per new product decreases the number or scope of research and development efforts that each company can afford if research and development budgets remain constant. A regulation-induced reduction in the number of companies producing new drugs[43] may also reduce the diversity of research efforts undertaken in the drug industry. It is not necessarily true, however, that innovation suffers with a reduction of research funding. A study of drug companies by Caglarcan *et al.*[15] finds that companies that concentrate research and development funds in relatively few areas of research tend to produce more new chemical entities in the 4 succeeding years than do companies with more diversified research efforts. This finding suggests that even if premarket approval does increase development costs per new product, innovation rates need not be affected.
- *Impact on patient outcome.* Wardell and Lasagna[135] and others[107] suggest that existing premarket regulation of drugs in the United States costs patients more than it benefits them.

Costs include those imposed by delayed introduction of beneficial drugs. Benefits result from fewer adverse patient reactions to new drugs and reduced use of ineffective drugs. Methodological difficulties in measuring a "drug lag" between the United States and other countries and in assessing its significance in terms of ultimate patient outcome hamper research on this issue.

Federal legislators have learned from the drug regulation experience. The medical devices amendments were written to avoid or reduce many of the problems outlined above. Medical devices regulation will differ substantially from drug regulation, offering greater flexibility and efficiency. Only devices for which general regulations and performance standards are inadequate will undergo the premarket approval process. The amendments provide for use of experts from the scientific and industrial communities on panels to classify devices and on advisory committees to review proposed regulations of performance standards, proposed product development protocols, and applications for premarket approval. Manufacturers of Class III medical devices can submit a product development protocol to obtain FDA assurance of the adequacy of its product evaluation procedure before embarking upon it. Manufacturers will thus be able to avoid the risk of committing resources to a testing program that is inadequate for approval or to one that generates superfluous data. In addition, the medical devices amendments require the establishment of an office within HEW to provide technical assistance for small manufacturers in complying with the law. These innovations in regulatory procedure were intended to prevent much of the delay, duplication of effort, strain on FDA manpower, and inadequate communication, which have plagued drug regulation efforts. However, it is too early to determine the effectiveness of these and other provisions in avoiding the unfavorable impacts described above.

The limitations and side effects inherent in a premarket approval process argue against significant expansion of this regulatory approach beyond the limited evaluative criteria of safety and effectiveness currently covered under the medical devices law. Because premarket regulation offers little effective control over the actual use of technology that has been approved, consideration of economic criteria such as cost-effectiveness or net social benefit is inappropriate.

DIRECT REGULATION OF THE ADOPTION AND USE OF EQUIPMENT-EMBODIED TECHNOLOGY

A commonly suggested mechanism for altering patterns of adoption and use is the exercise of direct control over these decisions

by a regulatory body. Two regulatory mechanisms currently in use exert this control directly: capital expenditures regulation and utilization review.

Capital Expenditures Regulation

Two different programs currently exist to regulate hospital capital expenditure decisions. They are the state-level certificate of need (CON) laws, which exist in approximately 30 states, and the regulation of capital expenditures under Section 1122 of Public Law 92-603 (1972). The programs are essentially the same; they differ only in the definition of what constitutes a regulatable capital expenditure and in the sanctions employed. Both programs call for approval of hospitals' proposals for large (usually at least $100,000) capital expenditures by a state health planning agency, with local health systems agencies acting as the first line of review. The Section 1122 program ties approval to reimbursement by Medicare for the associated capital costs; CON laws are frequently tied to facility licensure or certification. The National Health Planning and Resources Development Act of 1974 (P.L. 93-641) requires universal adoption of CON laws by 1980. At present, some Blue Cross plans refuse to reimburse health care providers for services that have been disapproved by the CON agency.

Capital expenditures review is essentially a negative instrument; it can be used to slow the diffusion of new equipment-embodied technology, but it cannot easily be used to speed the adoption of underdiffused technology. Except where health planning agencies have conditioned approval on the fulfillment of stipulations unrelated to the application* (as in Massachusetts[100]), the regulatory agency is powerless to encourage the development of coordinative technology.

The history of CON and capital expenditures review programs is discouraging. Not only have few projects been disallowed,[70] but CON appears to have no effect on the overall level of spending by hospitals.[106] However, one cannot judge the potential value of this regulatory strategy from experience to date. Existing programs suffer from serious structural weaknesses and implementation problems that may be surmountable.

Among the more obvious problems are the loopholes in existing laws. At present, capital expenditures review does not cover relatively small investments by hospitals, nor does it cover

*The legality of conditioned approvals of projects has been questioned.[100]

noninstitutional providers (for example, physician groups or independent clinical laboratories) in most states. It has been suggested that CON be extended to noninstitutional settings of care[60] and to a broader array of equipment purchases (under $100,000). These changes would purportedly close loopholes in the laws and provide more influence over technology adoption decisions.

A problem of equal importance is the lack of budget discipline within the program structure. The agencies are generally free to approve as many projects as they consider appropriate without considering trade-offs among alternative uses of capital funds. Indeed, in most areas, the boundaries of the health service area represented by the CON agency do not coincide with the boundaries of collective payment (which in the case of Medicare is the entire country). Thus, the local agency can spread the costs of a new service across the state or the nation while obtaining the benefits of improved access or quality of care and often increases in employment as well.

One solution to this problem is the adoption of an annual area-wide limitation on capital expenditures subject to CON as has been proposed under the present Administration's cost containment bill[121] and as under consideration in the State of Maryland.[95] The Health Systems Agency (HSA) would be responsible for allocating these funds among competing projects. This approach would materially increase the power and responsibility of the HSA's and would require them to make choices they have up to now appeared unwilling to make.[70] However, it is possible that such a program would induce hospitals to merely shift capital expenditures to the purchase of less expensive capital equipment not subject to the limit. It is also important that the HSA or local hospitals be able to accumulate capital spending allocations over multiple years to enable the implementation of especially large projects that may be needed.

Apart from the structural problems described above, the agencies suffer from a lack of timely information to assist in decision making, particularly in regard to new equipment-embodied technology.[58]

Assuming that the structural and implementation problems are overcome, capital expenditures review nevertheless presents serious generic problems. First, this regulatory approach requires detailed knowledge of individual equipment adoption decisions by review agencies, and the number of decisions probably increases exponentially as the dollar threshold for CON coverage is decreased. That is, there are many more different pieces of equipment offered in the $50,000-$100,000 price range than there are in the over-$100,000 range. Thus, as loopholes are closed, implementation problems increase dramatically.

Second, agency decisions are likely to be politicized through coalitions or compromises. The net effect may be expenditure decisions that are no improvement over those made by hospitals.

Third, certificate of need unquestionably adds to the cost of adopting new technology, both good and bad, and thus further biases capital expenditure decisions against the introduction of potentially cost-reducing coordinative technology such as medical information systems.

The question of whether direct regulation of capital investments by providers is a good approach to control the tendency to overadopt clinical and ancillary hospital technology ultimately rests on one's philosophy toward regulation. The committee recognizes the critical need to make such adoption decisions more consistent with the interests of society, but if similar results can be achieved through policies that alter incentives instead of counteracting them, then we believe that these other avenues are preferable to capital expenditures regulation.

Utilization Review

The review of the utilization of equipment-embodied technology is a mechanism that could conceivably reduce the tendency to overuse clinical and ancillary technologies. The term "utilization review" refers to several methods for controlling the use of services. These include prior authorization of service delivery, retrospective evaluation of services rendered, and review of claims for payment.

Various programs have been conducted by hospitals, third-party payers, foundations for medical care, and professional standards review organizations (PSRO's). For the most part, utilization review has been applied to hospital admission and length of stay and to claims for services rendered by physicians. Except where hospital admission has been expressly for the performance of a particular procedure, review of specific procedures has generally not been attempted. This is particularly true of diagnostic procedures in hospitals. The professional standards review organization program is currently encouraging its PSRO's to begin programs to review the utilization of ancillary services.[125]

The effectiveness of utilization review programs as they have been implemented has not been unequivocally demonstrated.[59] Some inherent weaknesses in the approach are: the need for detailed criteria to differentiate justified from unjustified utilization, the costs of implementation, and the potential rigidity of such a system over time. *More research is needed on the*

effectiveness of utilization review in controlling the use of technology-intensive services, particularly ancillary hospital services such as laboratory and diagnostic radiology, relative to more indirect methods of influencing the utilization of these services.

Both direct regulation of capital expenditures and utilization review require that regulators have detailed knowledge of individual transactions in the health care system. The committee remains cautious about the long-run effectiveness of this type of approach.

PAYMENT POLICIES

Virtually any change in reimbursement strategies will alter incentives to adopt and use new equipment-embodied technology. Desired strategies are those that reward providers for cost-effective adoption and use decisions and penalize them for decisions that clearly are not cost-effective from society's standpoint. As a corollary to this principle, providers should bear risk for their adoption decisions, either as a financial loss for a poor decision or as a loss of opportunity to invest in more effective technology. Several alternatives for changing reimbursement methods in this direction have been suggested.

Coverage Limitations

Perhaps the most obvious type of reimbursement reform is the refusal to cover hospital and physician expenses incurred for those procedures that have not been proven effective. The delay imposed by the Medicare program in reimbursing providers for CT scanning of the body is an example of such a strategy, as is the decision by the National Association of Blue Shield Plans not to pay for 26 surgical and diagnostic procedures that have been found to be largely without value.[85] The primary problem with this approach is that it is a gross discriminator between "good" and "bad" technology. The decision of whether or not to pay for a procedure can be used successfully only for the few procedures found to be generally without value, but it is relatively easy to show that a technology has significant value for some patients. Consequently, a comprehensive program of noncoverage would have to be augmented by detailed utilization review.

Third-party payers could be more circumspect in paying for new clinical and ancillary procedures. By requiring more proof of efficacy prior to payment, third-party payers could encourage the development of information on effectiveness. However, once a procedure is approved for payment, even for a limited patient

population, some control over the utilization of such services would be required if the tendency toward overadoption and overuse of clinical and ancillary technology is to be checked.

The committee is concerned about the implications of adding an additional layer of control over a process of technological change already heavily burdened with regulation. It would require most new equipment-embodied clinical and ancillary procedures not only to meet the safety and efficacy requirements of the medical devices law, but also to meet more or less stringent effectiveness or cost-effectiveness standards imposed by different payers under a coverage limit policy. The delay, uncertainty, and administrative costs entailed by the addition of a second regulatory structure in the prediffusion stage of technological change must be considered in evaluating this alternative.

Reimbursement of Hospitals

The reimbursement of hospitals on a prospective basis has been considered by many to be an important and needed change. Prospective reimbursement (PR) merely implies the determination in advance of the payment period of a rate of payment for services rendered by hospitals. There are many variations on this general approach. Third-party payers have established rates on the basis of negotiated hospital budgets and on cost-based formulas. A few have established flat rates of payment unrelated to services rendered. In some cases, hospitals bear the risk of deficits and reap the benefits of surpluses over the payment period. In others, savings and deficits are shared by the hospital and the third-party payers. The essential character of PR is lost, however, if levels of reimbursement are routinely adjusted retroactively to eliminate all accumulated surplus or deficit of the hospital.

In January 1976, 22 of the nation's 74 Blue Cross plans enrolling from 24 to 80 percent of their area populations were negotiating or establishing prospective rates or charges for their member hospitals.[12] (Nine of these plans in two states were operating in cooperation with state rate-setting agencies.) Nine state governments were administering rate-setting programs affecting from 8 to 90 percent of state hospital revenues. These state programs impose binding rates of payment under various payers, usually including Medicare, Medicaid, and Blue Cross.[12] The proposed hospital revenue limitations under the Administration's hospital cost-containment legislation[121] is a PR system. Each hospital, with certain exceptions, will be limited to a predetermined rate of increase of total revenues from one period to another.

A major problem in the implementation of PR systems is the need to treat different hospitals differently. Because hospitals vary widely in their mix of patients, and because the prospective rate sets up incentives to "dump" complex cases and to change the length of stay, it is imperative that PR systems adjust rates for hospital complexity or case mix. This greatly complicates the rate-setting process, and it has not been shown that an adequate adjustment method exists. A critical attribute of any prospective reimbursement system is the notion of regulatory lag, the time interval between successive rate decisions. The rates applied during this interval are generally based upon previously recorded accounting costs, although some systems use a flat rate determined not by previous costs but by administrative fiat. Where rates are cost-based, the interval between rate decisions is critical to the method's success in inducing cost-saving innovations. If costs fall during the period, hospital surplus increases, whereas, if costs rise, as is likely in inflationary times, deficits may occur. Many have argued that the regulatory lag offers a major and perhaps the only incentive for efficiency in regulated organizations--particularly to apply new cost-saving technology.[7,110] Most PR systems operate on a 1-year interval. The committee debated the merits of lengthening the interval to increase incentives to introduce new cost-saving technology. But in periods of rapid inflation, the regulatory lag may threaten the fiscal integrity of institutions. Thus, PR necessitates a built-in adjustment mechanism for price inflation. Apart from this requirement, however, increasing the regulatory lag would encourage the introduction of cost-saving technology, but it would also discourage the introduction of technology that is both cost-increasing and quality-enhancing. Unlike other regulated industries, hospitals do not produce a uniform product. An implicit cost is incurred in increasing the time between rate decisions. That cost is the loss of ability to adopt new quality-improving technologies.

In the opinion of this committee, *the potential for increasing the regulatory lag as an incentive to efficiency has not been fully explored by rate-setting agencies. More study of this approach to prospective rate setting is needed.*

Theoretically, PR should have a salutary effect on the adoption and use of new clinical and ancillary technology, since it requires hospitals to weigh alternative uses of funds. It is not clear that this does, in fact, happen. Bauer[12] has observed that the primary weakness of prospectively set hospital rates is that they do not control the volume of services offered; these are controlled by individual physicians. However, if over time rate limitations cause decreasing adoption of new technology by hospitals, limited capacity can be expected to control utilization.

Although there is little definitive empirical evidence on the impact of PR on adoption and use of technology, studies of six prospective reimbursement systems sponsored by the Social Security Administration provide some preliminary and indirect information. Prospective reimbursement as it was applied in the six situations did not unequivocally reduce hospital cost inflation.[1,23,55] Moreover, one study showed that PR had not significantly curtailed the use of ancillary services;[55] and in another study, the PR system appeared to have a negative impact on the number of clinical laboratory tests performed per case and a positive impact on the volume of radiology procedures per case.[23] It appears that hospital administrators attempt to control costs of the services they control, while the use of physician-controlled services does not change.[55] However, these programs may not have been in effect long enough when studied to induce desirable change in adoption behavior that would be reflected in later utilization statistics.

Reimbursement of Physicians

Changes in methods of reimbursing physicians have also been suggested. Hospital-based physicians (anesthesiologists, radiologists, etc.) who control the majority of clinical and ancillary equipment-embodied technology are now paid predominantly by methods that reward for high volume. It has been suggested that requiring all hospital-based physicians to enter into salary agreements as a condition for third-party payment is a solution to the perverse incentives operating in hospitals.[142] But it is not clear that this would significantly affect adoption and use of new technology. Certainly, for example, the impetus to the use of anesthesia is not the anesthesiologist, but the surgeon. And ordering physicians largely determine the use of clinical laboratory and radiological procedures in the hospital. A salary system might reduce the productivity of hospital-based physicians, and thus increase costs without decreasing utilization. It may appear plausible that if, for example, radiologists' incomes did not vary with the introduction of new equipment, such as the CT scanner, there would be less pressure on hospitals to adopt this technology. But experience has demonstrated that, at least for the head scanner, neurologists and neurosurgeons have favored adoption just as actively as have radiologists. The argument for putting hospital-based physicians on salary may be justified on the grounds of equity and income distribution; it is not supportable on the grounds of improving incentives to adopt and use new clinical and ancillary equipment-embodied technology.

The fee-for-service system, which regards physicians for the use of procedures, might be altered. Changes in the system could range from the institution of a salary system for all physicians to changes in the way fees are constructed. At present, fees for new procedures are based on historical precedent, not on prospective analysis of the resource costs to the physician for performing the procedure. The "usual, customary, and reasonable" approach to the establishment of physician fee schedules has been shown to be inflationary, and, although limits have been placed on fee increases in recent years, new procedures are generally not affected. A new procedure can be introduced at a high rate of payment by innovative physicians. This reimbursement rate can always be lowered, but the method for determining fees makes it difficult to raise a fee substantially once it has been established. Consequently, fees for new procedures are likely to be set at high levels. Third-party payers could establish fee schedules where payment for a procedure is linked to its effectiveness relative to other procedures or to its status as an experimental procedure. These incentive-based fee schedules would offer the physician higher economic returns per time period for more "desirable" procedures than for less desirable procedures.

A major problem with this approach is the need to discriminate between appropriate and inappropriate use of a procedure. The most valuable procedure can be misapplied. By establishing high fees for desirable procedures, the policy is likely to induce too much of a good thing. Consequently, the success of incentive-based fee schedules is inextricably linked to the detailed control of utilization of procedures.

Capitation Payment

Capitation payment methods reimburse for an agreed upon set of patient services with fixed periodic payments regardless of the value of services actually rendered. In principle, capitation rewards providers for efficient use of resources in producing the services covered by the capitation rate and penalizes inefficient providers.

The most common form of capitation payment is the health maintenance organization (HMO), which includes all inpatient and outpatient services in the services covered by the capitation rate. Two competing forms of HMO are the prepaid group practice, which directly employs physicians and other health care personnel, and the independent practice association (IPA), a federation of independent practitioners who agree to participate in the capitation plan but who maintain their individual practices and are often individually reimbursed on a fee-for-service basis. The degree to which the IPA approaches the prepaid group practice HMO in organization depends on the amount of financial risk that

participating physicians take. In some plans, the contract payers like Blue Cross and Medicare require that the third-party payers absorb the additional expenses if costs exceed the premium base. Here, the participating physician takes very little fiscal responsibility for his actions, and the IPA more closely approximates the fee-for-service system.

There is substantial evidence that prepaid group practices and IPA's do result in some economies of operation. Hospitalization rates are lower and lengths of stay in hospitals shorter than in the fee-for-service sector.[52] The prepaid group practice appears to perform more efficiently in terms of hospitalization rates than do IPA's.[37] There is also tentative empirical evidence that rates of surgery are lower at some HMO's than in the rest of the health care system.[71] However, evidence on the comparative rates of diffusion of new equipment-embodied technologies does not exist except by way of anecdotes. A major confounding problem is that relatively few HMO's own their own hospitals. Most contract for hospital services with institutions serving a wider population. Thus, equipment adoption decisions are generally made by hospitals with reference to the larger population, and valid inferences about HMO adoption behavior are not possible.

Much of the impetus for the development and demonstration of preventive technologies such as automated multiphasic health testing (Appendix C) and mammography screening (Appendix B) has come from the larger and older HMO's, whose resources have allowed these efforts. Much of the earliest and most successful developmental work on medical information systems was performed at the Northern California Kaiser Health Plan (Appendix E).

At present HMO's provide health care for about 3 percent of the U.S. population. Numerous hypotheses have been promulgated to explain such negligible penetration of the health care delivery market, including barriers arising from current health insurance arrangements and from the very law that was designed to encourage HMO's (the Health Maintenance Organization Act of 1973, P.L. 93-222).[61] Although recent amendments to P.L. 93-222 have reduced some of these barriers, HMO's still face significant obstacles.

Unfortunately, HMO's are subject to some counterproductive incentives that might produce behavior that compromises the quality of care, underserves subscribers, or selects subscribers to eliminate high-risk members. Thus, surveillance and reporting of HMO performance is mandated, possibly leading to regulation of HMO behavior.[50] This may compromise the administrative simplicity of the concept. Nevertheless, HMO's appear to hold promise for instilling appropriate incentives in health care providers both to adopt cost-effective technology and to resist

the overadoption and overuse of clinical and ancillary hospital technology.

HEALTH MANPOWER POLICIES

Because of the hypothesized effect of manpower (particularly physician) specialization on the adoption and use of new clinical and ancillary equipment-embodied technology, it is often suggested that the absolute number and specialty distribution of physicians be controlled. Training of new physicians in the clinical specialties and subspecialties could be decreased, while training in areas such as computer applications or medical information systems could be increased. Three policy instruments are available to alter the specialty distribution: (i) regulation of the number of residency positions offered by teaching hospitals; (ii) third-party reimbursements of residents' stipends; and (iii) training grants to teaching institutions. The regulation of the number of residency positions offered in any specialty or subspecialty is in the hands of the Liaison Committee on Graduate Medical Education, which represents five medical professional organizations. Self regulation by the profession appears to be a viable alternative. In 1972, the American College of Surgeons conducted a study of surgical services in the United States and concluded that the number of approved surgical residencies should be sharply curtailed.[4] Since then the number of approved residencies has indeed decreased.

Whether limitation of physician specialization will significantly affect adoption of new technology is conjectural at this time. It is not clear that by limiting the number of physicians in the technology intensive specialties there will be less use of equipment-embodied clinical and ancillary technology. The rapid increase in the use of radiology procedures in the past 10 years has not been met with a proportional increase in the number of radiologists. Between 1964 and 1970, the number of radiologists increased by approximately 10 percent; the number of diagnostic x-rays performed in the United States increased by 20 percent. Increased efficiency in the use of radiologists' time, substitution of nonphysician manpower for radiologists' time, and increased performance of simple radiologic procedures by nonspecialists may account for the difference. There is a substantial but unknown quantity of "trickling down" of procedures from specialist to nonspecialist performance. As specialists become busier with more sophisticated, newer procedures, the use of existing, simple procedures is taken up by nonspecialists. The performance of simple surgeries by nonsurgeons and the performance of simple laboratory tests outside of the laboratory might become commonplace.

INFORMATION DISSEMINATION STRATEGIES

In the previous chapter it is argued that perceptions of "quality" influence the adoption and use of equipment-embodied technology. If patients, physicians, and hospital administrators all view technological sophistication as good in and of itself and ignore cost in their decisions, then there is likely to be a bias toward the adoption and use of new clinical and ancillary technology.

Several information strategies are possible. These can be directed either at consumers (or their representatives) or at providers of health care services. Consumers (or consumer representatives) include individual patients, third-party payers, employees or unions who contribute to group health insurance plans, or public bodies such as health planning or rate-setting agencies.

Providers include practitioners, institutions, and professional associations. Provider education may be directed at the physician as gatekeeper of the use of new technology, at the hospital as primary adopter of new clinical and ancillary technology, or at organizations of professionals, including such quasi-public agencies as professional standards review organizations (PSRO's).

Suggestions for information strategies directed at physicians are based on the premise that medical education inadequately prepares the physician to consider cost in decisions to use services,[96] particularly diagnostic procedures. Policies to include concepts of statistical decision theory and cost-effectiveness in medical education have been suggested as solutions.[96] Recent research documents that educating physicians to consider costs when making clinical decisions can significantly affect the number and cost of diagnostic tests used.[24] Although it seems self-evident that medical students should be provided with a basis for rational clinical decision making, the effect of such a strategy on utilization would only appear after many years of such training, if at all. Moreover, adding required subjects to the medical education curriculum involves sacrifices in other areas of learning.

The education of practicing physicians through PSRO's and utilization review programs has also been attempted. Because these programs are of recent origin, their effectiveness in changing physicians' utilization behavior is unknown.

Hospitals could also use information on the costs and effectiveness of new equipment-embodied technology. Hospital administrators claim to have severe problems in evaluating the technical merits and cost implications of equipment and instrumentation.[123] The lack of standardization and the complexity of equipment used in clinical and ancillary services renders hospitals relatively

ignorant of the potential hidden costs and technical problems of equipment they purchase. Efforts have been made to provide hospitals with methods for evaluating equipment prior to purchase,[3] but more fundamental information about the effectiveness of new technology is badly needed by hospitals.

Education of individual patients can effectively improve patterns of use of new technology, particularly of screening technology. However, it is unrealistic to assume that patients can or should be gatekeepers for their own use of diagnostic and therapeutic services. Patients can be encouraged to seek "second opinions" prior to acceding to their physicians' advice, but the widespread use of second-opinion strategies has not yet been attempted, and their cost-effectiveness in curtailing utilization is unknown.

The information needs of consumers and providers depend, of course, upon other policies chosen to manage the introduction of new technology. If, for example, adoption decisions were taken away from hospitals and put in the hands of regulators, then information strategies would be best directed at the regulatory agencies. The next chapter of this report discusses the process for generating and disseminating evaluative information, and analyzes the extent to which changes in that system are warranted.

A CAVEAT ON THE EXPANSION OF REGULATORY PROGRAMS

In attempting to array and analyze public policies that can be used to influence the process of development and diffusion of equipment-embodied technology, the committee was impressed by the plethora of public policies, particularly regulatory programs, already in force governing every stage in the process. A complex regulatory structure has evolved that at least nominally controls many aspects of development and diffusion. In fact, with few exceptions noted in previous sections, federal legislation has already authorized direct control of many decisions regarding the diffusion of equipment-embodied technology through three major laws--the Medical Devices Amendments of 1975 (P.L. 94-295), the National Health Planning and Resources Development Act (P.L. 93-641), and the professional standards review organization (PSRO) provisions of the Social Security Amendments of 1972 (P.L. 92-603). These laws are administered at various levels of government; the medical devices law will be administered by the federal government, while the planning act and the PSRO program are administered at state and areawide levels by public and quasi-public agencies and organizations.

Leaving aside the question of each program's effectiveness in accomplishing its legislative or social objectives (a question

discussed above), it is important to consider the cumulative impact of these essentially independent regulatory programs on the process of technical change. The three mandates constitute a regulatory maze through which new technologies must wend their way. An equipment-embodied technology must first be approved as safe and effective under the Medical Devices Amendments. Those whose initial cost is $100,000 or more and intended for hospitals must usually be granted a certificate of need. Finally, the use of equipment-embodied technology may ultimately be controlled by utilization review criteria developed and administered by PSRO's. These decisions are made at several different points in the process of technological change and, for the most part, independent of one another. The multiple layers of regulation certainly increase uncertainty about the marketability of new technology and may require redundant administrative costs.

The problem of regulatory burden goes beyond these three programs. The development and diffusion of equipment-embodied medical technology occur in a complex regulatory environment involving federal, state, and local governments as well as private organizations. Table 1 shows the extent of direct regulatory authority that impacts on various participants in the process of technical change. (The table does not include the indirect impact of funding policies such as manpower training, biomedical research, and health care financing programs.) The significant potential for redundancy and inconsistency in regulations relating to a new technology as it works its way through development and diffusion is clearly demonstrated by the table.

While few would dispute the value of some regulation, two results seem evident. First, on balance, regulation has or is likely to slow the development and diffusion process. Unfortunately, the extent of such a slowdown and the resulting benefits and costs are difficult to evaluate, due partly to the newness of the regulatory machinery and to the inadequacy of our knowledge about benefits and costs of new technology. Second, the present body of regulations is in many respects duplicative and conflicting. The same results--however valuable--could be achieved in a streamlined system at lower cost.

Among the potentials for redundant regulations is the plethora of state and federal agencies involved in licensure, certification, and accreditation of health care facilities illustrated in Table 1. A study conducted in 1975 by the Task Force on Hospital Regulation of the Hospital Association of New York State[57] identified a total of 164 regulatory bodies involved with hospitals in New York. Of these, 40 are federal and 96 state agencies. Four federal and 23 state agencies are involved in licensure; 10 federal and 26 state agencies are involved in accreditation of the

TABLE 1 The Impact of Regulation on the Process of Technological Change for Equipment-Embodied Technology

Participants in the Process of Technological Change	Major Federal Regulations	Other Federal Regulations	Nonfederal Government Regulations	Nongovernment Regulations
Developers		--NIH Animal Welfare Act --Protection of human subjects --Radiation Control Act (1968) (P.L. 90-602)		--Industrial groups--standards AAMI, NEMA, underwriters
Manufacturers	--Medical devices law (P.L. 94-295)		--State medical devices safety laws	--Professional society performance standards (e.g., ECG performance)
Providers	--Health planning (P.L. 93-641) (certificate of need and appropriateness review)	--Clinical Laboratory Improvement Act (P.L. 90-174) --Medicare/Medicaid (provider certification)	--State clinical laboratory regulation --Facility licensure/certification --State rate-setting (hospitals)	--Accreditation
Practitioners	--PSRO's (P.L. 92-603) (utilization review)		--Professional licensure	--Certification of health professionals
Indirect federal regulations:		--Occupational safety and health --Environmental protection		

hospitals. The study clearly documents the duplication of inspections, reports, and administrative burdens of the many federal and state regulatory agencies in New York.

Similarly, a report on the health care regulatory control system in Massachusetts[67] identifies more than 40 discrete avenues of health regulation currently in force, an estimate believed to be conservative. The report also documents that Massachusetts hospitals undergo at least 5 inspections yearly; nursing homes undergo at least 14 such inspections. Although hospitals in New York and Massachusetts may be subject to more regulation than facilities in other states, the redundancies illustrated by these examples are indicative of similar patterns in most other states.

In sum, the health care industry is highly regulated by all levels of government and many private associations with varied objectives. In assessing the relative attractiveness of alternative approaches to improving the adoption and use of new equipment-embodied technology by the health care system, policymakers should be extremely cautious about the wisdom of developing new layers of regulatory authority over those already existing. Moreover, much could be gained by reassessing the linkages among existing regulatory programs in an effort to uncover conflicts, duplication, and inconsistencies ripe for reform.

SUMMARY

Two conclusions are clear: First, it is difficult to predict the magnitude of the impact of most policies on the adoption and use of new equipment-embodied technology due to a dearth of empirical evidence; and second, no single policy applied in isolation appears to be a viable solution to the problem of adoption and use of new equipment-embodied technology.

Nevertheless, certain policies appear more promising than others. Reform of the reimbursement system to promote appropriate incentives relative to the adoption and use of equipment-embodied technology is preferable to direct regulation of such decisions. In particular, limitations on third-party payer coverage of unproven clinical and ancillary technology, prospective reimbursement of hospitals, and especially capitation payment merit further exploration.

Coordinative and preventive technology has lagged behind clinical and ancillary technology in development and diffusion, because they are enormously costly to develop and difficult to integrate into the current system of care. Therefore, subsidization of the development of this class of equipment-embodied technology is justified.

5 THE EVALUATION OF EQUIPMENT-EMBODIED TECHNOLOGY

Providers of health care adopt and use new equipment-embodied technology only if they judge it useful in achieving their goals. Chapter 5 explored alternative approaches to ensuring that the goals of decision makers are consistent with social objectives. This chapter addresses the issue of whether the evaluative information available to support adoption and use decisions is adequate, and, if it is inadequate, what measures should be taken to improve the process by which such evaluative information is generated and disseminated to decision makers.

WHAT SHOULD POTENTIAL USERS OF EQUIPMENT-EMBODIED TECHNOLOGY KNOW ABOUT TECHNOLOGY?

The value of a procedure, product, or system can be measured by different criteria. Relevant evaluative criteria vary depending on characteristics of the user and of the technology, particularly the stage that the technology has reached in the process of technological change. Five general evaluative criteria, each more complex than its predecessor and subsuming the previous criteria within its purview, are possible.

Technical Validity

Technical validity refers to the extent to which a product, procedure, or system does what it purports to do and does it safely. If a fetal monitor is to measure fetal heartbeat, then it must do so with reasonable accuracy and precision and with a reasonable degree of safety to mother, fetus, and operator. It

might also be expected to behave reliably over some lifetime whose length would be an important indicator of the technical capability of the equipment.

The judgment of technical validity requires knowledge of the dimensions of performance and safety that are important to the use of the technology. Professional societies often develop standards for equipment using criteria against which the performance of a particular manufacturer's equipment can be assessed. The particular dimensions of performance that are selected often have a major impact on the design and long-run usefulness of the equipment. If the standards neglect important dimensions of performance, the equipment of different makers may vary widely along this dimension. Or, if the standards are set unreasonably high--for example, demanding a level of precision in measurement that is not needed in clinical decision making--then the cost of technology is made unnecessarily high.

Protection of individuals, even in experiments, requires the demonstration of reasonable safety prior to clinical use. Aspects of technical validity affecting safety must therefore be ascertained quite early in the development process. However, good performance standards cannot be developed until a technology has been in actual use long enough to determine which dimensions of performance are truly critical.

Effectiveness or Efficacy

Effectiveness refers to the extent to which a product, procedure, or system makes a difference for the objectives of medical care--improving the health status of the community. These improvements are often expressed as changes in patient outcomes, measured by indicators such as mortality, morbidity, or patient satisfaction. Because of the difficulty in measuring such changes, effectiveness is usually measured by intermediate results such as changes in therapy or improvements in diagnostic accuracy.[30]

The effectiveness of a technology may vary widely with the organizational setting in which it is applied or with the level of training or competence of its operators. Consequently, the effectiveness of a technology is often differentiated from its "efficacy," a term sometimes used to denote effectiveness when measured under optimal clinical conditions.[119]

Cost-Effectiveness

Cost-effectiveness refers to the extent to which a procedure, product, or system achieves a specified objective at a cost below

other methods of achieving the same objective. Alternatively, the most cost-effective option may be the one that achieves the highest level of effectiveness, as measured by selected indicators, for a given level of program or system expenditure.

A cost-effective technology is one that is superior to all other alternatives for the specific conditions evaluated. For example, when a diagnostic technology is found to be cost-effective, that finding must usually be qualified by the specific set of presenting symptoms and the testing sequence employed in the study.

Net Social Benefit

When the introduction of a new technology produces both increased expenditures for health care and improvements in patient outcomes, then the difference between the value of improved outcomes and the additional costs is the net social benefit. By reducing all measures to a commensurate scale, usually dollars, the net social value (benefit if positive, and cost if negative) is calculated. Unfortunately, calculating net social benefit is fraught with methodological and ethical difficulties,[97] including inability to measure the dollar value of life and changes in pain or worry[138] and the relative value of benefits accruing in different time periods in the future.[68] Although significant amounts of research have been devoted to these and other methodological questions, the state of the art in measuring benefits remains limited.

When measurement problems cannot be overcome, the physical benefits accruing from a technology (improved patient outcome) can be arrayed against the additional program or health care expenditures necessary to achieve them. Whether these benefits are worth the additional costs reduces to a political decision.[94]

Societal Impact

The introduction of new technology may affect the social and economic structure of communities or nations in addition to generating patient benefits. The environment, institutions, social structure, culture, values, and the law may be affected.[5] For example, automated medical record keeping could threaten basic privacy rights in the absence of safeguards.[140] The evaluation of a new or developing technology might include a prospective look at potential societal impacts in addition to the narrower set of patient benefits included in the previous criterion. In essence, this criterion is an extension of the net social benefit criterion, where nothing is assumed constant and all effects are assumed to interact.

Recent debates over the implications of genetic research highlight concern about societal impacts. This debate is occurring at an early stage in the process of technological change with respect to genetics. The major concern at present is with the safety of that research. The potential implications of technology that might emerge from such research have been studied in a few instances. (See, for example, a recent National Research Council report.[86])

Information regarding these five evaluative criteria always exists, although its quality and the evidence on which it is based vary widely. At one extreme lies pure opinion, based on casual observation of the technology or, indeed, on no evidence at all. At the other extreme are the results of formal studies in which technology has been scientifically assessed against one or more of the evaluative criteria. Decisions based upon opinion gleaned from informal observation are not always inferior to those based on formal studies; however, it is reasonable to assume that the more valid the information, the more possible good decisions become.

Ideally, then, one would expect new technology to be evaluated at all of the levels described above using strict methodologic standards. Only those procedures, products, or systems that are truly worth their cost would be developed and diffused, and diffusion would be limited to those uses for which the technology has been found valid.

In reality, of course, this rarely occurs due to the existence of barriers to the generation and use of evaluative information. These barriers include those inherent in the evaluative task and those arising externally, particularly from the economic environment. These two kinds of barriers to evaluation--natural and economic--are discussed below.

Natural Barriers to the Generation and Use of Evaluative Information

Natural barriers include problems in conducting evaluative studies arising from technical, ethical, cost, and time constraints that limit the quality of the information achievable. These natural barriers argue for a trade-off between the quality of information produced and the costs of obtaining it. Two examples will illustrate how they may lead to modification of study approaches: the use of randomized clinical trials to measure efficacy and the use of technology assessment to measure societal impact.

Randomized Clinical Trials

It has been claimed that randomized clinical trials represent the only truly valid technique to measure the effectiveness of any clinical intervention.[16] A randomized clinical trial is an experiment whose design assures that the true effectiveness of the technology can be isolated from other factors that might affect measured outcomes. Patients are assigned by chance according to a fixed probability distribution to alternative kinds of treatment, thereby minimizing the chance of biases in the selection of patients to one treatment mode or another. The design of the experiment is usually further refined to control for other possibly confounding effects.

Although such experiments, properly conducted, produce the highest achievable level of quality of information on efficacy, there are some fundamental problems in their implementation. First, and perhaps most important, randomized clinical trials are costly. The National Institutes of Health estimates that in FY 1975 it supported 465 randomized clinical trials at a total expenditure of approximately $72.8 million.[64] These trials differ widely in scope, duration, and cost. For example, a 10-year study at the Heart Institute on the interactive effects of risk factors on the incidence of heart disease is funded at $12.4 million per year. Another 4-year study at the Institute of Allergy and Infectious Diseases on the treatment of lethal bacteria has been funded at a yearly rate of $69,000. Other parameters influencing the cost of randomized clinical trials are the number of subjects involved and their degree of hospital insurance coverage.

Second, there are often significant ethical problems in conducting a trial. When a medical technology is new, its novelty and potential safety hazards often require that patients be selected on a nonrandom basis from special populations. But when early evidence shows promise for the technology, the physician faces the moral imperative not to deny his patients a preferred treatment regardless of whether its superiority has been demonstrated definitively.[72] McDermott[72] has observed that "for a physician to submit his patients to random decisions regarding their therapy, he must be genuinely undecided on the value of the therapy."

Third, it is often necessary to conduct trials over long periods of time to obtain enough subjects for adequate statistical accuracy or in some cases to measure long-term consequences of a technology. This delay in the face of accumulating informal evidence about the value of the technology often undermines the continuance of the trial.

Fourth, the proper design of a trial requires enough knowledge of disease processes to identify important differences in stages and subsets of the disease under study. If patients are aggregated in the study, the effectiveness of a technology for a particular subset of patients may be obscured.[72]

Fifth, there is a severe technological obsolescence problem in the conduct of efficacy studies. If the technology is changing rapidly, or if user competence improves dramatically with experience over long periods, early results may lose their applicability before they are published.

For these reasons, clinical investigators of efficacy often resort to cheaper, faster, more feasible methods for assessing efficacy. These compromises are not necessarily detrimental. Judgment is needed to assess the loss of information content against the gains in technical and economic feasibility.

Technology Assessment

Although formal methods to evaluate the societal impacts of new or emerging technology have not been fully developed or validated, the "technology assessment" (TA) method has been promulgated as a logical approach to the identification of such impacts. The method of technology assessment, whose purpose is to "assess holistically the potential short-term impacts and longer-term consequences of emerging technologies on society,"[5] sets forth a step-by-step process of identification and analysis of impacts. The method is formal, usually employing estimates by experts of the expected consequences of a development. However, because TA focuses on long-run, structural impacts, it is difficult to validate the technique. It is debatable whether anyone is able to foresee major societal shifts resulting from a new technology early enough in its development to influence the outcome. A study completed for the National Commission for the Protection of Human Subjects demonstrates that even experts have difficulty predicting what the major technological developments will be within a reasonably short (20-year) period.[130] Thus, in the case of the TA method, as in the case of clinical trials, the costs of the method must be weighed against the quality of the information to be obtained. For those technologies with major cumulative effects on society, it is prudent to conduct periodic technology assessments, but these technologies need to be selected cautiously and the results considered in light of the limitations of the methodology at this time.

Economic Barriers to the Generation and Use of Evaluative Information

The primary economic barrier to the generation of evaluative information at any criterion level is the lack of a market for such information. When, for example, decisions to adopt and use new technology are in the hands of individuals or institutions whose objectives differ from those of society, one would expect them to ignore evaluations that are irrelevant to those objectives. As the previous chapter contends, hospitals bear little or no risk for poor adoption decisions. Even though they may be motivated to adopt the most effective technology, they have an inadequate stake in ascertaining the effectiveness of such technology prior to the adoption decision. Also, they are clearly unmotivated to determine the cost-effectiveness of new technology. Thus, evaluative studies find no ready market for their findings. Were the financial incentives facing hospitals altered, or were regulatory processes over the adoption process instituted, then a market for such information might be created.

A second major economic barrier to the development of high-quality evaluative information is the existence of economies of scale in the production of information. A single patient, physician, hospital, or even third-party payer may lack the economic resources to conduct independent studies of technical validity, effectiveness, cost-effectiveness, and so on, of all new procedures, equipment, and systems. Collective efforts to produce such information are warranted. Yet collective evaluation groups such as independent product-testing laboratories similar to those that have developed in other industries have not developed to a large extent in medical instrumentation, probably due to the lack of a market described above.

The participants in a symposium on procurement practices in health care, sponsored by the Experimental Technology Incentives Program (ETIP) of the National Bureau of Standards in 1975, recognized the waste inherent in uncoordinated information generation when it reported that:

> . . . a number of government agencies, including state and local, are testing and evaluating medical devices in varying degrees and at various stages in their life cycle. When added to testing and evaluation by manufacturers and associations, there is a tremendous amount of useful information being developed regarding the relative merits of medical devices, much if not most of which goes no farther than the boundaries of the organization in which the effort takes place.[123]

The advent of the medical devices law substantially alters the situation at least with respect to the technical validity criterion. Manufacturers will now be responsible for proving that their devices either meet established performance standards (Category II devices) or are "safe and effective" (Category III devices). However, the medical devices program will not require studies of the effectiveness of new technology in improving patient outcomes nor will it consider cost-effectiveness or net social benefit. Furthermore, the data developed under the program are proprietary.

A third economic barrier to the development of information is related to the second: The conduct of evaluative studies is subject to external effects. That is, studies may often benefit those who do not pay for their implementation, but there may be no way to appropriate payment for the information provided by one organization to another. Here the solution is for collective sponsorship of such studies and the open publication of results to all parties represented by the collective body.

Conclusion

The natural obstacles to the production of high-quality evaluative information argue for the exercise of organized judgment in selecting technologies to be evaluated, evaluative criteria to be employed, methodologies to be used, and the stages in the process of technological change at which to perform such studies. This judgment must reflect the trade-offs between the cost of obtaining information and the quality and usefulness of the information to decisions.

The economic barriers to conducting studies argue for collective funding and coordination of information generation and dissemination.

TO WHAT EXTENT ARE EXISTING PROCEDURES FOR GENERATING AND USING INFORMATION ON EQUIPMENT-EMBODIED TECHNOLOGY INADEQUATE?

How is information on new equipment-embodied technology generated and transmitted to users at present? Each evaluative criterion faces a different environment. At present, there is no systematic approach to the initiation and conduct of studies to evaluate new equipment-embodied technology except with respect to its technical validity. In fact, the only systematic approach to evaluating equipment-embodied technology is in the regulation of medical devices. As noted above, the law requires

manufacturers to collect data documenting their products' safe and effective performance according to their claims.

This does not imply that studies of the effectiveness, cost-effectiveness, or benefits and costs of new medical technologies do not occur. In fact, the efficacy and effectiveness of new medical technology is studied and reported extensively in the clinical research literature. However, the quality of the evaluative information presented in that literature has been questioned by a number of observers. In a recent study of innovations in surgery, Barnes[10] found that "the most critical and central defect in [the] cited studies of innovative surgical therapy is the lack of control experience." There is some evidence that clinical investigators in the United States do not make adequate use of scientific opportunities to conduct controlled clinical studies. In a review of the international literature on gastroenterologic therapy, Juhl *et al.*[65] found that less than 1 percent of studies reporting on nondrug therapies followed a preestablished controlled research design, and that the United States lagged behind Britain in the absolute number of studies performed.

In the absence of information from valid research designs, knowledge of the effectiveness of medical procedures and technologies builds up through informal information channels during the diffusion process. The process of collection and digestion of information on the effectiveness of medical procedures has been characterized as a large, poorly designed clinical trial. That is, procedures and technologies are incorporated into medical practice, experience with the technique is obtained, informal analyses of the experience are conducted, and informal channels of communication are used to disseminate the results. Fineberg's study of gastric freezing (Appendix D) demonstrates how a new technique was used in nonexperimental, direct patient care to generate information on its effectiveness, risks, and side effects. The medical devices law was not in effect at the time that gastric freezing was developed. If it had been, it is possible that the technique would not have been permitted to diffuse quickly due to its implications for patient safety. However, if the technique had not presented obvious risks to patients, its effectiveness in improving patient outcomes would not have had to be proven prior to diffusion under the medical devices law.

It is interesting that while the protection of human subjects in medical experimentation evokes great concern,* this

*Witness the establishment of a National Commission for the Protection of Human Subjects and the promulgation of regulations governing the use of humans in experiments.

nonexperimental approach to the collection of information can be most harmful to the human subjects who are participating in an experiment under the guise of direct patient care. The cost of this current method of collecting effectiveness information is part of what is normally referred to as the cost of "unnecessary" utilization. Third-party payers and consumers bear the costs of the inefficient experiments by paying for new procedures as part of patient care.

