

MEDICAL TECHNOLOGY: A REGIONAL PRESCRIPTION

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EXECUTIVE SUMMARY

Medical technology: the words have become almost synonymous with modern American health care. The rate at which innovations in health care are announced seems to increase from year to year and, almost by definition, so do health care costs.

The last four years have seen double-digit increases in health care premiums in the Twin Cities Region. New medical technology is just one of many reasons cited for increasing health care costs, but it is one that is at the center of a growing public policy debate. While the nation's and the state of Minnesota's health policies have imposed increasing regulation on the health care industry over the past decade in the areas of third-party payment, utilization and quality assurance, they have left the diffusion of new medical technologies largely to the forces of the competitive marketplace.

A study conducted by the Metropolitan Health Planning Board, an advisory committee to the Metropolitan Council, found that the result of these policies has been the proliferation of sophisticated and expensive equipment, procedures and programs among a growing number of health care providers and the escalation of what's been called the "medical arms race." Interviews with patients, health care providers, insurers, government, business, labor and numerous other community groups focused on the problem of "halfway technology"--medical technology that is introduced into the Twin Cities health care system before its efficacy and need have been determined, which in turn increases costs and may even act as a threat to the quality of patient care.

Over the last few years, Twin Cities hospitals and, increasingly, doctors' offices and outpatient facilities have found themselves in an environment in which they have had to face the "competitor's dilemma." While most providers want to make decisions to acquire new technology based on patient and community need, they are increasingly being compelled to make those decisions based on market factors that have little or nothing to do with the needs of their patients or of the overall community. Many have deemed it necessary to take on new and expensive technologies in an attempt to capture or keep "market share" and stay competitive.

This has been so, in some instances, in spite of questions about the effectiveness, cost-benefit and wider social impact of many medical procedures, equipment, drugs and programs. In turn, questions have arisen regarding both the economic sense of unnecessary duplication of such services, and the appropriate use--and inappropriate overuse--of technologies that, once in place, have to be paid for. Excessive costs, as well as unnecessary tests and treatments, can follow. The

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result is an unhealthy form of competition in which too many expensive technologies and their providers chase too few patients.

These trends have been influenced by public and private policies on third-party payment that have encouraged the use of "high-tech" medicine; by the continued growth of physician specialties that tend to be the major users of high-tech; by antitrust laws that limit cooperation among health care