Until recently, little attention has been given to measuring the cost-effectiveness or benefits and costs of new or existing clinical and ancillary equipment-embodied technology.* Why have these studies not been forthcoming? Part of the answer lies in the methodological problems of studies of this kind. These include the difficulty of identifying valid measures of patient outcome, determining the costs unique to the application of a technology, and in the case of benefit-cost analysis, placing dollar values on benefits. Such studies have been further hampered by the lack of valid data from clinical studies. The cost-effectiveness of a diagnostic test, for example, cannot be determined without information on its sensitivity and specificity in particular populations and its impact on the speed of diagnosis and on changes in therapy. When this kind of information is not available from clinical studies, analysis of cost-effectiveness is impossible.

However, the fundamental obstacle to the conduct of cost-effectiveness and benefit-cost analysis has been the lack of a market, either in the private or public sectors, for the results of such studies. The irrelevance of these results to hospitals has been noted above. However, even regulatory programs expressly intended to control the adoption or use of clinical technology have been singularly uninterested in economic evaluations. The National Health Planning Act of 1974 (P.L. 93-641), which mandates the universal establishment of state certificate-of-need laws, requires agencies reviewing proposals for the adoption of expensive equipment to consider "the need . . . for such services [and] . . . the availability of alternative, less costly, or more effective methods of providing such services." However,

*Several studies have been directed at coordinative technologies such as mobile coronary care;[2] automated hospital information systems;[11] and telemedicine.[81,91] These have generally been funded as part of demonstration projects sponsored by the federal government. The National Center for Health Services Research has played a major role in seeing that these studies were undertaken, but funding cuts in recent years have reduced both the demonstration and evaluation activity dramatically.

in actual operation, these agencies generally do not consider more than medical criteria of need for expensive clinical equipment. The professional standards review program, which has established a network of agencies to monitor and control health services utilization, focuses on "medical necessity" as the criterion of interest. A test or procedure is considered necessary if it makes any difference at all to the diagnostic or therapeutic process, not if it is the cheapest approach to the management of the patient. It is not clear that the public wishes such regulation of the use of clinical technology to be based on economic as well as medical criteria, since Congress clearly had medical criteria in mind when it drafted the statute creating this program.

The pessimistic forecast for economic evaluation of clinical technology must be tempered by noting recent significant contributions both to methodology and to increasing the awareness of the medical community. For example, a compendium of studies on the costs, risks, and benefits of surgery published by the Harvard Center for the Study of Health Practice[14] has clearly linked the medical and economic disciplines in the production of useful case studies. McNeil and her colleagues[73,74,75,76] have made major contributions to the measurement of the cost-effectiveness of diagnostic and screening technologies, and for a number of years investigators at the Kaiser health plans have been using such analyses to assist in the selection and design of their preventive programs (Appendixes B and C).

Not surprisingly, technology assessments intended to identify the societal impacts of emerging technology have been conducted only on a sporadic or demonstration basis and virtually always federally funded. Another area of inadequate information occurs in the development of product standards. While standards have been established for years by voluntary industrial organizations such as the American Association of Clinical Chemists and the American Hospital Association, and while the medical devices law mandates development or adoption of performance standards for much equipment-embodied technology, these have primarily been concerned with safety and reliability and have not addressed significant information needs of the health care market and of developers.

In a study of voluntary industrywide standards in a variety of industries, Hemenway[56] has described the benefits of product uniformity standards that simplify product comparisons, assure interchangeability, allow scale economies, encourage price competition, and assure future availability. He concludes that while such standards are least likely to develop in a market where there is disaggregation of both buyers and sellers, such a market is most likely to benefit from them. The health care

system is such a market. Indeed, perceived equipment requirements may vary from specialty to specialty, from one patient population to another, and from one setting of care to another--a frustrating and costly environment for developers of new technology, as described by Gross[47]:

> . . . it is not surprising that private industry has often found it frustrating to design equipment for medical use. One consequence of this procrastination in setting standards has been the continued failure, after some five years and diverse research projects to develop a computer terminal that was or is acceptable as a man-machine interface in the hospital ward.

In light of the significant benefits possible through standardization and the difficulty faced by voluntary standardization efforts in a market with many buyers and many sellers, a national collective effort to encourage standards development is warranted.

In summary, the performance of evaluative studies of equipment-embodied clinical technology has been uncoordinated, undirected, and, particularly for economic evaluations, underfunded. Opportunities for obtaining improved information are not seized, either because of inadequate funds or lack of a perceived market for the information. Certainly, the lack of interest by regulatory agencies in economic evaluation constitutes a serious problem, as do the barriers to development of product standards. The market for the results of evaluation must be improved, as must the coordination of efforts in producing such information.

PROPOSED SOLUTIONS TO THE PROBLEM

The lack of and need for systematic approaches to the generation and dissemination of evaluative information on medical technologies have been widely recognized. A group of experts called together by the National Commission for the Protection of Human Subjects[130] has suggested that a Board on the Evaluation of Therapeutics and Scientific Advances be established. In the words of the panel's report:

> The precise specifics of any such proposal would need very close examination. Some very different patterns are clearly available: these could range from a publicly sponsored agency for "medical consumers," by way of a clinical research agency empowered to issue nonmandatory certificates of efficacy, to a full-scale

> regulatory agency similar to the FDA, with elaborate mandatory powers. At the very least, all authenticated information about the general efficacy, limitations and/or side effects of medical, surgical, psychotherapeutic, and other health related procedures, should be readily available to "consumers" of health services, or their organizations. Since the aim of this proposal would be to bridge the gap between "experts" and the lay public, this kind of evaluation could not be left to an expert panel alone. Rather, what is needed is a "consumer oriented" agency, having not only the power to assess "efficacy" and "social costs," but also the prestige to influence the direction of research on new types of therapy and treatment modalities.

In 1977, legislation was introducted in Congress to establish a Center for the Study of Medical Practice within the National Institutes of Health (NIH).[117] This proposal recognized the serious deficiency in information on the efficacy of medical procedures and practices. The legislation focused not only on emerging medical practices, but also on existing questionable medical practices.

The National Institutes of Health[127] has recently established a procedure for involving itself in disseminating information on biomedical advances with clinical usefulness to providers and practitioners. The procedure involves the establishment of advisory panels to assess the implications of advances in biomedical research for the practice of medicine. The intent of the NIH proposal is to seek a technical consensus on:

> . . . the clinical significance of new findings; whether validation for efficacy and safety has been adequate, and if not, what more needs to be done; whether costs, ethical or other social impacts need to be identified as points for caution when formal recommendations are made; whether the technical complexity of the new findings suggests the need for further demonstration of feasibilities in local community settings; whether recommendations are phrased for ready understanding and acceptance by health practitioners and include all appropriate cautions.

These and other suggestions for establishing systems for evaluating new technology places this committee's concern about the present lack of such systems in the mainstream of current thought.

The committee believes that a collective approach to planning, funding, and coordinating evaluative studies of new equipment-embodied technology is needed. Most important is the coordination function, which is totally absent at present. No single body, either public or private, currently has the authority or responsibility to monitor the emergence of new technology; determine whether, when, and what kinds of evaluative studies are needed; encourage the performance of such studies through funding; and act as an information clearinghouse for public and private users.

Numerous federal agencies are involved in funding, conducting, or requiring certain kinds of evaluative studies, but the interests of these agencies are narrow, generally as a result of limited legislative mandates. Certainly the Food and Drug Administration (FDA) will have access to information on technical validity and, in some cases, efficacy of new equipment-embodied technology. However, its legislative mandate is limited, and it cannot be expected to extend its concerns to other evaluative criteria or to technologies that fall outside the definition of a medical device. The National Institutes of Health fund clinical trials as part of their research agendas, and the commitment of funds for such activities relative to program size has been increasing in recent years.[126] But these studies are selected fundamentally to support the research mission of the institutes and not to assist in the allocation of health care resources. The Veterans Administration (VA) also supports clinical trials, but at much lower funding levels. As a self-contained health care delivery system, the VA should be interested in funding studies at all criterion levels, but, with a small and special patient population, cannot be expected to generate all the needed information for the larger civilian health care system. The military medical system is in a similar position. The Medical Equipment Test and Evaluation Division of the Army's Medical Material Agency represents a useful source of specialized evaluative information. The evaluation programs funded by other federal agencies, such as the National Center for Health Services Research and the Center for Disease Control, are other specialized resources that a coordinating body could use.

In the opinion of this committee, a national coordinating body should be established. Its purposes would be to:

(1) identify the need for evaluative information on equipment-embodied (and perhaps other) technology;
(2) fund planning and evaluation studies where existing funding programs are not adequate;

(3) collect and disseminate available information regarding new and existing technologies to users;
(4) encourage and foster national and international efforts to standardize equipment-embodied technology to achieve economy of equipment design, safety, and comparability of data;
(5) conduct and sponsor research into methodologies for evaluating medical technology; and
(6) coordinate evaluative programs of federal agencies.

The proposed coordinating body need not be governmental. Alternatives include a nonprofit organization such as a council on technology supported by a consortium of public and private third-party payers. However, many evaluative studies are currently sponsored or conducted by federal agencies such as the NIH, FDA, VA, and others. Major users of the information would be the Medicare and Medicaid programs, health systems agencies, and direct government delivery systems such as the VA, the military medical system, and the Indian Health Service. Therefore, the placement of such authority in an existing federal agency appears to be a reasonable alternative.

The best location within the existing federal bureaucracy for such a function is a question that needs more consideration than this committee was able to devote to it. A thorough analysis of the legislative and administrative mandates, interests, and competencies of various federal offices and their place within the organizational hierarchy of the federal bureaucracy is required.

Wherever the coordinating function is placed, it is important to assure that funds are not merely shifted from existing federal programs to a new agency, but are actually increased. If federal agencies with existing programs take the opportunity to transfer responsibility for evaluation to the organization in charge, their budgets should be reduced accordingly.

Although this committee calls for an increase in funding for evaluation studies, this does not necessarily imply a net increase in health care expenditures. At present, third-party payers reimburse for new procedures before their effectiveness has been definitely established. Because this is often an inefficient way to assess new technology, third-party payers even now bear a high cost of information generation and dissemination. If third-party payers were required to reimburse for procedures conducted on their beneficiaries as part of an evaluative study approved by the national coordinating body, then a major cost of such studies would be covered. Third-party payers could refuse to pay for procedures performed on patients not participating in

such a study when in enough doubt about the procedure's effectiveness. The administrative and analytical costs of evaluative studies should come from a collective funding source, which might include federal dollars or represent a consortium of payers.

GLOSSARY

Ancillary technology Medical technology used directly to support clinical services, including diagnostic radiology, radiation therapy, clinical laboratory, and other special services.

Capital equipment Equipment whose useful life covers an extended period, conventionally assumed to be more than 1 year.

Clinical technology Medical technology used in the provision of direct patient care, including medical and surgical services.

Coordinative technology Technology used to facilitate and support the provision of health care services but not directly associated with patient care, including administration, transportation, and communication both within and among health care facilities.

Cost-effectiveness The extent to which a medical technology achieves a specified objective at the lowest possible cost.

Effectiveness Extent to which a medical technology makes a difference to the objectives of medical care.

Equipment-embodied technology Medical technology primarily dependent upon capital equipment to perform health care tasks.

Medical technology Specialized technology applicable to the practice of medical care, including techniques, drugs, procedures, products, or systems combining these elements.

Net social benefit The difference in the value of improved outcomes and the additional costs resulting from the application of a new technology.

Practitioner Individual involved in the delivery of health care, including physicians, nurses, and allied health care personnel.

Provider Individual or institution that gives medical care, including institutions and individuals who practice independent of institutions.

Societal impact Changes in the social and economic structure of communities or nations resulting from the application of a technology.

Technical change Change in the methods of producing health care services.

Technical validity The extent to which a medical technology does what it purports to do.

Technology The body of tools emerging from the interplay of scientific knowledge and practical operation applied to specialized purpose.

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APPENDIX A
A DISSENTING OPINION

William S. Yamamoto

While I do not disagree with the findings or recommendations of the committee either singly or in their collective consequence, I am nevertheless left with a sense of disquiet. I am moved to write to try to identify the nature of that difficulty, which may concern others who examine this report. The limitations of the study and its scope are fully stated in the introduction. The limitations, on the one hand, justify the character of the entire report, but also avoid examination in this report of medical technology from other perspectives.

After carefully cataloging items that belong under the rubric "equipment-embodied technology," we treat it as a conceptually simple aggregate like "merchandise." This approach ignores critical differences such as: (1) how development of technology relates to advances in the sciences and medicine, (2) who made each item and why, (3) what medical purposes they are intended to serve, and (4) how other technological innovations not directed to the concept of large scale address the same medical problems.

The report seems to assume that technology is an entity in existence and that the issue of technology in medical care is that of disposition, distribution, cost, and management. It does not inquire as to how new equipment-embodied technology should come into existence, but rather into how the motivations of those who use the technology manage it in order to be responsive to the current preoccupation of the society with medical care costs. However well considered, this report is most succintly described as a document that states: Technology exists; it should be controlled for the purpose of keeping down costs. Its principal recommendations are directed at the production of disincentives through economic, financing, and, to a lesser

extent, cataloging and control procedures. It may well be that issues that trouble me do not have a substantive body of scholarly or public literature from which a committee can organize a perspective. It may also be that technological innovation proceeds under certain natural pressures and needs no scrutiny, or that the appropriate and final philosophy should be that someone shall create and the polity shall dispose.

But the paradigm, "If 'merchandise' is a villain which causes people to spend money, the wisest course is to take money away or somehow make 'merchandise' undersirable," is disquieting.

APPENDIX B

A CASE STUDY OF MAMMOGRAPHY

Morris F. Collen

INTRODUCTION

Mammography provides a good case study of equipment-embodied technology, since it exemplifies many of the problems considered in this committee's report. It is used for diagnostic purposes and involves a significant capital investment, special facilities, equipment, and trained personnel. It has sufficiently diffused into the practice of medicine to have a significant impact on the diagnosis of breast cancers (the most common cancer in women). The currently evolving policies for its use are controversial, since it has been difficult to evaluate its cost-effectiveness. Sufficient data and experience are now available on the use of mammography in older women, so that a reasonably good evaluation can be made of its effectiveness and benefits.

The evaluation methodology presented in this sutdy is that of cost-effectiveness, i.e., the comparison of the costs of alternative methods for achieving the specific objective of the detection of breast cancers. Cost-effectiveness analysis is usually the most appropriate method for evaluating equipment-embodied technology. However, a cost-benefit analysis, although more difficult to complete, would require policymakers to consider all the various benefits in patient outcomes that result from the different technologies. As will be seen in this case study, mammography can provide increased benefits to patients from earlier detection of cancer, but this is only partly recognized in a cost-effectiveness study.

DEFINITIONS AND PURPOSES

Definitions

Mammography is an X-ray examination of the breast that uses special roentgen equipment, films, and procedures to provide adequate photographic details of the soft tissues of the breast and expose the patient to a relatively low dose of radiation.

Screening mammography is the term applied to the procedure when used for cancer detection in asymptomatic women. It usually includes two views (cephalocaudal and lateral) of each breast.

Diagnostic mammography is the term applied when patients with a breast abnormality are referred to a radiologist for mammography and may include three views.

Xeroradiography is a modified X-ray procedure that records an electrostatically charged image on (a) a selenium-coated aluminum plate from which it is then printed by electrostatically charged powder, or (b) directly onto an electrostatically charged plastic film that, after exposure, is dusted with electrostatically charged powder. It produces high-contrast, good-quality pictures of the breast tissue.

Clinical examination is the physical examination of the breast by visual inspection and manual palpation by a physician (or other trained health professionals). It is the most commonly used method for breast examination; however, it can only detect palpable cancers and those with visible skin abnormalities.

Purposes

Generally, women seek advice from a physician when they discover a lump in the breast or have other breast symptoms, or they become anxious when they learn of someone else who has breast cancer. In the past decade, publicity by various media has motivated women to undertake periodic breast cancer screening by self-examination and/or visits to cancer detection programs.

Mammography is used for examination of the breast for both benign and malignant disease; however, its primary use is for the detection and diagnosis of breast cancer. This case study will evaluate its cost-effectiveness for breast cancer detection.

Since breast cancer is the most prevalent cancer in women and since the major decrease in mortality is achieved by its early detection before the cancer has spread to areas outside the breast, the primary goal of any program for breast cancer control should be its earliest detection.

When a woman discovers a mass in her breast by self-examination, or when a mass is detected in a clinical examination by a physician, then the patient is usually referred to a radiologist for a diagnostic mammography.

Principles of Operation

Mammography provides pictures of the breast tissue in which certain abnormalities of the glandular tissue can be visualized. The characteristic variations from normal, which are interpreted as being suspicious for cancer, include a mass or density with irregular borders, microcalcifications, skin thickening, alteration of blood vessel or glandular duct patterns, or a variation in architecture as compared to the same area in the other breast. In postmenopausal women (which includes women age 50 and over), the normal increase in fatty tissue in the breast provides more contrast in the mammograms and improves the sensitivity and specificity of the test. This, plus the higher prevalence of breast cancer in older women, explains the greater cost-effectiveness of screening mammography for postmenopausal women as compared to premenopausal women.

Certain attributes increase the risk of breast cancer in women,[9,15] and these include:

- increasing age;
- chronic cystic mastitis, single or multiple nodules, or irregularities in the breast;
- nipple discharge;
- history of cancer in the other breast;
- family history of breast cancer;
- no history of pregnancy before 30 years of age;
- early onset of menstruation (prior to age 12).

Accordingly, the cost-effectiveness of a *single* screening examination can be improved by selective testing of only high-risk cases. This short-term view has great implications for the long-term cost-effectiveness, as will be discussed later, since low-risk cases who later detect breast cancer on self-examination are more likely to have axillary node involvement and will have increased costs of care. (See pp. 106-120.)

The most important principle that has evolved from studying the course of breast cancer is that early detection while the cancer is still limited to the breast produces the highest long-term survival rates. Most studies show that about one-half of women with breast cancer with axillary node involvement will have a recurrence of their cancer within 5 years.[1,7,14]

HISTORY OF DEVELOPMENT AND DIFFUSION

The history of case-finding for breast cancer has been reviewed by Breslow,[1] Seidman,[14] and others who reported on the stability of breast cancer mortality in the United States from 1930 through the mid-1960's. More recently, Gilbertsen[7] reported some improvements in case survival rates from physical examination alone. Through the mid-1960's, early case-finding of breast cancer was principally carried out by periodic clinical examinations by physicians and by teaching women self-examination of their breasts. In the late 1950's, mammography was first advocated for breast cancer screening by Gershon-Cohen and Egan. Since the mid-1960's, X-ray and thermography techniques for breast cancer detection have been increasingly used. In the 1940's, about 63 percent of women with breast cancer had axillary node involvement at the time of diagnosis, in the 1950's about 57 percent, and in the 1960's about 50 percent.[1] Since the mortality rate from breast cancer did not change in 40 years from clinical examination alone, it is evident that more sensitive methods for earlier detection of breast cancer are needed.

Two large studies, supported by grants from the U.S. Public Health Service, evaluated in the early 1960's the effectiveness of mammography for breast cancer screening of asymptomatic women. One study was conducted by Shapiro and Strax at the Health Insurance Plan of New York,[18-24] and the other by Griesbach and Eads at the Kaiser-Permanente Plan in Oakland and San Francisco.[8] Both studies showed generally similar prevalence rates of breast cancer and effectiveness of mammography. Subsequently, routine screening mammography was continued by Strax at the Guttman Breast Diagnostic Institute in New York City and in the Oakland and San Francisco Kaiser-Permanente Multiphasic Health Checkup program for women age 48 and over.

Over the past 10 years, the technology of mammography has been modified to improve the quality of images for more effective cancer detection, to decrease radiation dosage and to decrease costs.

The National Cancer Institute (NCI) and the American Cancer Society (ACS) are currently sponsoring 27 Breast Cancer Detection Demonstration Projects (BCDDP) in the United States to evaluate mammography, xerography, and thermography for breast cancer detection and control, each center screening annually at least 5,000 asymptomatic women for 2 years plus a 5-year followup.

In March 1977, the National Cancer Institute issued guidelines that do not endorse mass screening mammography for women *under age 50*, unless they have a personal or family history of breast cancer.[3] This was primarily because of the risk that irradiation may increase future breast cancer rates in this age group.[15]

CURRENT STATE OF DEVELOPMENT AND DIFFUSION

Diagnostic mammography is now generally available in most radiologists' offices. Screening mammography is now widely used for breast cancer detection and is being evaluated in the NCI-ACS BCDDP mentioned above.

Present advanced technology for screening mammography uses an X-ray tube with a molybdenum target, a vacuum-packed rare earth fluorescent screen and film, and breast compression devices. This provides high-contrast images with good detail and exposes the breast tissue to a relatively low X-ray dosage.

Although mammography is no longer considered to be experimental and its effectiveness for breast cancer detection has been established, it has the disadvantage of exposing examinees to X-rays. The hazard of future cancer from these X-rays themselves is a small risk, and the epidemiological data from Hiroshima and Nagasaki have recently provided some measures of this risk. Several committees recently reported to the National Cancer Institute on this issue and concluded that periodic mammography could expose women aged 35 to 50 to significant X-ray dosage during their lifetime and potentially increase the incidence of breast cancer in their later years; but the consensus was that for women age 50 and over, the risk was not significant. Accordingly, it is current generally recommended policy[3] that screening mammography, if done, be provided only to asymptomatic women age 50 and over; and only diagnostic mammography be available for symptomatic or high-risk women under age 50. This case study therefore will evaluate the cost-effectiveness of periodic screening of women age 50 and over.

IMPACT OF PUBLIC POLICY ON DEVELOPMENT AND DIFFUSION

In the past 5 years, the newspaper publicity generated by the discovery of breast cancer in a President's wife and a Vice-President's wife resulted in a sudden increase in the use of mammography by the public and its widespread adoption in roentgenology services. The fear of having breast cancer was a powerful motivating force that essentially established a public policy.

Currently, public policy on screening mammography is being generally set by the National Cancer Institute and the American Cancer Society, and the results of their ongoing early Breast Cancer Detection Demonstration Projects will probably establish policy for the future.

EVALUATION OF MAMMOGRAPHY FOR BREAST CANCER SCREENING

Criteria for Evaluation

The evaluation of a diagnostic technology requires information on its yield rates and costs. Yield rates depend upon test sensitivity and specificity and disease prevalence.

A good test sensitivity is critical since it measures the ability of the test to detect patients with cancer and is represented by the proportion of test positive patients who actually have cancer (i.e., the ratio of true-positives to all of the women with cancer in the screened population). (See Table 1.) More serious is the effect of a poor test sensitivity, which is represented by the cases missed (i.e., false-negatives).

Test specificity is measured by the proportion of patients with negative tests who actually do not have the disease (i.e., the ratio of true-negatives to all the women without breast cancer). Poor specificity gives a high proportion of false-positive tests and increases the costs of the program.

The prevalence of the condition in the target population must be determined or estimated. The higher the prevalence, i.e., the more diseased people in the group being tested, generally the higher the yield and the more cost-effective will be the diagnostic technology.

The unit costs of the test must be established, as well as the costs of the followup tests and procedures necessary to identify true-positives and true-negatives.

If it is desired to add to the evaluation the impact of the diagnostic technology on the desired ultimate outcome of the patients, then additional information is required on the alternative treatments likely to be provided, the probable results of each treatment, the resources used for treatment, and the unit costs of all treatment procedures.

Alternative Methods for Breast Cancer Screening

In order to detect breast cancer early (i.e., while still localized to the breast), the following alternative methods for breast cancer detection will be considered:

1. *Clinical examination.* The physical examination of the breast by visual inspection and manual palpation by a physician (or trained nurse) is the most commonly used method.

2. *Mammography.* X-ray examinations of the breast are increasingly being used in breast cancer screening programs because mammography is a more sensitive test than clinical examination,

TABLE 1. Sensitivity and Specificity of Breast Cancer Screening Modes (Projected Cumulative 5-Year Experience for Women Age 50+)

Test Result	Total Test Results	Cancer Present	Cancer Not Present
Positive (+)	Total Tests(+)	True(+)	False(+)
Clinical examination	467	70	397
Mammography	180	90	90
Clin. exam. & mammo.	156	97	59
Negative (-)	Total Tests(-)	False(-)	True(-)
Clinical examination	9,533	30	9,503
Mammography	9,820	10	9,810
Clin. exam. & mammo.	9,844	3	9,841
Totals	Total Tested	Total Cancers	Total Noncancers
	10,000	100	9,900
	Clinical Examination	Mammography	Clin. Exam. & Mammo.
Sensitivity = $\frac{\text{True(+'s)}}{\text{Total cancers}}$	$\frac{70}{100} = 0.70$	$\frac{90}{100} = 0.90$	$\frac{97}{100} = 0.97$
Specificity = $\frac{\text{True(-'s)}}{\text{Total noncancers}}$	$\frac{9,503}{9,900} = 0.960$	$\frac{9,810}{9,900} = 0.991$	$\frac{9,841}{9,900} = 0.994$

since it can detect some nonpalpable cancers. However, some solitary dominant masses of the breast will not be detected by mammography,[23] especially in premenopausal women.

3. *Clinical examination and mammography*. Some breast cancer detection programs provide both a screening mammogram and a clinical examination of the breasts by physicians or trained nurses.

Since there is less controversy in the screening of women over age 50 due to their relatively high rate of breast cancer, the lower risk of radiation-induced cancer, and the increased sensitivity of mammography in this age-group, this analysis will assume that four groups each of 10,000 women age 50 and older were randomly selected and three will be tested by one of the above modes and one group will serve as controls.

Accordingly, Figure 1 shows the predicted 5-year experience of a control group of 10,000 women age 50 or more who are not invited to participate in a breast cancer screening program.

Figure 2 shows the expected 5-year experience of a similar group of 10,000 women who receive an initial and three subsequent annual clinical examinations of the breast. Figure 3 is the anticipated flow diagram for the group that receives an initial and three annual screening mammograms. The participants in the group in Figure 4 receive both screening mammograms and clinical examinations, for their initial and three annual reexaminations.

The costs of any test mode could be decreased further by prescreening out women with lower than average risks of breast cancer (i.e., examining only those with certain types of benign breast disease, with early onset of menses, no pregnancies, with a family history of breast cancer, etc.). However, not screening lower risk women eliminates the possibility of early detection of many cancer cases.

Periodic reexaminations for breast cancer would provide lower yield rates than would the initial examination, depending upon the interval between reexaminations. Reexaminations yearly would yield significantly fewer positives after the first examination, and would probably yield about the same number of positives each reexamination. Accordingly, estimates could be made of the most cost-effective interval between examinations for various combinations of examination modes, e.g., manual palpation annually with mammography every 2 years or manual palpation and mammography the first and second year, then manual palpation every 2 years with mammography every 4 years, etc.[5] In this example, it is assumed that periodic examinations are annual, but for purposes of simplification the results of the second, third, and fourth reexaminations in the 5-year study period are assumed to be similar and are combined.

Assumptions of Case Study

In this analysis, the assumptions made were based upon the studies from screening asymptomatic women in prepaid group practices by Shapiro and Strax[17-24] and Griesbach and Eads,[8] with modifications in estimates of sensitivity and specificity based upon improved current mammography technology as reported from BCDDP[15,30] and others.[2,4,5] In different populations with different examiners the results may be significantly different. The calculations in this case study are not meant to be definitive and are shown primarily to demonstrate the evaluation methodology for equipment-embodied diagnostic technology.

The following assumptions have been made for this case study:

1. For each examination mode, the initial examination was the first breast cancer detection examination for each woman.

For each group of 10,000 asymptomatic women age 50 or older, all who were invited complied with the initial and three annual re-examinations and with any advised followup care.

2. For each 10,000 women in this age-group, 100 cases of cancer of the breast would occur in the 5-year period. This assumes an expected rate of 40 per 10,000 on the initial examination and 20 per 10,000 for each of three subsequent annual reexaminations. Early data from NCI's BCDDP estimates for women age 50-59 an initial screening rate of 57 per 10,000 and a second screening rate 1 year later of 26 per 10,000.[15] To simplify this analysis, second cancers occurring in the other breast were not considered.

3. For each single screening examination, the sensitivity of the test made is such that clinical ex ination detects 60 percent of breast cancers, current mammography technology detects 85 percent (preliminary BCDDP data exceed 85 percent sensitivity[15]), and clinical examination plus mammography detects 95 percent.

Of those screened as "positive" by a clinical examination (i.e., dominant mass palpated) and/or mammography (i.e., suspicious for cancer), all will receive a diagnostic surgical biopsy. For those biopsied for a dominant mass after a positive clinical examination alone, 15 percent will be positive. For those biopsied after a positive mammogra alone, 50 percent will be positive. (Preliminary BCDDP data indicate about 90 percent true-positive mammograms.[30]) For those biopsied following both clinical examination and mammography, 90 percent will be positive for cancer in one-half of the patients who have both a palpable dominant mass and a mammogram suspicious for cancer. For the remaining one-half the percentages are as for either test cited above, or an overall average of 62 percent of biopsies for this group will be positive.

The 5-year cumulative experience from four exa inations will show projected sensitivity and specificity of the alternative modes as presented in Table 1.

4. All false-negatives (i.e., women with cancer of the breast who were not so detected on the screening examination) returned in the intervals between examinations and within the 5 years when they detected a lump in the breast; they then required a surgical biopsy.

5. For the control group that was not invited to receive screening examinations, during the 5 years (although perhaps three-fourths may see a physician who will do a routine clinical examination including the breasts without additional charge) 10 percent would seek a conventional clinical examination for a breast complaint and incur a separate cost thereby.

6. Axillary node involvement will be found: in 50 percent of the breast cancer cases in the control group,[1,17-24] and in the false-negative and interim cases; in 30 percent of cases with a dominant mass detected by clinical examination; and in 20 percent of cases detected by mammography.[13]

7. "Early" cases are defined herein as those with no axillary node involvement and cancer localized to the breast only; and in these 90 percent will not have a cancer recurrence within 5 years. "Late" cases are those with axillary node involvement and 50 percent of these patients will return within 5 years for more medical care and hospitalization. This analysis does not consider other benefits to patients associated with the varying outcomes.

8. In women age 50 or older, the long-term effects of exposure to X-rays from mammography are negligible. (In women under age 50, the risk of increasing the future incidence of cancer from X-ray exposure must be considered in any evaluation.)

9. Average costs used in these calculations for patients in 1977 for their examinations and treatment procedures are representative. It is important to emphasize that the calculations that follow are shown primarily to demonstrate the evaluation methodology. Since treatment regimens for breast cancer are even less standardized than are diagnostic procedures, each program should determine its own costs and then can use this model to calculate its cost-effectiveness. The costs used herein are generally based upon the California Relative Value Studies, and are as follows:

	Range ($)	Average ($)
Clinical examination of breast and axillae, by M.D.	10-20	15
Clinical examination of breast and axillae, by R.N.	5-10	5
Average screening cost for clinical examination		10
Mammography screening, bilateral (two views each breast)	5-62	20
Breast biopsy and associated workup for negative biopsy case (biopsy, anesthetic, operating room, frozen section, one hospital day at $125)	750-1,150	930
Surgery and care for early cancer case (biopsy, mastectomy, anesthesia, operating room, 6 hospital days and 5-year followup visits)	3,500-5,500	4,500

	Range ($)	Average ($)
Surgery and care for late cancer cases (biopsy, surgery as for early case plus 5-year followup with chemotherapy and/or radiation therapy)	4,500-6,500	5,400
Late care costs for cancer recurrence (recurrent hospitalization for 14 days and chemotherapy and/or palliative X-ray therapy)	4,000-8,000	6,000

Projected Results

Figure 1 shows the projected experience for breast cancer care for the 5-year period for the control (unscreened) group. It is predicted that for the 1,000 women who seek care for a breast complaint (at an average cost of $15 an examination), 700 will receive a clinical workup and surgical biopsy; and 600 will have a negative biopsy and will stay in the hospital for only 1 day with total costs ranging from $750 to $1,150 with an average cost of $930 each patient. (Note that the figures show costs for biopsies for only biopsy-negative cases since for biopsy-positive cases the biopsy cost is included in the cost for mastectomy.) The remaining 100 will be found to have a biopsy positive for breast cancer. Of these 100 patients, 50 will not have axillary nodes involved and their total hospital and surgical care with 5 years of routine followup visits will cost $3,500 to $5,500, with an average of $4,500 per patient. The remaining 50 patients will have axillary node involvement and require, in addition to surgery, followup care for chemotherapy and/or radiation therapy for about an added $900, giving an average total cost per patient of $5,400. Of the 50 patients with axillary nodes involved, 25 will require subsequent care for cancer recurrence with additional chemotherapy and/or radiation therapy and an average of 2 weeks hospitalization over the 5 years for a cost ranging from $4,000 to $8,000, or for an average cost of $6,000 per case. Of the 50 patients without axillary node involvement, only 5 will have a recurrence of cancer and require similar late hospital care. It is expected that of the 100 breast cancer patients in the group, 30 will have a recurrence or extension of cancer in the 5-year period. The total projected costs for the 5-year period for breast cancer are calculated to be $1,248,000. This can be expressed as a

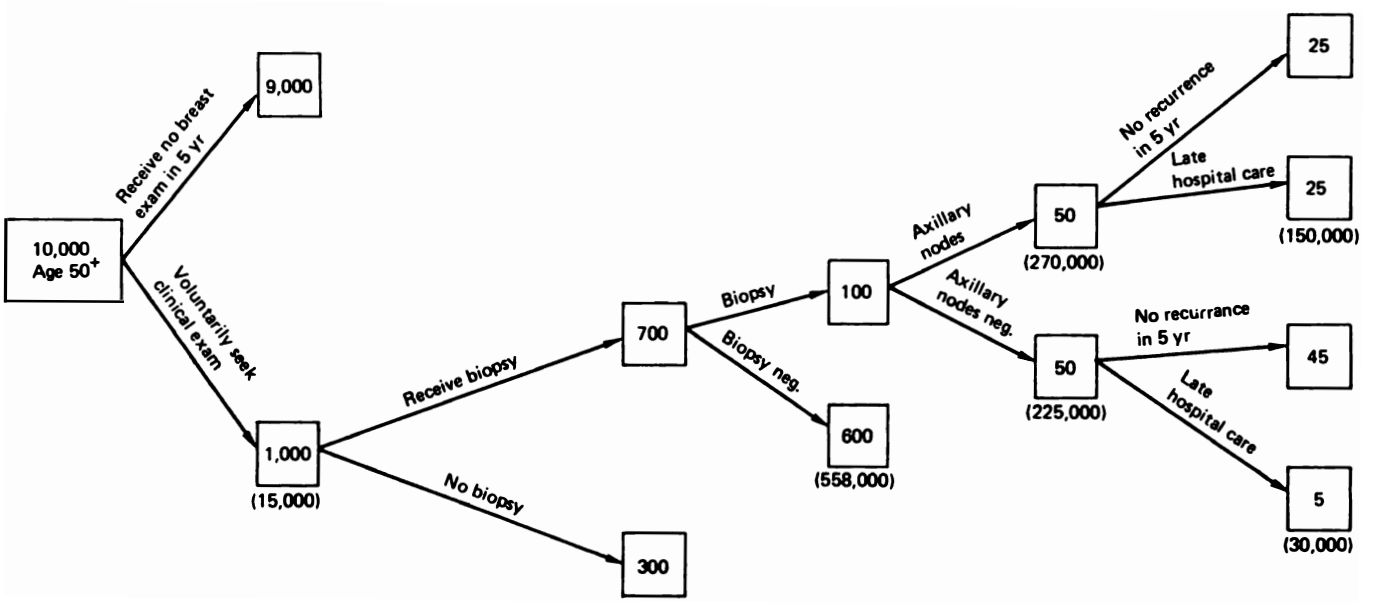

FIGURE 1 Nonscreened group: Decision flow diagram for projected 5-year experience of women age 50+. (Total projected 5-year costs = $1,248,000. Figures in parentheses are $ costs.)

cost of $12,480 per cancer patient or $125 per woman in the group of 10,000 for the 5 years.

Figure 2 presents the predicted experience for the group that receives annual breast clinical examinations from a screening program assumed to be able to provide such examinations at a cost of $10 per examinee. Over the 5 years, 39,790 screening examinations will be thus provided at a cost of $100,000 for the initial examination and $297,900 for the reexamination. These screening examinations will generate 467 clinical workups and surgical biopsies for a dominant mass palpated in a breast, and 70 will be found to have a positive biopsy for cancer with the followup experience shown in Figure 2. Over the 5-year period at times other than the annual screening examinations, it is predicted that 230 women will seek care from their physicians for a breast complaint and will undergo a surgical biopsy, and 30 will be found to have breast cancer. Of the total 100 breast cancer patients in this group, 23 will have some cancer recurrence in the 5-year period. The total projected costs for breast cancer care for this group of 10,000 women receiving annual breast clinical examinations are $1,573,510, or $15,735 per cancer patient, or $157 per examinee for the 5-year period.

Figure 3 shows the predicted experience for the 5-year period for the group who receive only annual screening mammograms. It is expected that 180 patients will be found to have mammograms suspicious for cancer from the initial and subsequent annual examinations, and 90 will be proven to have breast cancer by surgical biopsy. Twenty patients will seek care and receive mammograms at times other than the screening examinations, and 10 will be found to have breast cancer. Over the 5-year period, 18 of the 100 patients with breast cancer will receive late care for cancer recurrence. The cost for providing screening mammography, two views of each breast, varies considerably from $5 in the Oakland Kaiser-Permanente multiphasic screening program to $62 by fee-for-service hospital radiologists. Excluding the 10,000 initial and 29,730 reexamination mammograms, the costs associated with all the breast cancer care in this group are projected at $671,700, which allows $576,300 that could be expended for annual mammograms and still not exceed the total costs of $1,248,000 for the control (unscreened) group. Accordingly, up to $14.51 could be spent per patient examination for mammography and not exceed the 5-year costs of the control group. The total costs of $1,466,300 for the 5 years (shown in Figure 3) are calculated on the basis of a mammography unit cost of $20, which should be achievable by any well-organized mammography screening program. At Kaiser-Permanente's costs of $5 per mammogram (which includes radiologist's interpretation, for a screening load of more than 10,000 women a year in the Oakland and San Francisco

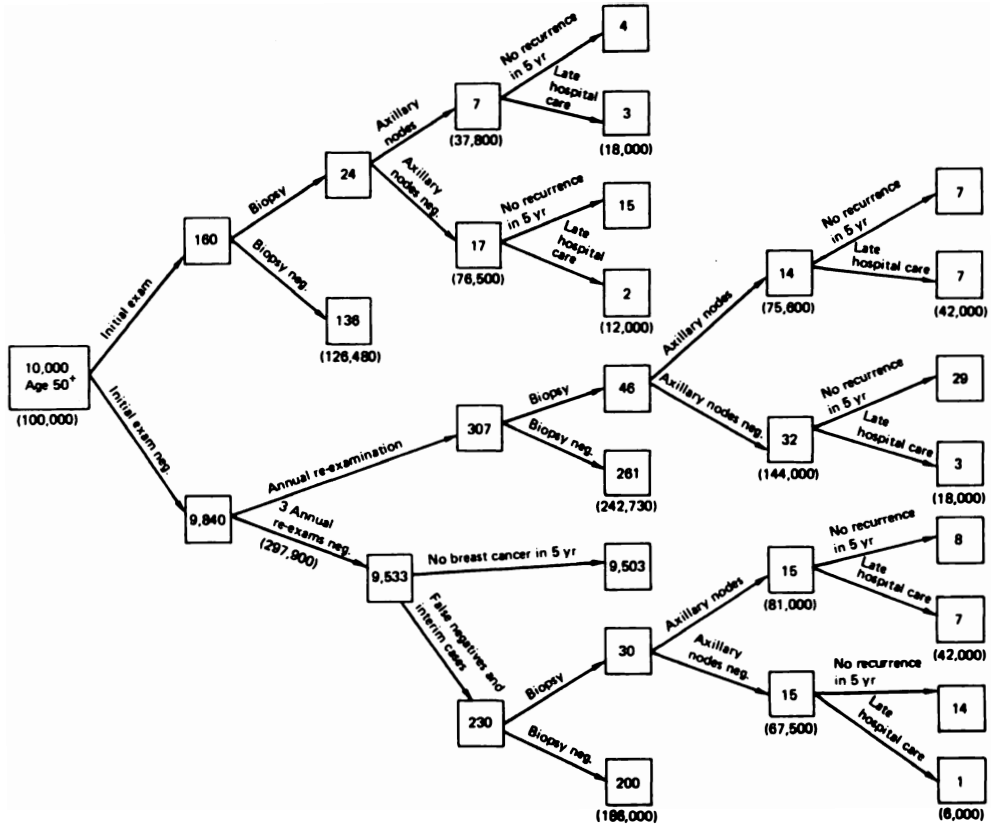

FIGURE 2 Annual clinical examination of breasts: Decision flow diagram for 5-year experience of women age 50+. (Total projected 5-year costs = $1,573,510. Figures in parentheses are $ costs.)

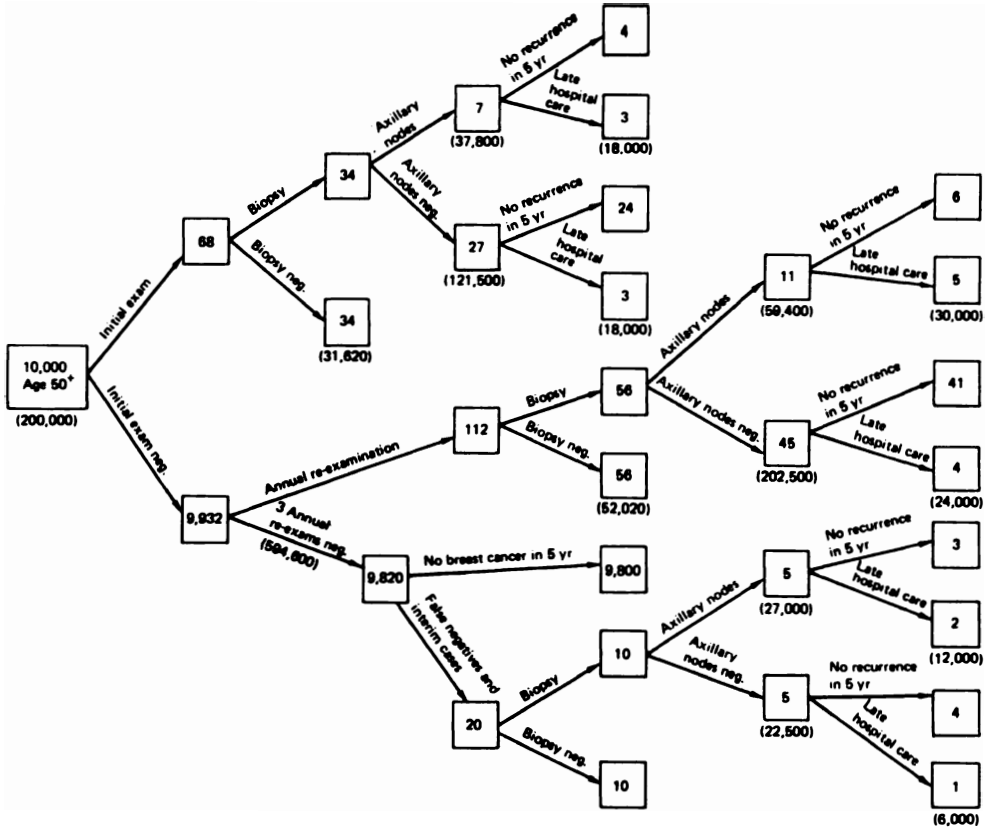

FIGURE 3 Annual screening mammograms: Decision flow diagram for 5-year experience of women age 50+. (Total projected 5-year costs = $1,466,300. Figures in parentheses are $ costs.)

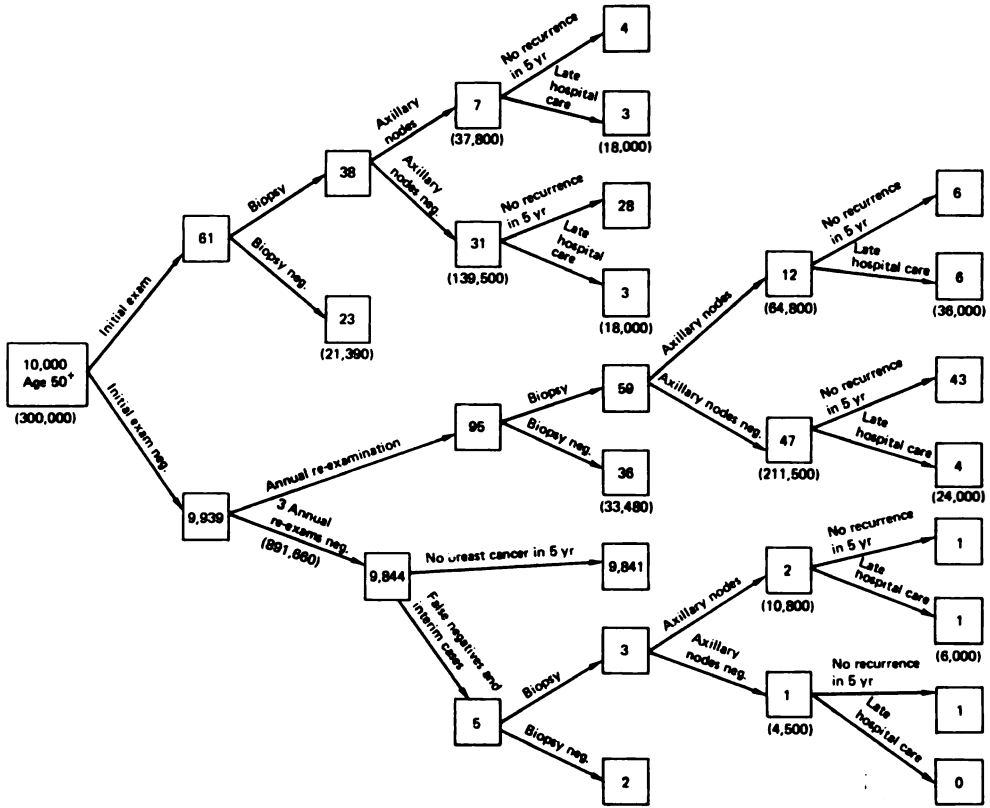

FIGURE 4 Annual clinical examinations and screening mammograms: Decision flow diagram for 5-year experience of women age 50+. (Total projected 5-year costs = $1,819,290. Figures in parentheses are % costs.)

programs), the total costs for the group for 5 years would be only $920,750; this can be expressed as a cost of $9,208 per cancer patient, or $92 per examinee for the 5 years.

Preliminary BCDDP data indicate a 90 percent true-positive experience with mammography.[30] Using this rate of true-positives in this example would decrease the number of false-positive biopsies done by 89 and decrease the total 5-year cost for this group by $82,770.

Figure 4 presents the projected experience for the group who would receive annually both breast clinical examination and mammography, at an average cost of $30 per examinee. From a recent survey, Oldfield[12] estimated $35 per patient to be a comfortable figure for the cost of examining 25 patients a day for a comprehensive breast screening program with mammography, xerography, and thermography. The end results over the 5-year period would be to predict 17 late recurrent cancers. The total costs would be $1,819,290, or $18,193 per cancer patient, or $182 per examinee for the 5 years.

The increased sensitivity of four annual examinations in 5 years as compared to a single examination in this period is shown in Table 1. The percentage of breast cancers detected in the 5-year period increases from 60 percent for a single clinical examination to 70 percent from four annual clinical examinations. For mammography this would increase from 85 percent for a single to 90 percent from four annual mammograms. For both clinical examination and mammography, this would change from 95 percent for a single examination to 97 percent from four annual examinations. In other words, the least sensitive test, a single clinical examination in 5 years, will miss 30 breast cancers in 10,000 women; whereas the most sensitive testing alternative, annual clinical examinations and mammography, will miss only three breast cancers in 5 years in 10,000 women.

The four groups show the following comparative predicted outcomes for their 100 patients with breast cancer over a 5-year period:

	Axillary Nodes +	Late Cases	No Recurrence in 5 Years
Unscreened group	50	30	70
Annual clinical examinations	36	23	77
Annual mammograms	23	18	82
Annual clinical exam. & mammo.	21	17	83

The primary advantage of mammography over clinical examination from the viewpoint of effectiveness for breast cancer screening

(see Table 1) is its better sensitivity and specificity, thus decreasing the number of biopsies performed on false-positive cases without breast cancer, increasing the number of early cases detected, and increasing the number of patients who have no recurrences in 5 years.

Discussion

This evaluation model did not consider estimates of "lead time," i.e., the time between diagnosis with the screening program and the usual time of diagnosis under current medical practice,[6,10,15] since it does not compare survival rates over this 5-year period. However, if a 10-year cost-effectiveness study were made, it might affect the time that late cases appeared in years 6-10.

Without consideration of any benefits to the patient from decreased disability and added years of life, that is, strictly from a cost-effectiveness viewpoint, ideally the total costs of care with screening should be less than the total costs of care without screening.

It must be emphasized again that the costs and yield rates given in the calculations for this case study, although probably representative, are used primarily to demonstrate the methodology for evaluation of this diagnostic technology. In Figures 2 and 3, the cost of a mammography examination is assumed to be twice that of a clinical examination, and any change in this ratio will significantly alter the final 5-year costs. Similarly, the sensitivity of mammography as compared to clinical examination is very critical in determining the higher rate of detection of early cases from mammography. Each mammography program should determine its own unit costs and yield rates and then can use this evaluation model to calculate its own cost-effectiveness. If the unit cost for mammography were higher than $20 or if the sensitivity of the test were less than 85 percent, then the costs and patient outcomes from the screening program would be different from the example given in this case study. The costs for care of patients with axillary node involvement and for late care for recurrent cancer are extremely variable since these are less standardized and will need to be individualized in accordance with the prevailing medical and surgical practice of each community.

Based upon the assumptions presented in this study, for women age 50 or more with an expected 5-year rate of breast cancer of 100 per 10,000 or more, health care costs for 5 years from annual screening mammograms can be projected to be less costly than: (1) annual clinical examinations, (2) annual mammograms plus clinical examinations, and (3) less costly than not screening if the cost per mammogram does not exceed about $14.50. This

conclusion is based upon the estimated comparable costs for the nonscreened group, and the predictions that annual mammograms will result in patient outcomes over 5 years comparable to good current medical experience for the detection and treatment of breast cancer.

The yield rate of breast cancer will vary, of course, with the population being studied. By this evaluation model, for women ages 35 to 50 years, the yield rates from screening mammography will be insufficient to make the procedure cost-effective, since the prevalence of breast cancer is about one-half that of women age 50 or greater and the sensitivity of mammography is less in premenopausal women (since there is less fatty tissue in the breast, which makes it more difficult to visualize early cancer). Furthermore, as already mentioned, the cumulative X-ray exposure to the breast by periodic mammography in younger women introduces the hazard of the increased incidence of breast cancer in later life due to radiation.

Mention should be made of xeroradiography (see p. 102), which is very competitive with mammography for breast cancer screening in women age 50 or more. It may cost slightly more, and yields slightly more false-positives than current mammography; but it provides slightly less X-ray exposure than mammography, and it is easier to interpret. The dense glandular breasts of young women are demonstrated in better detail by xerography than on mammography.

In addition, thermography is an alternative procedure wherein the breast surface is scanned with an infrared camera and the infrared radiation emitted from the skin is recorded on a photographic film. After a prior 10-15 minute cooling period of the patient in a temperature-controlled room, a cancer nodule in the breast may show a localized warmer area on the picture. Thermography is less sensitive than mammography for breast cancer detection in postmenopausal women. It will be less cost-effective than mammography for women over age 50, since it is less sensitive and less specific than mammography (that is, it will have fewer true-positives and true-negatives, and more false-positives and false-negatives).[25-29] However, for women 35 to 50 years of age, screening thermography may be competitive with screening mammography, since in this age-group mammography is also less sensitive; and periodic thermography does not increase the irradiation risk of future breast cancers. Thermography has also been recommended as a method for identifying high-risk women of all ages prior to diagnostic mammography.

The National Center for Health Statistics reported[11] from health interview surveys that, in 1973, 76 percent of females 17 years and over admitted to their ever having a breast examination, of which 63 percent said they had it less than 1 year,

23 percent in 1 to 2 years, 6 percent in 3 to 4 years, and 8 percent in 5 years or more. It appears that the majority of women in the United States already are receiving clinical examinations of their breasts; the current cost-effectiveness for this mode of breast cancer detection and control is represented by Figures 1 or 2, and the costs per 10,000 women age 50 and over for 5 years are probably $1.2 to $1.6 millions. Sufficient data are now available for health care planners and policymakers to make the decision as to whether for a similar 5-year cost the greater effectiveness of mammography should make it the method of choice for breast cancer screening of women age 50 and over. The determination of the most cost-effective method of breast cancer control for women age 35-50 can follow this evaluation model when sufficient relevant data have been accumulated.

POLICY IMPLICATIONS

Evaluations, such as described in the preceding section, carried out by large screening programs so as to provide their own data on costs and effectiveness will help to establish firm guidelines and policies for mammography in breast cancer detection and control. Especially necessary are more followup data on women age 35-50 who already have been exposed to periodic mammography, adjusting for the fact that with current technology (1) the extent of X-ray exposure is much less than it was prior to 1975, and (2) the sensitivity and specificity of testing is now improved.

Limiting screening mammography to only those with higher risk of developing breast cancer (see p. 103) will decrease the initial screening costs and increase the short-term cost-effectiveness of the program--and this is the current policy guideline for women age 35-50. Data are not yet available to estimate the 5-, 10-, 15-, or 20-year cost-effectiveness of such a policy. For women age 50 and over, data are available (as indicated in the preceding section) to show that the limiting of screening mammography only to high-risk cases will decrease the periodic screening costs. However, since the lower-risk patients not screened will return when they detect breast cancer on self-examination and since their costs will then be higher (and outcomes poorer), it is unlikely that a policy to screen only high-risk women age 50 and over will be cost-effective over a 5-year or longer period. One of the limitations of such a cost-effectiveness model is that it does not consider all the benefits gained by those women who become early rather than late cancer cases.

It is evident from these data that from the viewpoint of the policymaker the differences in costs ($1.25-$1.82 million) for 5 years are not so different since there is clearly a trade-off between early care and late care in the four alternatives considered. The increased benefits from earlier cancer detection in decreasing the numbers of late cases become paramount, since the study shows so little difference in 5-year costs. Therefore, it becomes advisable for policymakers to do a cost-benefit analysis and assign some values to the various increased benefits from screening mammography for women age 50 and over.

If one has the responsibility for the continuing care of a defined population, then it is essential to evaluate the cost-effectiveness of any equipment-embodied technology that is directed to a potentially postponable disability (such as breast cancer) over a sufficient length of time to include all of the major costs of medical care for the disability. An easy way to decrease immediate short-term costs is to deny access of patients to relevant care resources, but this type of short-sighted economy often results in postponing care to a later date when it can no longer be deferred, and the disability may then be more serious and require more costly care resources. HMO's soon learn that good *early* care is the best and the most economical care by decreasing the numbers of costly late, complicated, advanced and neglected cases.

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APPENDIX C

A CASE STUDY OF MULTIPHASIC HEALTH TESTING

Morris F. Collen

INTRODUCTION

Multiphasic health testing (MHT) is an example of an equipment-embodied technological system. It has a long history of irregular development and sporadic diffusion as it has attempted to satisfy a variety of objectives in preventive medicine and in health care delivery. The most advanced MHT systems have complex problems of interfacing people (both patients and health professionals) to equipment and equipment to computers. Most patient users find it very acceptable, but many physicians are reluctant to adopt it. Some national governments have a policy of actively supporting MHT and others discourage it. Industry has not found it profitable to market, but many companies make MHT available to their employees. MHT is difficult to evaluate since the total MHT system has benefits greater than the sum of its parts. With the increasing public interest in health care, preventive medicine, and "health maintenance organizations" (HMO's), it is likely that the role of MHT in this country will require careful reexamination by policymakers.

DEFINITIONS AND PURPOSES

Definitions

Personal preventive services in primary care are based to some extent upon periodic reevaluation of the health status of people. Such health examinations (health evaluations, health appraisals, or health checkups) are usually initiated by the patient, but

they may result from the recommendation of a physician, a health care program, or a public health agency.

The traditional method for a patient to obtain a health checkup is to see a primary care physician, who takes a medical history from the patient, provides a physical examination, and then arranges for diagnostic tests and procedures that in the physician's judgment are necessary to complete the health evaluation. The physician then makes a determination as to whether the patient is well or sick and recommends appropriate followup care.

MHT is a systemized approach to providing the laboratory testing portion of a health checkup and it employs automated laboratory procedures and specially trained allied health personnel to collect data on patients' medical histories, clinical laboratory, X-ray, and other physiological test measurements in a programmed sequence. A multiphasic health checkup (MHC) is a health examination provided by using MHT followed by a physical examination and a physician's decision if the patient is well or sick, with recommendations for appropriate followup care. MHT developed from the experience of public health mass screening, which was modified in order to furnish personal preventive medical services to meet the needs of individual patients and their physicians. Automated multiphasic health testing (AMHT) additionally employs automated equipment and computerized decision rules to sort out those who have diseases. Multiphasic health testing services (MHTS) is the expanded use of MHT programs (either manual or automated) within health care delivery systems to provide adjunctive services such as entry triage, health counseling, health education, and preventive health maintenance. MHT involves more equipment-embodied technology than the traditional health checkup, and, as used herein, multiphasic health testing includes both MHT and AMHT programs.

Functions and Purposes of MHT

Since MHT should always function as an integral part of some medical community, program, or system (e.g., a medical foundation, a health care delivery system, a public health program, an industry, a military program, etc.), its functions and purposes should support the goals and objectives of the overall program.

Functional Objectives of MHT

For personal preventive services in primary care medicine, the usual purposes of MHT are:

1. Provide reassurance, since many patients who come to see their physicians for a health checkup are worried about their health.
2. Define the health status of examinees and determine individual fitness (health appraisal). Monitor the status of the continuing health of individuals by periodic examinations (health surveillance).
3. Detect unknown abnormalities (disease detection or case finding). Monitor previously detected abnormalities by the periodic examination of patients with known diabetes, hypertension, etc. (patient surveillance and disease monitoring).
4. Serve as a referral laboratory for physicians for their patients who need early sickness or diagnostic surveys (diagnostic adjunct).
5. Serve as an entry mode to the health care system (triage).
6. Provide hospital admission examinations.
7. Improve accessibility of health care by making health checkups more readily available.
8. Provide health education and health maintenance to improve health habits and behavior.
9. Provide efficient, satisfying, and good-quality testing service to patients.
10. Provide efficient, satisfying, and good-quality service to physicians. Save physician time by providing a high-utility report, comprehensive in content and readable in format.
11. Provide a comprehensive, good-quality, patient health profile to furnish baseline measurements for continuing or future care.
12. Be a cost-effective program.
13. Help to contain the cost of the process of providing medical care by decreasing use of hospital beds and cost of ancillary (clinical laboratory and X-ray) services.
14. Improve the outcome of patients by decreasing morbidity, disability, and mortality.

Specific Functional Objectives for Each Test Phase

Each MHT program must define specific objectives for each test selected for its examinees, depending upon their racial, ethnic, and socioeconomic characteristics. Objectives should include:

1. A desired sensitivity and specificity for each test. The determination of the accuracy required for each test and the setting of boundary limits for "normal" and "abnormal" will define the percentage of true-positives and true-negatives, and false-positives and false-negatives. This determines the prevalence of true-positives for each phase in the population to be tested.

2. An expected cost-effectiveness for each phase. The usual objective of a test phase is to detect a significant number of true-positives for the target conditions at a reasonable cost.

Principles of Operation of MHT

General Principles

Many writers have advocated principles to guide MHT programs, and these generally include that MHT should be an integrated component of a health care program and closely related to its physicians' services. Such integration is most effective in a formal organized system of care, but it can also function in an informal cooperative relationship, in which case the linkages must be truly operational. Provision for diagnoses, followup, and treatment is essential, for without it MHT will fall into disrepute. Thus it is necessary that there be (1) a defined or target population of adequate size that agrees to use MHT for checkups and (2) a group of primary care physicians who will support MHT by referring to it patients for examination and accepting patients referred from MHT for followup care.

Test Selection for Health Problems

It is important to identify a set of health conditions, test, and preventive procedures for each MHT program, customized to fit the needs of its target population. A different MHT group of tests is appropriate for children than for adults. It is advisable to have a somewhat different battery of tests for young, middle-aged, and older adults. The World Health Organization advocates stringent criteria[111] before a screening program is undertaken.

From the Kaiser-Permanente experience, it is recommended that MHT for personal health services should select (1) conditions and (2) tests that fulfill the following criteria:

1. *Criteria for Selecting Conditions for Testing*

a. They are important health problems for the individual and/or the community. These include not only conditions that are potentially disabling or life threatening (e.g., hypertension, breast cancer, etc.), but also conditions that impair the quality of life (e.g., impaired hearing, anxiety, etc.).

b. Each condition should (i) be prevalent in the population tested with a sufficient frequency and (ii) have a test available to detect the condition with sufficient sensitivity and specificity so that the cost per positive test is acceptable to both

provider and user of services. In other words, the predicted yield rate in the target population must be appreciable; if the condition is rare it will probably be too expensive to detect.

c. Appropriate health care services should be available for the condition, whether this be further diagnostic, curative, or rehabilitative services; health and psychosocial counseling; or palliative care--as may be indicated for each patient's problem. It is ideal (but not always achievable in reality) if the test can detect the disease early enough and if effective therapy is available such that the entire process of detection, diagnosis, and treatment can be demonstrated to be cost-effective.

2. *Criteria for Specific Test Selection*

a. Cost per test must be acceptable to users as a reasonable charge.

b. Cost per positive test. This criterion is the result of the cost per test and the prevalence in the target population and is basic to test selection. (For reassurance of health and absence of disease, the cost per true-negative test becomes important.)

c. Cost per true-positive test. This criterion introduces the essential specification of sensitivity and specificity of a test, which impact followup costs. (See pp. 133-158 and Table 4.)

d. Cost-effectiveness. This criterion attempts to measure the cost to effectively detect the condition early. Ideally, a test should be able to detect a condition before irreparable changes disable the patient. Cost-effectiveness is sometimes defined as including therapy, i.e., the ability to alter the course of the condition or disease.

e. Acceptable to patient. The test must be harmless, cause no unreasonable discomfort, and take a reasonable length of time.

HISTORY OF DEVELOPMENT AND DIFFUSION OF MHT

Over the past 45 years, multiphasic health testing (MHT) evolved as a systemized approach to provide health examinations more efficiently to large groups. The concept of health checkups is not new, as for decades the practice of periodic health examinations has been recommended generally. In order to decrease the cost of providing such examinations, some of the principles and methods of systems engineering have been applied in multiphasic health testing. There was a gradual evolution through the various historical steps of screening, mass screening, multiphasic screening, automated multiphasic screening, and multiphasic health testing to the most advanced automated multiphasic health testing services.

Screening as a public health measure in the United States began prior to 1900, with the screening of immigrants by the Marine Hospital Service in order to identify those with significant disease who might become a burden on the country. This was extended to screening communities for communicable diseases. As communicable diseases gradually diminished in importance, the Public Health Service expanded its attention to screening for chronic noncommunicable diseases.

In order to decrease the costs of examinations of large numbers of people, screening techniques were developed that consisted of simple, quick, and often only approximate tests that could, with reasonable accuracy, sort out persons likely to have the disease that was to be detected. In 1948, Breslow[16] first introduced the term "multiphasic screening" as an extension of the mass screening technique. Since tuberculosis, syphilis, diabetes, and heart disease had been proven to be detectable in the general population on a mass scale, and since it was not uncommon for a group of people to be surveyed for tuberculosis and then surveyed again some months later for syphilis or diabetes, the multiphasic survey was conceived with a view of combining tests for several of these diseases in one "package."

As early as 1948 an editorial in the *Journal of the American Medical Association* suggested that "in contrast to periodic health examinations, these screening procedures are capable of a very wide application; they are relatively inexpensive per person tested, and they require relatively little time on the part of physicians. . . ."[66]

In 1950, Ryder and Getting[140] reported the historic action of the Council of the Massachusetts Medical Society, which voted in May 1949 to establish five pilot multiphasic clinics (called "Health Protection Clinics") offering, on a voluntary basis, health examinations under the auspices of the district medical societies in cooperation with the community hospitals and other interested groups.

In 1951, the first multiphasic screening project within a comprehensive prepaid health plan was initiated in Kaiser-Permanente's Oakland medical center and a year later in its San Francisco medical center.[35] These were supervised and conducted by the same physicians who furnished the physical examinations, treatment, and followup care as an integral part of the group practice, prepaid medical care plan.

In 1951, the President's Commission on the Health Needs of the Nation recommended periodic health examinations as a means of chronic disease control and suggested that multiphasic screening be used to detect early disease.

In 1955, the American Medical Association began to offer health examinations to its physicians at its annual meetings, and in 1961,

through its Section on Pathology and Physiology, initiated typical multiphasic health testing examinations at its annual meetings.

In 1960, the American Public Health Association strongly endorsed multiphasic screening, and in 1961 the U.S. Public Health Service established the Chronic Diseases Division, which began to provide grants and contracts to establish and evaluate multiphasic screening programs.

In the late 1950's, multiphasic screening began to receive severe criticism for its poor quality of testing. The advent of electronics and automation into medicine improved the quality of testing and augmented screening capabilities so that not only more tests, but also more accurate and quantitative measurements, could be used.

In 1963-64, with the partial support of a grant from the U.S. Public Health Service, the multiphasic screening programs then operating in the Kaiser-Permanente Oakland and San Francisco medical centers were replaced by the first automated multiphasic health testing (AMHT) programs.[38,39] The two programs have operated continuously since that date and have provided more than one-half million examinations.

In 1966, a special committee of the U.S. Senate held extensive hearings on multiphasic screening, which resulted in a publication of abstracts[63] but no legislative action. Comprehensive bibliographies were published in 1963 (Siegel,[150] Mandel and Lillick[110]) and in 1971 (Gelman[84]). The first books on multiphasic screening were published in 1968.[149,188] The first comprehensive monograph on multiphasic health testing and adjunctive services (MHTS) appeared in 1977.[40]

A great impetus to multiphasic health testing resulted from a series of joint meetings of physicians and engineers arranged by Devey of the Engineering Foundation[5,13] in the late 1960's and early 1970's, followed by conferences sponsored by the Society for Advanced Medical Systems (SAMS),[59] the International Health Evaluation Association (IHEA),[130] and the annual Technicon symposia.[14]

By 1968, organized medicine recognized the increasing importance of MHT by establishing the Intersociety Committee on Multiphasic Health Screening, which included 10 major national medical groups, as well as the American Medical Association.

Although it was not unusual for some MHT programs to incorporate physical examinations performed by physicians on site, in 1969 in the Kaiser-Permanente Oakland's MHT, a team of specially trained nurse practitioners (under physician supervision) began to provide complete physical examinations. Garfield advocated MHT as an entry mode to medical care[81-83] using multiphasic testing and physical examinations provided by nurse practitioners to triage patients into health care, preventive care, or sick care.

In 1970, Sanazaro, then the Director of the HEW's National Center for Health Services Research and Development, sponsored a series of workshops that resulted in the publication of *Provisional Guidelines for Automated Multiphasic Health Testing and Services,*[132] a major milestone in providing definitions and guidelines for operation and test selection.

In 1972, the American Medical Association published its comprehensive *Statement on Multiphasic Health Testing,*[160] in which it reviewed the status of MHT programs at that time and advocated that multiphasic testing "should be integrated into the health care system in a manner that will assist the physician in the management of his patients." It prescribed principles and ethical concepts, and provided guidelines for establishing and operating MHT units. The *AMHT Program Directory, International 1972-73*[146] detailed specifications of about 200 operational MHT programs.

CURRENT STATUS OF MHT

The Kaiser-Permanente multiphasic health testing (MHT) program, which has been operational in the Oakland medical center since 1964, has served as a demonstration model and provided the basis for many of the MHT programs that followed. It also served as the research and developmental center for evaluating many test phases of MHT.

Recently multiphasic health testing centers have been reported to be opening at a rate of two a week in some urban areas of the United States, some operated by nonphysicians; and at least in the State of Florida, legislation has been introduced to regulate MHT centers as to their supervision, quality, costs, and advertising.[108]

MHT programs are now widespread throughout the developed countries of the world. As of 1976 there were about 300 in the United States, about 40 in Japan, about 30 in Europe, and a few in Australia, Asia, Canada, and Latin America. Based upon the experience of the Kaiser-Permanente program, it is predictable that, as health maintenance organizations (HMO's) increase throughout the United States, about one-fourth of adults served by those HMO's will have a health checkup each year by a systemized multiphasic-type approach.

IMPACT OF PUBLIC POLICY ON DEVELOPMENT AND DIFFUSION

On pp. 128-131, the historical impact of governmental agencies and of public policies on the development and diffusion of MHT was presented chronologically. It is evident that official government policy can have a great influence on the diffusion of MHT.

Japan has at least 40 MHT units, and its government supports the concept. England's ministry of health does not support MHT, and there are only two units in that country.

Community policies and public attitudes also have enhanced or inhibited the diffusion of MHT, especially from the viewpoint of the consumer (patient). The increasing trend to organized arrangements for payments for health care will probably encourage personal preventive health maintenance services and stimulate MHT development customized for the community it serves.

Consumer cooperative groups and unions are increasingly negotiating for periodic health examinations as a health welfare benefit. It can be expected that the general public increasingly will want health checkups as it becomes more aware of the fact that company executives, political leaders, union groups, and health plan members are receiving such health services.

An aspect of the community's traditional protection of its members that can be fulfilled by MHT is the detection of asymptomatic communicable diseases such as tuberculosis, gonorrhea, and syphilis. The experience with sickle-cell screening programs has alerted minority groups that, in addition to the potential benefits, there can be problems associated with identifying genetic or environmental high-risk groups.[35] It has been suggested that one should balance any possible medical benefits against potential societal harm (such as by having health status stigmatize an ethnic group[98]).

Elinson[67] believes that whether or not a person will use MHT services or engage in any preventive health behavior is likely to depend on a wide variety of personal, social, and psychological factors, and on factors characterizing the organization of health services. On the one hand, for example, preventive behavior depends on the person's orientation to health care, the perceived value of the service offered, and concern about health. On the other hand, the utilization of preventive opportunities depends on the physical proximity and convenience of the services offered, the response one expects from health personnel, and the monetary and psychological costs of using the service.

Concern is often expressed that systems technology provides assembly line medicine and that computers tend to dehumanize and depersonalize the medical care process. Hall,[90] Past-President of the American Medical Association, coined the acronym "AMHTLC" to emphasize that "Automated Multiphasic Health Testing" (AMHT) must include "Tender Loving Care" (TLC), and advised that all MHT personnel show concern, patience, understanding, and kindness to each patient, as health care personnel should do in all medical care services. MHT patients have no difficulty in separating the laboratory services (whether clinical laboratory, X-ray, or MHT) from their primary care physician, so the extensive technology of

the laboratory does not detract from the patient-physician relationship; on the contrary, the more modern the laboratory technology, the more confidence the patient has in the physician's technical support. The common practice of AMHT to apply individualized normal values to each patient (by age, sex, etc.) greatly enhances quality and individualization of test results.

EVALUATION OF MHT

MHT, to be properly evaluated, must be studied to determine to what extent it achieves its defined objectives within its overall health care delivery environment (see pp. 125-127).

Evaluation of Resources Used

An essential aspect of the evaluation of MHT involves identifying and measuring all resources used in the program. The number of full-time equivalents of personnel and the use of space, equipment, and supplies are also important to identify and measure by a cost analysis. For the health care delivery system within which MHT is located, the costs of resources used should include the costs of followup care from MHT referrals.

Cost analyses of the Oakland Kaiser-Permanente MHT have been reported[41,42] and will be used as the basis of this case study. Included are the physician costs for interpretations of electrocardiograms and X rays. The total direct costs are made up of about 70 percent for salaries and wages (including fringe benefits), 21 percent for supplies, and 9 percent for equipment depreciation. Indirect expenses are allocated to each test phase and applied to salaries and wages to cover actual expense of services from other departments, such as accounting, payroll, personnel, and purchasing. Indirect costs also include plant operation, comprised of "equivalent costs of ownership" (depreciation, finance charges, interest, and interest expense) and "maintenance" (janitorial services, maintenance supplies, telephone, and utilities). For this MHT, the total cost per MHT examinations has been maintained around $20 primarily by gradually increasing the volume of patients processed to offset increasing payroll costs. Unit costs of MHT are critically related to the patient load. The Oakland Kaiser-Permanente MHT examined in 1973 about 3,000 patients per month. If only 1,000 patients were examined monthly, the cost per patient would probably increase to $40-$50.[40]

Effectiveness of MHT

The measurement of the degree of attainment of program objectives is usually defined as the effectiveness of a program. The primary objective of MHT is to economically provide a good-quality health checkup, i.e., to determine the health status of the examinee, detect unknown disease, monitor the status of known disease, and reassure the well. Accordingly, evaluation of MHT effectiveness should as a minimum determine the yield and referral rates, the effectiveness of detecting targeted asymptomatic disease, and the patient's satisfaction with the process. Some measure of physicians' acceptance of and satisfaction with the program should also be included in effectiveness evaluation, if MHT is to function as a successful participant in the health care community.

WHO advocates that evaluations of effectiveness of screening programs should consider the effect of MHT on patient outcome.[111] However, patient outcome is probably more dependent upon effectiveness of therapy than upon effectiveness of disease detection. The ability to favorably alter the course of the condition should be a criterion for MHT test selection and is an important factor in MHT cost-benefit analysis, but it is essential that evaluation distinguish between the medical care process of (1) disease detection and diagnosis and (2) treatment and rehabilitation. For example, from the viewpoints of the patient, family, employer, and society there are clear social benefits for planning purposes from effective early detection of an incurable disease, even though the treatment may not be effective in altering the natural course of the disease.

Determination of Health Status of Examinees

There has accumulated an extensive literature on health status indices. A useful and simple method for the triage of MHT examinees for referral to appropriate care services is that developed by Garfield[83] and Richart,[135] and it will be used in this case study. Such classification of patients is done after the MHT data and physical findings become available. These results are compared with the patient's complaints to determine health status. A patient (Pt.) is classified as "well" if he has no significant medical complaint or problem (see Table 1) and if the doctor (Dr.) or other examiners record that he has no clinically significant finding or abnormality. He is classified as "worried-well" if he has a significant medical complaint or problem but there are no clinically significant findings. A patient is "asymptomatic-sick" if he has no complaints but he is found to have a clinically significant finding (e.g., elevated blood

TABLE 1 Average Health Status (HS) Mix for New Patients Receiving Health Evaluations[a]

Health Status	(Dr./Pt.)	Number	HS Group,%
Well	(Well/Well)	3,573	56.8
Worried-Well	(Well/Sick)	729	11.6
Asymptomatic-Sick	(Sick/Well)	247	03.9
Sick	(Sick/Sick)	1,736	27.7
		6,285	100.0

[a]Modified from Garfield *et al.*[83]

pressure). A patient is "sick" if he has a significant complaint and is found to have a significant abnormality.

For example, a group of adults who had not seen a physician in the last year and who asked for a multiphasic checkup were classified as shown in Table 1. Those classified as "well" comprised 56.8 percent, as "worried-well" 11.6 percent, as "asymptomatic-sick" 3.9 percent, and as "sick" 27.7 percent. Thus it is evident that in this group, "health" care was indicated for 68 percent ("well" and "worried-well") and "sick" care was needed for only 32 percent ("sick" and "asymptomatic-sick"). Thus MHT can be used to evaluate health status and to separate out those who need "health" care from those who need "medical" or "sick" care. Each patient can then be referred to followup care in accordance with his individual needs.

Yield Rates of MHT

The yield rate of positive findings from a given test depends upon the prevalence of the abnormality in the population being tested and upon the sensitivity and specificity of the test. Yield sometimes is applied to previously undetected abnormalities, but herein it refers to all positive tests. The yield rate for a test is defined to be the number of positives as a percentage of the total number of patients tested. Table 2 shows how the yield rates, or percent positive (%+), are greatly influenced by the ages of the examinees. The yield rate essentially determines the referral rate of patients to physicians for followup care.

One can predict the yield by knowing the prevalence of the conditions that produce a positive test and the sensitivity and the specificity of the test. The yield will be the sum of the true-positives and the false-positives. For a sample of *N* persons, one

TABLE 2 Cost per Positive Test by Age-Group[a]

Test	Under 40		40-59		60 and Over	
	%+	$/+	%+	$/+	%+	$/+
Blood pressure	0.4	88	4.3	8	11.5	3
EKG	10.2	9	17.7	5	31.5	3
Chest X ray	2.1	69	7.4	20	19.2	8

[a]Modified from Collen *et al.*[42]

can predict the yield *(y)* of positive cases from MHT if the population being tested has a disease with a prevalence *(p)* and the test has a sensitivity *(a)* and a specificity *(b)*, then:

$$y = Np(a) + N(1 - p)(1 - b).$$

For example, the predicted yield for breast cancer from four annual examinations of a group of 10,000 women age 50 and over, in which the prevalence is 0.01, for which testing by mammography detects 90 percent of cancers and 99.1 percent of noncancers,[49] would then be:

$$y = (10{,}000 \times 0.01 \times 0.90) + (10{,}000 \times 0.99 \times 0.0091)$$

$$= 180 \text{ "positives."}$$

This yield would result in a referral of 90 true-positives and 90 in whom the surgical biopsies would not confirm the presence of cancer (false-positives).

If a population group of younger women (e.g., age 35-50) were selected wherein the prevalence of this disease was only 0.005, the sensitivity was 80 percent, and the specificity was 99 percent, then:

$$y = (10{,}000 \times 0.005 \times 0.80) + (10{,}000 \times 0.995 \times 0.01)$$

$$= 140 \text{ "positives,"}$$

or 40 true-positives and 100 false-positives would be referred. This demonstrates the relatively higher costs of testing for lower prevalence diseases due to the larger proportion of the case yield who are false-positives.

Diagnoses Reported Following MHT

The final diagnoses reported by the physicians following the MHT and physical examinations comprise the conventional measure for evaluating the effectiveness of MHT in disease detection of a population group, since these diagnoses are an indication of (a) whether the physicians decided that the positive test was a true or false one, and (b) whether they thought the positive test was clinically important (i.e., warranted therapy). In one group of "new" examinees, less than one-third had clinically important abnormalities (asymptomatic-sick or sick in Table 1). Table 3 shows that for another group of more than 30,000 examinations (for which the criteria were not identical and some persons had more than one examination) some clinically important abnormality was reported in almost two-thirds of the examinations. The most common diagnosis was obesity and the second most common was hypertension. For many cases, the condition was already known (not "new" to the physician), and the MHT was being used to monitor the status of the disease.

Effects of False-Positives and False-Negatives

The validity of a screening test is the measure of the frequency with which the result of that test is confirmed by an acceptable diagnostic procedure--i.e., the ability of the test to separate out accurately those who have the condition sought from those who do not. Applying a screening test to a population will

TABLE 3 Ten Most Frequent Diagnoses Found in 30,000 Consecutive Checkups and Percent Newly Detected

Rank	Diagnosis	Per 100	% New
	Some Important Abnormality	65.0	
1	Obesity	17.3	25
2	Hypertension, primary	7.6	28
3	Anxiety state	7.3	31
4	Osteoarthritis	3.8	20
5	Diabetes mellitus	3.3	39
6	Fibrocystic disease, breast (women)	3.2	29
7	Varicose veins	3.1	34
8	Psychophysiological Reaction, Gastrointestinal	3.0	40
9	Benign prostatic hypertrophy (men)	3.0	58
10	Anemia (women only)	2.0	78

produce four categories of results, provided that the whole population is also examined definitively to establish the actual prevalence of the disease. These four categories are shown in Table 4 and they have been discussed extensively in the literature.[14,71,87,159,172]

For quantitative and semiquantitative tests it is possible to vary the sensitivity and specificity by changing the screening level at which the test is considered to be positive. However, changing the screening level to increase the sensitivity will decrease the specificity, and a change to increase specificity will correspondingly decrease sensitivity.

MHT tests are selected with a sufficient sensitivity to detect an acceptable proportion of patients who have the disease (true-positives), but if the test is too sensitive it will produce some test results that may identify a person as having the disease (or abnormality) when in fact this is not true (false-positives). Similarly, the test selected usually will have sufficient specificity to identify an acceptable proportion of patients who do not have the disease, but if it is too specific it will miss too many who do have the disease (false-negatives). A frequent criticism of MHT from physicians has been that it produces an excessive number of false-positive test results, thereby increasing costs by generating secondary tests, using more doctors' and patients' time, and increasing patient anxiety. More serious is the increasing concern to providers of care from medical liability from false-negative tests. Accordingly, it is important to consider in detail the effects of false-positive and false-negative tests when evaluating an MHT.

TABLE 4 Categories of Screening Test Results[a]

Screening Test Results	Patients Health Status: Sick	Patients Health Status: Well	Total Test Results
Positive (+)	True +'s	False +'s	Total +
Negative (-)	False -'s	True -'s	Total -
Total cateogry	Total sick	Total well	Total tested

$$\text{Sensitivity} = \frac{\text{True +'s}}{\text{Total sick}} \qquad \text{Specificity} = \frac{\text{True -'s}}{\text{Total well}}$$

[a]Modified from Thorner and Remein.[172]

Costs of False-Positives Attempts to evaluate and quantitate the costs of false-positives involve comparisons of the expected value of treatment with the expected value of nontreatment in a group of patients with known disease prevalence, the value (costs) of treating the sick, the value (costs) of reassuring the nonsick, the costs of working up the nonsick, and the costs of not treating the sick who, if not tested, would have gone undetected. These types of cost-benefit studies are difficult to carry out. A cost-effectiveness study bearing on this issue follows on pp. 143-145.

The costs of false-positives must be shared by those who benefit by having the disease detected early and by those who are reassured by the fact that they do not have the disease. The value of detecting the disease early is, of course, influenced by the ability of the treatment to alter the natural history of the disease and prevent or postpone overt disability.

For example, there is now convincing evidence that the higher the blood pressure, the shorter the life. In order to treat hypertension earlier and decrease the subsequent incidence of stroke, there is increasing support for early detection of asymptomatic hypertension--especially since hypertension is a relatively high-prevalence disease.

Although for lower-prevalence diseases the problem of false-positives is relatively more costly, again, the potential disabling capabilities of the disease are a basic consideration. For example, the prevalence of breast cancer is low, but the value of periodic mammography for asymptomatic women over age 50 is becoming more convincing. (See Appendix B.[49])

Costs of False-Negatives A false-negative is a more serious error if the condition missed is potentially a disabling one, e.g., failing to detect early pulmonary tuberculosis by the screening chest X ray has always been a great concern to the radiologist, whether the screening program was only for a single disease, tuberculosis, or whether in a multiphasic program it was for several conditions including tuberculosis.

Failing to detect by mammography an early nonpalpable cancer of the breast may cost the patient a possible cure if she does not come in until she palpates a lump in the breast or axilla.

As MHT testing increases its sensitivity to attempt to minimize false-negatives, its testing costs and followup costs will increase. Since it is unlikely that any program has sufficient resources to achieve 100 percent sensitivity, the actual expenditures will be limited by the program's goals and budget, and the community's rate of malpractice suits. The increasing impact of medical liability (malpractice) settlements upon the practice of medicine has generated the concept of "defensive medicine."[12] This results in

a physician ordering additional tests, procedures, and consultations that he deems necessary to support or defend, if challenged, the diagnosis and treatment that he has provided his patient. The increasing accountability of a physician for false-negative diagnosis significantly influences the average physician's mode of practice.

On pp. 143-145 is presented a cost comparison of patients evaluated by MHT as compared to the traditional physician's health examination, and Table 5 shows the significantly lower costs for the MHT group for the initial workup and 12 months followup care. These data do not indicate any increased costs which might be due to excess false-positives in the MHT group, and may even raise the question whether the higher costs in the traditional group might be due to excess numbers of false-negatives.

Value of Finding a Negative Test It is difficult to objectively evaluate the worth of finding a negative test. We know how to express the value to the patient of telling 1 in 12 adults that they have hypertension, or 1 in 500 women over age 50 that they have a breast cancer, in terms of the likelihood of future disability and mortality. On the other hand, how do we express the value of a negative test, that of telling the other 11 adults that they do *not* have hypertension or the 499 women that they do not have breast cancer? Surely the reassurance and the avoidance of the costs associated with a positive test to the patient, to the family, to the community, and to the health care system have some value, perhaps even more value than the finding of a positive test. Garfield[81] has stated that the emphasis on disease by the evaluation of MHT on its yield of sickness rather than its yield of health is a product of preoccupation with sickness that has historically prevailed throughout medicine.

Efficiency of MHT

In health care systems, the evaluation of program efficiency is usually defined as the ratio between an output (net attainment of program objectives) and an input (program resources expended, usually expressed as average dollar costs). Often this ratio has been inverted and expressed, for example, as dollar cost per positive case for multiphasic testing.

In evaluating the efficiency of MHT to achieve its objective of providing a disease detection and monitoring program, it is necessary to measure costs to identify clinically important conditions for the various MHT phases. In such a study, it is essential to establish accurate cost centers to provide reliable unit costs and to define precisely which clinically important

test results or findings are considered to be "positive." Such a study provides useful information as to which tests will be most efficient in the examinations of a specified population.

Using a cost analysis for the Kaiser-Permanente program, the MHT costs for a representative test (chest X ray) will be considered as an example. Table 2 shows the cost per positive test for young, middle-aged, and older persons. The unit cost for a chest X ray, including the radiologist's interpretation, was $1.45. Clinically important abnormalities that were reported included: suspicious density or lung lesion, lung fibrosis, hyperlucent lung, mediastinal abnormality, hilar enlargement, other cardiovascular abnormality, or bone lesion. Not included were the following conditions: lung calcifications, fibro-nodular or fibro-calcific lesion, pleural thickening or adhesions, blunted costrophrenic angle, rib anomaly, scoliosis, previous chest surgery, mastectomy, calcific or tortuous aorta. The definition of "abnormal" is critical in establishing yield rates and unit costs.

Table 2 shows for chest X rays the tenfold increase in frequency of clinically important abnormalities (as defined above) reported in adults over age 60, as compared to those under age 40. The unit cost per positive chest X ray for a clinically important abnormality in the 60 years or older age-group was $8. The low prevalence and high unit cost per positive test for chest X rays for young adults has caused many MHT programs to omit chest X rays for this group.

It must be emphasized that these unit costs were related to an MHT patient load of about 2,000 per month at that time. If only 1,000 persons were examined monthly, the cost per patient would probably double. If 3,000 persons could be tested per month, the unit cost would probably decrease by about one-third. These data clearly demonstrate how the prevalence of an abnormal test is dependent upon age composition of specific population examined. Finally, it is important to emphasize that in order to evaluate the true efficiency of any test for case detection, it requires an extension of the analysis to determine the cost per proven "true" positive case, which requires expensive followup confirmatory and validating procedures. (See Appendix B.[49])

Cost-Effectiveness of MHT

Introduction

A very useful method of evaluating MHT is by comparing its costs to some alternative process for achieving the same specified objectives. Comparing MHT with another program (or even *no* program) as to costs to achieve the same objectives does not

TABLE 5 Comparative Use and Cost of Services (Initial and Followup) for a Health Examination (Adjusted for Age, Sex, and Health Status

	Initial Examination Services						Examination Followup Services						Total Costs		
	TMC[a]		MHT-MD[b]		MHT-RN[c]		TMC		MHT-MD		MHT-RN		TMC	MHT-MD	MHT-RN
	No.	$	No.	$	No.	$	No.	$	No.	$	No.	$	$	$	$
Medical dept. M.D.(min.)	30.0	28.52	15.0	14.75	3	2.95	12.2	9.39	8.7	5.61	9.3	6.64	37.91	20.36	9.59
Other depts. M.D.(min.)	--	--	--	--	--	--	1.4	1.43	1.8	1.84	1.5	1.54	1.43	1.84	1.54
Nurse pract. (min.)	0	0	0	0	30	8.22	0	0	0	0	1.8	1.25	0	0	9.47
MHT	0	0	1	17.46	1	17.46	--	--	--	--	--	--	0	17.46	17.46
Clinical lab. (tests)	6.45	10.71	0	0	0	0	3.14	5.21	1.48	2.45	1.78	2.96	15.92	2.45	2.96
X-ray (films)	0.87	3.60	0	0	0	0	0.31	1.27	0.38	1.57	0.32	1.30	4.87	1.57	1.30
EKG, etc.	0.13	0.71	0	0	0	0	0.10	0.58	0.20	1.12	0.14	0.78	1.29	1.12	0.78
TOTAL		$43.54		$32.21		$28.63		$17.88		$12.59		$14.47	$61.42	$44.80	$43.10

[a] TMC = 2,040 persons.

[b] MHT-MD = 1,916 persons.

[c] MHT-RN = 2,329 persons.

SOURCE: Modified from Collen *et al.*[40,50]

require putting dollar values on the changes in health status or other patient outcomes that may be affected.

Cost-Effectiveness of Alternative Health Examination Modes

If it is necessary to respond to the public's demand for periodic health examinations, or if an organizational decision is made to provide health examinations to a group of people, the question then arises as to which is the most cost-effective examination method. The following study compared, for patients "new" to the doctor, the costs of health examinations provided by MHT (with and without nurse practitioner physical examinations) to the traditional health examinations provided by physicians.[48,50,83]

The Kaiser-Permanente Oakland medical center's MHT has been described elsewhere.[40] One group of patients received a systemized battery of tests and a self-administered history, followed by a 15-minute scheduled visit for a physical examination by a physician in the medical department (the MHT-MD group). Patients who completed the MHT could alternatively receive an immediate physical examination by trained nurse practitioners, supervised by a physician (the MHT-RN group).[163] Also available was a "traditional" medical checkup (the TMC group) provided by the same medical department physicians who, during a 30-minute scheduled visit, took a history and did a physical examination. The physicians who provided care in the traditional medical department were the same internists who did followup MHT physician physical examinations and also who supervised the nurse practitioners. After the physician saw the patient, in any of the above modes, he (and/or the nurse practitioner) would refer the patient to appropriate specialty clinics for "examination followup" clinical laboratory tests, X rays, EKG's, and other special diagnostic procedures necessary to arrive at a final diagnosis.

This study was conducted in 1972-74, comparing 6,285 similarly selected patients receiving (a) traditional medical checkups (TMC), (b) multiphasic health checkups with physician physical examinations (MHT-MD), or (c) multiphasic checkups with nurse practitioner physical examinations (MHT-RN). Their health status was determined by chart review and they were classified as "well," "asymptomatic-sick," "worried-well," or "sick" (see pp. 125-126). All data were then adjusted so that the groups were comparable by age, sex, and health status. Since the same physicians provided the examinations and arranged followup care for all three groups, the quality of care was assumed to be similar.

Table 5 shows the use and cost of services for the initial examination visit by the three modes. The costs shown are costs to the Health Plan for the services provided to its members and do not represent fees or charges that would have been paid by

nonmember patients (e.g., MHT cost to Health Plan for a member was $17.46, but the charge to a nonmember patient would have been $30-$40). The multiphasic panel of tests replaced the individually selected tests that were ordered by the physicians in the traditional mode. The great decrease in physician time for the initial physical examination was obviously the main saving in both MHT-MD and MHT-RN.

Table 5 also shows the followup visits and tests ordered by the physicians to complete the health examination. Many patients did not have their health examination fully completed at the initial visit since the evaluation of possible variations from normal required further diagnostic tests (clinical laboratory, radiology, ECG, etc.) and/or physician specialist consultation visits (internal medicine, ophthalmology, gynecology, dermatology, etc.) to confirm the validity of the finding or for further diagnostic evaluation. The costs for ancillary services (clinical laboratory, radiology, ECG, and other diagnostic procedures) used for the followup evaluation workups are also shown. The impact of the more comprehensive initial testing of MHT is shown here by comparing the sum of clinical laboratory plus radiology plus special diagnostic procedures for followup evaluations ($7.06 for TMC, $5.15 for MHT-MD, and $5.05 for MHT-RN). These data show that any false-positive tests generated from the initial MHT examination did not produce excessive followup tests and did not increase followup costs of ancillary services.

The total physician time (initial and followup) represented by scheduled minutes used for each of the three health examination modes was very different. The traditional (TMC) examination method, based upon the required use of physicians for both the initial examination and the followup visits, used a total of 43.6 minutes of MD time, on the average. The MHT-MD mode reduced the physician time used in the initial examination by one-half and decreased somewhat the physician time used for followup evaluation, so that the average total was only 25.5 minutes, or 42 percent less MD time than was associated with the traditional health examination. The MHT-RN approach further decreased the use of the *initial* physician time to only that for supervising the nurse practitioners who performed the routine physical examinations. As a result, the total MD time used for the MHT-RN mode of health examination was only 13.8 minutes, or 68 percent less than TMC and 46 percent less than MHT-MD.

Table 5 compares the total costs for providing health examinations by the three methods tested. The total cost for a health examination is the sum of the resources used on the initial examination visit and on the evaluation followup visits. The average total cost for a health examination by the traditional

(TMC) physician mode was $61.42. As an alternative, by first providing a multiphasic health testing battery of tests, followed by either a physician (MHT-MD) or nurse practitioner (MHT-RN) physical examination, the total costs for a health examination were decreased to $44.80 and $43.10, respectively (for a decrease in total costs of 27 percent and 30 percent, respectively). Since the total costs for ancillary tests (MHT), clinical laboratory, X-ray, and ECG) were similar for all three modes (about $22), the cost differences are entirely due to saving of physician time.

Of additional importance was the finding that the initial increased comprehensiveness of the MHT examination, when serving as the entry mode to a health care system, had a significant economic impact on the subsequent followup care for at least 1 year. Table 6 compares the total resource costs utilized per 1,000 patients for 12 months beginning with the health evaluation. These costs include all physicians plus all supporting personnel, overhead, and facilities' costs, etc. Patients who received the multiphasic health checkup (MHT-MD group) saved $25,213 per 1,000 patients per year as compared to those who received initially a traditional medical checkup (TMC). Contrary to statements that multiphasic testing increases cost of care, the total cost of care for the MHT-MD group over 12 months was only 80.8 percent of the TMC group (for the MHT-RN group only 75.2 percent of TMC). This decrease of 19 percent in total care costs per year was primarily due to saving in physicians' time, and this saving generally applied to patients in all health status categories.

TABLE 6 Summary of 12-Month Total Resource Costs ($/Yr/1,000 Examinees, Adjusted for Age, Sex, and Health Status)

	TMC	MHT-MD[a]	MHT-RN[b]
MD costs	93,673	68,714	54,683
(% of traditional)	(100)	(73)	(58)
Total costs	131,179	105,966	98,629
(% of traditional)	(100)	(81)	(75)

[a] Modified from Collen.[51]

[b] Modified from Garfield, B. R., *et al.*[83]

TABLE 7 Cost-Benefit Analysis of Periodic MHT Examinations in Men (Ages 45-54 at Entry)

		1965	1966	1967	1968	1969	1970	1971	1965-1971 Total
A. Percent of initial group with no or partial disability									
1. No disability	C	86.8	83.9	81.0	78.6	76.2	73.1	70.1	
	S	87.5	85.5	83.2	82.2	81.2	77.8	74.2	
2. Partial disability	C	10.4	11.4	12.5	13.2	14.0	15.2	16.4	
	S	10.3	11.1	11.9	11.2	10.6	11.3	12.1	
B. Average annual earnings/man	C	$7,038	$7,132	$7,350	$7,850	$8,271	$8,678	$9,270	
	S	$7,083	$7,234	$7,488	$8,036	$8,510	$8,863	$9,371	
C. Average earnings difference/man	S-C	$45	$102	$138	$186	$239	$185	$101	$996
D. Net difference after deducting MHT & OPD expense	S-C	$41	$78	$113	$157	$210	$155	$68	$822

NOTE: S = Study group of 1,229 men (in 1965) urged to have a MHT examination every year.
C = Control group of 1,364 men (in 1965) not so urged, but voluntarily could obtain such MHT examinations.
SOURCE: Modified from Collen *et al.*[40,46]

Cost-Effectiveness of MHT Test Phases

An important evaluation of MHT is to assess each of its test phases as to its costs and its effectiveness in detecting the targeted condition, as compared to (a) no testing at all (i.e., the traditional custom of waiting for patients to come in with a complaint), or (b) some alternative testing method. Since this is a very time-consuming and expensive process, it is usually not done for every phase. "A Case Study of Mammography," as an example of a specific test-evaluation process, comprises Appendix B.[49]

Cost-Benefits of MHT

Although it would be desirable to conduct cost-benefit studies of health checkups and of the MHT mode of providing such checkups, no such cost-benefit studies have yet been completed due to the inability to measure and include all benefits. Klarman[102] classifies benefits under three headings: (a) direct benefits, which are potential savings in the use of health resources; (b) indirect benefits, which represent gains in future savings; and (c) intangible benefits, which relate to value and quality of human life. Emlet[69] has suggested a comprehensive model for cost-benefit analysis of MHT, but such a study has not yet been completed.

A limited cost-benefit study of MHT has been conducted at Kaiser-Permanente Oakland and San Francisco. It measured the effect of MHT on disability, mortality, and the earnings of nondisabled survivors.[56-58] In this project, a "study" group of approximately 1,229 men who were Kaiser Health Plan members, initially ages 45-54, were urged to undertake annual MHT examinations. A "control" group of similar composition and size were not so urged but were followed up in a similar fashion for each subject's health experience. The group described herein constitutes the one age-sex subgroup in which a favorable effect on disability was found, and is referred to again in the following section.

Expenses associated with health-related events were compiled for the study and control groups. Medical care utilization was measured in the study and control group subjects in the Health Plan. Disability rates were measured in subjects who remained in the Kaiser Plan and responded to mailed questionnaires. Self-rated disability has limitations but does provide some measure of health status.

Table 7 depicts the net difference in earnings in the study and control groups. Rows A contain the proportions of survivors

with no disability and partial disability adjusted to relate to the initial population, so as to account for additional losses in earnings due to mortality. "No disability" was defined in the survey questionnaire as a present state of health enabling one to do one's usual work with no limitation. "Partial disability" was defined as a present state of health that caused one to limit or cut down on the amount or kind of work one was doing.

The combined proportions of living men with no disability and partial disability (Rows A) were multiplied by annual income estimates to give the average annual earnings per man in the initial populations (Rows B). The study-control group differences, shown in Row C, represent the differences in average annual earnings due to differences in disability prevalence and mortality, per man in the initial populations.

The study-control group differences in net earnings, after deducting the MHT expenses and additional outpatient clinic expenses, are shown in Row D. It can be seen that the total economic impact favored the study group every year. The total difference for the 7-year period is more than $800 per man. It can therefore be concluded that urging 45-54-year-old men to have an MHT examination every year has important cost-benefits. It should also be pointed out that the amount of the savings associated with greater MHT exposure applied to men in the middle income range, who formed the majority of the subjects in this study. For men with higher incomes the difference would be greater; for men with lower incomes, it would be less. The study did not demonstrate, however, that multiphasic health checkups provided similar cost-benefits for other groups, such as 35-44-year-old males or 35-54-year-old females.

Effect on Mortality of Urging Multiphasic Checkups

The most important objective of periodic health checkups is to decrease morbidity and mortality. The only randomized clinical trial, a long-term controlled study of the effect of urging adults to have annual multiphasic health checkups, has been conducted over the past 10 years by the Kaiser-Permanente Medical Care Program and has been reported in several articles,[46,55-57,133] and recently reviewed by Friedman.[78] From a pool of 46,000 eligible Kaiser Foundation Health Plan members, ages 35-54, two groups were randomly selected. The "study" group of 5,156 members has been urged to have a multiphasic health checkup (MHC) every year. The "control" group of 5,557 members has been left alone. Both groups have been followed up in idential fashion to assess mortality.

The major findings to date are summarized in Tables 8 and 9. Although the control group subjects are entitled to the checkups and voluntarily take them (about 20 percent of the group comes in each year), the "dosage" of checkups has been higher in the study group (about 65 percent each year) due to urging. By July 1975, the average number of checkups per person was 5.2 in the study group and 2.0 in the control group. About 68 percent of both groups are still Health Plan subscribers. The death rate through 1973 has been significantly lower in the study group for conditions hypothesized in advance to be detectable by checkups and amenable to therapy that would prevent or postpone mortality. The death rate for these potentially postponable conditions (largely the accessible cancers and hypertensive disease) has been 6.8/1,000/9 years in the study group, based on 35 deaths, and 10.7/1,000/9 years in the control group, based on 59 deaths ($p < 0.05$). The two conditions chiefly responsible for the study-control difference in mortality were hypertension and colorectal cancer.

Although the overall mortality rates from all causes are similar for the study and the control groups (Table 8), an interesting observation has been made that in the entire population of 10,713 persons there is a gradient risk of mortality from all causes according to the number of checkups the subjects have received, whether in the study or control group. The mortality rates and age-standardized mortality ratios for all causes of death in all subjects are shown in Table 9. The mortality rates were calculated on a person-year basis in such a way that having more checkups was not confounded with survival. It has been determined that serious illness at the start of the study was not responsible for this mortality gradient. Obviously, in departing from comparison of the study and control groups, and comparing different degrees of cooperation of use of checkups, the bias of self-selection can become important. The characteristics of the low and high utilizers of checkups have not yet been compared to determine the extent to which the mortality gradient can be explained by the effects of self-selection. The differences in mortality attributable to checkups are thus overstated in Table 9, whereas in the study versus control group comparison they are understated due to the effect of crossovers between the two groups. A true measure of the effect of checkups on mortality probably is somewhere between the figures shown in Tables 8 and 9.

Acceptance of MHT to Patients

Studies of social determinants of the use of preventive medical services,[93] which would include MHT, suggest that people are less

TABLE 8 Deaths and Death Rates in Study and Control Group Subjects, 1965-73

	Number of Deaths[a]		Death Rate (per 1,000 for the 9-Yr Period)		Chi Square Value
	Study	Control	Study	Control	
Potentially postponable causes	35	59	6.8	10.7	4.51[b]
Cancer of colon and rectum	3	14	0.6	2.5	6.34[b]
Cancer of breast (women only)	12	11	4.3	3.8	0.10
Cancer of cervix and uterus (women only)	0	2	0.0	0.7	0.46
Cancer of prostate (men only)	0	1	0.0	0.4	0.00
Hypertension, hypertensive cardiovascular dis., and hypertensive hemorrhagic cerebrovascular dis.	10	22	2.0	4.0	3.65
Hemorrhagic cerebrovascular dis. without hypertension	9	9	1.8	1.6	0.00
Other causes	240	247	46.7	44.6	0.27
All causes	275	306	53.5	55.3	0.16

[a] Populations alive as of January 1, 1965; Study-5156, Control-5557.

[b] $p < 0.05$.

TABLE 9 Mortality Rates and Standard Mortality Ratios, All Subjects, 1965-73

No. of MHC's to Dec. 1973	Person-Years of Observations in This Category	Number of Deaths	Crude Mortality Rate (Deaths/1,000 Person-Years)	Standardized Mortality Ratio
0	38,384.33	310	8.08	1.38
1	19,039.42	112	5.88	1.02
2	11,188.58	51	4.56	0.74
3	7,873.67	36	4.57	0.71
4-6	13,282.50	59	4.44	0.62
7+	3,959.00	13	3.28	0.40

likely to use preventive services when they are poor, have little education, are isolated from community groups and social networks, have limited health knowledge, have unfavorable attitudes towards preventive care, and have little confidence in the health care system. They are also less likely to use such services when their pattern of medical care is fragmented and episodic as compared with a more regular and continuous association with a medical provider. Table 10 shows that in one group of patients their acceptance of MHT was related to their social class; upper classes expected more and so the majority rated MHT to be about as expected, whereas lower classes apparently expected less so the majority rated MHT to be much better than expected. Patients' acceptance of and satisfaction with MHT is dependent upon prior orientation of examinees as to the multiphasic process, how it

TABLE 10 Patients Acceptance of MHT Compared to Expectations (843 Patients)

	Social Class (Hollingshead)			
	All	Upper	Middle	Lower
Much better than expected	28	19	30	59
A little better than expected	17	15	20	18
About as expected	54	65	49	22
Disappointed	1	1	1	1
($p < 0.001$)				

TABLE 11 Patient Satisfaction Survey with Three Alternate Health Checkup Modes, by Presence or Absence of Health Complaints[a]

Question: How satisfied or dissatisfied were you with this checkup?

	Percent of Respondents					
	Very Satisfied	Fairly Satisfied	Neither	Fairly Dissatisfied	Very Dissatisfied	No Answer
Patients with Complaints						
TMC (N = 163)	73.6	19.1	5.5	1.2	0	0.6
MHT-MD (N = 175)	60.0	27.4	6.3	2.3	0	4.0
MHT-RN (N = 182)	82.4	13.7	1.2	2.7	0	0
Patients with No Complaints						
TMC (N = 134)	75.4	19.4	0.7	1.5	0	3.0
MHT-MD (N = 170)	75.9	17.1	5.3	0	1.2	0.5
MHT-RN (N = 140)	80.7	15.7	2.9	0	0	0.7

[a]Modified from Collen *et al.*[50]

works and what it is expected to accomplish. Once patients have an understanding of the MHT process, their acceptance of the multiphasic examination is excellent.[156] The individual patient's relationships with MHT are, in one respect, similar to those of a patient in any clinical laboratory or X-ray department, when the MHT serves as a referral or auxiliary service for the physician.

The 25-year experience of Northern California Kaiser-Permanente supports the view that MHT is very acceptable to patients. Many surveys have been conducted, and the results of one recent patient satisfaction survey is shown in Table 11. The great majority (87-96 percent) of examinees were as satisfied with a checkup that was provided using the multiphasic approach either with physician (MHT-MD) or nurse-practitioner (MHT-RN) physical examinations as compared to the traditional medical checkup (TMC). This was true whether or not the patients were symptomatic (i.e., with health complaints).

Patient compliance with medical advice is another measure of the effectiveness of the care process. An evaluation of patient arrivals following referral for recommended followup medical care showed similar arrival/referral ratios for the multiphasic and traditional modes of health checkups.[48]

Patient time used for an MHT checkup, on the average, is considerably less than for a traditional checkup. Accordingly, time lost from work or usual activity is usually less from a multiphasic health checkup.

Acceptance of MHT by Physicians

Health checkups are generally accepted by primary care practitioners as a routine part of their work. In the traditional mode of practice, the patient comes to the physician because he wants reassurance that he is well, or because he has some medical complaint, or because he has been advised by the physician or someone else to have a checkup. In the MHT approach, the reasons for the checkup are usually the same. The process, however, is untraditional in that the physician does not usually see the patient until after the individual has had the multiphasic battery of tests and the physician is presented with a computer-generated multiphasic report, which often is unsolicited. Most physicians, on initial exposure to a multiphasic followup patient and its computer report will resent this variation from their customary and traditional routine.

The acceptance of physicians of MHT is also influenced by ethical and medicolegal considerations. McKeown[113] emphasized the unconventional impact of screening on the usual practice of the physician in which the screened patient arrives following

MHT examination. In those instances where a public health authority or an organization has initiated the screening procedures and not the patient, McKeown raises ethical questions as to the physician's responsibility in such cases. This question applies primarily to mass screening programs and not to personal health checkups, whether the latter use the traditional or multiphasic modes. The American Medical Association in its guidelines has attempted to formulate ethical principles for MHT.[160] Bates[7] surveyed 417 physicians to ascertain their acceptance and followup of multiphasic screening tests and demonstrated the lack of responsiveness of practitioners in confirming an abnormal test or initiating management of detected abnormalities. He suggested that MHT was of value to the physician in providing new diagnoses, and in providing data for the physician which, even for normal tests, may make other tests unnecessary and furnish baseline information against which to compare future test results. Bates suggested that, since physician behavior constitutes the "major block" in patient followup, three choices appear open: improve followup through physician education, make alternate arrangements for followup, or delete the test from MHT because followup is not carried out. Williamson,[186] in a study of physician responses to hospital admission screening test results, found that only 35 to 78 percent of physicians, depending upon educational efforts, showed any response to unexpected abnormalities, as determined by a retrospective chart review.

Mechanic[119] points out that medical decisions are influenced by the physician's willingness to assume risks involved in the decision-making process. Physicians usually adopt a conservative decision rule, which makes it a more serious "error" to dismiss a sick patient than to retain a well person; accordingly, a large part of the differential diagnostic process is involved in "ruling out" possible diseases that also might account for the patient's symptoms. However, it is a basic concept of MHT to comprehensively screen for a large number of symptoms and laboratory tests. The result is that many physicians express concern that the larger number of tests increases the number of false-positives and thereby increases the evaluation followup costs of a health checkup. On the other hand, the possibility that the fewer tests provided to a patient by the traditional approach increases the number of false-negatives and thereby increases the followup total costs of medical care must also be considered. Both problems are very difficult to evaluate and have been referred to in prior sections.

Personal economics undoubtedly have some role in the acceptability of MHT by physicians. Medical checkups are often an important source of income for internists, general practitioners, and other primary care physicians. On the other hand, many

physicians find that giving routine physical examinations is boring and uninteresting. They are glad to turn over health assessment activities to MHT and nurse practitioners or other paraprofessionals so that they can devote most of their time to the care of the sick.

Recommended Tests and Periodicity for MHT

Lists have been published of recommended specific tests for screening or health testing, but each MHT program should select tests in accordance with its objectives, the population it serves, and the criteria for selection of tests and conditions as described in prior sections. Studies are needed to determine the optimal interval between health checkups, since there is little data available directed to this question.

Frame and Carlson[77] provided a critical review of tests suitable for periodic health checkups. Gelman reviewed tests furnished by 40 MHT units, and Bates[7] reviewed physicians' use of screening tests in ambulatory practice. Breslow *et al.*[19] developed lists of recommended conditions and tests for personal preventive health services for adults; and these are used as the basis for Table 12. Breslow's task force advised that these tests should be given three times during the 17-35 age period: one between 17 and 20, another in the mid-twenties, and a third in the mid-thirties. Subsequently, Breslow and Somers advocated a "lifetime health-monitoring program."[20] The Mayo Clinic is quoted as recommending two examinations at regular intervals for persons between the ages of 18 to 30, three between 31 and 40, four between 41 and 50, five between 51 and 60, and annually for persons over 60.[26]

Table 12 lists a summary of recommended tests for adults age 35 or more. Kaiser-Permanente's studies indicate that periodic multiphasic health checkups do favorably decrease mortality after age 35, so it would appear advisable to recommend health examinations every 1-2 years after age 35, and less often for younger persons.

Summary of MHT Evaluation

Since MHT is still an evolving component of health care delivery, its objectives are still developing and its applications are becoming more diversified. Accordingly, its evaluation must be a continuing and iterative process. However, as of 1977, the extent to which MHT has achieved its objectives can be summarized as follows:

TABLE 12 Recommended Tests for Adults Ages 35 or More[a]

	FIC	ASPH ATPM	APHA	TF	B&S	CKP
History	x		x	x	x	x
Height and weight	x	x	x	x	x	x
Blood pressure	x	x	x	x	x	x
EKG	x	x	x	x(1)	x	x
Vision		x		x	x	x
Tonometry	x	x	x			x
Hearing	x(1)	x(1)		x(1)	x	x
Spirometry			x			x
Mammography (females)	x	x		x	x(2)	x(2)
Chest X ray			x			x
Podiatric examination	x(1)					
Dental examination	x(1)					
Laboratory examinations						
Serum cholesterol	x	x	x	x	x	x
Serum triglycerides	x		x		x	x
Serum glucose	x	x		x	x	x(3)
Serum uric acid	x					x
Serum SGOT	x					x
Serum BUN			x			
Serum creatinine			x			x
Serum calcium						x
Serum triiodothyronine (T_3)						x
Serum tryoxine (T_4)						x
Hemoglobin/hematocrit	x			x	x	
Blood count (exclude differential)			x			x
Urinalysis	x		x			
(exclude microscopic sediment)						x
VDRL			x	x	x	x
Tuberculin			x	x	x	
Pap smear (females)	x	x	x	x	x	x
Stool guaiac	x	x	x	x	x	
Physical examination, general	x	x	x	x	x	x
Breast examination (females)	x			x	x	x
Rectal examination	x	x	x			x
Sigmoidoscopy			x			x

KEY: Recommended age 60+; (2) recommended age 50+; (3) after challenge dose. FIC = Fogarty International Center Report for HEW, 1974; ASPH = Assoc. of Schools of Public Health, Breslow Report, 1973; ATPM = Assoc. of Teachers of Preventive Med., Breslow Report, 1973; APHA = American Public Health Assoc. Proposal for National Health Ins., 1974; TF = Breslow's Task Force, 1975; B&S = Breslow and Somers[20]; CKP = Collen, Kaiser-Permanente, 1977.

[a]Modified from Breslow *et al.*[19] and Collen *et al.*[40]

1. From the viewpoint of the patient, MHT:

a. Decreases the length of time necessary to complete a health checkup, is less costly, and is very acceptable.

b. Effectively detects some diseases before symptoms appear, evaluates health status, and refers for appropriate followup care.

c. Improves long-term outcome by decreasing mortality from potentially postponable conditions; and for men aged 45-54 (in one study) decreases losses due to disability, which increases net earnings.

2. From the viewpoint of the physician, MHT:

a. Serves as a referral center for his patients for good-quality testing at a low cost, effectively detects some previously unknown disease, and monitors status of some known disease.

b. Saves physician time by transferring many routine repetitive tasks to allied health personnel and automated instruments.

c. Can improve quality and personalization of health checkup by providing (1) normal values individualized for each patient by age, sex, etc., and (2) greater accuracy by automated equipment and better quality control measures.

d. Can improve the data base available to physicians, thereby decreasing the amount of time spent in routine data gathering for diagnosis and allowing more time with the patient for therapy. Can store data in computerized files for subsequent clinical, epidemiological, and health services research.

3. From the viewpoint of the medical facility administrator, MHT:

a. Provides a "health center" component to a medical facility for health care and personal preventive health maintenance services.

b. Can be customized for the medical needs of the population that uses his facility, including its outpatient clinics, hospital, and surrounding community physicians.

c. Provides a good-quality, effective health examination process at a lower cost per examination for ambulatory outpatients or hospital admissions.

4. From the viewpoint of the health care systems planner, MHT:

a. Is effective and efficient for early disease detection, health surveillance, and disease monitoring.

b. Provides the most efficient method of providing health examinations to a large population.

c. Increases accessibility to and decreases costs of primary care services by an alternative entry mode (especially if

physical examinations, determinations of patient health status, and triage to needed services are performed by nurse practitioners).

In summary, although it is not yet possible to quantify all the benefits of multiphasic health checkups to patients, there is now accumulating evidence of improved outcome to some middle-aged groups; of effective reassurance to the well and worried-well who constitute the majority who seek health checkups; of effective early disease detection and monitoring; of improved quality of testing; and of overall improved cost-effectiveness of health care delivery for all health status groups when multiphasic health checkups serve to provide the entry mode to primary care.

POLICY IMPLICATIONS

In the United States, the increasing interest in preventive medicine, the inclusion of health checkups by some Blue Shield plans, the passage of the Health Maintenance Act of 1973, and the concept that "health care is a right"[81] will all tend to increase the public demand for periodic health examinations. Already this demand is encouraging the opening of MHT programs as stand-alone, commercial for-profit laboratories, and these will require governmental regulating just as do clinical laboratories.

A review of 25 years of MHT experience suggests the following guidelines[45] for a successful MHT program:

1. MHT must have good standards of quality, including:
   a. Accurate testing procedures, so as to achieve acceptable reproducibility and validity of test measurements. This requires a continuing program of quality control monitoring of personnel and equipment.
   b. High utility, that is, provide good test sensitivity and specificity for detection of important diseases for which effective therapy is available.
   c. Comprehensiveness of testing, so as to screen for many common conditions (e.g., a chemistry test panel alone will not satisfy patients who expect a relatively complete battery of tests).

2. MHT must provide good service, which means:
   a. Integrating the MHT program into the community of patients and physicians. All patients should be referred to their physicians, and MHT laboratory reports should be provided only to the patient's physician for interpretation and prescription.

b. Acceptability to the community physicians, so as to obtain their support and conserve their time. MHT reports should be provided in sufficient time, and be of such format and content so as to significantly decrease the physician time requirements for a health checkup.

c. Acceptability to patients, through prompt and pleasant service to examinees at each test station and efficient scheduling, organization, and followup procedures. Reliable service is essential, since patients will be dissatisfied if equipment or personnel failures too often result in "test not done," or "unsatisfactory test," which requires return of the patient to the laboratory for repeat testing.

d. Maintaining continuing patient records. The occasional checkup is of lesser value than periodic health examinations. Providing the physician with test results of prior examinations for comparison permits trend analysis for borderline abnormalities and aids in better diagnoses.

3. MHT must achieve a good economy, which means:

a. Processing a sufficiently large number of patients each day so that the unit cost per patient for the MHT laboratory will be less than by traditional methods.

b. Selecting tests with an acceptable cost per positive case. This requires "tailoring" the MHT test phases to the specific needs of the community of patients and physicians served (e.g., providing chest X rays to adult groups but not to children, modifying medical questionnaires for different socioeconomic and ethnic groups, etc.).

History shows that whenever one of these basic requirements of quality, service, or economy has not been met, the MHT program failed. Where all three requirements are fulfilled, the program should be successful for the MHT unit, the patients, the physicians, and the community.

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APPENDIX D

GASTRIC FREEZING--A STUDY OF DIFFUSION OF A MEDICAL INNOVATION

Harvey V. Fineberg

INTRODUCTION

Duodenal ulcer disease is a chronic condition that afflicts 1 in 10 Americans at some time during their lives.[1] The disease is more common in men, who often first become symptomatic between the ages of 20 and 50 years, the most productive period of their lives. Peptic ulcer causes 1 percent of all disability due to chronic conditions in the United States.[2] While it is not a leading cause of death, as many as 10,000 lives are believed lost annually as a result of this disease.[3]

Pathologically, duodenal ulcers are irregular, generally round, erosions in the first part of the small bowel. A number of causal factors have been proposed to explain the development of ulcers, including genetic predisposition, personality, endocrine abnormalities, and excessive gastric acid secretion.[4] One principle in which all authorities concur is that ulcers never develop in the absence of acid,[5] and reduction of stomach acid is a basic goal of therapy. While some patients with ulcer symptoms do have measurably excessive stomach acid, many have gastric acidity within the normal range.[6]

Clinically, duodenal ulcers produce abdominal pain, which is relieved by the ingestion of food or antacid.[4] The natural history of the disease is characterized by remissions and exacerbations.[1,4] Typically, symptoms last for days, weeks, or months, remit for varying periods of time, and then recur without apparent cause. Most symptomatic episodes subside with conservative treatment, usually consisting of antacids, dietary regimens, and other medication. A minority of patients develop complications, the most serious of which are gastrointestinal bleeding,

bowel obstruction, and perforation of the ulcer into the abdominal cavity. Ten to 20 percent of patients develop intractable pain or serious complications that require hospitalization and may lead to surgery.[4] Ulcers account for 1.25 percent of all patient admissions to short-stay hospitals in the United States and for 1.5 percent of all bed days in those hospitals.[7] A variety of surgical interventions is employed in the treatment of complicated ulcer disease. The preferred surgical procedure is controversial, but each operation carries some risk of mortality and may be followed by uncomfortable sequelae.[8,9] Given the operative risk and postoperative morbidity, surgery has rightly been regarded as a treatment of last resort.

Gastric freezing was developed as an alternative to surgical treatment for patients with intractable pain from duodenal ulcers. First introduced clinically in 1962, the treatment disseminated rapidly and was employed in thousands of patients over the next few years. Most physicians became disenchanted with the procedure, and its use in the United States all but disappeared by the latter part of the decade.

This paper describes and analyzes the diffusion of gastric freezing in medical practice, the process by which it was developed, disseminated, and later abandoned. Special attention will be given to the evaluation of this technique and to the relation between its evaluation and diffusion. Finally, policy lessons of this study will be described.

DEVELOPMENT OF GASTRIC FREEZING*

Dr. Owen H. Wangensteen of the University of Minnesota Medical School became interested in the mid-1950's in the use of gastric cooling to treat gastrointestinal bleeding. Then Professor of Surgery, Wagensteen was highly regarded as an imaginative and expert surgeon, and a gifted teacher. In the 1950's, one standard treatment for patients with acute gastrointestinal bleeding was to lavage the stomach with iced saline passed through a nasogastric tube.[10] Wangensteen went further and in 1958 proposed use of refrigerated alcohol circulated through a rubber stomach balloon as a means of stanching blood flow and in some cases averting the need for surgery.[11] Dr. Wangensteen also became fascinated with the idea of using gastric cooling to reduce the secretory activity of stomach cells, which produce gastric acid.

*Some material in this and the following section was obtained from personal interviews in 1973 with Dr. Owen Wagensteen, Dr. Richard Goodale, and representatives of the Swenko manufacturing company.

He and his colleagues conducted many experiments in dogs, frogs, and other animals and were impressed by the reduction in stomach acid output following gastric cooling. In 1959, Wangensteen published an article speculating on the potential of gastric cooling to treat peptic ulcer disease.[12] Wangensteen and his colleagues then set out to determine the temperature and time limits for safely cooling the stomach of animals, and to measure more completely the effect of cooling on gastric acidity.

In conducting this research, Wangensteen needed an efficient and reliable cooling device, and he turned to a small refrigeration company in Minneaspolis called Swenko. Engineers from Swenko collaborated closely with Wangensteen and his laboratory staff. At one time in 1960, Wangensteen specified substantial improvements in cooling capacity and machine characteristics, which the Swenko people were able to supply in only 28 days. Under Wangensteen's prodding, Swenko developed and improved a refrigeration device that would rapidly cool alcohol to below 0°C and hold the temperature within narrow limits as the fluid circulated through the machine and entered and returned from the stomach via a double-barreled nasogastric tube.

Wangensteen was convinced the reduction in gastric activity he had observed in animals after gastric cooling could occur in humans as well. To his surprise, he found he could safely treat the stomach of dogs with alcohol at -15°C or lower without causing apparent harm. After trials in numerous animals, Wagensteen was prepared to try this gastric freezing method in ulcer patients with persistent pain in order to promote healing and obviate the need for surgery.

A middle-aged lawyer with duodenal ulcer became, in October 1961, the first person treated with gastric freezing. The awake patient was placed in a semirecumbent position. After local anesthesia of the pharynx, a specially folded rubber balloon was passed to his stomach and alcohol at a temperature of -15°C was circulated through the balloon. The first human trial lasted about 15 minutes, but the usual duration of treatment in subsequent patients was three or four times as long. Afterwards, the refrigeration unit was turned off and the system allowed to warm up, and then the alcohol, balloon, and tubing were withdrawn. The first patient happily reported that his symptoms had completely abated, and he was able to eat a regular meal 1 hour after the procedure.

Wangensteen found the same remarkable results in the next two dozen patients treated, and he presented these dramatic findings at a meeting of the American Surgical Association in Washington, D.C., in May 1962.[13] Wangensteen conceived of gastric freezing as a means of achieving "physiological gastrectomy," eliminating stomach acid without surgical removal of the stomach, and he so

titled his paper published May 12, 1962, in the *Journal of the American Medical Association*.[14]

In this paper, Wangensteen and his coauthors argued that gastric freezing is a simple, safe, and effective treatment for duodenal ulcer disease. They presented results of animal studies and experience in human patients to support this assertion. Stomachs of test animals were frozen "rock-hard"; yet tissue damage was minimal. Patients experienced no serious side effects from the procedure. Stomach acid output was markedly reduced in both humans and animals. Ulcer pain was immediately relieved, and radiographic healing of ulcers regularly followed. Because of gastric freezing, no surgery had been required on any patient with duodenal ulcer referred to Wangensteen since mid-1961 for elective operation. In addition, speculated the authors, because of its brevity, simplicity, and safety, the procedure could become accepted practice for treatment of outpatients, and so eliminate the need for hospitalization as well as surgery.

For a scientific publication, this article is striking for its discursive and anecdotal style, as well as its enthusiastic tone.* The authors earnestly believed they had discovered a major breakthrough in the treatment of duodenal ulcer disease, and their writing conveys their excitement. They had a sound physiological rationale, extensive experiments in animals, and clear-cut results in humans. Over the next few years, every important assertion in this introduction of gastric freezing to clinical medicine was disputed, and practitioners became disenchanted with the practice. In the meantime, however, several thousand gastric freezing machines were sold and thousands of patients underwent the procedure.

DIFFUSION OF GASTRIC FREEZING: ADOPTION, EVALUATION, AND ABANDONMENT

Wangensteen's presentation at the American Surgical Association meeting and publication in the *Journal of the American Medical Association* in the spring of 1962 created a sensation among the public as well as the medical profession. Many local newspapers printed accounts of Wangensteen's new treatment, and *Time* magazine carried an article on gastric freezing on May 18, 1962.

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*Franz Ingelfinger, abstracting this article for the 1962-63 *Year Book of Medicine*, commented: "Is this the new approach to ulcer treatment everybody has been yearning for? The report is certainly dramatic and stimulating, but the nature of the presentation--discursive, fragmentary, and with tables that are hard to comprehend--precludes meaningful editorial comment" (p. 488).

Wagensteen refused an invitation to appear on NBC's "Today" show because he did not feel that would be appropriate, but the new procedure was also discussed on television. Wangensteen sought to disseminate his ideas and findings through professional meetings and publications. In the fall of 1962, Wangensteen and his associates published equally impressive results in an expanded series of patients[15] and also presented their findings at the October meeting of the Surgical Forum. Around the same time, the American College of Surgeons prepared an instructional film describing the technique of gastric freezing. The public continued to be informed through an article in *Today's Health* in January 1963, which appeared in condensed form in that same month's issue of *Reader's Digest*.[16]

By the end of 1962, Wangensteen was inundated with requests for information and assistance from all over the United States and, indeed, the world. Swenko already had received more than 300 American orders for gastric freezing machines. At the time, the company had no distinct marketing activities and was unprepared for the flood of orders. At one time there was a backlog of nearly 200 unfilled orders, but production gradually geared up to a peak of 99 units per months. Several thousand physicians visited Swenko and Dr. Wangensteen to witness the procedure firsthand. One enterprising visitor from Texas later described proudly how he convinced the Swenko management to ship him a unit ahead of others.[17] He wanted to try the procedure on outpatients in his rural clinic and reasoned with the Swenko people that if really large numbers of units were to be sold, the procedure would have to be proved outside university centers; his unit arrived the next week. After trying the procedure in 78 patients, he wrote a glowing report in early 1963:

> We consider it certain that a real breakthrough has been made; that the resistent [*sic*] duodenal ulcer now can be brought under control; that gastrectomy for duodenal ulcer will henceforth rarely be required.[17]

While Swenko was the first and probably the dominant manufacturer of gastric freezing devices, the devices did not have an exclusive market. Devices from at least two other manufacturers* are identified in the literature, but neither could be located today. According to records provided by Swenko, that company sold approximately 1,500 machines in the United States and had received orders for 80 percent of this total by the end of 1963. One

*Shampaine Industries of New Jersey and Thermatrol Corporation of Indiana.

writer estimated near the end of 1963 that 1,000 devices were in place and 10,000 to 15,000 procedures already carried out nationwide.[18] Most published papers that identify manufacturers report use of Swenko devices, but at least one claimed technical advantages for another manufacturer's machines.[19] A conservative assumption that the other two major manufacturers each sold one-third the machines sold by Swenko would bring the total distributed in the United States to 2,500.*

The diffusion of Swenko gastric freezing machines over time is represented in Figure 1. The abrupt fall in orders after mid-1963 probably reflects in part competition from other manufacturers. Half the machines sold by Swenko went directly to hospitals; the remainder were divided evenly between physicians' offices and dealers, who presumably resold to both physicians and hospitals. The cost of the Swenko machine increased by several hundred dollars between 1962 and 1966, but most machines sold for approximately $1,800.

The number of patients who received gastric freezing treatments can only be indirectly estimated.† Several thousand patients are included in studies reported in the literature. If we assume that each machine treated only 10 patients, then 25,000 persons in the United States were treated with gastric freezing, and the number might well have been double that. Professional fees for gastric freezing varied widely, but some physicians allegedly charge the same fees as for a gastrectomy.[20]

Anyone familiar with the history of treatment for duodenal ulcer disease would have had reason to be skeptical of claims made for gastric freezing at professional meetings and in the popular media in 1962. Peptic ulcers have been treated with an enormous variety of drugs and nostrums, and there even were claims of success for agents now used to provoke stomach acid secretion or now considered dangerous in patients with ulcer disease.[21] Some responsible observers were appalled by the early, rapid, and uncritical adoption of the new treatment by so many physicians.[22] At least one editorial in 1963[20] and several more in 1964[23,24] described the procedure as experimental, urged caution, and emphasized the need for careful clinical evaluation.

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*A newspaper article in the *New York Times*, October 29, 1963, page 38, states that 5,000 machines had been sold, but that seems exaggerated to this author on the basis of other available evidence.

†The number of gastric balloons sold would have been a useful index, but the major supplier before 1966, Pioneer Rubber Company, was unable to provide this information.

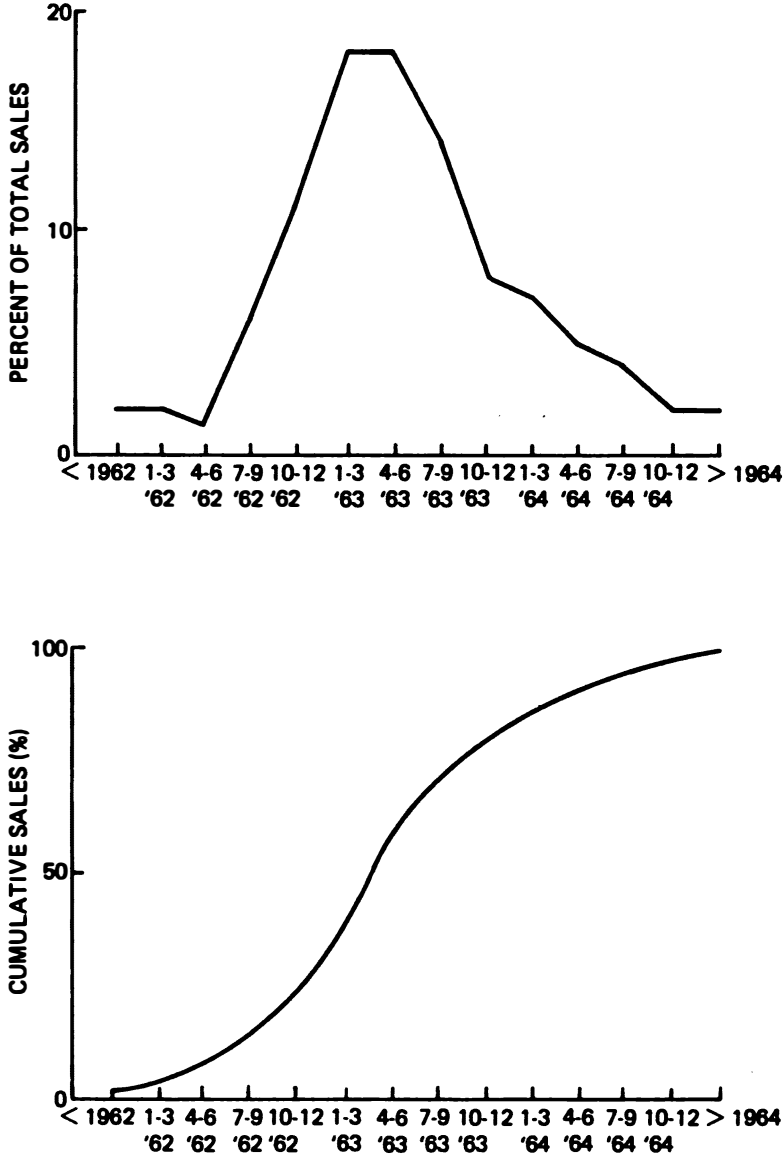

FIGURE 1 Sales of gastric freezing machines by leading manufacturer. Based on date orders received by Swenko, Minneapolis, Minn.

Beginning in 1963, the physiologic rationale and safety of gastric freezing were questioned. Researchers using experimental dogs discovered that the procedure did not really freeze the entire stomach; the "rock-hard" feel reported initially was due to a thin shell of gastric contents surrounding the balloon.[25] As it turned out, the absence of truly frozen tissue was fortunate because where patchy freezing did occur, necrosis followed.[26,27] In July 1963, Wangensteen and his colleagues extended their earlier work.[28] Other clinical reports in 1963 were generally favorable because of marked symptomatic relief.[29-32] However, at least one early investigator failed to detect clinical improvement,[33] and noteworthy side effects began to be documented,[34] including gastric ulceration,[33] bleeding which required transfusion,[31] electrocardiographic changes,[30] burnlike damage to gastric tissue, pneumonitis, and perforation of the lower esophagus due to faulty placement of the balloon.[35] Questions were raised about the physiologic effects of gastric freezing,[36] and one research group was unable to document any association between symptomatic improvement and changes in gastric acid secretion.[31]

Physicians attending the American College of Gastroenterology meeting in October 1963 and the Southern Surgical Association meeting in December 1963 expressed diverse opinions regarding the value and risks of gastric freezing and growing appreciation of the technical complexity of what initially appeared to be a simple technique.[37,38] For example, the extent to which stomach temperature would drop depended not only on the temperature of the alcohol and duration of the procedure, but also on volume and shape of the balloon, balloon wall thickness and material, flow rate of the alcohol, and blood flow to the stomach.[18,38] Some also noted that the duration of symptomatic improvement was variable,[37,38] and some patients required repeat freezings.

In 1964, for the first time, published reports concluded that gastric freezing was not worthwhile because acid suppression was limited or unrelated to pain relief, symptomatic improvement was short-lived or due to placebo effect, and important risks attended the procedure.[21,39-42] Several critical review articles emphasized the need for controlled and comprehensive evaluations of the method.[22,43] Others remained more neutral in their overall assessment of the procedure, but stressed the limited evidence to date[44] and potential dangers of the procedure.[18,37,45] Gastric ulceration or bleeding occurred in 1 out of 10 patients,[21,45-48] and there were two deaths and one near-fatality reported that year due to gastric ulceration following the procedure.[18,37,40] There were additional reports of cardiac ischemia and electrocardiographic abnormalities related to gastric freezing, which persisted in some patients beyond the duration of the procedure.[18,49]

A survey reported in 1964 of 83 physicians and institutions who had purchased gastric freezing machines found some patients had been exposed to substantial risks without regard even for the indications for the procedure.[18] Nine percent of respondents performed gastric freezing as an outpatient procedure and an equivalent percentage did *not* require history of medical intractability before doing the procedure. What was developed and promoted as a last, safe resort before surgery was by this time not only evidently risky and questionably efficacious, but also being indiscriminately applied by some.

Reports favorable to gastric freezing also continued to appear in 1964. Wangensteen and his associates published temperate extensions of their clinical series showing continued excellent clinical results, though 25 percent of patients required refreezing and there were a few minor complications.[50-53] The authors contended that gastric freezing produced immediate and complete symptomatic relief in 85 to 90 percent of patients and offered a direct rebuttal of criticisms leveled against the procedure. While he still had faith in gastric freezing, Wangensteen realized the practice had burgeoned and suspected it was being applied sloppily. Papers from his group in 1964 stressed the importance of careful technique and the need for further evaluation. Others also published favorable reports in 1964, but all stressed risks as well as benefits and urged limiting the procedure to medical centers where patients could be properly supervised by experienced personnel.[54-57]

During 1964, variations in technique became an important arguing point for proponents of gastric freezing.[50-53] Wangensteen and his colleagues continued to experiment and vary the treatment duration, temperature, flow rate, nozzle opening, balloon coolant, balloon shape, and ancillary measures used in the procedure. At one point, an adjunct intravenous vasoconstrictor was touted,[58] only to be discarded quietly in a footnote 6 months later.[59] Articles by Wangensteen and his co-workers commonly included some variation in technique applied at different times in the reported series or had addenda describing the latest adjustments.[14,50-52,58] Some procedural and equipment variations appeared minor, but any might be sufficient to explain differences in side effects or clinical results obtained by different investigators. An associate of Dr. Wangensteen at one point invoked an admonition he attributed to Claude Bernard: "Technic," said the great physiologist, "is everything."[59] In the midst of the controversy, Wangensteen also reminded his colleagues of the sluggish professional acceptance accorded some earlier advances in gastric surgery.[58]

Clinical use of gastric freezing passed its zenith in 1964. To be sure, articles discussing the physiology and physical

effects of gastric freezing continued to appear[60-64] and there were many more reports of complications in patients and experimental animals.[65-73] In some clinical reports published in 1966 and 1969, the authors state they had discontinued gastric freezing in 1964.[74,75] Several panelists discussing gastric freezing at the American College of Gastroenterology meeting in October 1964 made it clear they had abandoned clinical use of gastric freezing at their institutions earlier that year.[59] Evidence of declining interest in clinical application parallels the drop in orders for new machines received by the leading manufacturer after 1963 (Figure 1). By 1966, clinical use of gastric freezing in the United States had spent its course, though units still were being purchased overseas. One editor introduced a 1967 article on gastric freezing's effects on the heart by apologizing, "Though the clinical use of hypothermia for duodenal ulcer has 'come and gone,' a study . . . is of interest for the record."[73]

A review of literature by the author produced 36 clinical reports on gastric freezing published between 1962 and 1969 (Table 1), though a few publications report the same study. The trend over time was toward more negative appraisals of the technique (Table 2). Eight studies with control groups or with double-blind, randomized designs were identified[41,57,64,76-80] and five of these appeared in 1966 or later.[64,77-80] Dates when patients were administered gastric freezing are provided in three of these papers; in one[80] the study began in 1963 and in the other two [64,79] the last patient was treated in 1964. None of the studies published after 1965 reached conclusions favorable to gastric freezing, but of the three double-blind studies published in 1964 and 1965,[41,57,76] two concluded that clinical improvement was probably related to gastric freezing.[57,76] Many physicians became disenchanted with gastric freezing without compelling evidence in the literature that the procedure was inefficacious, though questions had been raised; most likely, the substantial morbidity and occasional mortality evident by the end of 1964 persuaded many to abandon gastric freezing. Evaluations of clinical efficacy published after 1965 only reinforced those decisions. Interestingly, only one group of investigators published one article with conclusions favorable to gastric freezing[57] and later wrote a second article with unfavorable conclusions.[79]

In 1966, Dr. Wangensteen lost support from the National Institutes of Health for research in gastric freezing. He remained convinced the procedure was promising and obtained funds from the other sources to continue his work. More than 10 years after he first proclaimed clinical success with gastric freezing, Dr. Wangensteen maintained the procedure was worthwhile, and,

TABLE 1 Clinical Studies of Gastric Freezing

Ref.	First Author	Date of Publication	Extension of Earlier Ref.#	Study Type	#Pts.	Effects Measured: Acidity	Pain Rel.	Side Effects	Overall Evaluation
14	O. Wangensteen	5/62		Observation	24	x	x	x	Favorable
15	Peter	9/62	14	Observation	80	x	x	x	Favorable
13	O. Wangensteen	10/62	15	Observation	120	x	x	x	Favorable
17	Nichols	1/63		Observation	78		x	x	Favorable
29	Brown	5/63		Observation	50	x	x	x	Qualified Favorable
30	Heineken	6/63		Observation	10	x	x	x	Qualified Favorable
32	Griffin	6/63		Observation	7		x	x	Qualified Unfavorable
28	Bernstein	7/63		Observation	33	x	x		Qualified Favorable
32	DeWall	7/63		Observation	75	x	x	x	Qualified Favorable
31	Artz	10/63		Observation	81	x	x	x	Qualified Favorable
51	Bernstein	1/64	17	Observation	286	x	x	x	Qualified
52		2/64							Favorable
53		2/64							
54	Artz	2/64	31	Observation	100	x	x	x	Qualified Favorable
55	Nabseth	3/64		Observation	6	x	x	x	Qualified Favorable
44	Owens	1/64		Observation	36	x	x	x	Neutral
56	Artz	5/64	54	Observation	150	x	x	x	Qualified Favorable
12	White	5/64		Observation	120			x	Neutral

TABLE 1 (continued)

Ref.	First Author	Date of Publication	Extension of Earlier Ref.#	Study Type	#Pts.	Effects Measured: Acidity	Pain Rel.	Side Effects	Overall Evaluation
37	Scott	5/64		Observation	55	x	x	x	Neutral
39	Hitchcock	5/64		Observation	168				
40	Sutherland	7/64	39	Observation	173	x	x	x	Unfavorable
57	Rose	7/64		Double-blind Randomized	36	x	x	x	Qualified Favorable
41	Perry	7/64		Double-blind Randomized	40	x	x	x	Unfavorable
21	Spellberg	9/64		Observation	64	x	x	x	Unfavorable
42	Karacadag	10/64		Observation	100	x	x		Qualified Unfavorable
81	S. Wangensteen	1/65		Observation	31	x	x	x	Neutral
67	Manlove	2/65		Observation	53		x	x	Neutral
76	S. Wangensteen	5/65		Double-blind Randomized	60	x	x	x	Qualified Favorable
82	Scott	10/65	37	Observation	60	x	x		Qualified Unfavorable
77	Lubos	4/66		Control group	188	x	x	x	Unfavorable
64	McIntyre	5/66		Control group	108	x			Neutral
74	Barner	8/66		Observation	91	x	x		Unfavorable
78	Zikria	3/67		Double-blind Randomized	16	x	x	x	Unfavorable
79	Harrell	4/67	57	Double-blind Randomized	52	x	x	x	Qualified Unfavorable
75	McIntyre	4/69		Observation	74	x	x	x	Qualified Unfavorable
80	Ruffin	7/69		Double-blind Randomized	160	x	x		Unfavorable

TABLE 2 Overall Evaluation of Gastric Freezing by Clinical Studies

	Evaluation				
Year	Favorable	Qualified Favorable	Neutral	Qualified Unfavorable	Unfavorable
1962	|||				
1963	|	|||||		|	
1964		||||[a]	|||	|	|||[a]
1965		|[a]	||	|	
1966			|[b]		||[b]
1967				|[a]	|[a]
1968					
1969				|	|[a]

[a] Double-blind, randomized study.

[b] Study with control groups.

"apart from a note of optimism," did not think there was anything inaccurate in any of his papers. Further refinement of technique and research in dogs culminated in a 1972 research report from Dr. Wangensteen's laboratory.[83] Here the authors conclude:

> The technology of the gastric freeze procedure has now progressed sufficiently to justify prospective controlled clinical studies of its effectiveness in the management of some aspects of the peptic ulcer diathesis by interested, qualified, and critical investigators.

One can only wonder how the course of medicine's misadventures with gastric freezing might have been different had so circumspect a conclusion been offered 10 years earlier.

OBSERVATIONS AND ANALYSIS

This case study has attempted to trace the complete life cycle of a medical innovation, from inception through dissemination,

and finally, abandonment. In gastric freezing, a medical practice was abandoned not because a newer and better alternative became available, but because the practice itself turned out to have more drawbacks than benefits.

Gastric freezing was not a crackpot scheme generated on the fringe of medicine. It began as a scientific insight by a skilled and respected surgeon who developed the idea on the basis of physiologic reasoning and substantial laboratory experience. In retrospect, Dr. Wangensteen did admit to excessive enthusiasm at the beginning. If he and his colleagues had further fault, it was their reluctance to yield a beautiful concept in the face of ugly facts presented by outsiders.

Other medical innovators have also been known to persist in their convictions when the majority disagrees. Vineberg continued to champion internal mammary artery implants for angina pectoris years after controlled studies and expert consensus had denied their value.[84] Perhaps the same independence and drive that allow the innovator to be a pioneer also enable him to ignore the collective wisdom of his colleagues. The fact that a creative individual leads the way for one beneficial innovation lends no assurance that future judgments will be correct. In his pathbreaking study of resistance to medical innovations written 50 years ago, Stern recounts how nineteenth century advocates of antisepsis bitterly opposed the later idea of surgical asepsis.[85]

Factors that help explain the early, rapid dissemination of gastric freezing include Dr. Wangensteen's stature, confidence, and optimism, the high prevalence of duodenal ulcer disease and its natural tendency toward exacerbations and remissions, morbidity and mortality of alternative surgical treatments, promotion in the public media, ease with which physicians could learn to perform the procedure, and the opportunity for financial gain by physicians. A respected surgeon advocating a nonsurgical treatment may be especially credible, and the allure of nonsurgical treatment appealed to well-informed physicians as well as to the public. In the latter part of 1964, a prominent gastroenterologist assessed the status of gastric freezing in an editorial and concluded, "At this time there is no justification for its general adoption by the medical profession."[23] At a meeting of the American Gastroenterological Association the very next month, the same physician responded to his own question, whether he would consider gastric freezing for himself:

> Being fundamentally a physiologist, and knowing the dire circumstances of losing not only an important part of my gastrointestinal tract but having its continuity disturbed, I think I would subject myself to this procedure. . . . If

> relief of symptoms is due to a placebo effect, I think I would be just as susceptible to the psychological effect. I certainly would not anticipate that my gastric secretion or mobility would be significantly altered or even that my crater might heal. Just last week I saw a patient who still had a crater six weeks after having this procedure, but he denied any symptoms whatever. I honestly think I would probably give it one try.

In gastric freezing, thousands of ulcer sufferers saw a quick, easy, and safe means to gain relief. Many had undoubtedly been told they faced surgery when news of the breakthrough appeared on television and in newspapers and magazines across the country.* As a member of the medical school faculty, Dr. Wangensteen received no fees for any of his services. However, some physicians apparently felt justified charging patients the same fees for gastric freezing as they did for surgery, so as to suffer no sacrifice of personal income when they substituted the simpler procedure.

Other characteristics of the development and dissemination of gastric freezing also deserve comment. Commercial interests were not prominent in promoting this innovation; the principal manufacturer was unprepared for the early surge in demand for gastric freezing machines. Swenko printed brochures and entertained many medical visitors, but never mounted any direct marketing effort. Technical entrepreneurs in industry are characteristic of many medical innovations,[86,87] but gastric freezing had none. Essentially, gastric freezing for duodenal ulcer was a new application of existing refrigeration technology. Once the clinical advocate conceived the idea, technical expertise was available to produce desired equipment modification in a matter of weeks.

Early laboratory and applied clinical research was supported by the National Institutes of Health and private foundations. The 2 years that elapsed between initiation of directed research and general availability was shorter than all but 2 of 25 medical innovations reviewed recently by the President's Biomedical Research Panel, and those two involved drugs.[87] The development of gastric freezing is an example of ideal collaboration between government-supported researcher and private-sector engineer,

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*Some years earlier, public clamor for a new medical device similarly followed an article in the *Saturday Evening Post* about an apparatus to measure oxygen in newborn incubators. The device had been available for several years, but high volume sales began with that magazine article.

between science and industry. Except that the procedure proved to be risky and without benefit, it would be a marvelous success story.

Beyond the unwarranted enthusiasm of early proponents, two features of the diffusion of gastric freezing are disturbing. First, at least some early adopters applied the innovation without regard for the clinical criteria recommended by its proponents. No responsible authority had suggested use of gastric freezing in patients who responded to medical treatment, yet one early survey found that 1 in 11 users did not require a history of medical intractability. Even if gastric freezing were a worthwhile alternative to surgery, routine use in patients with less severe symptoms could not be justified. The value of any medical technology is inseparable from the clinical context in which it is applied; procedures that may be beneficial in a particular set of circumstances are liable to be used as well where they are not worthwhile.

The second and most disheartening aspect of this study is the minimal relation between properly designed clinical trials and the diffusion process, a problem that might be described as the inefficacy of efficacy studies. Gastric freezing was purported to relieve subjective symptoms and to reduce objectively measured gastric acid. The placebo effect is a concern when any subjective feeling is involved and especially with pain. Variability in gastric acidity among normal persons and the real possibility of falsely low measurements further confounded efforts at objective assessment. The majority of clinical studies of gastric freezing were observational (Table 1), and there are problems with the design and comparability of those studies that were controlled.[88] Responsible observers recognized early the need for randomized, double-blind studies to evaluate gastric freezing. In fact, such a well-designed multicenter trial was initiated in 1963.[80] Multicenter studies are difficult to organize and conduct, and properly designed clinical trials often require long-term patient follow-up. Results of this major study did not appear in the literature until 1969. The report was unequivocal in its negative conclusions, but of little practical consequence, as if a marble tombstone were erected over the grave of a patient already several years deceased.

Shortcomings in design and delays in completion and publication of well-controlled studies are only part of the problem. Clinical evaluations published in the medical literature are only one determinant of clinical practice. Information from colleagues may be more influential than published articles on a physician's awareness of new findings and choice of practice.[89] Other influences may outweigh even compelling evidence from

clinical evaluations. Chalmers cites a number of examples where physicians continue to use treatments despite well-controlled trials demonstrating they are worthless or harmful.[90] In the second volume of *Controversy in Internal Medicine*, published in 1974, the editors review the status of the 23 controversies included 8 years earlier in their first volume. Ingelfinger summarizes:

> The lesson appears both clear and discouraging: some controversies in Internal Medicine persist for years and years; others subside gradually as interest wanes. Very few if any appear to be resolved by some elegant study that dramatically demolishes one side or the other.[91]

The lament does not end there; when finally published, an elegant study may be too late, and, even if timely, it may have little effect on medical practice.

POLICY LESSONS

In general, the desirability of disseminating a medical innovation depends on five features:

1. Technical practicability--performance characteristics of the new drug, device or equipment.
2. Safety--degree of hazard to the patient, provider, and population at large, in the short run and long run.
3. Clinical efficacy--comparative effectiveness in specified clinical circumstances; measured effect may range from proximate influence on care to ultimate effect on health.[92]
4. Cost--net resources required to utilize the innovation.
5. Societal effect--impact, if any, on social values and institutions.

Each of these elements is typically unknown to some degree when an innovation is introduced, and sometimes for considerably longer. A dichotomous classification of an innovation as either "experimental" or "established" fails to do justice to any one of these features, much less to the combinations that may occur.

If a new technology is on balance beneficial and is adopted, that constitutes appropriate use. If an innovation turns out, all things considered, to be of negative value, and it is shunned, that is appropriate nonuse. Obviously, two complementary types of error are possible: overdiffusion of a bad technology and underdiffusion of a good technology (Figure 2). Because the clinical value of any new medical technology is

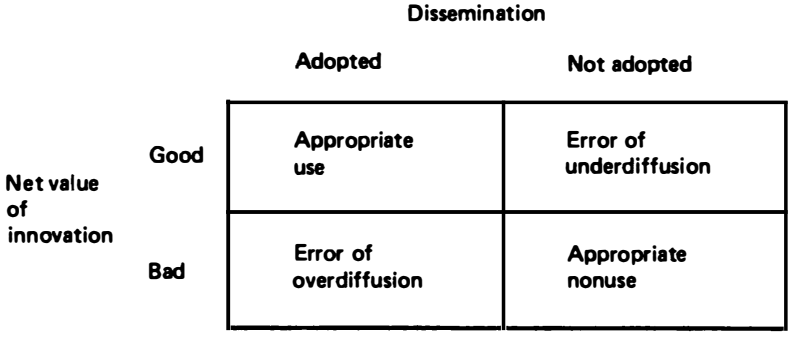

FIGURE 2 Possible consequences of a medical innovation.

unknown, there is always some finite risk at the outset of committing each type of error. This dual risk is reflected in the contradictory functions of different government agencies; some, such as the National Institutes of Health and National Science Foundation, encourage development and dissemination of new medical practices, while others, such as the Food and Drug Administration, serve to retard the availability of new practices.

Most case studies of medical and other innovations have concentrated on triumphs, "good" innovations that sometimes were delayed in their full development and dissemination.[87,93] These studies attempt to discern the causes of delay or "lag periods" in diffusion and the reasons for successful dissemination. Thus, they limit themselves to the upper two cells of Figure 2, and for this reason, even taken collectively, they may be misleading. For example, an enthusiastic advocate, identified as important in many cases, is characteristic not simply of good innovations, but of widely disseminated innovations, whether good or bad. Case studies, such as gastric freezing, introduce the complementary risk of overdiffusion, a concern that should also guide policy. However, any general policy that retards dissemination of new innovations and so reduces risk of overdiffusion simultaneously increases risk of underdiffusion, and vice versa.

Recent federal legislation aims to make future episodes such as gastric freezing less likely. The Medical Device Amendments of 1976 (P.L. 94-295) empower the Food and Drug Administration to require premarket approval of medical devices. The principal rationale for this authority expressed in the statute is consumer protection. Devices classified in the most restrictive category, Class III, must satisfy a premarket test procedure to establish safety and efficacy. This premarket test clearance

entails well-controlled investigations, but, unlike clearance for new drugs, does not necessarily require *clinical* investigations. Absent from the legislation is any concern with cost implications of new devices. Also, the FDA devices legislation does not deal with possible improper use of an innovation after it has been approved.

It is too early to assess the effect of this new authority. Since the number of devices covered by the legislation is enormous, the FDA will need to establish some priorities to guide its activities. The extent to which the law will retard premature dissemination of unproved devices depends on how it is implemented, i.e., FDA's readiness to classify devices in the most demanding category, the nature of research requirements to establish efficacy of each type of device, and the agency's willingness to delay marketing in the face of pressure from business, the public, and the medical profession. One lesson from gastric freezing with regard to safety is that the earliest reports may be misleading, and it would be unwise to rely too heavily on any single research team. In terms of efficacy, clinical evaluation may be difficult and time-consuming, but extrapolations from nonclinical laboratory studies are liable to be erroneous. Well-designed and carefully conducted clinical trials are essential, but it may be possible to obtain useful information more efficiently with study designs other than randomized, double-blind.[94]

Issues of cost and appropriate utilization, outside of FDA's authority, are to some extent within the ambit of other health regulatory and planning activities, such as PSRO and utilization review, certificate-of-need laws, rate-setting commissions, and health systems agencies. At present, no single body both has responsibility for assessing all five features of medical innovations and authority to intervene in the diffusion process, either to speed or to slow it. If such a body did exist, it would be handicapped by inadequacies in evaluation methods and meager knowledge about the effect of different types of control over diffusion.

The physician remains the principal decision-maker regarding use of most medical innovations. Physicians will inevitably make mistakes, but they should not err for the wrong reasons, such as misplaced reliance on fragmentary information, succumbing to the force of authority rather than depending on the strength of evidence, suspicion of population-based studies, ignorance of the pitfalls and requirements for statistically and scientifically valid clinical research, a need to have the latest gadget, a desire to achieve prestige, defend a reputation, or gain financially. Every decision to use or not to use a medical innovation entails some chance of success and of failure,

but it should be an informed judgment, based on the best evidence available, and with the interests of patients foremost.

Gastric freezing posed substantial risk to patients, and decisions to adopt or abandon the innovation properly could be weighed according to potential harm and possible benefit to the individual. More troubling are decisions that may require trade-offs between what may be best for the individual patient and what is best for society or for patients collectively. The possible adverse consequences of medical innovations for the individual are safety and health hazards and the possibility that use of the innovation delays or precludes other, more beneficial interventions. From the point of view of society, an innovation may have long-term risks (such as environmental consequences or genetic damage) and typically entails some financial cost. As we collectively assume a greater proportion of the costs of health care and as these costs continue to rise, the financial implications of medical innovations increasingly become a societal concern. Every decision, whether explicit or implicit, to apply or withhold a medical innovation, is in effect a resource allocation decision. Physicians should remain primarily individual patient advocates, but they must also become cognizant of societal interests, of the interests of all patients.

Fortunately, the interests of the individual patient and of society frequently converge. Gastric freezing was good for neither. Many medical interventions benefit the individual and represent worthwhile social investment. But there remains a perplexing group of innovations, exemplified recently by computerized tomography, whose major drawback is high cost, whose safety is relatively ensured, and whose ultimate clinical efficacy is unknown.[95] With this group we are just feeling our way.[96]

Gastric freezing reminds us that proposals for public policy toward medical innovations should consider all four possible consequences of an innovation. Physicians should be trained to be descerning in their interpretation of clinical findings and should be sensitive to societal as well as individual costs and benefits. Appropriate and timely clinical trials are essential for informed decision-making. We need to devise strategies for making decisions in the face of uncertainty accompanying new innovations. Logically, this should include surveillance and evaluation both before and after an innovation is generally available. We need better understanding of the diffusion process and especially of characteristics that lead to non-adoption of relatively good innovations and excess use of relatively bad innovations. Finally, we need more effective means of hastening or retarding the diffusion of medical practices, and the ability to do both wisely.

APPENDIX: CAPSULE HISTORY OF GASTRIC FREEZING

Background	1924	Prout	Proves stomach acidity due to free HCl
	1953	Kay	Augmented histamine test to measure gastric acid production
	1958	Wangensteen	Introduces gastric hypothermia for control of gastrointestinal bleeding
Conception	1959	Wangensteen	Describes possibility of gastric freezing to treat peptic ulcer
Initial research and development	1960-61	Wangensteen	First human application in October 1961
Clinical availability	1962	Wangensteen	Success announced at professional meeting in May; widely publicized in popular media
		Swenko Corporation	Full production capability by second half of year
Dissemination	1962-64		Over 1,000 machines sold by latter part of 1963, 10,000-15,000 treatments
			Substantial risks to patients become evident by end of 1963
			Unfavorable conclusions reached by some investigators in 1964 because of lack of efficacy and high risk

Abandonment	1964-66	Physicians begin to abandon procedure in 1964
		Adverse evidence continues to accumulate 1965-66; advocates defend value of procedure, continue technical improvements
		Clinical use effectively ends in U.S. by 1966
		Estimated 2,500 machines sold in all; 25,000 treatments
Later evaluation	1967	More negative evaluations published 1967-69
		Research use continues, deemed clinically promising in 1972

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APPENDIX E

THE DEVELOPMENT AND DIFFUSION OF A MEDICAL TECHNOLOGY: MEDICAL INFORMATION SYSTEMS*

Donald A. B. Lindberg

THE CONCEPT OF MEDICAL INFORMATION SYSTEMS

Systems Rationale

There is no official body to authenticate the definition of the term "medical information systems." Nonetheless most workers in the field are likely to agree that medical information systems have certain attributes in common. It is clear that the phrase implies an automated system, generally a digital computer-based system. The information is about persons, at least that information about them that is relevant to their health, their health complaints, the management of their complaints, and the treatment of their illnesses by health professionals. To most of us there is a strong implication that whatever information the system contains is organized relative to the person to whom it pertains. That is, there is an integrated patient record. Similarly, there is the strong implication that the system itself is meant to facilitate treatment or health maintenance of the individuals whose information it contains.

Most people familiar with medical computing would assume that a medical information system contained information about patients

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that arose--or at least entered the system--from multiple sources. This circumstance has historically provided the major rationale for the development of such systems. Some workers might disagree, however, believing that even single source data systems such as those containing sets of observations made in a private physician's office might be called medical information systems.

About a number of other common attributes of past and current medical information systems there would also not be agreement among workers in the field. For example, many workers would stipulate that in a medical information system the integrated patient record would be available to and used by a number of health professionals in addition to the person who initially entered the information.

An especially critical issue is the property of some medical information systems, that they are designed and implemented *in toto*, cut from whole cloth, as it were. Hodge argues that this is an essential characteristic:[27] "MIS is achievable only through an integrated approach and direct professional use. . . . An integrated approach implies a single integrated system serving the institution. 'Generalized' means application independent."

An equally strong argument has been made by others that MIS's to be successful must be built up from a number of subsystems. In this view, the integrity of the system arises in the conceptualization of the interrelationships between the parts. The component subsystems are implementable individually in various sequences, and in various combinations. Presumably they may come and go over time, and presumably multiple copies of subsystems might exist within one overall MIS.

Barnett has been an advocate of the view that the MIS must be made up of subsystems: " . . . developing a modular system is far better for the present, than seeking a so-called 'total medical information system.' Although the long-term objectives of the two strategies are identical, the methods of procedure and the intermediate goals are very different, as is the prognosis for their relative utility and near-term success."[7]

Collen defined a medical information system in operational terms: "A medical information system . . . is one that utilizes electronic data processing and communications equipment to provide on-line processing with real time responses for patient data within one or more general medical centers, including both hospital and out-patient services."[12]

In his view, subcomponents of MIS's may include a hospital information system, a laboratory data system, a hospital administrative information system, and (presumably) others. He provides further specifications for immediate objectives and general functional requirements.

Clearly, both the holistic and the subsystem philosophy could produce workable systems, which ultimately might be indistinguishable from one another. I shall, for the purposes of this report, reject Hodges' argument and shall accept that MIS's can be either holistic or can be the sum of the subsystem "parts."

Definition

In order to facilitate our analysis of alternative approaches to the MIS problem, it is tempting to fall back upon the fundamental approach of the system designer. This is to ask one's self: What data elements are being collected, and what is being done with the single elements and the combination of elements?

Essential Data Elements

Listed below are the barest bones of the content of a medical information system. That is, there are the minimum essential data elements that would need to be collected, disregarding for the moment all considerations of purpose, usage, and setting. They are: patient identification (number, name, address); hospital or ambulatory care location; demographic information (including sex and age and sometimes occupation); past hospitalizations; diagnosis/diagnoses; linkage information (this would vary from one installation to another) Something more than name and number is required in order to link new information transactions in this kind of file to the preexisting patient record. Some systems would use items such as maiden name, mother's name, check digits on patient numbers, transaction numbers, source codes, or time-data qualifiers.

So far as I know there is no MIS in the United States that collects only these minimal elements. The Danderyd System in Sweden, however, limits itself to not much more than these elements.[1] One notes that Danderyd is one of the largest operating MIS's in the world, even though limited in its depth of data.

Optional Data Elements

There is a host of data elements that are included in some systems. These are: billing information; insurance status; physician(s) responsible for the patient's care; invariant physiologic information (e.g., blood type, leukocyte antigen type[s], chromosome karyotype); elements of health status provided by the patient (e.g., complaints, history of present and past illnesses, health status as reflected by daily work and personal functions, immunizations, etc.); results of measurements or observations

performed upon the patient (e.g., height, weight, laboratory test results, ECG's, radiological studies, results of physical examinations, including the traditional physician's general examination, and special examinations such as range of motion, proctoscopy, pelvic and cystoscopy, etc.); and interpretive information (generally provided by the physician, such as problem list, provisional or working diagnoses, treatment plans, therapeutic and diagnostic orders, descriptions of surgical procedures.

CURRENT STATE OF THE TECHNOLOGY OF MEDICAL INFORMATION SYSTEMS

The data elements collected by a particular medical information system identify it in a kind of common sense way. The various circumstances in which many MIS's have been operated, considered with the purposes for which they were operated, may be taken to characterize the state of the art of such systems.

Using this kind of a general analytic framework, we can examine the extent to which the entire possible range of MIS settings (i.e., the problem domain) has actually been explored, and to what extent applications have been successful. In this sense, each general aspect of an MIS may be considered as a dimension that bounds the problem domain.

Dimensions of a General Analytic Framework

The "dimensions" of a general analytic framework are: (1) data elements collected, (2) functions that are being performed, (3) medical service area (usually a hospital or ambulatory care department or division), (4) health care of institutional setting, (5) patient population, (6) uses of the output of the system, and (7) financial basis of the system.

Each of the individual "dimensions" have subdivisions or multiple values.

The data element content and the function undertaken by a medical information system are interrelated. That is, a function may not be possible unless a data item or group of data items has been collected. However, collecting data elements (with purpose *A* in mind) does not assure that they will be used (either for purpose *A* or purpose *B*). Collection of data elements is a necessary but not sufficient condition for the functions to occur.

Careful consideration of the dimensions will convince the reader that the interrelationship between the dimensions is not limited to data content and function. All of the dimensions are

in some ways interrelated, and in other ways unrelated. Consequently, the dimensions are not independent in a mathematical sense. I make no pretense that it is clear how to assess this technology in any overall sense by numerical techniques. I assert that the potential contribution of medical information systems to progress in health care, and the assessment of the present state of the technology, can only properly be done within the true full problem domain that is characterized by the dimensions named.

One may define a medical information system by selecting one or more attributes from each of the seven dimensions or aspects. Together they will define a valid form of medical information system.

Example: Feasibility of MIS's With Many Kinds of Medical Service Functions

When we examine the current and past MIS's along one sample dimension, i.e., medical service areas, it is clear that a considerable range of application systems have been feasible. The medical service areas have included: Admissions Office;[14,16,31] Business Office;[5,23] Medical Record Department;[2,14,17] Clinical Laboratory;[2,35,38] Radiology;[5,40,42] Electrocardiography;[10,11,52-54,60] Intensive Care;[30,51,55,58] Obstetrical Care;[46] Mental Health;[15,20,24,59] Pharmacy.[5,21,29,32,45] Each of these sytems has other dimensions, or secondary characteristics, such as type of patient population, institutional setting, etc. Space does not permit presentation of the full characterization of feasible systems.

Tasks Thus Far Infeasible

Not all applications of MIS's will necessarily prove feasible--even in a technical or scientific sense. From outside the medical domain, the best-known example of an infeasible computer function is automatic language translation. There may well be similar functions in medicine that appear to be reasonable but that will remain technically infeasible.

The following set of important elements that have thus far proven infeasible, I offer merely as a personal view: (1) creation of a generally usable thesaurus with a standardized medical terminology, (2) processing of free text medical entries, (3) processing of text diagnoses, (4) execution of a general diagnostic logic, (5) automated certification of clinical medical

competence, (6) positive specimen identification in the laboratory, (7) automatic clustering of symptoms so as to recognize new clusters, (8) automatic analysis of cardiac arrhythmias, (9) recognition of *n*-tuple drug interactions, (10) automation of even simple treatment plans, (11) basic improvement in clinical laboratory control, (12) a practical means of recording the general physical examination, (13) a computer programming or even command language for use by the medical staff as opposed to the expert programmer.

DESCRIPTION OF EXAMPLES OF MEDICAL INFORMATION SYSTEMS

Systems Designed for a Particular Institution

There are medical information systems that have been successful in more than one medical application area simultaneously, and certainly have been successfully used by many kinds of health care professionals for many different purposes simultaneously. By considering a few of these, albeit briefly, one can achieve a kind of gross inspection of the rather considerable extent to which the total problem domain has been explored.

The specific instances to be reviewed are--like any other short list--an arbitrary selection. Examples are:

Institute for Living, Hartford, Connecticut.

Overall Description: This medical information system serves an entire 400-bed private mental institution. The system grew out of 15 years of experience with computer-based information systems under the direction of Bernard Glueck. The institution has been a pioneer in such developments. The primary purpose of the system is to facilitate patient care. It utilizes two DEC PDP-15 computers; the code was written in the MUMPS-15 language.

Detailed Description: The system provides an integrated patient record that includes essential data elements, plus results of psychological test instruments, nurse's progress notes, general physical, medications, and recordings of diagnoses.[24,25,61]

Special Features: Experimental programs for prediction of patient behavior, optimum classification for therapeutic purposes, and various customized searches and reports in support of research and management objectives. System costs are entirely recovered from patient fees at $2.60 per day.

Clinical Computer Applications: University of Utah, Salt Lake City.

Overall Description: Many subsystems have been created within the Department of Biophysics and Bioengineering of the

University of Utah, under the direction of Dr. Homer Warner and his associates, with implementation within Latter Day Saints Hospital. The systems operate (generally) on CDC computers under the Med Lab operating system.

Detailed Description: The medical application areas and functions include: a computerized integrated computer patient record with input from physician's diagnosis; automated multiphasic screening; computerized electrocardiogram interpretation; automated compilation of various laboratory tests, including blood gases; pulmonary functions; clinical chemistry; analysis and interpretation of cardiac catheterization; and physiological monitoring of intensive care units. Output of the subsystems is used primarily by physicians and nurses for direct patient care. Output of the integrated record system is also used for quality of care monitoring by hospital committees.

Functions include many physician assistance systems related to diagnosis and interpretation of measurements.[23,68]

Special Features: The HELP system is an advanced attempt to formalize the medical logic that interprets and integrates the numerous data elements incorporated with the automated patient record system.

Massachusetts General Hospital Computer System, Boston

Overall Description: There are a number of operational systems and subsystems that were created by the Laboratory for Computer Science under the direction of Dr. G. Octo Barnett and associates. They all operate from terminals to DEC computers and were written in the MUMPS language.

Detailed Description: COSTAR is a computer-based system for ambulatory patients served by the prepaid Harvard Community Health Plan. It provides the only record for about 60,000 patients.[6,44] In addition, other subsystems in the hospital itself handle the data acquisition and recording for clinical chemistry and bacteriology. Another subsystem provides physician assistance functions in an anticoagulation clinic. Others assist undergraduate medical education through automated testing and patient simulation.

Special Features: The most outstanding special feature of the programs themselves is their ability to share and modify files using the MUMPS language.

Commercially Offered Systems

Systemedics prepared a survey of commercially offered automated hospital information systems for the Health Resources Administration in October 1976.[62] Battelle Laboratories conducted an extensive evaluation study of one particular commercially offered

automated hospital information system: that of Technicon Corporation, installed in El Camino Hospital, Mountain View, California.[8] The present report draws from these previous studies and from vendor literature. It should be noted that all the systems referred to in this section operate at a level of medical sophistication that is far below that seen in the noncommercial systems designed for particular institutions. The latter are generally university-based, and often serve a research as well as a service function. The merit of the commercial systems is that they are designed, potentially at least, to be replicatable in other institutions. An additional strong point of the commercial systems is that they have succeeded in implementation across a substantial number of hospital departments. Thus they are made up of a relatively large number of the subsystem components that are the building blocks of the ultimate mature medical information systems of the future. Along with the relative breadth of coverage across the hospital, which is offered by the commercial systems, there is a tendency for a somewhat shallow approach to any individual medical area.

Medical information systems are offered commercially by Burroughs Corporation, Data Care, IBM, McDonnell-Douglas, National Data Communications, Inc./Honeywell Corporation, and Technicon Corporation. Historically it should be noted that the McDonnell-Douglas McAuto System was developed jointly with the Sister of the Third Order of Saint Francis. The NDC system was originally developed by National Data Communciations, Inc., later marketed jointly with Honeywell (since it utilizes Honeywell computers), and later marketed once again solely by NDC. The Technicon MIS system was purchased from Lockheed Corporation and subsequently enhanced.

There are currently six installations of the Technicon system. There are four installations of the medical version of the McAuto system and four installations of the NDC/Honeywell system. Burroughs, IBM, and Data Care each have one or two hospital installations of medical information systems. The actual count on any given day of just how many MIS commercial systems are operational is always subject to dispute. This is because installations will come and go, and there is no central registry for recording new sales and/or failures. Companies competing in this field also come and go. Since the Systemedics survey was completed, two new companies have announced medical information systems. These are Shared Medical Systems of King of Prussia, Pennsylvania, and Medicus of Chicago, Illinois. The last reason for ambiguity concerning the actual number of such installations is that it is the marketing policy of some companies, for instance Shared Medical Systems, to encourage the installation of incremental functional modules over and above the basic accounting packages, so as gradually to convert towards a medical information system.[57] This is the apparent policy of Medicus Systems as well.[47]

All six vendors offer application options that include the following hospital areas: admissions, medical records, pharmacy, laboratory, radiology, nursing stations, dietary, administration, business office, emergency room, and outpatient departments. Three of the vendors also offer packages for heart station, utilization review, and surgery. The extent to which these sytems can support extensive and sophisticated functions at all of the hospital areas named is said by the vendors to be essentially unlimited. They do caution, however, that the systems must be tailored to local hospital standards and procedures. This is a reasonable limitation in cases such as the standard battery of orders and treatments. Such commercial companies, as, for example, Technicon, take the position that they do not propose to offer standardized medical treatments as part of their systems. They insist that these items be undertaken by the hospital staffs. In some respects this is not only wise but advantageous. The Technicon system in El Camino offers the very desirable option that medication orders may be completely tailored to each individual physician. That is, after identifying himself through a keyboard entry, the doctor can call up on the cathode-ray tube his own particular set of commonly used orders and/or drug specifications. The system provides him with the capability of entering these to begin with, and of altering them at will. Each of the commercial systems varies, but all have roughly the same operational characteristics. One of the consequences of the necessarily disciplined approach to data entry is to enhance completeness. The systems have the ability to prompt.

The six systems differ in the data entry modalities employed. The Technicon system utilizes CRT's and a light pen. The NDC/Honeywell VITAL system also utilizes a CRT terminal, but this includes special function buttons and a badge reader. McAuto and IBM systems utilize a variety of standard terminals. The first system, Technicon, is designed to encourage direct data entry by the physician; the last three systems present this possibility, but do not normally operate with physician entering either data or orders.

Some of the commercial systems are quite sizable. The number of computer terminals employed is: Technicon Corporation, Maine Medical Center, Portland, 107 terminals; Technicon Corporation, El Camino Hospital, Mountain View, California, 56 terminals; NDC/Honeywell, Deaconess Hospital, Evansville, Indiana, 83 terminals; McAuto, Missouri Baptist Hospital, St. Louis, Missouri, 40 terminals. The cost of these systems is said to vary between $4 and $6 per day per patient.

There are limitations upon all the commercial systems described. In no case do the systems accept physicians' progress notes, the patient history, nor the results of the general

examination by the physician. Since these three types of information are central to the traditional medical record, it appears that the present-day commercial systems fall quite short of being truly medical information systems.

Systems of Historical Interest

The G.E. Medinet Division was established in June 1966, and its completed computer center and permanent offices dedicated on May 11, 1967. It proposed to offer computer services of a wide variety to health care institutions anywhere in the country via time-shared computers and connected by dedicated telephone lines and transmission networks. The parent company, General Electric, already had the advantage of an extensive telecommunications network on a nationwide scale.

Medinet's initial plans called for services to be provided in the following hospital and clinic application areas: admission and discharge, laboratory reporting, doctors' orders, pharmacy and medications, medical record statistics, inventory, patient billing, and hospital payroll.[48]

At its peak it employed 106 individuals in the categories of programmer and hospital or systems analysts. Hardware development included production of 400 custom computer terminals based on the KSR33 teletype. A central computing complex was built up based on the GE-485 with smaller Honeywell process control computers in the proposed message network. Software developments included creation of a new string-processing interpretative language and special file procedures.

The system was demonstrated at the American Hospital Association meeting on August 12, 1967. At this time, a press release announced that "nationwide availability of the system to the medical community would not come until late 1968 or early 1969."

A major administrative reorganization was announced publicly in December 1967. Early in 1968 it ceased to make offerings of medical computer services and elected to make offerings of business office and administrative services, aiming at a potential of 600 hospitals. At this time, Medinet had spent about $16 million on systems development, mostly aimed at the medical information systems market.

The Medinet Division was eliminated as an administrative entity in April 1975.

Kaiser-Permanente MIS: By far the most advanced of all American general MIS's was that at Kaiser-Permanente. The destruction of what had been built can most simply be attributed to unique and unfortunate circumstances.[66]

The original multiphasic screening system had been built as a response to internal company needs and client demands. Twelve years of development were financed internally and successfully before any government research funding was accepted.

At its furthest development, this system included extensive general outpatient screening and follow-up data; data for a special, prospective study on benefits of periodic health examination on a population of 10,000; an emergency room patient record and physician's assistance function; prospective records on patient pharmacy records; and a developing system of hospital terminals for orders, record-keeping, and reporting.

At a critical juncture, when there were very serious technical problems during expansion, the two major sources of federal funding were precipitously withdrawn. These were: designation as one of a dozen Health Service Research Centers, followed by the elimination of the federal program for all such centers, and cancellation of a major contract with FDA for important prospective drug reaction and toxicity studies.

The Medical Methods Research Group was in essence pulled off-balance by the elimination of research support of developments that had been premised upon a balance of service and research funding.

Missouri laboratory systems: The laboratory system based upon on-line computer terminals at the University of Missouri was an early one, developed in 1963.[36] This system succeeded an even earlier off-line automated reporting system.[35] The off-line system was developed with institutional funds. The on-line system was developed with NIH research grant support.

Taking the on-line system as an example, one may note that the technology was successfully implemented within budget and on schedule in 3 years. Follow-up and internal evaluation studies were completed.[37] The host institution assumed the entire cost of the operation of the system. In many ways the system achieved all of its objectives, and succeeded in satisfying the then current NIH standards for success. Namely, it "worked," and it was adopted by the hospital.

The system continues to this day (with evolutionary improvement). It has had no federal research support for 11 years.

On the negative side, however, is the fact that the absence of research support for this application has meant that no research has been done on the system *per se* for 11 years. Consequently, it is now patched, inefficient, out of date, and incompatible with the many advances and changes in laboratory technology which have arisen in the past 11 years. The programs are still doing their job. There is no parallel manual arrangement. Yet this system is no longer innovative. Consequently, it is no longer able to exert a beneficial influence upon the

development of laboratory systems elsewhere, nor to enhance the diffusion of MIS technology more generally.

BARRIERS TO THE DEVELOPMENT OF MEDICAL INFORMATION SYSTEMS

Operational Difficulties

Throughout many system developments, implementations, and evaluations, certain difficulties have been reported by the authors involved with surprising consistency. While it is difficult to classify each and every problem, it is clear that these barriers are technical, social, and managerial. For this reason at least some of the barriers to MIS development could be considered to be similar to those associated with any large and complex system effort. Nonetheless, they will be recapitulated briefly, since these are the raw data of our review. After this we will examine the possibility that two categories of obstacles are more or less inherent in the particular medical application area.

A Variety of Problems Described by MIS Designers

Many investigators identify their problems in terms that echo Collen's formulation.[13] After an analysis of successful and unsuccessful attempts to produce operational medical information systems,[21] Collen concluded that the reasons for failure were: "(1) a suboptimal mix of medical and computer specialists . . . (2) inadequate commitment of capital for long term investment . . . (3) a suboptimal system approach" (that is, either inability to fuse incompatible subsystems or a too grand initial total design) "(4) . . . unacceptable keyboard terminals . . . (5) inadequate local management." In his view, factors that would tend toward success would be correction of all the above deficiencies. He feels that for success "a hospital (or group of hospitals) of sufficient size is required, with effective organization and management by technically sophisticated men who can make reliable decisions after considering technological alternatives."

In a recent survey of automated ambulatory record systems, Henley and Wiederhold summarized the "problems encountered" at each of the system sites visited. Their list is remarkably similar to Collen's, and like his is a combination of technologic difficulties and social and management problems. Examples of the former are: "man-machine interaction limited" and "diversity of . . . record formats" and "voluminous text." Examples

of social barriers include "lack of interest from . . . management," "poor management interface between [university and health care facility]" and "city funding intermediary has other priorities."[26]

Another viewpoint on barriers and limitations is presented by Friedman and Gustafson.[22] Among other things they conclude that a critical fault has been in "not succeeding in producing applications which exceed the capabilities of the physician without the computer."

In a review of 28 computer projects in health care, Giebink and Hurst in 1975 report in each case on the developmental and operational problems as perceived by directors of the projects.[23] This valuable list contains the same mixture of technical and social problems. Examples of the former are: "moving head disk hardware problems," "no back-up computer system," "slow response time of terminals and unreliable terminals," "major technical problems in computer representation of extensive medical logic," and "overly optimistic expectations for speedy implementation." Explicit examples of social barriers are: "clinics' resistance to change, and social problems resulting from change," "poor acceptance of the system because of 'top down' decision making in its creation," and "insecurity of future funding."

Difficulty with the management of complex systems was also a theme repeatedly reported. One project manager said that the systems finally became so complex that he could not implement programming changes and additions without intolerable delays.[13] Regrettably, that particular project manager is himself experienced and extraordinarily competent. Much simpler difficulties in the management of technical work forces baffle other projects. There are excellent managers for highly technical large tasks (witness the NASA successes), but they are rare and apparently not often associated with MIS developments.

The Particular Problems of Computer Hardware and Software

While there have been vast improvements in computer hardware during the past 20 years, there are still obvious major defects and obstacles. Awkward, slow, expensive computer terminals have been an impediment to all computer system builders. Likewise, all users suffer from the malfunctioning of moving head disk information storage devices. In spite of encouraging increases in disk storage capacity, large medical record files still frequently exceed storage capacity of many systems. In a sense this issue is something of a trade-off against costs. That is, at a greater cost one can often obtain an increase in storage capacity. Yet the combination of costs and direct access memory capacity remains a general problem.

Computer reliability has likewise improved enormously. Yet people expect more of computers now. Clinical systems must be reliable, just as many other critical control systems must be. In the case of missile launches, the costs are acceptable. In the hospital, they are not currently acceptable.

One example of this problem, and a workable solution, is the Technicon MIS at El Camino Hospital. A backup computer is available at a service center for reliability. The records given Wiederhold[26] showed that the backup machine was used an average of 33 minutes per day. When billed by the minute, the redundancy is quite inexpensive. In this case, Technicon is able to use the backup machine profitably in other tasks. Had the hospital been obliged to keep a second machine, as Kaiser had to for their pharmacy and ward terminal system, the costs of the system would have been doubled. Reliability is still a major impediment to medical information system implementation in most settings.

Software development costs remain high, and progress remains slower than in hardware systems. The software interface is still with the computer professional, rather than with the physician user, or with the other subject matter experts. This tends to increase personnel costs and to make management of system redesign difficult. Worse yet, it tends to separate the health care professionals from direct participation in the creative aspects of the application development.

Medical Barriers to Medical Information Systems Development

There is nothing about the computer techniques used in medical information systems that makes them in any way fundamentally different from such systems in nonmedical fields. There are, however, two special nontechnical barriers that have to some extent been inherent to the medical application. These are: limitations on the state of medical knowledge about illness and health, and limitations on the state of medical systems management.

Limitations of Medical Knowledge

There simply is still much art in medicine. Often this is inherent to our ignorance of basic bodily mechanisms and mental processes. Friedman and Gustafson warn that we must try to make computer systems that do things physicians cannot do.[22] Yet at least one barrier to this happening certainly is to identify the person with the idea. There are ways to encourage more people, and even more imaginative people, to join the field. Still, the fundamental barrier is the idea for the significant new medical function that can be accomplished with the help of the computer.

It is the occasional insights into useful new information systems tasks that create major benefits from computer-based systems. The alternative is merely automation of current practices.

In the use of data base systems for patient and medical records, this difficulty is most apparent. For example, after one knows or guesses that the variables "first trimester pregnancy" and soporific "Thalidomide" are relevant to the diagnosis "phocomelia," it is technically easy to construct the appropriate data base system for patient records. The same is true of preparturient estrogen therapy and endometrial adenocarcinoma, or, of leukocyte antigen typing and spondylolisthesis, and also of a variety of industrial carcinogen exposures and drug-drug interactions. In the absence of such fundamental health knowledge, enormous complexity is required of the data base systems in order to "shoot in the dark" searching for relevancy among the patient record variables.

Undesirable medical practices stem from this incomplete knowledge. These include irregular terminology and ad hoc identification systems. Both present serious barriers to automation. The language of medicine is simply unstructured. This lack of standard vocabulary is a considerable obstacle to the creation of medical information systems, as well as to the transplantation of a given successful system to other locations.

The second difficulty is comparable but not so easily solved: the problem of identification of individuals, their medical samples, and observations about both in a computer-based information system. Corn flake boxes and railroad cars are now made with "zebra stripes"; people are much more difficult to identify.

Limitations of Management of Medical Systems

The second barrier that is peculiar to medical information systems is the medical environment, or what is now more properly called the health care systems environment. The U.S. health care system is made up of thousands of relatively autonomous units, centering on large hospitals, which are themselves made up of relatively autonomous divisions and departments. There is no common ownership nor meaningfully common accounting system. In addition there is an apparent shortage here too of individuals capable of managing--or even rearranging--complexity. To the extent that health care institutions do not work smoothly and sensibly with one another, the medical information system cannot be shared or transplanted. To the extent that health care institutions are balkanized into small administrative parcels, the information systems must of necessity be small as well. It is quite clear why minicomputers are so popular in medicine, and why

large data base systems are so rare. The mini system matches the miniadministrative fiefdom. The large data base systems represent one of the many institutional goals to which the institutions often cannot *manage* their way.

Socioeconomic Barriers to Medical Information Systems Development

Health Professions' Response to Information Systems Technology

Clearly technical changes can and generally do occur more rapidly than society's adjustment to them.[49,63] This has certainly been true of computers in general, medicine in general, and the combination of the two fields in particular. Evidence for this can be seen in the shortages even today of skilled and experienced computer technologists and the even smaller number of medically trained individuals who have experience or cross-training in computer or information science. Medical school curricula have been notoriously slow to change, so that none currently provide formal courses in computing to students of medicine as a part of their regular curricula. Likewise no testing for information-processing skills is included on the examinations of the National Board of Medical Examiners. This is in spite of the fact that the M.D. exam itself is totally processed and scored by computer.[28]

Postdoctoral training in medical computer work is provided at eight institutions.[50] The oldest program is 5 years old.

Problems with operational medical information systems also attest to the claim that social engineering proceeds less rapidly than hardware engineering. There are repeated mentions of difficulty in getting communication between medical and computing personnel on the same research team, and in establishing communication and cooperation between health care institutions in the same city.

What is demanded of the development of medical information systems is creativity and technological innovation. No one knows very surely how to manage the creative process, in science or elsewhere. The building of medical information systems is known to require teamwork by a multidisciplinary group, which complicates matters by adding a substantial management problem. Furthermore, the activity is expected to proceed in the face of unstable financing, intermittent encouragement from government, and disincentives from medical specialty societies. None of the latter have requirements for nor "give credit" for computer and information systems experience as part of their postgraduate educational curriculum. Hence, they strongly penalize those who invest postgraduate training years in obtaining computer skills.

All in all, there is a long way to go before social adaptation to the computer has caught up with the technical state of the art.

The Computer Industry's Response to Medical Needs

There has at times been moderate enthusiasm for developing and marketing medical information systems. In 1973 Ball reviewed 15 commercial systems.[4] By 1977, six of the companies were not in the MIS business.

Major companies leaving the computer field altogether have included RCA and GE. IBM, an early enthusiast for medical information systems, has virtually abandoned medicine as a high-priority marketplace.

There are of course still large numbers of computers going into hospital business offices to do accounting jobs. One can only conclude that industry takes its mandate from stockholders to maximize profits over the long run, and that medical applications, especially medical information systems, are not judged to be the most profitable investment.

Yet there are profits to be made elsewhere in the medical computing field. Witness the installation in the United State alone of 320 computer tomography units (i.e., CAT scanners) at about $500,000 each with another 224 units approved and the orders on backlog as of July 1976.[3] Witness 11 U.S. companies in the marketplace, and 8 foreign competitors. Note that all this has transpired since Hounsfield's first demonstration in England in 1971 and in the United States in 1972. CT and MIS developments have much in common. The computer tomography problems are both challenging and scientific. They involve multidisciplinary teams for advances in the state of the art. The state of the art has advanced, indeed quite rapidly. Third-generation equipment has been announced while there is still a backlog of orders for first-generation EMI scanner.

Contrasting the problem of slow development of medical information systems with all too rapid diffusion of the technology of computerized tomography presents the question: Why the difference? One can only conclude that industry does not "respond to economic and scientific challenge" at all. Industry responds to opportunities to sell hardware at a profit. Customers likewise seem to buy more of those hardware items with which they in turn can increase earnings. Computer tomography units increase hospital and professional earnings. Automated laboratory instruments increase hospital and professional earnings. Medical information systems cost everyone a great deal of money and anguish.

If the desired outcome of the development of medical information systems is really recognition of new diseases, or creation

of community medical data bases, or more complete reporting to PSRO or Medicare intermediaries, or shorter hospitalizations for illness, or recognition of occult disease in ambulatory population, then someone is needed to pay for these outcomes. All the outcomes are desirable (and even cost justifiable) on the basis of society as a whole and within a time frame of decades. Yet each of them either decreases the revenues of an individual hospital, or increases health care overhead in the short term, or both. In no case do any of the most desirable outcomes--so long pursued--present the opportunity to offer the manufacturers the kind of hardware sales "challenge" that compares with either simple automation or new and costly measurement technology, nor even just selling a few more accounting systems.

IMPACT OF PUBLIC POLICIES ON THE DEVELOPMENT, ADOPTION, AND DIFFUSION OF MEDICAL INFORMATION SYSTEMS

Federal Research Policies

Research Support for Computers in Medicine

The creation of hospital accounting and business office computer-based information systems has proceeded on the basis of local funding and commercial development and sales. This application area for computers has been recognized for many years as more or less analogous to business office and accounting functions in other institutions. Hence it has always been an opportunity for entrepreneurial development, the success of which could be measured by cost reductions, labor savings, or at least some kind of suitable cost displacement.

In contrast, attempts to develop research applications of computer-based information systems in medical areas has necessarily had to be contingent upon funding *cum* research. Since the end of World War II, the federal government has become far and away the largest funder of medical research. Consequently, it was of great importance to the development of medical information systems that such efforts were formally recognized as legitimate research. This recognition came in 1960 with the establishment at the National Institutes of Health of the Advisory Committee on Computers in Research, which was charged to define general areas of biomedical computing and to stimulate interest in them.[43] This group was established as a regular Study Section on Computer Research in 1964. It became the Computer and Biomathematical Sciences Study Section in 1970. The Study Section was abolished on June 30, 1977.

With the creation of the Health Services and Mental Health Administration and its National Center for Health Services Research

and Development in 1969, additional study sections were created that had the ability to support some aspects of the development, diffusion, and evaluation of the technology of medical information systems. Certain special aspects of such systems have also been supported by the National Library of Medicine through the Biomedical Library Review Committee. The NLM has also been the main support for training programs to provide the special education and experience, both pre- and postdoctoral, to individuals entering this field from medicine, as well as from the computer-related disciplines.

It should be emphasized that, regardless of whether one considers the priorities and funding policies of these institutions to have been wise and/or consistent, they did nonetheless give legitamacy to attempts to explore and define research users of medical information systems.

Government-Sponsored Computer Centers

The initial research grants from NIH in this area took the form of facility support awards. These were made to encourage and subsidize the creation and operation of computing facilities in selected major medical centers. The purpose of the facilities was by no means specific to medical information system development. Rather, they were to provide appropriate and convenient computational support to biomedical investigators in the local or regional environment. Efforts to develop patient data base systems came relatively early. The most general rationale was reasonable enough: namely, to render the records of patient care suitable to be the subject of research.

The NIH supported computer centers were roughly comparable with the general university computer centers that were obtaining financial support at the same time from the National Science Foundation. Both agencies soon found that the country's appetite for such funds was large, indeed beyond the agencies' means. Both began encouraging the computer centers to shift to "fee for service" mode of operation, so as to be self-sustaining after the initial federal subsidies were withdrawn. University and medical facilities managers were encouraged to take a strong administrative hand, so as to shift the operational costs to the individual institutions. Similarly, individual investigators were obliged to budget for, request, and defend computer use charges as an integral part of their individual grant applications. The various scientific study sections were instructed to honor these requests (when the research proposals themselves were meritorious), because computing was no longer free.

The net effect of these moves was to encourage--almost to compel--the development of large central computing facilities at

major medical centers. This has turned out to be a mixed blessing. At least, however, it was accompanied by a legitimization of attempts to utilize information systems in support of medical research, this is to say, to support the asking of new questions about human health and disease, and to support attempts to do new things in health care by using the emerging computer-based information processing technology.

Effects on Medical Information System Development

Biomedical research support has been provided through relatively short-term funding of generally modest size. Regrettably, this pattern has never been suitable for computer projects. Lusted[43] said that even in 1960 it was apparent that computer grant applications differed from all other kinds of grand requests by being for larger sums of money and by including the puchase of computers (certainly a long-term commitment) within the request. Development of information systems has never been compatible with year-to-year funding mechanisms. The fact that the professional literature is not full of such pleadings is merely an artifact of the policies of refereed journals and the chameleon nature of information system developers.

After conducting a survey of health computing projects, Giebink and Hurst[23] conclude that funding policies placed a "premium on quick transitions from applied research to operational demonstration." They identified two serious undesirable consequences of this policy. First, systems were declared operational before they actually had been fully developed. Second, "much research essential to subsequent development" was never performed. Their implication is that there was not time within the original grant award period to complete all essential research, and that it could never subsequently be justified for funding because the investigator was obliged to "go operational."

Encouragement of Medical Information Systems Development

In the light of ever clear hindsight, one must conclude there has not been a systematic federal government plan for deployment of the technology of medical information systems. Several issues require special notice. These are: (1) mention of formal views concerning the sequence by which technologic innovations can progress, (2) the time frame for such accomplishments, and (3) the magnitude of developmental costs.

Sequence of Technologic Innovation

Students of history, sociology, and engineering note a number of stages that technical innovations go through before becoming accepted as traditional marketplace items or services. Frequently the sequence is represented to be: research, development, demonstration, commercial prototyping, production. Some writers show "invention" or "discovery" preceeding this list. Some show "marketing" as following the list. Whatever terms best describe this process, it is clear that transitions between the stages occur at irregular intervals and that total costs for each phase typically increase as one moves toward the market. Certainly it is clear that there is a major hiatus between a scientifically interesting and valid research system and anything that could be considered commercially practical.

For medical information systems, the hiatus between scientific success and successful demonstration in a somewhat more practical environment is mirrored geographically by the distance from the NIH campus at Bethesda and the HSMHA (later Health Resources Administration) in Rockville, Maryland (later moved to Hyattsville).

Projects have existed in which demonstrations of information systems (and other health care innovations) required support. The Health Resources Administration has been authorized--although not always sufficiently well funded--to support such demonstration and evaluation projects. The transition from research support by NIH to HRA support for hospital demonstration can be rough, but some projects have survived it. The transition from HRA support to commercial viability is unheard of for anything as large as a medical information system.

Officials of funding agencies and peer review groups who undertake review of research grant proposals have been unaware of the problems of transition. It has always been considered a wise plan to propose withdrawal of federal funding and substitution of hospital or institutional support for systems once they have achieved their research objectives. On the other hand, one must acknowledge that very frequently the hospital support has not been forthcoming.

The results of scientific research, that is, new knowledge do not always--even often--save money for the institution in which they were developed.

In a noncomputer field, the discovery and creation of the polio vaccines did not save any money and surely did not make money for hospitals. Indeed they eliminated the patronage of polio victims. Likewise, a computer system that has solved some aspect of medical records processing, for instance how to record automatically a patient interrogation history, cannot save

money for the teaching hospital in which the system will typically have been developed. Consequently, the funds for operating, transplanting, exporting, and/or expanding such a system cannot be demanded of the host hospital.

In brief, there is no clear path for a research system to follow that can provide transition to a practice setting, unless that system makes money for its original host institution. In the absence of a strong national policy to manage technical innovation, the development must add to health costs or it cannot succeed.

Time Frame for Accomplishments

In the simplest possible terms, it has been the mission of NIH to support research, and it chose to include medical information system research in this mission. The support has always terminated once the scientific success of the project has been declared (or earlier in the case of a failure). Research grants have been typically 1 to 3 years, never more than 5 years. This time frame may be consistent with the conduct of the research phase of a project. It clearly is not consistent with the time frame needed to bring a medical information system to the stage of even a prototype commercial system. Such systems have been shown to require up to 10 years for prototype development.[9,26] Completing a study "on time" in the terminal year of a grant has presented a serious problem: How to provide for transition of the system to a self-sustaining basis. Often this translates to: How to get the hospital administration to pick up the costs.

The Magnitude of Developmental Costs

Since no real example exists of a full Medical Information System in a practical environment, it may be illusory to speak definitively of developmental costs. Nonetheless one can reason from the substantial developmental costs that have been reported for existing partial systems. Henley and Wiederhold report on development costs for nine operational systems that had been designed to be full MIS's for ambulatory patients.[9,26] Costs for the nine ranged from $230,000 to $10,000,000. Five of the nine had development costs greater than $1,000,000. The five had annual costs for continuing development that ranged from $154,000 to $539,000. This study did not include hospital MIS's. In this category, the National Data Communications/Honeywell system cost $12,000,000 to develop.[62] Development costs for the Technicon MIS were reported to be $25,000,000.

It is a serious problem that no operational unit of the Department of Health, Education, and Welfare actually has grant budgets of the magnitude required to support the big systems.

Research grants typically run $30-$50 thousand per year. Research grants for computer work typically are somewhat larger: perhaps $25-$150 thousand per year, with really large ones reaching $400 thousand per year. In the aggregate, of course, DHEW spends substantially for support of biomedical research. The amounts available to single functional offices, however, are typically small compared with the magnitude of commitments that appear to be required to "see through" the development of a medical information system.

Health Care Reimbursement Policies

The most profound effect upon medical information systems certainly was the initiation of the Medicare system under PL 89-97 (42 USCA 1395 *et seq.*). This program, with its series of entitlements of an ever larger number of individuals, provides for reimbursement to hospitals (and under Medicaid to physicians and other providers) of actual costs of care for citizens 65 and older (plus other entitled groups). The enumeration of charges, the justification of costs, the certification of entitlement, and the huge cash flow problems associated with delayed and partial reimbursements have forced all hospitals to devote greatly increased resources to these business office matters. The expenses are "reimbursable" and as such are folded into the rising per diem bed charges. With space at a real premium in most hospitals and trained clerical personnel never plentiful, most hospitals have been quite willing to shift these costs to support of computer installations or services, and to support of the administrative portions of medical information systems. Indeed these federal programs have created whole industries within the computer field that prosper mightily in computing, printing, and even reading the documentation of the health care services required for "third party" reimbursement.

An example of the new computer services (outside the field of medical information systems *per se*) is Electronic Data Systems Corporation in Dallas. Computer processing of Medicare claims by this company constituted a $133 million business in 1976.[64]

With respect to the effect of this legislation upon hospitals, figures are a bit hard to come by concerning the increases in business office personnel associated with Medicare *per se*. Everyone agrees they are substantial. One isolated example may be offered. The University of Missouri Medical Center in Columbia found that, as a direct effect of Medicare, it had to increase its business office claims processing staff from 25 to 32 and increase the record room staff from 22 to 26. In 1976, 82 percent of the 2,800 hospitals with 100 beds or more had computers or used computer service bureaus.[62]

This strong increase in demand for accounting-oriented information systems for hospitals and clinics has had absolutely no effect upon the development of the medical components of medical information systems. How can this be?

It's really quite reasonable. A system does not need to contain any medical information in order to print a valid and current bill, any more than the Texaco Company needs to understand one's vacation plans in order to forward gasoline charge tickets. The hospital accounting systems are not really simple, but they are well within the state of the art. No research is needed. Their purpose is to collect bills, either from the patient (who used to pay far smaller and simpler statements than he now receives) or from the federal government's Medicare intermediaries. Adding medical information to the accounting systems would be costly. It is not required and it will not be done under the present system. Indeed the cost of adding medical information would probably not be considered "reimbursable" or "allowable" by the same intermediaries who currently wonder at increasing hospital costs.

Regulatory Legislation

Monopoly and Restraint of Trade

The only obvious effect upon medical information systems from our antimonopoly policies has been to preclude the development of systems jointly between equipment manufacturers. This is probably not a major disadvantage to the field except in the medical application areas using remote terminals and telecommunication systems. Here it is a definite disadvantage. Our strongly competitive system has resulted in much deliberate built-in incompatibility. Manufacturer A's terminals simply are *personna non grata* on Manufacturer B's teleprocessing unit. In spite of standards for the hardware interface (e.g., EAI pin specifications) and standards for the data format (e.g., ASCII character definitions), there are many other means to assure incompatability (transmission protocol being the neatest). Mixed systems do not happen frequently. If it is true that the developer of a medical information system should not be attempting fundamental computer research, then his only reasonable recourse is to develop systems based upon the equipment of a single hardware manufacturer. This is almost universally the pattern.

This is a marriage of great inconvenience. It has the predictable consequence that transportability of any system to another location is dependent upon compatible (i.e., identical) computers being available at the two or more locations involved.

In the case of good systems or subsystems, it puts the developer in the role of being an unpaid hardware salesman.

Patents

This issue is discussed in a separate report.

PROBLEMS IN EVALUATING MEDICAL INFORMATION SYSTEMS

Some students of technology have distinguished between three stages of work: invention, innovation, and diffusion. In this scheme, invention is more or less equivalent to the early or fundamental phase of basic research. Innovation is taken to be the first successful application of the basic research. This is equivalent to the stages in other schemata that are variously called technological development and demonstration. The diffusion stage is taken to be the widespread repetition of the innovations. This corresponds with stages that are called by others clinical trials and implementation, or prototyping and production. One writer notes that "only invention defies costing or economic fitting."[18] She feels that it is proper to attempt measurement of economic costs during the stages of innovation and diffusion.

Cost-Effectiveness and Benefit Costs

The cost-effectiveness of a given methodology is traditionally measured by comparing it with an alternative methodology. Given that the tasks accomplished are roughly the same, then it is not conceptually difficult to put a relative cost on the two operations. A familiar and happy example is a manual procedure versus an automated procedure. It is frequently the case that the automated procedure can be shown more cost-effective.

Many of the components or subsystems of the medical information system can be compared in this way with some predecessor technology or a manual method. Often this is an entirely fair comparison and an entirely sufficient basis for preferring the cost-effective method.

It should be noted of course that human decisions are based on many factors, and that cost-effectiveness analysis is only intended to assist in formalizing the relative economic merits of the question to be decided.

An example of a choice that could reasonably be based upon cost-effectiveness analysis is that between automated clinical chemistry analyzers as compared with manual methods. Briefly,

the automated system does more tests per hour at a small fraction of the unit cost for manual procedures.

Assuming that observational data are available for both modalities, then a number of comfortable choices exist for ways to conclude the analysis. A reasonable decision criterion might be "net present benefit," although "return on investment" might be chosen if this seemed more appropriate because of limitation of investment funds.[39]

For the case of any particular institution--as opposed to the general case based on average data--there are complications that need to be taken into account in the performance specifications.

Many subsystems of what we now think of as a medical information system can be evaluated by the cost-effectiveness method, whether in the general case based on average data, or with respect to a specific institution. This method for evaluation is suitable for all those subsystems of the medical information system that have a manual counterpart. Some of the comparisons must be contingent upon some condition (such as patient acceptance or equal safety, etc.), but under these conditions the evaluations and choices will still be reasonable from an economic point of view.

The method of cost-effectiveness is unsuitable for evaluation of the entire medical information system because there is no alternative methodology. The *raison d'etre* for MIS's is to bring together all available parts of the patient record, i.e., to be more than the sum of the parts. Hence, there is not a valid basis for accepting a cost-effectiveness comparison. There will also very likely be difficulty in getting solid observational data or estimations.

Cost-benefit analysis is suitable, and cost-effectiveness analysis is unsuitable, if one is attempting to answer the question, should a new technology (such as MIS) be employed? It is reasonable to question whether to expend resources on MIS's versus some other purpose. This is a valid application of cost-benefit analysis. The analysis will, however, require measurement of the costs and benefits of all the schemes being considered, including the nonhealth related ones.

One medical information can, of course, be evaluated against another MIS, if they are doing the same job. The evaluation measure, i.e., the basis for the comparison, could be cost, or thoroughness, reliability, precision, training requirements, space utilization--one of these or all, weighted or unweighted.

Such scales are generally measures of the process. In the case of methodologies that have no counterpart or predecessor methodology--and even in many other circumstances--one is urged lately to prefer measures that compare the outcome of employing each method, or of employing the method in question (e.g., an MIS)

versus not employing the method. This strategem is useful partly because it tends to ask two questions at once: namely, which method tends to reach the goal best, and what is the validity of the goal in any case. It is especially desirable to estimate health outcomes for such a comparison.

One writer warns, however, that: "The growing literature on evaluating medical care and health status clearly indicates that studies rigorously documenting relationships between changes in health delivery process and changes in health status are difficult and costly to undertake."[62]

In the case of medical information systems the outcomes or benefits to be measured may be specified in terms that are centered upon the patient, the institution, society, or all of these and others. The evaluator can be left to weigh the relative importance of each outcome measure either before or after the analysis has been made. One obvious difficulty is that outcome measures that have been expressed in these various terms will often not have the same unit of measure (and hence are difficult to weigh or combine). An example of such benefits might be: improved access to care, improved productivity, and patient satisfaction. Second, some outcomes that are thought to be important may not have any readily apparent unit of measure at all. The most classical example of such a benefit is improved quality of care. The last difficulty is that some outcomes are not measurable immediately after the methods have been tested, and often not within the same system under consideration.

An example of the third difficulty, externalities, arises in consideration of a universally desired benefit: cost containment. If the cost saving of a given procedure is accrued to some societal unit above that of the institution under study (e.g., to a community or a state), then the benefit may never be measured within the institution. The obverse, that is, cost escalation, presents a like problem. The patient who is denied a computer tomography scan at Institution *A* will not have saved society's health care dollars by traveling across town or across the state to get one at Institution *B*.

Specifically, with respect to the type of MIS's providing for ambulatory patients, Henley and Wiederhold[9,26] looked for outcome benefits. In spite of the obvious difficulties in quantitation, they concluded in over half of the 17 systems visited for the purpose of evaluation that "quality of care had been improved." They were not convinced that MIS's affected the problem of initial access to care, although "improved secondary access was a major benefit at many sites." They found consistent evidence of medical information systems contributing to improved institutional management. Patient satisfaction was found to be difficult to measure.

Few of the particular systems they chose to visit were implemented with research as the primary goal. None did patient education as an MIS activity.

After this exercise in informal and nonquantitative evaluation, it was clear that there were identifiable benefits, no negative benefits, and readily calculable dollar costs. To make a formal cost-benefit analysis would require the following: that one extend the time frame for studying benefits; extend the domain in which benefits and costs are measured so as to include the externalities (e.g., other institutions in the communities studied); express benefits and costs in commensurate terms (i.e., dollars); and select a decision criterion. It would then only be left to decide if the costs involved were of greater or lesser value than the benefits in the cases studied, and over the range of costs and benefits that had been identified.

At the end of this process, one would have identified the relative economic merits of the question. If there were other relevant aspects of the question of evaluation of MIS systems (e.g., social, political, or moral), then these could be considered against the background of the formalization of the economic analysis.

Potential Benefits From Medical Information Systems Utilization

There is some reason to suspect that the benefit from medical information systems is a summation of a number of small gains, plus the very large potential gain in the additional desirable activities that an MIS will permit. This means that we cannot look for all the benefit in one place.

More importantly, however, we should not look for major benefits of MIS support of clinical decision making necessarily to be reflected in dollars and cents. The MIS approach at Duke, for instance, collects data from many sources to build an integrated record for a special class of cardiac patient. The desired benefit is to base the decision for surgical bypass procedures on the computer matching of the outcomes of like patients treated by medical and by surgical regimens. The system does appear to result in measurable improvement in clinical decision making and in improved patient outcomes. It may actually be possible to associate a savings in dollars at least with the cases who avoid surgery. It may. But the real benefit of such an MIS is the new knowledge relevant to prognosis and therapy that it produces for use by the entire profession.

The medical information system in radiology at the University of Missouri has been thoroughly cost-justified merely on fiscal

operational grounds, but this misses the point of the real benefits.[19,33] These exist in the research data base, which has permitted formalization of the logic for medical diagnoses,[40-42] physician assistance functions, and the substantial but untouted education benefits for residents and students that the rigor of the system imposes. The same kinds of benefits are associated with the HELP component of the MIS at the University of Utah.[23]

Operation of the medical information system in the multiphasic screening clinic at Kaiser-Permanente has benefited medicine in many places besides those patients seen at the Kaiser Clinic.[14] The benefits include evaluation of screening tests such as pain tolerance, anthropometrics, and breast thermography; refinement of normal ranges; evaluation of statistical measures; validation of screening concepts; and creation of a valuable health care management model.

Even when one agrees that such outcomes or goals are beneficial, however, it is not easy to fit the data to a cost-benefit analysis. As a practical matter, it is too easy to fix upon financial measures. Traditional accounting methods and economic variables often come to dominate system evaluations.

A potential way around these difficulties may be to pay more attention to the evolutionary stage in which each system is evaluated, and to insist upon using only a set of measures that is relevant to the stage of development of the system in question. Figure 1 presents an example of such a scheme for evaluations of health care technology at various stages in an evolutionary process. The scheme was proposed by Wallace and Fairman.[67] The description of diffusion of technology often provides for five stages. Since past analyses have often been more focused on hardware developments than health care methods, the last two stages have often been referred to as "industrial development and marketing." In this scheme, the last two stages have been called "clinical trials" and "implementation." The important point is that the general classes of evaluation criteria that are appropriate will depend upon the stage of the system being examined. The individual measurement to be made (within the class of evaluation measures) would not usually be determined by the individual or local peculiarities of each study site.

Effects of Major Technological and Economic Developments

Medicine will continue to be the beneficiary or the victim of the large forces of technology and our economy that medicine itself does not control or even influence.

If the computer hardware were suddenly to become absolutely free, the costs of developing medical information systems would

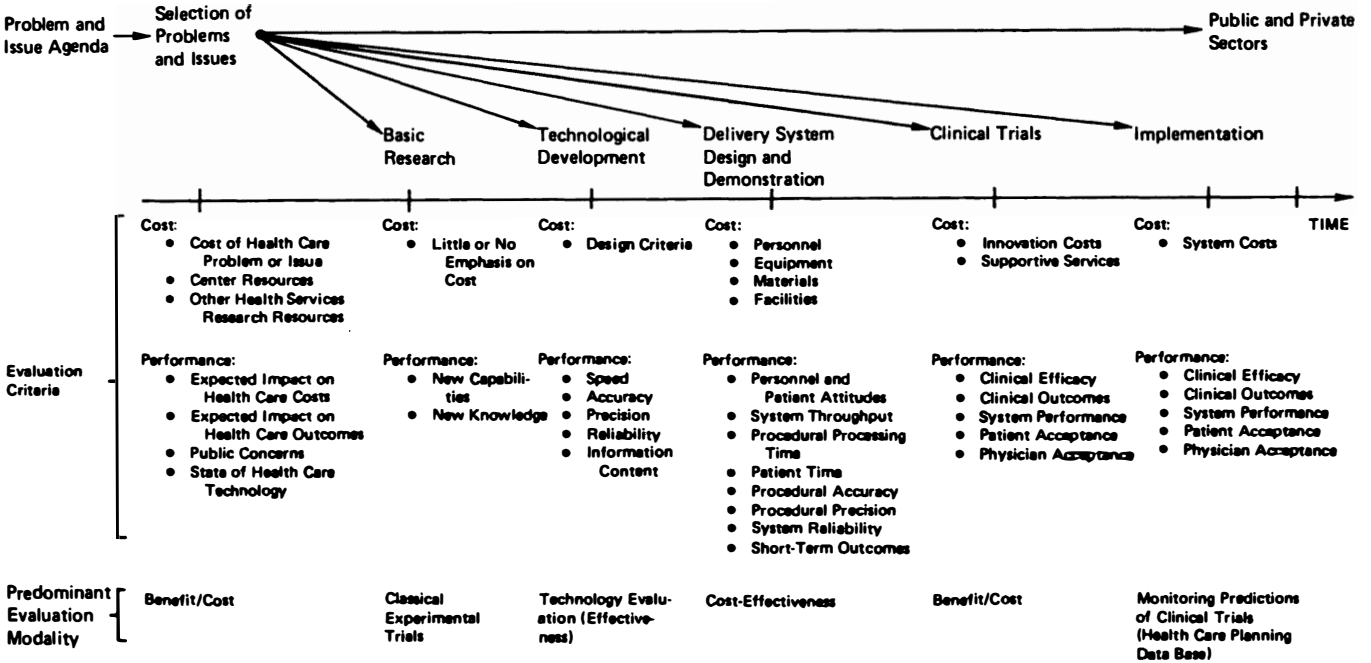

FIGURE 1 Health care technology evolutionary process.

fall more than 25 percent and less than 50 percent. That is, one would be left with the personnel costs (and relatively minimal supply costs) and the communication costs. This ignores facility costs entirely. Computer project budgets made up of slightly less than 50 percent hardware and communication costs combined and about 50 percent personnel costs have ben observed for many years in such projects during the developmental phases.[34,55] Once operational, personnel costs are expected to fall to 10-25 percent of the total budget.

If hardware performance were to become extremely reliable because of new technological advances, the hardware cost portion of medical information systems could be cut roughly in half because of the possibility of eliminating the redundancy that is now demanded in order to achieve acceptable reliability.

If a new technology were to bring the much prophesied trillion bit direct-access memories at roughly the cost of present-day memories, then implementation of medical information systems in small or moderate sized clinics might become possible without remote time-sharing to a large central computer. The consequence again would probably be a reduction in cost, by eliminating telephone line charges and the associated communication devices. If the computer costs did not change, and based on current cost experiences, the reduction in cost could be as large as 50 percent of the computer hardware budget.

A special problem of time-shared computer facilities is communications costs. These frequently equal the size of the computer rental bill. Communication costs will be less if time-sharing is done within a city. They approach or exceed equality with the computer costs when time-sharing occurs within a state. Intrastate line charges are controlled by state utility commissions. They are very high as compared with interstate long-line charges, which are controlled by the Federal Communications Commission. A change in this policy would create quite a stir in the computer field in general. It would definitely represent a major influence upon the costs of shared computer facilities in support of medical information systems. The future prospects for computer communications companies is consequently also much entwined with the future relative cost, and hence the benefit-cost, of medical information systems. Under the marketing policy adopted by communication companies such as Tymnet, the effect of the pricing policy is essentially to eliminate the importance of the relative distance of various users from the computer service provider.[65]

The fate of such ventures is really determined by public policy (largely federal)--not by technology, and certainly not by medical computational considerations.

Another major factor in the future value of all forms of automation in medical services, including MIS's, is the cost of labor.

One need not be a seer to recognize that wages in the computer and health fields, relative to anything, have been climbing steadily. Perhaps the greatest single factor increasing hospital costs in the last two decades was the Fair Labor Practices Act of 1967. This bill did indeed put an end to some unfair practices, including the extreme underpaying of nonprofessional hospital personnel. It also essentially imposed a 40-hour work week, which was a substantial reduction from the minimum 48-hour and above that formerly had been demanded. Whether or not there will be general hospital labor unions in the future, the actual cost of labor in health care facilities will be determined by general market conditions outside of our control. By and large, more expensive labor has made automation in other fields increasingly attractive. If this trend continues, it will encourage computer systems, even medical information systems, simply as labor savers and even at the level of mere automation of manual procedures.

Effects of Regulation

One last large factor confounds projections of benefit-costs of medical information systems. This is federal government policy specifically directed to MIS's. Certainly this is not a simply economic factor, but, in such a field as health, it may well be the only factor that really matters. We can encourage or discourage deployment of this technology (and quite effectively) simply by regulation. The requirements for certification for Medicare would be a possible means, although there are many others. Implementation of such systems could be encouraged and made attractive simply by making specified services reimbursible costs. It would be especially encouraging if these services (e.g., physician assistance functions, quality assurance analyses, screening studies, risk estimates, prognoses, treatment plans, or patient educational services) were made billable as services outside the negotiated per diem. Hospitals and practitioners have traditionally implemented those services for which there was a true marketplace demand. No one can doubt that such a policy would create this demand and strongly influence the diffusion of the technology.

The medical computer market is not sufficiently large as to be able to influence any of the large technologic determinants. Consequently, to evaluate how economical or how practical are certain applications is to guess contingent upon these major external factors.

FUTURE MANAGEMENT OF MEDICAL INFORMATION SYSTEMS TECHNOLOGY

Medical information systems technology can be managed under a variety of governmental attitudes. The consequences are estimated for three separate paradigmatic views of the field. These are essentially the judgmental, the observational, and the managerial.

The Consequences of Assuming That We Must Examine, Evaluate, Appraise, and Permit

The present *de facto* federal policy for managing the development of medical information systems is to shut off research support for the further development of MIS's or the creation of new ones, and to emphasize evaluation of existing systems. Examination and appraisal is proceeding, often with barely favorable appraisals. Some secondary gains have appeared, mostly in the form of well-written documentations and analyses that are a great benefit to others in this and related fields. The anticipated decision to permit or not to permit will unfortunately be based on considerations that may be quite relevant to some aspects of the health planning process but that may be quite unrelated to the priorities and potentials of the medical information systems themselves. Often the analyses must lean heavily upon financial measures. Often there are substantial unmeasured benefits in other areas.

If survival of the various forms of MIS's must be dependent upon the best we can do now by way of formal cost-benefit analyses, then there is a clear danger. Systems of borderline merit, which concentrate primarily upon business office and institutional management functions, will be "permitted."

Some systems that are of great merit because of their clinical features (e.g., physician assistance, education, prospective community data base building, etc.) will be immune to evaluation based on dollar accounting; and will be harmed or destroyed.

If one believes that the correct paradigm is to examine, evaluate, and permit, then one must surely also include the need for further research in the methodology of evaluation. Cost-benefit analysis, in health fields especially, merits further research.

The Consequences of Assuming That We Should Observe and Predict

A laissez-faire strategy of management of these developments (i.e., not much management) will mean that ideas for innovative research based potentially on medical information systems will either hibernate or will seek support as traditional, small, discipline-specific research projects funded over short time

periods. As such they will (even if successful) not be capable of supporting the development of true full medical information systems. A research program cannot be funded by a collection of research projects.

An alternative for some research ideas is to emerge repackaged as unnecessarily large clinical trials.

Medical information systems that are primarily oriented to hospital administration will pay their own ways by producing small savings for individual institutions. There is no known case in which a business office system has even evolved into a medical information system. The concept of the medical information system under a laissez-faire paradigm will simply not be developed.

The Consequences of Viewing Such a System As a National Intent

This paradigm implies managing the development and maturation of the concept of the medical information system. It is clear that the MIS concept, like many other innovations, has to find its proper place in its problem space. That is, one must determine by experimental exploration of the problem domain just which areas are feasible and fruitful.

Next, at least some sample of the various kinds of medical information systems must be selected to pass as far as possible through the known sequence of the phases of maturation. That is, we must be prepared to see systems that are moved from research phase to development to demonstration to clinical trial use to full implementation in the market. Each of the stages will need evaluation, but each will require quite a different set of measures. Each phase should have distinct limits but not a predetermined time for each phase. One must plan for costs to increase as a project moves through such a sequence. Different phases could properly be supported by separate branches of government, but it should be government's responsbility to provide for a smooth transition between phases. There must, of course, be strict criteria for evaluation, and unsuccessful projects must be selected out. Transition or selecting out should be accompanied by formal reporting from the project so as to document the experiment and its results.

The process of managing the development and documenting the growth and changes in the field, and relevant other fields, should rest with a permanent government office or agency.

The consequences of this paradigm would be to complete maturation of the concept, exploration of appropriate problem areas, and transition to commercial availability of those systems for which such a metamorphosis is appropriate.

In short, this paradigm sees medical information systems as a concept of potentially great national value. It sees government as having the opportunity and responsibility to manage the development of this technology and to assure that society gains the benefits.

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APPENDIX F

THE IMPACT OF STATE REGULATION ON THE ADOPTION AND DIFFUSION OF NEW MEDICAL TECHNOLOGY

Jack Needleman and *Lawrence S. Lewin*

In 1950, acute care hospitals spent $10 per patient day; in 1975, they spent $150.[1] Changes of comparable orders of magnitude have occurred for other medical services. Part of these increases is simply the result of inflation. A significant part of the increase, however, has been the result of changes in the product. These changes, especially those that have resulted from the development of new equipment--"machine introduced technology"--have recently been the focus of considerable public attention. Issues have been raised regarding the magnitude of investment in this technology, the payoffs of such investment in terms of patient care and comfort, and the factors that influence the distribution of new technology within the medical system.

This paper focuses on one aspect of these issues, the current and potential impact of state regulatory programs on the adoption and diffusion of equipment-embodied technology.

This discussion is presented in three sections:

I. *Background* A discussion of the scope and limitations of this analysis, the nature of relationships between regulation and technology policy, and the importance of this issue in formulating policies regarding medical technology.

II. *Analysis of the Impact of State and Local Regulation* Six principal modes of state regulation are identified and analyzed:

- Certificate of need
- Reimbursement controls
- Medical devices regulation

- Utilization review and quality assurance programs
- Institutional licensure and accreditation
- Personnel licensure

Following a brief description of the nature of the regulatory program and how it operates, empirical evidence of impact is presented, followed by a discussion of factors likely to determine its effect and the probable implication of each regulatory mode for technology policy.

III. *Policy Issues and Implications* The concluding section synthesizes the policy implications discussed in Part II and offers some caveats and guidelines for those involved in making both regulatory and technology policy.

I. BACKGROUND

Scope of this Paper

While the most visible direct form of regulating equipment-embodied medical technology is the federal Medical Devices Legislation of 1976, P.L. 94-295, considerable influence over the adaption and utilization of medical technology is exerted by regulatory programs at the state level. Because the direct regulation of equipment is relatively new and almost nonexistent at the state level, the greatest influence at this level appears to result from the secondary effect of such activities as control over reimbursement for services. This paper discusses a wide range of regulatory activities at the state level, including direct control modes such as certificate of need, medical device regulation, and institutional licensure and the indirect modes such as reimbursement controls, utilization review and quality assurance programs, and personnel licensure.

The analysis of these modes in Part II draws, where possible, on existing evidence of the impact of technological change; but with the exception of certificate of need, prospective reimbursement, and the Economic Stabilization Program there is little empirical evidence available. In the absence of such evidence the authors have presented a logical analysis of the probable effect of regulatory practices both to date and in the future.

A review of the literature failed to produce a model that could be used to test the impact of interactive regulatory modes on the adoption and utilization of medical technology. While this paper does not presume to present such a model, much of the discussion in Part II is devoted to defining factors

that influence regulatory impact and will hopefully facilitate subsequent efforts to develop such a model. In conceptualizing regulatory impact, a major difficulty arises from the fact that many of the state regulatory practices that affect medical technology are designed primarily to meet other objectives and the effect on adoption or utilization of technology is in many of these cases a side effect. The modeling effort is further complicated by the absence of a clear objective function or a statement of desired outcomes for technological change.

Relationship Between Regulatory and Technology Policy

To make qualitative judgments about the desirable or undesirable effect of state regulation requires an understanding of the goals of technology policy. While in general the goal of medical technology can be to improve the effectiveness of medical diagnostic, preventive, treatment, and rehabilitative services and the efficiency with which these services are provided, such statements are too imprecise to provide practical guidance. It is not within the scope of this paper to set forth specific policies; however, the type of policy statements that are needed would be in response to such questions as:

- In what areas is more sophisticated, efficacious, and efficient technology most/least needed?
- How can decision makers deal with the often conflicting strains of cost and effectiveness? How, for example, can decisions be made regarding the cost level at which specific improvements in medical technology are, from a societal standpoint and in the face of constrained resource, no longer cost-effective?
- Since many high-cost technology utilization decisions involve judgments about the value and quality of life, how are these judgments to be made and by whom?
- Where cost containment is a major concern, to what extent should regulators make service- or equipment-specific decisions as compared with more general decisions that produce constraints and that in turn force providers to make specific trade-off decisions? For example, with respect to CAT Scanners regulators could (1) prohibit a hospital from purchasing one, (2) limit reimbursement to a level that assumed full utilization, or (3) place a ceiling on each provider's capital expenditures for new services and let individual providers decide whether to buy a CAT Scanner or some other piece of equipment.
- Since medical services once established tend to remain in use even at low levels of utilization and despite high unit

costs, what constitutes optimum rates of diffusion, particularly before efficacy and cost-effectiveness are fully established? Put another way, how can regulators most intelligently decide how widely and rapidly untested technologies should be installed? In making these decisions, how should they consider the opportunity cost of foregoing treatment or diagnostic benefits, and the need to test the technology's efficacy and efficiency?

The purposes and goals of regulatory policy in the health care services field are somewhat clearer. For our purposes, regulatory goals can be classified into three broad categories:

- *Protection of the consumer from unsafe or high-risk situations.* This purpose may be achieved by requiring a product to be tested before being marketed or to meet preestablished quality standards with regulators empowered to either prohibit or limit use or to require that specific product information be provided to the consumer. Another approach is for regulators to assure protection by requiring providers of services to meet certain competency standards through professional licensure.
- *Assuring the accessibility of services in a rational system.* While there is vigorous debate as to whether this goal in practice works for the ultimate protection of the consumer or for the industry, the notion of stable and reliable provision of services accessible to all has become a conerstone of public utility regulation. With respect to accessibility, it takes the form of readiness-to-serve and community service requirements. With respect to stability and the rationality of the system it takes the form of franchising of exclusive service areas and of "gatekeeping" functions like certificates of necessity. Since this latter requirement erects serious barriers to entry, it often is limited in its application to so-called "natural monopolies" like power generating public utilities where economies of scale are significant. The health field, which uses certificates of need extensively (now virtually universally) relies on this form because of the unique characteristics of its financing mechanisms and its characteristics of supply-induced demand.
- *Constraining the prices of services and total system expenditures.* Economic regulation usually draws its rationale from structural deficiencies in the marketplace that in the absence of regulation would result in either destructive competition or monopolistic pricing. In the case of the health care services industry, economic regulation can also be designed to constrain total expenditures in response to what appears

to be supply-induced, price-inelastic demand characteristics. This relative inelasticity of demand reflects in part the unconstrained nature of the financing system wherein the demand for health care services has many of the characteristics of a free good. The basic human values at stake in the provision of health care services and the growing preoccupation with new technology as a means of delivering a greater intensity of medical services further contribute to the problems of constraining total expenditures. This regulatory goal is achieved in a variety of ways, including establishing prices or tariffs either across the board or differentially by service or product, by constraining total institutional revenues as a function of actual or prospective costs, or by rationing or otherwise influencing the utilization of services. For purposes of our analysis, an important distinguishing characteristic is whether the focus of the regulation is on overall costs or revenues or whether it becomes involved in decisions about the utilization of specific services or products. For example, Phase IV of the Economic Stabilization Program for hospital services (and the Carter hospital cost control proposal as well) sought to constrain average revenues per admission, leaving it up to the hospital to determine the mix of services, new technology, etc., that could permit needed care to be provided without costs exceeding allowable revenues. In British Columbia and other Canadian provinces, however, provincial officials approve hospital budgets on a line-by-line basis that requires them, and not just the hospital administrators or medical staff, to share in the trade-off and investment decisions.

Why the Impact of Regulation is a Timely Issue

The rapid growth of medical technology is widely acknowledged as a major contribution to the inflation in health care costs whether measured in terms of cost per day, cost per admission, cost per encounter, charge per unit of service, expenditures per capita, or total personal health care service expenditures. Gaus and Cooper have estimated that the "technology factor" (changes in intensity from new equipment, supplies, and personnel) represents 47.3 percent of the 9-year increase in the expense per patient day in community hospitals from $49 to $147.[2] Although not all new technology contributes to higher costs or higher intensity, there is little doubt that new technology presents increases in both unit and system costs.

The role of new medical technology in the health care cost spiral, coupled with a growing consensus for increased regulation of the health care for other reasons, almost certainly means

that technological innovation, adoption, and diffusion will be increasingly under the influence of public regulation, much of which is at the state and regional level.

While regulatory initiatives are occurring in a number of areas, regulators and students of the subject are looking more and more to a strategy of controlling supply and capacity as a way of constraining demand and, thereby, total expenditures. This strategy can be carried out through direct controls such as certificate of need strengthened by the application of regional caps, and indirectly through reimbursement controls. If this tack is pursued, policymakers will need to understand more clearly than they now do how such strategies will affect the adoption and utilization of medical technology as well as other capital investments.

The capacity of regulatory bodies to be sensitive to sound technology policy is very much at issue. First, most regulatory modes do not incorporate specific goals with respect to technology, nor have they even considered the need for such goals. Second, there are few guidelines available to help planners and regulators make the trade-offs among alternative service/technology options. Finally, there are serious questions as to who should be making what can become triage decisions. As the Congress appears reluctant to extend open-ended coverage like that afforded under the End Stage Renal Dialysis Program to other diseases, the capabilities of medical technology may outstrip the public's willingness to finance its application and "who shall live" decisions may become increasingly acute and politically uncomfortable.

For these reasons, the likely impact of state regulation on medical technology and the need for a more conscious linkage between regulatory goals and technology policy must be better understood by policymakers.

II. ANALYSIS OF THE IMPACT OF STATE AND LOCAL REGULATION

This section reviews six types of state or local regulations that have the potential to influence the introduction and diffusion of medical technology. The six regulatory programs reviewed are:

- Certificate of need
- Reimbursement controls
- Medical devices regulation
- Utilization review and quality assurance programs
- Institutional licensure and accreditation
- Personnel licensure

For each, the purpose and administrative mechanisms are described, the impact on the introduction of new medical technology examined conceptually and, where possible, empirically, and the policy implications of this analysis presented. The section following this one addresses policy issues that cut across individual types of regulation.

Certificate of Need

Certificate of need is a program of public review and approval of the capital expenditures and service changes of health care providers. Review in most states is conducted by both state agencies and local health systems agencies, with local review advisory and state review final. As part of this review process, judgments are made on the need and desirability of proposed expenditures. In reaching these judgments, reviewers can consider a wide range of factors, including the efficacy or usefulness of the proposed project, the appropriate distribution pattern for the service or equipment sought (both geographically and with respect to the preferred provider or setting), the reasonableness of the financing arrangements, cost and proposed charges and financial feasibility, the adequacy of the proposed staffing and physical layout, and the competence of the provider and overall quality of the services to be offered. Because of the scope of review, certificate-of-need programs directly confront states with the full range of issues affecting the introduction of new medical technology.

These programs are widespread. Currently, 33 states have certification programs. Thirty-seven states have contracted with the federal government to do similar reviews under the authority of Section 1122 of the Social Security Act. Only Missouri has neither program.[3] The National Health Planning and Resource Development Act of 1974, P.L. 93-641, virtually mandates all states to enact certificate-of-need programs.

The programs do not cover all medical equipment purchases, but they are extensive. The federal regulations for state programs require hospitals, nursing facilities, health maintenance organizations, kidney treatment centers, and ambulatory surgical facilities to be subject to review. For these providers, all capital expenditures over $150,000, bed changes, and all new services must be reviewed. The services offered and equipment purchased by private practitioners are not included in most laws, but two states have introduced some controls on physicians' purchases, and more are considering this step.

These programs are intended to serve a number of purposes. There is a concern with cost containment, although it is a very specific one. The impetus for these programs has been a belief that there has been uncessary overinvestment, leading to inefficient use of capital and additional operational expenses, and encouraging inappropriate utilization of facilities and services. The concern is not with absolute levels of costs, nor with the desirability or impact of expanding medical services per se. Most programs have retained a commitment to assuring access to care that is at least as strong as their cost containment goal.

There have been several analyses of the effects of certificate of need on the investments of health care institutions. Hellinger, based on early data, concluded that certificate-of-need legislation had not lowered hospital investment and that hospitals had increased their investment in the period immediately preceding the enactment of the legislation in anticipation of the program.[4]

Salkever and Bice concluded that certificate-of-need programs had constrained the increase in hospital bed supply but did not reduce total hospital investment. Instead, assets per bed had increased faster in certificate-of-need states, suggesting that investment had been redirected into modernization and special equipment. They also found that certificate of need was associated with decreases in patient days but increases in the costs per day. Since these have opposite effects on the overall costs of health care and the relative magnitude could not be determined, the ultimate impact of certificate of need on total costs was not estimated.[5]

In an update of their analyses with data through 1974,[6] the authors found continued support for their earlier conclusions. An analysis was made of the experience of the five states that had certificate-of-need programs prior to 1971, and for these states the programs were found to be associated with control of assets per bed, although at levels the authors judged not statistically significant. (The significance level was 0.07.) Four of these five states, it should be noted, have institutional rate review programs.

In its 1975 study of the impact of the Section 1122 and other programs to control capital expenditures, Lewin and Associates[7] concluded that these programs had not been particularly successful in controlling hospital investment. Forty-six percent of the 20 states and 40 areawide agencies included in the sample had approved hospital beds in excess of their published 5-year need projection. While approved increases in assets per hospital bed between 1972 and 1974 were less than the estimated amount of inflation plus economic growth

in most surveyed states with these programs, this could not be compared with the growth of assets in states without this form of regulation. Those states that were most successful in controlling per bed assets generally had some form of institutional reimbursement control.

The Lewin study also found that proposals to purchase equipment and add new hospital services are almost always approved. The principal exceptions are X-ray and other scanner equipment, where the still infrequent denials are largely the result of several institutions applying to purchase the same equipment and only one being approved. A table of approval rates is presented in Table 1.

In sum, based on evidence drawn from the first years of operation of these programs, there is little evidence that operating independently they have limited the ability of institutional providers to invest in new technology. There is also some evidence that the process, by defining its coverage in terms of types of providers rather than types of

TABLE 1 Approval Rates by State Agencies under Certificate of Need and 1122 Reviews for Equipment and Service Projects in Sample States

	Applications Received	Percent Approved
Equipment		
CAT scanners	91	96.7
Radiological	106	93.4
Renal dialysis	24	100.0
Cardiac catheter	9	100.0
Other equipment	5	100.0
All equipment	235	95.7
Services		
ICU-CCU	14	92.9
Renal dialysis	14	78.6
Other specialty	69	94.2
Emergency medical services	19	89.5
Other outpatient	73	97.3
Rehabilitation	28	100.0
Other ancillary	8	100.0
All services	224	94.6

services that require regulation, has encouraged the introduction of secondary and tertiary level technology into primary care settings. For example, the Office of Technology Assessment reported that 15 percent of CAT scanners were in private physician offices or clinics.[8]

Several factors have influenced this current level of performance by these agencies. The programs are relatively new, as are many of the agencies involved. The ideal situation would be one in which the standards for project review, including definitions of need, were established prior to project submission, so that they could be immediately applied. In most agencies, however, planning activities and standards development have lagged. A frequent pattern has been for agencies to approve the first project (sometimes the first several) of a given type and begin developing a standard for a new service or equipment after the first application has been received.

The standards development process itself has a number of weaknesses. There is now available a considerable body of literature with suggested standards that have been developed at both the national and local levels. These materials cannot simply be adopted by a health planning agency. Rather, they are reviewed to address local circumstances and patterns of treatment. These reviews often blend local health politics with technical adjustments.

In addition, the development of standards for new services, particularly standards regarding the appropriate number of service units, can often only be done once there has been experience with the service. Requests for new technology, however, will often precede the development of information on efficacy or levels of utilization, placing pressure on review agencies to act before standards can be developed. There has been a tendency in the agencies to grant approval when uncertain. (This is not inevitably the case; it is a function of agency orientation. In Quebec, under the province's hospital insurance program, which includes both certificate of need and reimbursement authority, the province's announced policy is to limit technological diffusion to services of demonstrated efficacy. As part of this effort, the province had limited the introduction of *in vivo* radioisotope facilities to only a few hospitals and required these to develop research protocols to evaluate the efficacy and cost impact of these services.[9])

There also appear to be some areas in which prior standards development is infeasible, or at least very difficult. Some of the most subtle decisions agencies must make involve determining the appropriate level of technical sophistication in existing services. This includes questions such as: Does a

150-bed community hospital need tomographic or radioisotope capacity in its radiology department? Or, is laboratory volume sufficient to justify an automated analysis and, if so, with what capacity? Standards have not been developed because the decisions involve a great many situational factors that limit general answers. Since these issues do not involve large projects, they have received lower priority in the standards development process than bed planning or plans for entire services. Yet, collectively, these decisions have a major impact on the technological level of routine care.

Finally, there is an issue of whether the entire standards development--and indeed certificate-of-need--process is misoriented. Currently, these efforts are directed at assessing the need and appropriateness of services, beds, and equipment on an absolute standard of whether the service is productively and efficiently used. If so, it is approved. The process does not address the basic issue of establishing priorities to allocate limited resources. No certificate-of-need program has incorporated into its planning process judgments of the rate at which resources should be added to the health care system or medical technology diffused. It is therefore not surprising that these programs seem most able to limit investment in states where reimbursement control programs have introduced separate limits on available resources.

It is within this context that the proposal to limit hospital investment incorporated into the administration's cost containment program should be noted. If adopted, this limit would introduce a fundamental change into the certificate-of-need process. Agencies will be forced to assess projects on the basis of relative as well as absolute need. This has occurred on a limited scale in Rhode Island under the reimbursement control program for hospitals, but for other agencies this would be a new experience. Among its other consequences, it is likely to place basic service expansion into competition with new technology.

The potential impact of certificate-of-need programs on the adoption and diffusion of technology is great. This includes the potential to severly limit the total level of investment. Without the introduction of financial pressures into the certificate-of-need environment, however, the relative ease with which new services and equipment have been approved is likely to continue.

Reimbursement Controls

While certificate of need can directly regulate the introduction of new technology, the effect of reimbursement controls on service decisions is potentially greater. Ultimately, reimbursement policy influences the resources available to invest in services and equipment and the incentives for their use. Furthermore, the effects of reimbursement may be unintentional, inadvertent results of policies directed toward other goals or priorities. In certificate of need, there is at least explicit consideration of the value of the technology.

All payment programs reimburse providers within specific rules. In this sense, all have reimbursement controls. The term is generally meant to distinguish a payment system from those widely in use that give providers considerable discretion to determine their reimbursement.

Physicians

For physicians and invidual practitioners, there are two common payment approaches used by third-party payers. One is the payment of the provider-established usual and customary fee. The other is the payment of a flat amount under a fee schedule established by the payer (sometimes with provider participation). The provider may ask patients to supplement the fee schedule payment or, for those public programs where he cannot, may refuse to treat the patient. Under fee schedules, payment for procedures that are not included is at the provider-established level or based on a comparison of comparable procedures.

The main controls that are introduced into these systems are to limit the ability of the provider to charge an additional amount and to refuse to reimburse for procedures not initially included in the schedule. This last has particular relevance to the development of new techniques and procedures.

The U.S. experience with controls on physicians' fees is limited. Medicare only reimburses for approved procedures, and DHEW has established a system in which the Bureau of Quality Assurance, Food and Drug Administration, and National Institutes of Health will be consulted to determine whether a new procedure should be added, based on demonstrated safety and efficacy. Some Blue Shield plans negotiate fee schedules that are accepted as payment in full by participating physicians. These types of activities are not common at the state level.

There has been limited systematic examination of the impact

of fee levels on practitioner behavior. There is limited evidence from Canada that physicians modify their patterns of practice in response to fee levels. The provincial governments have considered adjusting the fees for specific services in an effort to use this effect (e.g., increase vaccinations, decrease routine physical examinations).[10] In the United States, it has been claimed that the development of proprietary hemodialysis centers was fueled by high levels of reimbursement and that some procedures, such as cardiac bypass, are used in marginal cases because they are well reimbursed.

Conceptually, it can be argued that manipulating fee schedules can provide one mechanism for modifying physician use of specific treatment methods or technologies. The extent to which fees would influence choice is not known, however. Changing physician practice patterns would have an indirect effect on the medical technology investment decisions of hospitals, since these are made largely in response to staff requests.

There are two current practical limits on the use of this technique. First, not enough is known about how physicians respond to fee levels. Specifically, it not clear whether most physicians respond to fees for individual procedures or whether the response is to the total pattern of fees in a field that, taken together, defines the potential earnings of practicing in a specific technical style. Until this is better understood, a comprehensive regulatory strategy could not be constructed. Efforts to manipulate the use of specific technologies might nontheless be attempted.

The second practical limit is the likely inability of states to enact regulatory programs to control physician fees and the inability of individual purchasers to impose the stringent fee limits necessary for this policy. Physicians have been in the forefront of opposition to the financial regulation of institutional providers, largely because of their fear that this is an initial step to the regulation of their incomes. In many states, this opposition has been a key factor in limiting the scope of the programs developed. It is unlikely that in any state their opposition could be overcome and general regulation introduced.

The regulation through individual third parties is flawed by the general effects differentials in fee levels have--refusal by physicians to treat patients, requiring additional payments of them (in the case of Medicaid and Medicare, illegally), and encouragement of fraud. Whether this would occur if general fee levels were comparable but specific technology-related fees had differentials is uncertain. In all likelihood, it would not. But unless a given technology encompasses

a significant portion of a physician's practice (such as in the dialysis situation), or unless no reimbursement at all is available, adjusting fees should only have a marginal effect.

Hospitals

The incentives that can be created at the institutional level through reimbursement are much greater than at the physician level, primarily because regulation can be introduced for institutional providers with greater ease (although not easily) and because they are more sensitive to the impact of changes to reimbursement patterns from individual third parties.[11]

The two most common forms of reimbursement for hospitals are payment of hospital-established charges or payment of an allocated portion of actually incurred costs. In both these cases, it is the hospital's decision that determines the level of costs and reimbursement for services. Coupled with the growth of third-party payment and the concommitant reduction in bad debt and charity loads, these payment mechanisms have improved the financial conditions of hospitals and generated the funds used for service expansion and upgrading technology.

Nine states have introduced programs to regulate the payments to hospitals and establish payment rates on a prospective basis.[12] These programs vary in their coverage. Some only cover Medicaid and/or Blue Cross rates (e.g., New York and New Jersey). Some cover all payers (e.g., Connecticut, Maryland, and Washington). One is a program of nonbinding mandatory state review of rates (Arizona). In some cases the programs regulate per diem or individual service charges; in others, total institutional budgets or revenues.

There is some evidence that controlling reimbursement has an impact on capital expenditure plans and, consequently, the introduction of new technology. A survey of hospital administrators on the effects of the Economic Stabilization Program at the end of the first year of the program indicated that approximately one-fifth had reduced their capital expenditure plans for that year, and that the average reductions among those was 43 percent. Approximately 13 percent indicated that they had foregone the introduction of a new service.[13]

Cromwell examined the impact of Economic Stabilization Programs and concluded that it had lowered the rate of adoption of complexity-expanding and community services, although this effect declined over time. A comparison of a sample of New York hospitals to a sample from a state without prospective reimbursement indicated that the adoption of complexity-expanding services in New York was lower, although because of

the existence of the certificate-of-need program, he hesitated to attribute this solely to the reimbursement controls. For smaller hospitals, contraints were associated with changes in net revenues, although with significant lag. No similar constraints were found for larger hospitals, which the author speculated reflects their better access to external funds.[14]

Thus, the potential for reimbursement controls to influence the investment decisions of institutional providers appears to be confirmed. Not examined in these studies is the impact of alternative methods of introducing controls over the capital and operating budgets of providers.

There are two broad alternative approaches to the imposition of reimbursement controls. One is to exercise close scrutiny over the individual expenditures or charges of the provider. Under these systems, the efficiency of individual departments or appropriateness of specific activities is examined. The results of these reviews can be implemented in two ways: by prohibiting the institution from making an expenditure or by establishing reimbursement at levels that will not allow the expenditure to be recovered if it is made. The latter method is more common and is assessed in the discussion that follows.

To take an example, under the detailed review or line-item approach, if a radiology department were judged overstaffed, an amount equal to the estimated savings would be subtracted from the budget base. If a service were judged unnecessary, the estimated operating expenses would be subtracted from the budget. If a service or new piece of equipment is to be added to the hospital, its estimated operating expenses would be added to the budget base. Alternatively, a standard reimbursement rate can be established for a service, such as a brain scan, based on estimates of the per-unit expense of an efficiently organized institution providing an appropriate volume of services. For those services judged inappropriate for a given institution, the rate might be zero, that is, the service would not be reimbursed. Establishing standard reimbursement rates allows the institution to calculate whether it can break even on the service. In either case, whether the adjustment is to the budget base or the reimbursement rate, the institution is free to continue the service if it can finance it from other sources, such as gifts or research grants.

With respect to the introduction of new technology, the line-item approach requires reimbursement agency concurrence in each investment decision. This allows considerable control by the state, but also requires greater sophistication in the reimbursement agency. One element in this sophistication is a health planning capacity similar to that required in

certificate of need to evaluate the need and appropriateness of the proposal. In fact, this is usually obtained by accepting the certificate-of-need decision as a commitment by the state to allow reimbursement for the service. The level of reimbursement may be disputed, however. There have been instances where the reimbursement agency has not agreed with the level of capital or operating cost approved by the certification agency and renegotiated the scope of the project. To limit the possibilities for this occurring and to approve the level of cost and financial analysis in certification decisions, reimbursement programs are increasingly participating in the analysis of certificate-of-need applications.

The alternative to line-item review is establishing overall limits to the growth of hospital charges, budgets, or revenues. The hospital is free to allocate its resources at its discretion. This was the approach taken in the Economic Stabilization Program and in the administration's cost-containment proposal. It is essentially the method used in New York and as a screening device in New Jersey.

Under an overall increase approach, the hospital retains its discretion to invest in new technology (subject to other regulatory constraints). The control's main impact is on the level of funds available to support these investment decisions. Programs can directly manipulate the amount they make available. In the final Phase IV regulations under Economic Stabilization, for example, an estimate of the base inflation rate for unchanged operations was adjusted to reflect estimated improvments in productivity (1 percent) and an allowance for increase intensity, i.e., an increase in the complexity and number of services provided per patient of 2.5 percent. Both these factors reflect assumptions about technological change. The New Jersey reimbursement methodology adopted in 1976 assumed a 1 percent increase in intensity to be offset by a 1 percent increase in productivity. This was a statement of public policy regarding new investment in sophisticated services rather than a history-based projection. The New York system includes neither a productivity nor an intensity factor, implicitly assuming that the production function does not change from year to year. Because rates have been exclusively cost-based until this year, if a hospital could finance expansions in services through working capital or charges to patients not covered by the control program, these would ultimately be built into the rate base. It is clear that other policy goals, such as contraction of the system, could be incorporated into overall increase limits.

It should be noted that no system in use is a pure representative of either approach. The Economic Stabilization

Program and New York systems both allowed providers to request changes in their rate bases to reflect large capital expenditures and their associated operating expenses. These reviews were quite similar to those described in the line-item approach above.

In addition, specific ceilings, penalities, or incentives can be incorporated into the general increase approach.

For example, in New York, hospitals are expected to maintain minimum volumes of certain complex services (open-heart surgery, cardiac angiography, transplantation) or rates are adjusted down by formula.

Similarly, in line-item systems, review is simplified through the use of analytic screens. If technological changes can be introduced within these limits, they may not be subject to detailed review. (Some programs, however, focus their review on operational and technical changes by asking for separate line-item capital budgets and breakdowns of new costs to be incurred because of changes in service.)

The Rhode Island system of project prioritization mentioned in the preceding section on certificate of need is another illustration of the blending of these two approaches. Rhode Island engaged in line-item budget negotiation within a fixed total budget ceiling for the state. The inclusion of new services into budgets was subject to agreement on the level of operating costs of existing services.

This examination of institutional reimbursement controls makes it apparent that any control program includes an explicit or implicit policy toward capital expenditure in general and new technology in particular. Such a policy has several components:

- It sets limits on the overall level of allowable investment, although these may be fluid. Line-item systems without priorities or targets for total increase limits can be prepared to add any amount of new services to the system, so long as they have been certified as needed by the appropriate planning agency.
- It determines who is to be involved in establishing priorities among new technology, specifically defining the relative roles of regulators and institutional personnel. Regulatory personnel are not a homogeneous group, but can be divided broadly into service planners and financing categories. State policy determines not only the degree of institutional autonomy but also the relative participation of the two sets of regulators.
- It distributes the costs of new technology. This was not discussed in detail above, but one of the critical decisions

made in reimbursement regulation is the distribution of costs among different patients and third parties and between patients and other sources of revenue such as gifts, tuition, or research grants.

All these are inherent in rate regulation. The regulatory mechanism is flexible enough to accommodate virtually any policy desired within these components.

Medical Devices Regulation

Under the 1938 Food, Drug and Cosmetic Act, the federal government assumed a number of regulatory roles with respect to drugs and medical devices. The drug role was an extensive one, involving premarket approval of new drugs, as well as authority to require reports of manufacturers and monitor the manufacturing process and files of the producer. Approval to market a drug could be withdrawn. With respect to medical devices, however, the authority was limited. The government was given the authority to seize a sample of a misbranded or adulterated device and begin judicial proceedings to halt distribution. The burden of proof was on the government, and sales could continue while the case was being adjudicated.

Most states followed the federal lead and adopted laws allowing them to proceed against devices that were adulterated or misbranded. In general, the guidelines adopted for assessing this followed the federal guidelines, so the net effect was to create a national approach to regulating medical devices with both federal and state enforcement mechanisms.

In 1976, the Medical Devices Amendments to the Food, Drug and Cosmetic Act were signed into law. These strengthened the regulatory authority of the Food and Drug Administration to control medical devices, increasing the information device manufacturers were required to provide the government and shifting the burden of demonstrating safety and effectiveness to the manufacturer. The act requires the government to classify all devices into one of three groups defined by the appropriate level of regulatory control the device requires. The groups are: premarket approval, establishment of performance standards, and general controls regarding adulteration and misbranding. To date, the Food and Drug Administration has not published its proposed regulations classifying devices. The agency is not likely to quickly follow the final classifying devices. The agency is not likely to quickly follow the final classification regulations with its performance standards.[15]

While the amendments preempt state activity in this area, they contain provisions that allow states to request an exemption to administer their own medical devices program. It is unlikely that this provision will lead to intensive state regulation or that the introduction of state programs would limit the introduction of new medical technology more than the federal program operating alone.

The judgment that states are not likely to adopt this form of regulation is based on four factors:

- California is the only state currently operating a similar program that has expressed its interest in receiving a waiver. The low level of activity by other states in this area is probably an accurate reflection of interest.
- The resources, especially the technical resources, needed to develop a program encompassing performance standards and premarket clearance are extensive and only a few states are capable of developing a program in this area.
- Unlike some forms of regulation in which state actions to complement or reinforce federal programs are encouraged (e.g., fair trade), the intent of this act is federal preemption and states are less likely to move into a new area of regulation under these circumstances.
- States are likely to be preoccupied with regulation in the health planning and finance areas.

The resource issue also makes it unlikely that state programs will operate so at variance with federal efforts that it will impose additional barriers. It is useful to distinguish between the enforcement aspects of these programs and the technical evaluation aspects. California's interest is sparked primarily by concern over enforcement. The state began its program of premarket approval because it felt federal efforts were inadequate and that stronger licensure and surveillance were required. A primary reason for seeking the exemption under the Medical Devices Amendments is concern over the time the federal government will take to establish standards and begin operating the program. These are enforcement issues.

On a technical level, however, the state is unlikely to duplicate the standards development process undertaken by the federal government. It is, among other things, very expensive. Currently, the state is essentially a consumer of standards, using those developed by national organizations. It will probably adopt federal standards, and currently a bill is pending in the legislature that would require this. Similarly, the California requirements for premarketing demonstrations of safety and efficacy are also likely to be comparable to

the requirements adopted by the federal government, at least in terms of basic approaches to be used. The state may examine the evidence more or less critically, but is not likely to require a different research protocol. Marginal modifications rather than new systems should be expected from the states in this area.

The parallel operation of this form of regulation by the federal government and a small number of states might have a negative impact on the diffusion of efficacious technology in several ways. First, since the main reason for California's interest in the program is to bring devices under regulation sooner than the federal government is prepared to, it is likely that the state will establish standards before the national standards are established. If the federal requirements are more stringent than state standards, it is likely that the standards will be upgraded. If federal requirements are less stringent, the state may not downgrade, producing a situation comparable to that with respect to automobile emission standards. With a tenth of the medical market in California, it is unlikely manufacturers would fail to modify equipment and leave the state unsupplied with the technology, but responding to two separate standards might increase the production and distribution costs.

Costs might also be increased by the need for manufacturers to deal with two separate sets of regulators. This is an additional, marginal cost, which may be high enough in some cases to make the introduction of a new device infeasible. If our judgment of the extent to which state standards of demonstration are likely to be consistent with federal standards, and if the state and federal governments are prepared to coordinate their requests of manufacturers even while reserving the right to make independent judgments, the impact of this factor should not be great.

Utilization Review and Quality Assurance Programs

Another form of regulation that might have an impact on the adoption and diffusion of medical technology are programs to review the appropriateness of the utilization of health care services and the quality with which services are provided. For the most part, these are not state regulatory activities but are locally and regionally organized.

The concept of reviewing medical care practices to assess the quality of care and appropriateness of the services provided has evolved over a period of 40 years. One of the first formal organizational settings for such review was

created in 1954 when the first private medical foundation was established to review patterns of care within the context of fee-for-service independent practices.

The development of Medicare in 1965 increased the demands on the medical system to develop mechanisms to assess utilization by requiring all institutional providers to have utilization review programs for their Medicare patients. In 1967, this requirement was extended to Medicaid. These programs were institutionally organized, although requirements were established for state medical audits of nursing home patients under Medicaid.

The Social Security Amendments of 1972 created the Professional Standards Review Organization (PSRO) program. This program was a distinct break from previous utilization review efforts in that it called for the establishment of a network of review organizations external to the individual institutions and separate from government to assume responsibility for assuring that health services reimbursed by federal or federally assisted programs under the Social Security Act are medically necessary, meet professionally recognized standards of care, and are provided in the most economical and appropriate setting.

To meet this responsibility, PSRO's will review admissions to hospitals and other health facilities, certify the need for continued treatment, review extended or costly treatment, and review the patterns of practice of individual providers, institutions, and the community as a whole. The PSRO's will, as part of their activities, conduct medical care evaluation studies and develop standards and protocols for care of specific conditions.

PSRO's have initially focused on reviewing the length of stay of patients, and the few evaluations done to date have focused on this aspect of their performance. The results, while preliminary and needing more analysis and verification, suggest that most programs have not affected length of stay.[16]

It is in the development of the standards for appropriate patterns of treatment and the application of these standards to review of individual cases or provider profiles that these programs might most influence the adoption of new medical technology. There is a strong likelihood that the standards they develop will become norms for medical practice. Aside from the pressures inherent in the peer review process, the current malpractice crisis creates additional incentives for physicians to practice consistently with one another. State actions to address the malpractice problem by establishing new insurance pools or changing the liability laws might

therefore have an influence on the impact of the PSRO program on provider practice patterns.

If a PSRO is conservative, it can create pressures to maintain current practice patterns and retard the introduction to new methods and technology. If a PSRO adopts standards and treatment protocols that call for the routine use of the best available technology, this might create pressures on institutions for new investment to meet the recognized community standard. While there is considerable conjecture on the likely direction this standard-setting process will take, there are no current studies of the impact of PSRO's on the level of technology used in medical treatment. Nor is there any reason to assume that the impact of PSRO's will be consistent, given local governance. Variations, reflecting differences in the perspectives of the medical community in different regions, are rather to be expected.

There are several vehicles to coordinate policy among PSRO's. These include the National Professional Standards Review Councils and the DHEW staff in the Bureau of Quality Assurance. Efforts to introduce common approaches for incorporating judgments on new technology into local standards of practice will have to be made through these coordinative bodies.

There is another role PSRO's might play in the introduction of new technology. It is to serve as the locus of efforts to evaluate the impact of new technology on the costs and outcomes of medical care. Such a role is envisaged in the scope of medical care evaluation studies that these agencies are obligated to conduct. The PSRO program manual, in giving examples of possible studies, includes:

- Studies of the outcomes of hospitalization for given diagnoses.
- A study of the use of combination antibiotics with the criteria specifying the indications and contraindications for their use.
- Detailed analysis of the process of care for a particular problem, the criteria used in the study to be based on scientifically derived evidence of the efficacy of given diagnostic or therapeutic procedures. For these last studies, the manual recommends that if no evidence is available, the best judgment of experts be used. An alternative approach would be for the PSRO to initiate or supervise the clinical studies needed to make these judgments or to cooperate with other efforts to do this through the use of their review records to assess outcomes. This would involve the PSRO's not only in the standards-setting process, but also the research process necessary to establish standards.

Institutional Licensure and Accreditation

Institutional licensure is one of the most widespread forms of state health regulation. Virtually all states license hospitals, although it was not until 1946 under the impetus of the Hill-Burton Act that most states developed comprehensive licensure laws. Other health facilities, such as nursing homes and clinical laboratories, are also frequently subject to licensure.[17]

Licensure is a mandatory program in which a provider must meet minimum standards in order to receive permission from the state to operate. The licensure programs focus on fire and life safety considerations, water and sanitation standards, minimum service standards, and guidelines for staffing and staff qualifications. There are generally three aspects to the licensing program: a review of architectural plans of proposed facilities for consistency with the construction code, an initial licensure inspection, and periodic inspections once the facility is opened.

One of the few studies of licensing programs that has been conducted concluded that regulations were stronger, less ambiguous, and more stringently enforced in matters relating to construction, maintenance, and sanitation of the physical plant than for matters relating more directly to patient care.[18] It has been asserted that institutional licensure programs have intended to over specify the techniques and inputs that institutions must use.

Closely related to licensure are two voluntary programs for reviewing institutional quality--accreditation and certification. Accreditation is conducted under private auspices and goes beyond minimum standards. The main accrediting organization in the United States is the Joint Commission on the Accreditation of Hospitals (JCAH), operating under the sponsorship of the American College of Surgeons, American College of Physicians, American Hospital Association, and American Medical Association. The program is intended to assess the quality of institutions, but, like licensure programs, has been accused of focusing too much on inputs and not enough on process or outcome measures.

Certification is a process by which third-party payers, most notably the federal government but also Blue Cross, assess facilities as meeting the standards required to receive reimbursement from the program. Under Medicare, JCAH accreditation is one basis for certification. If an institution is not accredited, it may be surveyed and assessed against Medicare standards. The federal government has contracted with the states to make this survey, and in most states it is conducted by the licensing agency using the federal standards.

Little is known about the impact of licensure or accreditation on the operations of hospitals and specifically on the introduction of new technology. The standards established focus on physical layout and personnel, and in the accreditation process on training and the maintenance of appropriate policies and procedures for each department. In determining the appropriateness of equipment and technology, both processes rely on the professional judgment of surveyors. The New York State standards for laboratory services, for example, require the extent and complexity of service to be "commensurate with the size, scope and nature of the hospital."[19] The standard for radiology is comparable, calling for facilities to be available "according to the needs of the hospital." If radiotherapy services are provided at the hospital, they must "meet professionally approved standards for safety and personnel qualifications."[20] JCAH standards similarly call for professional judgment, requiring, for example, in laboratories, that "equipment and instruments be appropriate for the services required,"[21] or "that radiation therapy facilities shall be adequate for modern and appropriate treatment according to the needs and size of the institution."[22]

The character of these programs may have several influences on the introduction and diffusion of new medical technology, although analysis of these influences is currently only conjecture. Their direct effect on the introduction of new technology is likely to be slight, except in those cases where it affects basic construction methods or the layout of the facility, areas in which the standards are most specific. The attention these programs pay to the adequacy of personnel and in particular formal training and qualifications may slow the diffusion of technology if specialized training is required. Reliance on professional judgments by the review teams of the availability of appropriate equipment may, because of professional orientations, encourage the introduction of new, "best available" technology.

Personnel Licensure

Personnel licensure laws are intended to assure the quality of health care by:

- Reserving certain functions to only those capable of doing them well and prohibiting others from performing them.
- Identifying the individuals judged able to perform the function.

In recent years, several complaints have been raised about the operation of these laws--that they often use the wrong criteria to assess competence; that the multitude of categories and variations among states has reduced occupational mobility of health workers; that they do not distribute tasks among different classes of personnel based on their ability to perform them, and, as a result, prevent the efficient delivery of health services; that the proliferation of narrow licensing categories has created not only inefficiencies but obstacles to innovation.

In understanding the potential impact of these laws on the introduction of new technology, it is this last issue that is critical, and it is relevant primarily with respect to allied health professionals.

Specifically, as new technology has been developed in the last decade, there has been a proliferation of personnel trained in the technical support of specific technology. The specificity of the technical knowledge required of the allied health personnel has encouraged movements for licensure of each specialty. The potential effect of too many narrow licensing categories on health care institutions may be to reduce their ability or increase the costs of introducing technological change, by fixing staffing patterns and assignments, by requiring larger investments in manpower when introducing new services, and by increasing training costs. It is not clear that licensing regulation has had any of these effects, and interviews with individuals knowledgeable about licensing programs suggest that the impact has not been great. Indeed, impact appears to have been in the other direction, with rapid changes in technology leading to a multiplication of professional and occupational categories.

The growth in new state licensure categories was raised as a federal concern in the Health Training Improvement Act of 1970, and the federal government prepared a report on licensure and related programs in 1971. That study identified 17 categories of allied health personnel which were licensed in at least some states. These included:

- Clinical laboratory directors
- Clinical laboratory medical technologists
- Dental hygienists
- Inhalation therapists
- Midwives
- Opticians
- Optical technicians
- Optometrists
- Pharmacists
- Physical therapists
- Physical therapy assistants
- Physician assistants
- Psychiatric attendants
- Psychologists
- Radiologic technologists
- Sanitarians
- Sanitarian technicians

As a result of the study, the federal government called for a 2-year moratorium on state adoption of new licensing categories, while additional study was made of a number of issues including: the potential of national volutary certification programs to serve as a substitute for state licensure, the development of national standards for health worker licensure, and the need for continuing education activities and periodic relicensure.[23] In 1973, DHEW recommended a 2-year extension of the moratorium.[24] The moratorium appears to have had only a limited effect on state actions in this area.

A recent report by DHEW on the issue, *Credentialing Health Manpower*, calls for a restraint in the introduction of state licensing for new categories of workers. It advises states to "entertain proposals to license additional categories of health personnel with caution and deliberation."

As an alternative, the report stresses the role that can be played by private certification programs. These programs are also intended to identify individuals able to perform specific functions. Unlike licensure, the category is not defined by law and the functions are not reserved to the individuals certified.

Certification programs are often related to the completion of formal education programs in the field and the range of such programs gives an indication of the scope of certification activities. The American Medical Association Council on Medical Education has established accreditation standards for 26 programs. These include (with the date the standards were established):

- Occupational Therapist (1935)
- Medical Technologist (1936)
- Physical Therapist (1936)
- Medical Record Administrator (1943)
- Radiologic Technologist (1944)
- Medical Record Technician (1953)
- Cytotechnologist (1962)
- Respiratory Therapist (1962)
- Certified Laboratory Assistant (1967)
- Radiation Therapy Technologist (1968)
- Medical Assistant (1969)
- Nuclear Medicine Technician (1969)
- Nuclear Medicine Technologist (1969)
- Orthopaedic Physician's Assistant (1969)
- Histologic Technician (1970)
- Assistant to the Primary Care Physician (1971)
- Medical Laboratory Technician (1971)
- Specialist in Blood Bank Technology (1971)

- Medical Assistant in Pediatrics (1972)
- Operating Room Technician (1972)
- Respiratory Therapy Technician (1972)
- Urologic Physician's Assistant (1972)
- Electroencephalographic Technician (1973)
- Electroencephalographic Technologist (1973)
- Surgeon's Assistant (1974)
- Opthalmic Medical Assistant (1975)

The advantage certification may have over licensure in this area is that it is not tied to legal limits on the scope of activities. Hospitals are encouraged to hire certified personnel because of the institutional accreditation process, but they are not barred from using uncertified personnel or shifting them to new functions. The certification process appears also to be better able to shift standards in the light of changes in technology and, for both these reasons, to be more responsive to an environment of rapid technological change.

III. POLICY IMPLICATIONS

Even though the impact of state regulation on medical technology cannot be fully assured, it is clear that the potential exists for the various forms of regulation to have considerable impact. This effect will likely be felt at both the level of aggregate capital investment and the level of individual equipment and service decisions.

The regulatory modes most likely to influence the adoption and diffusion of medical technology are certificate of need and reimbursement controls. The growing emphasis on cost control, which guides their policies, places a premium on technological innovations that result in more efficient use of resources. However, these two programs, and reimbursement controls in particular, do not focus on technology policy per se, and their impact could be inadvertently and unintentionally adverse. If the appropriate development of new technology is to become a matter of public activity, then a productive and rational relationship between regulatory and technology policies will have to be developed. For this to occur, the scope of these policies, the individuals to be involved in making policy, and the technical capacity to make decisions consistent with policy will all have to be established.

Currently, there is little formal consideration of technology policy in regulation. But it is not clear what the nature of such a policy would be. There is no agreement on the current

need for new technology or its priority relative to other goals for the medical system, such as improved access to primary care. Without specific goals and objectives with respect to technology, and the integration of these goals with others, the explicit consideration of these issues in regulatory settings is impossible.

Critical in the process will be the questions of who should be involved and how should technology policy be set. This is likely to remain a decentralized process, in which individual regulatory programs preserve their right to establish their own approaches. Conflicts will occur among agencies that will be negotiated much as other current conflicts are. The processes of local policymaking and conflict resolution can be improved, however. There is a critical need for the potential decision makers to obtain much more information than they have on the nature and scope of these issues, the effect their decisions can have, the critical issues or factors that should be considered as they establish policy in their programs, and the best available objective information and analyses by advocates of various positions on the current technological orientation and needs of the American medical system.

Finally, moving from the level of policy to individual decisions, it is not at all clear that the technical capacity to make good planning, review, or investment decisions regarding the diffusion of medical technology exists within the regulatory agencies or, for that matter, elsewhere. Considerable effort will be required so that technical questions and issues of human values can be addressed by regulatory agencies, where appropriate, in logical and informed ways.

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APPENDIX G

THE COST OF CAPITAL-EMBODIED MEDICAL TECHNOLOGY*

Kenneth E. Warner

I. INTRODUCTION

Of all the problems which constitute the medical care "crisis," none receives more attention than the consistently and rapidly escalating costs of personal health services, especially those associated with hospital care. Two decades ago, health expenditures totaled less than 5 percent of the nation's Gross National Product; today, Americans devote over 8.5 percent of GNP to health. The cost of a day of hospital care grew by more than 1,000 percent from 1950 to the present, while general consumer prices rose only 125 percent. In the public sector, the health share of the federal budget has risen from half a percent 20 years ago to more than 8 percent. With consumption of services increasingly freed from direct financial liability through the vehicle of insurance, and with the supply of services functioning with only limited regulation and controls, there is no clear end in sight to the problem of medical cost inflation.[1]

*The Committee on Technology and Health Care has elected to use the prase "equipment-embodied technology." The use of the word "capital" rather than "equipment" simply reflects my personal preference. No substantive distinction is intended.

[1]The Carter administration's proposal to limit hospital cost increases represents a potentially significant initative. As noted below, some analysts believe that inflationary pressures are subsiding of their own accord (McMahon and Drake, 1976).

The search for a villain in this economic drama has included both people, most commonly physicians, and inanimate objects, especially costly and sophisticated capital equipment. The profusion of such equipment is certainly one of the dominant characteristics of modern medical care. A federal official has concluded that "the long-term cumulative effect of adopting new health care technology is a major cause of the large yearly increases in national health expenditures. . . . " (Gaus, 1976, p. 12). This conclusion derives from both theoretical reasoning and empirical evidence. The thrust of the theoretical argument, developed in the next section of this paper, is that the environment in which technology adoption and use decisions are made is relatively unconstrained by conventional economic factors and, in fact, is conducive to the adoption and use of technology. The empirical evidence comes from analyses of the causes of hospital cost inflation and from numerous individual case studies, discussed later in this paper. Both of these sources suggest that capital-embodied technology contributes significantly to medical cost increases, though no evidence places it as the principal factor, and it should be emphasized at the outset that the empirical evidence on the costs of technology is largely anecdotal and far from definitive.

The costs of medical technology are numerous and diverse in kind. I will focus principally on direct economic costs--the capital and operating costs associated with capital-embodied technologies. This means that two important categories of costs will be generally ignored.

1. Indirect economic costs consist of

(a) work productivity losses resulting from application of the technology (productivity gains would be indirect benefits) (Cooper and Rice, 1976); and

(b) the costs associated with additional medical care services consumed as an indirect result of use of the technology (ies) in question (e.g., the normal medical needs of patients cured or maintained alive who would have died in the absence of use of the technology); and the "negative costs," or benefits, of resources whose use is avoided by use of the technology in question (e.g., CT scanning substituting for pneumoencephalography).[2]

[2]These costs are included implicitly in several studies of the role of technology in health care cost inflation, particularly studies that measure technology as a residual. (These are discussed later.) However, such costs will be neither measured nor even considered explicitly in this paper.

2. Noneconomic costs are also ignored. These range from the mundane (e.g., pain) to the subtle and profound, such as: the impact of technology on encouraging physician and nurse specialization, which in turn has complex implications for the delivery of care;[3] the role of "miracle technology" in increasing the demand for care in general; a reduction in self care (e.g., good personal health practices) resulting from greater reliance on the medical care system, due to a perceived improvement in the efficacy of medical technology; the ethical costs and questions associated with artificial organs, genetic surgery, and so on.

While our knowledge of the costs of medical technology is limited, it must be emphasized that even complete knowledge of such costs would not answer the question, Do we have (or use) the "right" amounts and kinds of technology? Cost is only one side of the economic equation. The marginal cost of a technology must be compared with its marginal benefit to determine optimal usage. While this principle is frequently acknowledged, separation of consideration of benefits and costs pervades the technology literature: Medical journals are replete with analyses of the diagnostic or therapeutic benefits of technologies, with little if any attention to costs, while the health economics literature emphasizes the costs of care and too often ignores the benefits. In the present context, the importance of this is that we need to distinguish cost increases that reflect improvements in care from those that are purely inflationary, i.e., higher prices for the same care. The former may well be tolerable, even desirable, while the latter are clearly undesirable.[4,5]

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[3]Mahler (1975) argues that expensive medical technology dictates too much of the structure of care delivery systems, and that this technology is one reason that we have "medical care systems," rather than "health care systems." Illich (1975) sees technology as contributing to the "medicalization of society."

[4]The view that new technology, though costly, is responsible for saving many lives that were necessarily lost before has been referred to as the "benign theory of hospital inflation" (Davis, 1972, p. 1359).

[5]There is little doubt that there is considerable waste in the practice of medicine, e.g., inappropriate or excessive use of lab tests, whether intended (e.g., for profit or to protect against malpractice) or unintended. It has been estimated that a 10 percent improvement in medical resource utilization efficiency would save more than $5 billion (DeJong and Shaw,1975).

The essence and importance of this distinction are captured by Gaus and Cooper (1976, pp. 3-4):

> [W]e spent 4 billion dollars for new technology [for Medicare patients in 1976] and we do not know if it did any good, much less how much. . . .
> . . . If we had continued providing hospital services to the aged, as they were in 1967, then we could have spent that 4 billion dollars last year [to] . . . have
> + Brought *all* aged persons above the poverty line [with at least 3.3 million currently living below it]; or
> + Provided the rent to raise 2 million elderly from substandard to standard housing units; or
> + Brought all the elderly above the lowest accepted food budget and more; or
> + Provided eyeglasses and hearing aids to all who needed them [estimated at 18 million needing or wearing glasses and over 3 million needing hearing aids], and more.
>
> Which would have helped the most, [medical] technology or food?

The profusion of expensive and sophisticated medical technology is likely to continue for many years to come. Given the multiyear lag between the discovery and application of innovation, and the even longer lag from basic research to application, the growth years of NIH through the mid-1960's and this decade's applied research and development work augur a "technological boom" in the decade to come (DeJong and Shaw, 1975). The government's interest in this phenomenon, reflected in the work of the committee, is obvious: Under our current health care system, the government has an economic responsibility in all phases of technology and medicine, from financing the initial research and developmental work to purchasing the technology both directly (e.g., through the VA hospitals) and indirectly (e.g., Medicare). In addition, many believe that the government has a role as "protector of the public" to assure the safety and efficacy of medical technology (Office of Technology Assessment, 1977), a role which has been acknowledged legislatively at the federal level recently with the passage of the Medical Devices Amendments of 1976 (U.S. Congress, 1976).

The remaining sections of this paper examine what we know, and how we might learn more, about the pecuniary costs of capital-embodied medical technology, from both a theoretical and an empirical perspective. Section II describes the environment in which medical technology adoption and use

decisions are made, suggesting why it is often asserted that the medical system encourages excessive use of technology. The third section defines "capital-embodied medical technology" and the costs of such technology, to serve as a basis for discussion in the ensuing section. Section IV reviews the theory and practice of allocating medical care costs to capital-embodied technology and suggests future directions and data sources that might be exploited to increase our knowledge. The fifth section presents a brief summary and conclusion.

II. FACTORS INFLUENCING THE ADOPTION AND USE OF MEDICAL TECHNOLOGY

Many observers of American health care believe that there are relatively few constraints on the adoption and use of medical technology by hospitals and physicians. To the contrary, there appear to be positive inducements--both pecuniary and nonpecuniary--favoring adoption and use. As a consequence, the argument runs, we purchase and use too much technology. Furthermore, the economic and professional environment encourages the development and utilization of cost-increasing technology. In a predominantly fee-for-service system characterized by widespread insurance coverage, there are few incentives to develop or employ cost-saving technology. Understanding this environment helps to explain the concern about the excessive use of technology in medicine and the resultant costs, and it places the cost-of-technology issue in perspective as a factor in overall medical cost inflation. This section reviews both noneconomic and economic factors affecting the adoption and use of medical technology.

Noneconomic Factors

The physician, it has been claimed, is driven by a "technological imperative" instilled during medical training (Fuchs, 1973). Medical schools are showplaces of modernity, and the student's role model, the medical faculty member, is engaged in attempting to advance the scientific frontiers of medicine, owing in large part to the government's support of biomedical research and development. Thus the image of quality medicine with which a medical student leaves training is predicated on a scientific approach to problems, with modern technology constituting the instruments with which that approach is practiced. As is discussed below, the economic system does nothing to discourage the technological imperative in ordinary

practice, and indeed seems to reinforce it through relatively complete insurance coverage of the use of much medical technology. The existence of high-cost, hospital-based technology is considered a factor in the trend toward increasing physician specialization. Increasing specialization, in turn, reinforces the hospital's growing importance as a source of care. In addition, it increases the demand of physicians for still more technology (Rice and Wilson, 1975). Possession of modern, sophisticated technology confers prestige on physicians (Feldstein, 1971a; Newhouse, 1970), and it may well contribute to their economic well-being (Pauly and Redisch, 1973).

The lay public seems to share the physicians' fascination with technology. We ". . . often look to [technology] to solve problems when less expensive solutions lie elsewhere. This may be particularly true of health care" (Fuchs, 1973, p. 58). Growing faith in the power of science in general and curative medicine in particular accelerates the demand for technologically advanced methods of care (Feldstein, 1971b).

Physicians' and the public's technology orientations influence the decision making of hospital administrators. It is commonly asserted that administrators acquire sophisticated capital equipment and facilities in order to attract and hold high caliber physicians on their staffs (e.g., Davis, 1972; Muller and Worthington, 1970). A recent study found evidence to support this assertion (Abt, 1975).[6] In addition to using technology to compete for staff positions, "administrators themselves derive utility from having the best equipped and most modern facilities" (Davis, 1972, p. 1358).

In the role of the patient's demand agent, the physician is obligated by the "social contract" to provide the "best possible care" (Arrow, 1963). In medically desperate situations,

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[6]Some observers argue that equipment acquisition decisions, though formally lodged in the administrator's office, reside in fact with medical department chiefs, and that "The operational reality resulting from the physician's policy control has been a physician dominance of the resource allocation function. Consequently hospital investments are primarily evaluated along medical dimensions: rarely are economic considerations integrated into the investment evaluation function (Lusk, quoted in Dittman and Ofer, 1976, p. 27). Of course, the *ability* of physicians to make resource allocation decisions with only limited attention to economic considerations is a function of the permissive economic environment discussed below.

this implies using the technically best therapy that is available. This may lead to very early adoption and diffusion of a technological innovation (Warner, 1975), though diffusion of an unproven medical technology is not restricted to medical crisis situations (Altman and Eichenholz, 1976; Gaus, 1976; Gaus and Cooper, 1976). Early and extensive diffusion is encouraged by medicine's protreatment bias and a permissive economic environment.

Obviously there is a wide array of innovations from which to choose, due in part to the heavily governmentally subsidized biomedical R&D sector (especially NIH). The direct federal contribution to applied research and developmental work in the medical equipment area is small though growing--most of such R&D is funded by private industry--but for decades basic research has been the ward of the state. This research has contributed both directly and indirectly to the pool of medical technology.

Governmental involvement in the medical technology arena can promote the development and diffusion of capital equipment, as does its support of research, but it can also restrict equipment production and use, principally through regulatory policies. Regulation is alternately viewed as a means of compensating for the unorthodox economic environment in which technology adoption and use decisions are made, or as a mechanism to protect the public against ignorant or unscrupulous users of technology. In some instances, regulation is consciously directed toward limiting the spread of "unnecessary" equipment (for example, certificate of need); in others, the objective is assuring high-quality equipment and its appropriate use (e.g., FDA's new medical device regulation [U.S. Congress, 1976]).

The effects of regulation on technology adoption and use are uncertain, though the available evidence is not encouraging: Where regulation is intended to limit the spread of medical capital, it appears to be reasonably ineffective. For example, where certificate of need has succeeded in limiting growth in hospital bed supply, purchase of other equipment has increased, resulting in no overall savings in capital expenditures (Salkever and Bice, 1976).[7] In contrast, the new medical device regulation procedures, which are intended only to assure the safety and efficacy of medical services, have raised the fear that "overregulation" will stifle entrepreneurial initiative and thus reduce the discovery and production of new safe and efficacious devices.

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[7]The capital purchase (CAP) proposed in the administration's cost-containment bill would be expected to have a significant effect on capital expenditures in the future.

It has been argued that FDA's regulation of drugs, on which the device procedures are modeled, has had a deleterious effect on drug R&D (Peltzman, 1974; Grabowski, 1976).

With the possible exception of the regulatory mechanisms, the above forces combine to produce a noneconomic environment that is favorably disposed to the adoption and use of modern, sophisticated technology. For a variety of reasons, both economic and noneconomic, such technological change seems biased toward the cost-increasing variety (Feldstein, 1971b).

Economic Factors

The economic environment of medical care provides some positive incentives and few disincentives to adopt and use technology. Beginning with the subsidization of research and development, the government pumps considerable money into medical schools and elsewhere to encourage the development of new knowledge and technical innovations.

But the most salient feature of the medical technology market is the mixture of the seller's profit incentive (e.g., device manufacturers) and the buyer's relatively unconstrained position. For hospitals operating on a cost or cost-plus reimbursement basis, "A quality-enhancing or service-expanding project looks just as good as a cost reducing project in terms of the resulting cash inflow from . . . reimbursement of depreciation charges" (Silvers, 1974, p. 294). In short, there is no economic incentive to adopt resource-saving technology, at the same time that the noneconomic forces favor adoption of sophisticated and generally costly equipment.[8] Some observers even argue

[8]Given this intuitively appealing logic, it is interesting that studies of the role of cost-based reimbursement have not found it to be a significant contributor to overall hospital inflation. The methodology of some of these studies leaves their findings open to question. For example, Pauly and Drake (1970) simply used a dummy variable to indicate hospitals that were in states in which Blue Cross reimbursed on the basis of costs, thus ignoring the proportion of costs covered by such a reimbursement scheme. Davis (1973) used a measure that captured the proportion. She did not find that cost reimbursement influenced costs within the range of proportions studied. However, she did observe significant increases in average costs in the Medicare period. While Davis proposed alternative explanations, she did not effectively rule out the influence of reimbursement.

that the availability of financing governs the rate of adoption of high-cost technology, with the technology's medical efficacy being of secondary importance (Rice and Wilson, 1975), as may be demand or costs (Ginsburg, 1972).

Hospitals acquire capital through a number of mechanisms, including private philanthropy and government grants, borrowing, and internal generation of equity capital. None of these forces hospitals "to experience the real discipline of the capital markets" (Silvers, 1974, p. 304). Philanthropy and grants provide "free" working capital; however, this source of funds, which once dominated capital budgets, now accounts for only 10 percent of hospitals' capital. Borrowing ability has been enhanced significantly by the tax-exempt status of many bond issues and by the safety factory associated with guaranteed reimbursement through major third parties. Nearly two-thirds of hospital capital funds is now derived from borrowing. Rate controls, inflation, and the limitation of cost-reimbursement to eligible costs have restricted the internal generation of equity funds (Blume, 1976).

The use of funds to acquire equipment and facilities has been aided by a growing trend toward leasing, which "can serve as a hedge against obsolescence, and . . . affords the hospital greater flexibility in replacing its equipment" (Ofer, 1976, p. 51).[9] But whether through leasing or purchase, hospitals have incentives to overinvest: If interest payments are reimbursed, the effective interest cost to buyers is lower than the true interest. Thus more marginal projects may look acceptable to the purchasers. Also, frequent upgrading of existing services and addition of new ones gives providers greater leeway in the allocation of overhead. Most cost-based reimbursement schemes probably allow considerable latitude in this area (Silvers, 1974).

For the consumer, increasing insurance coverage and affluence have significantly reduced the real direct (or out-of-pocket) cost of much medical care, especially that provided in hospitals.[10] Feldstein (1971b, 1977) sees insurance as having

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[9]For many kinds of medical equipment, obsolescence rates appear to run 5 to 8 years (Abt, 1975).

[10]Patients now pay less than one-eighth of the average hospital bill directly, compared with one-half in the early 1950's. In addition, increases in real income over the period mean that patients must now work fewer hours to pay the direct cost of a day of hospital care (Feldstein and Taylor, 1977).

increased the demand for care, particularly for "style" and "high quality." The hospital administrator's response has been "improvements," including the acquisition of fancy technology, which have driven costs up. Completing the circle is the consumer's response to the higher costs--namely, to buy more insurance. "Thus as third party payment has increased over the years, the benefit required to justify a decision in the eyes of doctors and patients has declined. This has led to increased use of resources in all sorts of ways--including the introduction of technologies that otherwise might not have been adopted at all and, more often, the more rapid and extensive diffusion of technologies that had already been adopted to some extent. . . ." (Russell, 1977, p. 3.) Empirical findings are becoming available that provide evidence that the ability of patients to pay for services, and not simply illness and need, influences the complexity of hospital care (Abt, 1975). (See also Russell, forthcoming.)

Finally, the efforts of suppliers of medical technology can be credited in part with what some perceive to be rapid and indiscriminate adoption of technologies (Fuchs, 1973). While the purchasers of technology operate with limited and certainly unorthodox economic constraints, most of the sellers are conventional profit-seeking firms.[11] The situation is not unlike (though not identical to) that of fee-for-service physicians and their patients. It is often claimed that fee-for-service physicians overutilize tests and other services, frequently involving capital-embodied technology, because they will produce profit for the physicians while not (directly) affecting well-insured patients.

"In short, when those making the decisions pay none of the cost, resources are used as though they cost nothing" (Russell, 1976c, p. 3). The unusual financing relationships that define an economic transaction in medicine have been the subject of many studies, though relatively few have focused on the area of expensive capital equipment, where the potential impact seems especially great. All of the elements come together here to

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[11]The profit potential of the medical market is suggested by the fact that pharmaceutical companies spend over $4,000 per year per physician in advertising and promoting their products (Fuchs, 1974). Producers of scientific and medical instruments spend on advertising an amount equal to about 2.5 percent of sales, compared with an average rate of 1.4 percent for all manufacturing corporations. While the technical or marketing complexity of scientific equipment might require greater advertising, the figures are suggestive of high profit potential (Peterson and MacPhee, 1973).

produce a situation in which the binding constraint may be the state of the art, i.e., the technology itself, and not, as elsewhere, considerations of all costs and benefits. "[T]he present system allows expenditure, especially for hospital care, to be made for little or no return, when the fact that the resources available to the economy as a whole are limited forces expenditure on goods and services other than medical care to meet a higher standard. Given the concern about the effects of life style and environment, this does not make sense even if our only goal was to improve the health of the population" (Russell, 1977, p. 9).

III. DEFINITIONS AND CONCEPTS

In order to discuss the allocation of medical costs to capital-embodied technologies, we must define terms more precisely. As this section will suggest, the need for definitions reflects the somewhat arbitrary distinctions created by separating "capital-embodied" technology from all technology and the costs of the former from all operating and capital costs. It is obvious from the Charge to the Committee (memorandum of September 29, 1976) that the Committee acknowledges these distinctions. This section should clarify their importance.

Capital-Embodied Medical Technology

A technology is a defined configuration of inputs used to produce a specified output, either a physical good or a service. Thus a medical technology is a configuration of inputs used to produce a specified medical output. A medical technology may be as simple as a nurse's taking a patient's temperature, or it may be as complex as the combination of surgical specialists, nurse specialists, technicians, supplies, sophisticated equipment, and surgical suite used to perform open-heart surgery. In general, medical technologies may be classified by their physical nature[12] or by their medical purpose.[13]

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[12]Congress's Office of Technology Assessment identifies technique (the action of a provider without specialized equipment), drug, equipment (machines and smaller devices and instruments), and procedure (a combination of technique with drugs and/or equipment) (Office of Technology Assessment, 1976b).

[13]For example, preventive (or health maintenance), diagnostic, therapeutic, rehabilitative, organizational (management and administration), and supportive (Behney, 1976; Office of Technology Assessment, 1976b).

A capital-embodied medical technology is a medical technology that utilizes, as one of its principal inputs, the services of one or more pieces of capital equipment. Capital equipment refers to durable items that were not consumed in one (or a few) use(s), but rather that provide services over an extended period of time. This can include anything from a pencil sharpener to a computer. In most instances in what follows, I will be using the term to refer to reasonably expensive, major items. (Obviously, to develop an operational definition one would have to define the minimum cost, quantity, durability, and so on.)

One might justify the distinction between capital-embodied and other technology, or between expensive major capital equipment and other capital equipment, simply on the grounds of public or medical interest. For example, the CT scanner has created quite a sensation among the lay public, as well as within the medical profession. Perhaps that interest is sufficient to warrant an independent consideration of this innovative technology. However, other than the interest factor, the relevance, or nonarbitrariness, of making definitional distinctions between, for example, "major" and "minor" capital equipment must reside in either (a) a technical difference in the circumstances under which major and minor capital equipment are produced, distributed, used, or paid for; or (b) differences as to how such equipment is treated under the law. There is little evidence on the former. However, there are legal distinctions in that, for example, some certificate-of-need laws apply only to equipment or facilities costing more than a specified amount (e.g., $100,000). Otherwise, the distinction remains arbitrary, and it will introduce difficulties in cost analysis, as described in the next section.

The Cost of Capital-Embodied Medical Technology

The first and most sensational cost of much medical technology is the capital cost. However, it is generally agreed, and empirical evidence demonstrates, that the most significant costs of major capital equipment derive from the ancillary personnel and supplies needed to use the equipment (e.g., Abt, 1975; Ginsburg, 1976). Much new medical capital technology is not labor-saving; to the contrary, it creates the need for additional and often specialized technicians and nurses. Thus the true direct costs of a major piece of capital equipment are its fixed (capital) costs (and associated financing costs) plus maintenance and the variable costs associated with its use. This is implicit in referring to "capital-embodied medical

technology" rather than just to capital equipment: The latter is simply one component of the technology, one that is useless in the absence of the other variable inputs.

The problem in measuring the true costs lies in defining the technology in a systematic and meaningful manner. Is "radiotherapy" limited to the actual administration of radiation, or does the technology of radiation therapy include the supportive services that precede and follow the irradiation? Where are the lines drawn? This question is central to identifying the direct costs of medical capital-embodied technology. As is discussed below, narrowly construed, capital-embodied technology probably does not impose a sizable cost burden on the medical care system; broadly construed--that is, to include all services and procedures that have a significant link with the use of capital or with another procedure dependent on capital--such technology is probably enormously expensive. A theoretical resolution of the problem is to ask what would have happened to the patient in the absence of the capital-based technology, and then to compare the costs associated with that hypothetical management of the case with that which actually occurs. The difference would be a measure of the direct costs of the capital-embodied technology. The difficulty in making this concept operational is one reason why so little empirical work has been attempted along these lines. It is important to recognize, however, that even if the concept could be translated into effective quantification, it would miss some subtle factors that should be included in a measure of the costs of the technology; for example, the case mix may have changed in response to the existence of the technology (Rice and Wilson, 1975); or there may be more cases amenable to treatment by the new technology than would have been identified in the absence of the technology.[14]

It is also important to distinguish three sources of high cost due to technology. One is simply the existence of a high-cost technology that also produces a significant benefit. Here, the question of the desirability of the technology is one of comparing benefit and cost. A second source is excessive use of the technology. A technology with a cost-reducing potential (e.g., it substitutes for a technology that is more costly on a unit or per-use basis) may actually increase costs because it is used so often. The third source has frequently been identified as an important inefficiency in medicine: excess capacity or underutilization of expensive technology.

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[14]For example, the existence of the CT scanner may significantly alter the amount, timing, and possibly nature of brain surgery.

In its study of Boston area hospitals, Abt (1975) found 50-60 percent of capacity utilization of autoanalyzers, diagnostic X-ray machines, and patient monitors. A 1972 survey found that 62 percent of hospitals equipped with open-heart surgery facilities did fewer than 100 operations annually (Roche and Stengle, 1973), while a professional Surgery Study Group had recommended 200 procedures as the minimum number necessary for surgical teams to maintain their skills. In 1967, 31 percent of equipped hospitals had not used their open-heart facilities for at least a year (U.S. DHEW, 1971). The cost of underutilization is suggested by the estimate that the short-run cost of maintaining an unused hospital bed is roughly two-thirds the cost of an occupied bed (Altman and Eichenholz, 1976). A potentially significant cost of excess capacity may be the added incentive to use the underutilized technology in more marginal or questionable cases.[15]

Finally, to repeat, an analysis of the direct costs associated with the technology will miss numerous indirect costs resulting from the availability and use of the technology. The latter could conceivably have a much more significant economic and/or social impact.

Technology's Costs and Its Contribution to Cost Inflation

A final distinction is between the costs associated with the stock of capital equipment--e.g., the equipment in use during 1977--and changes over time in the costs of medical care resulting from additions to and changes in the nature of the stock of equipment. An understanding of this distinction and separate measurement of these different costs are essential to sound policymaking. If it were learned that the existing stock of capital equipment does not impose unreasonable cost burdens, but the flow into the system appeared to be an excessive rate, policy should focus on research and devlopment and the diffusion of innovations (e.g., through biomedical R&D funding, FDA certification of devices, etc.). If by contrast

[15]In many instances, "excess" capacity may be justified on the basis of option demand. That is, we are willing to pay a price (i.e., the costs of unutilized capacity) in exchange for the certainty of the ready availability of the technology whenever it might be needed. While option demand is a legitimate basis for unused capacity, the amount of excess capacity often documented considerably exceeds that which option demand would recommend.

the stock of capital equipment seemed to be contributing excessively to the current costs of care, while the rate of change in the stock was low or moderate, policy might more profitably focus on the use end of the spectrum (e.g., on reimbursement policies). In the remainder of the paper, I will consider both the costs of technology and technology's contribution to inflation, though the reader should be forewarned that, as a reviewer of the literature, I will be unable to draw confident conclusions about either.

IV. ALLOCATING MEDICAL CARE COSTS TO CAPITAL-EMBODIED TECHNOLOGY

The preceding section discussed both conceptual approaches to and problems in allocating medical costs to capital-embodied technology. The first subsection below will extend that discussion by considering methods of measuring costs, with the next subsection presenting the results of attempts at such measurement.

Methods of Measuring Costs

Case Studies.

The first and most obvious approach to measuring the costs of a capital-embodied medical technology is to undertake a case study focusing on a specific technology. A capital-embodied technology is identified and its components defined precisely. The actual costs of inputs are then measured, including reasonable allocations for depreciation, imputed prices where necessary, and so on. These are then summed and, ideally, compared with the costs that would have been incurred in the absence of the technology (i.e., using the best alternative technology, if any.[16] While this approach may yield excellent estimates of the cost of a given technology, it does not (inherently) permit generalizations or conclusions about the overall cost of capital-embodied technology.[17] One must be wary not only

[16]If benefits from the two technologies differ, they too need to be compared. A benefit-cost or cost-effectiveness analysis might be performed.

[17]If sufficient uniformity emerged from numerous case studies, one might draw inferences of a larger or more general nature. This is considered in the discussion of the next method and is done, illustratively, later in the paper.

of the quality of the studies, but also of the possibility of selection bias.

A second case study approach involves adopting treatment of a specified illness as the basis of analysis, rather than beginning with the technology. Here it is assumed that the output (outcome) remains constant, and variations over time in the costs of treatment are measured. Assuming that the treatment in question has a significant capital input, this approach has the appealing logic of defining a technology by a health outcome. The method is expensive, and again it suffers from the usual limitations of case studies (Scitovsky and McCall, 1975).

A third approach is similar to the first two, though it attempts to introduce broader coverage of hospital (or medical) activities. "Capital technology" is defined (for example, all pieces of equipment with a capital cost greater than or equal to $100,000) and then analysts specify all related capital-embodied technologies. These are then costed-out in a (rather heoric) manner analogous to that of the first approach. Alternatively, one might focus on a capital-intensive department or unit (e.g., radiology) and simply modify its budget appropriately, attempting to link inputs to specific services.

Estimation Based on Case Studies.

A second method combines the first and third case study approaches to produce a rough estimate of the systemwide costs of capital-embodied technology. As in the preceding approach, capital technology is defined and then the budgets of a representative sample of hospitals are studied to determine direct expenditures on such capital. Rather than attempting to specify the precise production functions, the analyst applies a multiplier to the capital costs, where the multiplier is derived from case studies of the first type. That is, suppose that examination of numerous case studies of individual capital-embodied technologies suggests that the average ratio of total costs to the capital costs alone equals 3. Then the representative hospital's direct expenditure on capital can be multiplied by 3 to estimate the costs of capital-embodied technologies.

Obviously this method can provide no more than a ballpark estimate of the desired figure, but in so doing it offers a glimpse of the order of magnitude of the cost of technology. Clearly the credibility of the method depends on the quality and variability of the findings of the case studies.

Proxy Methods

The great difficulty in finding a systematic approach to answering the question, what are the total direct costs of capital-embodied technology, reflects the lack of a direct measure of "technology" with which one could isolate technology's costs from other medical costs (Davis, 1974). Several researchers have attempted to estimate the total "technology effect" by use of proxies. One approach is to include time in an econometric analysis of inflation in the cost of hospital care, where time is interpreted as representing technological change (Davis, 1974).[18] While this may provide order-of-magnitude estimates, time can also capture several other factors (Wagner and Zubkoff, forthcoming). In addition, this approach is not intended to distinguish capital-embodied from other technology.

A similar problem arises in another technique that has been misinterpreted as providing an estimate of the contribution of technology to inflation. The cost effect of increases in nonlabor input intensity can be established by controlling hospital inflation for unit price increases (wages and nonlabor prices) and the quantity of labor. The residual is the effect of increasing nonlabor inputs (Feldstein, 1971b; Waldman, 1972). While this is quite substantial, nonlabor inputs include nondurables and low-cost capital and exclude the labor associated with capital-based technologies. As such, this bears no relationship to the effect of capital-embodied technology on costs. This is discussed further below.

Empirical Cost Studies

The empirical evidence makes it clear that "if major movable . . . equipment constitutes an important source of hospital cost inflation, it must be because of the complementary inputs required to operate and service it, for total equipment purchases amount to less than five percent of hospital costs on the average" (Abt, 1975, p. 9). Ginsburg (1976, p. 174) echoes this theme: "[I]nterest and depreciation are a small part of hospital costs and cannot be considered an important cause of cost increases directly. However the indirect effects may be substantial."

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[18]The inclusion of time as a proxy for technological change is a common if not universally accepted practice in economic studies of productivity growth.

Case Studies

The importance of the noncapital costs of capital-embodied technologies emerges clearly from numerous case studies, despite the fact that few of these carefully examine all of the variable costs associated with use of the capital equipment. An instance in which it is relatively easy to measure operating costs occurs when "the technology" is a hospital unit; for example, coronary care units (CCU's). Bloom and Peterson (1973) report that the costs of building and equipping all of the CCU's in Vermont, New Hampshire, Massachusetts, and Rhode Island in 1970 was $3.7 million, but the annual operating cost of these units was $6.4 million.[19] Russell's (1976a) study of intensive care units (ICU's) found that the capital costs of equipping the units could be relatively small (as little as $2,000 per bed in the late 1960's[20]), but ICU beds' operating costs run 3 times those of ward beds. With ICU and CCU beds totaling 5 percent of all short-stay hospital beds in 1975, approximately 15 percent of 1975 hospital costs can be attributed to intensive care. Two-thirds of that total represents an excess over what would have been necessary to maintain the same number of ward beds. Given the questionable value of intensive care for many patients (Gellman, 1971; Mather *et al.*, 1971), one must ask how much of that additional expense was necessary.

The rapid diffusion of CT scanners provides a classic example of the medical profession's ability to quickly adopt an expensive new technology of unproven value. Undoubtedly a significant technical breakthrough in diagnostic capability, the scanner's potential effects on human health are unestablished.[21] The effects on human wealth are becoming quite clear. In 1975, $150 million worth of CT equipment was ordered or installed in the United States. The purchase

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[19]Bloom and Peterson also observe that half of the patients in the CCU's had not had myocardial infarctions and were low-risk patients.

[20]In practice, per-bed costs at times often ran 4 or more times greater than the $2,000.

[21]While earlier, more accurate diagnosis might lead to decreases in mortality or morbidity, it might produce increases, e.g., by promoting risky surgery.

price of a scanner is in the vicinity of half a million dollars. Operating costs are estimated at an average of $300,000 to $400,000 per year. The costs of excess capacity, which already seems to exist in several major metropolitan areas, is illustrated by a calculation that an increase from 40 to 80 examinations per week--i.e., a doubling of the number of patients--increases total costs only 14 percent (Office of Technology Assessment, 1976a).

Other case studies suggest staggering costs associated with single technologies. The Public Health Service projected that the fifteenth year costs of kidney disease treatment would equal roughly 4 percent of all U.S. health service costs (Gellman, 1971). We currently spend over 12 percent of the nation's health dollars on clinical laboratory services, some $15 billion in 1975 (Banta and McNeil, 1977). X-ray services cost almost $5 billion in the same year (Office of Technology Assessment, 1976b). In 1970 there were some 17 million skull X rays (from a total of 4.2 million examinations, each having multiple films) at a cost in excess of $120 million. This is a procedure generally of dubious value, which is often performed solely to protect against malpractice charges (Office of Technology Assessment, 1977).[22] Electronic fetal monitoring adds $35 to $75 to the cost of a delivery. Thus, electronically monitoring all deliveries would cost over $200 million. This estimate ignores the costs, both monetary and otherwise, of the additional caesarian sections that result from electronic monitoring (Office of Technology Assessment, 1977).[23]

If operations are included in the category of capital-embodied technology (due to the capital equipment in operating rooms), then some common surgeries of unclear necessity add immensely to the costs of technology. Every student of medical care is familiar with the current debate on unnecessary surgery (Committee on Interstate and Foreign Commerce, 1976) and the link between the supply of surgeons and the amount of surgery that is performed (Bunker, 1970). Most experts believe that hundreds of thousands of tonsillectomies and hysterectomies are done needlessly each year, with the attendant risks to the patients. Over $350 million is spent annually on

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[22]The monetary cost implications are obvious. In addition, unnecessary X rays subject patients to unnecessary radiation dangers.

[23]The benefits of electronic fetal monitoring are unestablished. The most certain consequence has been a sizable increase in the number of caesarian sections.

appendectomies; yet recent evidence is causing clinical researchers to question the necessity of this standard operation (Office of Technology Assessment, 1977). The effects of coronary artery bypass surgery are uncertain;[24] but Americans spent over $650 million on this surgery last year, at more than $10,000 per operation. A proponent of the procedure argues that the United States should prepare to do 80,000 coronary arteriograms a day to screen for coronary disease. The national bill for such a screening program would come to more than $10 billion a year (Office of Technology Assessment, 1977). If, as has been predicted, coronary artery bypass surgery becomes the most common surgery in the United States, with approximately 700,000 operations per year, the annual cost of this procedure would total over $7 billion (Neuhauser and Jonsson, 1974).

In one of the few studies to systematically examine the costs associated with several major pieces of hospital capital equipment,[25] Abt Associates concluded that it is the capital's complementary inputs, such as labor and supplies, which contribute most significantly to hospital cost inflation. Total equipment purchases per se accounted for less than one-twentieth of hospital costs. However Abt did observe that total equipment expenditures had risen 23 percent per year from the mid-1960's through the mid-1970's. Thus, "Weighting this percentage by the percent of equipment in total costs, [they] estimate the direct contribution of equipment expenditures to hospital per diem cost inflation at 1.15 percentage points. The per diem cost inflation in [their] sample of 15 Boston hospitals was 13.4 percent per annum over the same time period, implying that *the direct contribution of the growing equipment-intensity of service provision to inflation was on the order of nine percent* (*1.15/13.4*)" (Abt, 1975, pp. 9-10).

This is probably the most systematic direct estimate of the contribution of capital cost to hospital inflation, but it ignores those "complementary inputs" that convert a piece of equipment into a usuable component of a technology. In

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[24]The surgery seems to reduce angina pectoris, but this might be a placebo effect. Through an unorthodox controlled clinical trial, a placebo effect was established in the 1950's for mammary artery ligation (Neuhauser and Jonsson, 1974).

[25]These were: cardiac catheter labs, automated blood analyzers, patient monitors, diagnostic X-ray machines, computers, and dishwashers.

addition, as the authors observe, their sample of Boston hospitals had a disproportionately large number of teaching hospitals, which tend to purchase more capital equipment than nonteaching hospitals. Hence the above estimate likely overstates the contribution of equipment purchases to inflation nationally.

Proxy Measures in Studies of Hospital Cost Inflation

Employing a variety of proxies for technology, scholars who have studied hospital cost inflation attribute anywhere from 30 to 50 percent of that inflation to technology. It should be noted at the outset of this discussion that there is much confusion in the interpretation of the findings by proxy, and, while 50 percent would seem to provide a high upper bound, the true contribution of technology to inflation, particularly high-cost technology, may be less than the "low" estimate of 30 percent; clearly the contribution of expensive capital-embodied technology must be less than the total effect of technology.

The upper-bound, or 50 percent, estimates are based on the studies that break up hospital cost inflation into labor and nonlabor components and price and quantity components within each of those (e.g., Feldstein, 1971b; Waldman, 1972). Over the last two and half decades hospital wage rates have risen rapidly, hospital employment less so. Assuming that the Consumer or Wholesale Price Index adequately reflects the prices of nonlabor inputs in hospitals, the quantities of nonlabor inputs have been increasing rapidly. Overall, changes in hospital input prices account for slightly more than half the rise in hospital costs, with the remainder representing additional quantities of old and new equipment, supplies, and labor. Gaus and Cooper (1976, p. 1) have labeled this "essentially the 'technology factor'." Others have picked up on such evidence, and interpretations of it, to echo the conclusion that nearly half of recent hospital cost increases is due directly or indirectly to medical technology (Office of Technology Assessment, 1976b). However, the only conclusion warranted by these data is a tautological restatement of what was calculated: Half of hospital cost increases has been due to unit price increases; the other half represents increases in the quantities of inputs. Much of the latter might simply

reflect changes in tastes or attitudes or behavior--changes in demand.[26]

Other estimates of the "technology factor" place technology's role in cost inflation between 30 and 40 percent. For the early Medicare period of 1968 through 1971, Redisch (1974) claims to explain 39 percent of the rise in operating cost per adjusted patient day, and 42 percent of the rise in operating cost per adjusted admission, as the result of "explosive growth" in a handful of physician-controlled medical services: pathology tests, nuclear medicine procedures, anesthesiology, pharmacy items, lab tests (inpatient and outpatient), radiology procedures (inpatient and outpatient), therapeutic radiology procedures, and blood bank units drawn.[27] Davis (1974) uses time as a proxy for technological change in a study of cost increases from 1962 through 1968 in approximately 200 private, nonprofit hospitals. She suggests that her finding of a 2 percent increase in cost per year, controlling for demand and supply variables, is a reasonable upper limit on the effect of technological change. This translates into 38 percent of the predicted increase in expenses per admission. While plausible, Davis' upper limit argument is not entirely convincing (Wagner and Zubkoff, forthcoming).

In another study, Baron (1974) estimates that technology and case mix changes, together, account for 35 percent of the cost increase in adjusted patient days and 30 percent in adjusted admissions. Baron's contribution is to acknowledge the change in case mix that, while potentially occurring all the time, appears to have shifted significantly with the advent of Medicare and Medicaid. Unfortunately, he did not separate the technology and case mix factors.

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[26]Strictly speaking, this can legitimately be considered an increase in technology, if technology is defined simply to be inputs producing medical services. However, given the context of the word "technology" in this paper and in most current discussions on the topic, the 50 percent residual in cost inflation after controlling for unit prices should not be labeled the "technology factor."

[27]While Redisch's regressions do indicate that growth in these services was a significant factor, his attribution of all the explained variance to the service variables is unwarranted. His equations also include highly significant time dummy variables.

In general, hospital cost inflation studies single out increasing demand, promoted by growing insurance coverage, as the most important factor in inflation. Wage catch-up in the hospital industry through the decade of the 1960's certainly influenced inflation, but in no way can it be considered "the" explanation (Feldstein and Taylor, 1977); and as noted above, the cost-plus reimbursement theory of inflation has received little support. While all of the major studies give credence to the demand-pull theory, it should be recognized that the nature of the demand increases is more complex than that which is normally construed as demand-pull. For example, Redisch's (1974) conclusion, that a significant amount of the inflation rate can be explained by increases in the utilization of physician-controlled medical services, suggests that *physicians'* demands may have been pulling costs up, and not simply patients' demands.

The importance of recognizing the significance of demand is to distinguish those increases in input intensity that simply reflect increases in demand from those that represent technological change. Much of the concern with the costs of technology seems to focus conceptually on the latter, while alarm appears to derive in part from erroneously attributing both sources of actual cost increases to technological change. The obvious policy significance is that demand-induced inflation may require a different policy approach than inflation produced primarily by technological change.

Toward an Estimate of the Costs of Capital-Embodied Technology

None of the inflation-based studies distinguishes capital-embodied from other technology; and none definitively captures technology alone. With the exception of the Abt study, no research has attempted to examine the costs of capital-embodied technology beyond the case study level, and the Abt findings relate only to the costs of expensive capital equipment in a non-representative sample of hospitals. However, the literature reviewed above permits some tentative conclusions, or guesstimates, as to the costs of capital-embodied medical technology. Based on the case studies (and recognizing the potential hazards of their nonrandom method of selection), we can assume that on average the operating (variable) costs associated with capital-embodied technologies at least equal and probably exceed the capital cost by a factor of 2, 3, or more. Using as a base Abt's estimate of the direct contribution of high-cost equipment expenditures to hospital cost inflation (8.58 percent), this suggests that, in the Boston area, capital-embodied technology may have accounted for between 17 percent and 34 percent of hospital

cost inflation in recent years, at least in the hospitals sampled by Abt. However, as these hospitals are disproportionately involved in medical education,[31] and teaching hospitals consume more capital equipment than nonteaching hospitals, these estimates should be reduced if they are to represent the situation nationwide. While it is no more than an educated guess, I would therefore place the contribution of expensive capital-embodied technology to hospital cost inflation at less than a quarter, quite possibly considerably less. In any event, the procedure for estimating the contribution seems reasonable. All that is needed are data comparable to those Abt derived, but based on a representative sample of hospitals. A more systematic review of the case study literature might refine one's sense of the variable cost: fixed cost ratio.

The cost of capital-embodied technology in a given year could be established in a similar manner. First one would need to determine capital expenses per year for major equipment and then this figure would be multiplied by 1 plus the variable-to-fixed cost ratio. Needless to say, determination of the latter is central to the overall estimation, and the ratio is clearly sensitive to how broadly technology is defined. Based on Abt's findings that the rate of growth in capital inputs exceeds the rate of growth of other inputs, the cost of capital-embodied technology in a given year, as a percent of total cost, should be less than the percentage contribution of such technology to inflation.

The conceptual work and data needed for further analysis are suggested above. Once concepts are agreed upon, data acquisition becomes simply a cost-accounting exercise, with analysts turning to actual hospital budgets to procure representative figures. A few states have good uniform accounting systems that might yield satisfactory numbers (e.g., California, Massachusetts, New Jersey, New York, Washington). In order to determine whether or not they will reimburse for particular capital items, rate-setting commissions in at least three states (Washington, Connecticut, and New York) consider the noncapital costs related to equipment purchases (Gaus and Cooper, 1976). Their cost-impact studies might provide useful data and suggest methodological approaches to performing analysis. Examination of the data in other centralized systems might be fruitful, though few of these will be representative of national patterns of medical care (e.g., the

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[31] Over half of the sample are teaching hospitals, while nationally only about 10 percent of hospitals are affiliated with medical schools.

Veterans Administration hospitals or Kaiser). A few public sources could be explored (e.g., the "Guide Issue" of *Hospitals*), though data in these are generally reasonably crude. Other potentially interesting sources of information include the manufacturers of medical capital equipment and federal funders of technology R&D. And, of course, analysts would have to scrutinize the case study literature to determine a reasonable multiplier.

The perplexing problem is the starting point: conceptually and operationally defining "capital-embodied technology." This requires defining capital equipment in a meaningful way (e.g., choosing a capital cost minimum that corresponds to a legal requirement, such as certificate of need) and specifying boundaries as to what constitutes a technology that is capital-embodied. Loosely defined, capital-embodied technology could encompass almost all of medicine; narrowly defined, it might be restricted to 6 or 7 percent of medical costs. The difficulty in arriving at an acceptable definition relates to the arbitrariness of distinguishing capital-embodied from other technology. While there may be a structural reason to make such a distinction--for example, concern with equipment and facilities subject to certificate of need--there is no obvious logical reason.

V. SUMMARY AND CONCLUSION

To date, social policy with respect to medical technology has been fragmented and piecemeal, a reflection of the evolution of our medical care system. The perception of the need for a unified policy reflects either a belief that there is something fundamental that distinguishes capital-embodied technology from other facets of care, or else a frustrated acceptance of the inevitability of an incrementalist approach to contolling the system, combined with a belief that capital equipment is responsible for considerable medical cost inflation. As Wagner and Zubkoff observe (forthcoming, p. 6), "To the extent that the tendency to overinvest in and overuse sophisticated services is just a part of a larger tendency to overuse health services or to invest too many labor or nonlabor resources in the production of hospital services, the problem is not related to technology itself and should not be singled out as a technology problem." This is a perception which warrants serious consideration by policymakers.

The literature sheds little light on the quantitative cost importance of capital-embodied technology; neither does it answer the question of whether the tendency to overinvest in and overuse sophisticated services is qualitatively distinct from a similar

general tendency in the provision and consumption of medical care. However, an assimilation of the numerous case studies (tempered by an awareness of selection bias) can be combined with the analysis of more general studies to draw some tentative conclusions:

- The high costs associated with capital-embodied technology result principally from the ancillary personnel and supplies required to use the capital equipment. These variable costs, which may include specialized labor (nurses or technicians), run from 1 to 3 or more times capital costs.
- Adoption and use of capital-embodied technology is probably a significant though not primary cause of hospital cost inflation. A methodology was suggested as to how one might estimate both the current cost of such technology and its contribution to inflation. For high-cost equipment, as a guesstimate I place the latter at less than 25 percent of the annual hospital inflation rate. The former would appear to be smaller still.
- The failure of the literature to deal directly and thoroughly with capital-embodied technology reflects the difficulty of defining medical production functions in a uniquely meaningful way. The same problem arises in considering medical technology more generically. In part, this difficulty suggests an arbitrary element in defining and distinguishing these terms.
- The true social cost of a capital-embodied technology, or of any medical care, cannot be evaluated in an output vacuum. That is, lacking knowledge of the benefits derived from a technology, one cannot determine whether the technology's costs are purely inflationary or whether they represent a "good buy," producing a benefit of at least comparable magnitude. Still, theory suggests the existence of strong incentives in the existing medical care system for overutilization of technology; case studies seem to confirm significant and widespread instances of this.
- There are reasons to anticipate continuation of a "technology boom." Given the multiyear lag between research and technology application, the generous finding of R&D a decade ago and the recent emphasis on technology development augur numerous capital-intensive innovations during the next several years. Part of the "technology boom" of recent years undoubtedly owed to the growth in private and public insurance coverage. For example, Russell (1977) documented sharp increases in ICU's and diagnostic radioisotope facilities in small hospitals with the advent of Medicare and Medicaid; electroencephalographs rose rapidly in larger hospitals. It can be argued that "the historical pressures for hospital inflation have been greatly reduced

in the mid-1970's. . . . [F]uture increases in demand for hospital services similar to those experienced before are unlikely to occur" (McMahon and Drake, 1976, p. 136). With 90 percent of all direct hospital costs covered by insurance, it is probably correct that the economic pressure for increasing the quantity of services will be small. However, this will not necessarily alter the growing demand for higher *quality* of services, with its attendant implications for the use of sophisticated technology.

The general concern is expressed by Gaus and Cooper (1976, p. 11): "Given our tremendous technology-induced costs, it is apparent that in the U.S. today we have neither the capacity to determine how much of what technology is appropriate nor the mechanism to control adoption." In the extreme, the fear is that the state of the art in technology is the binding constraint on medical costs. Unless we learn how to assess the cost-effectiveness of technologies and then how to implement effective controls on adoption and use, we can anticipate that technology will continue to contribute to rapid inflation in the cost of medical care.

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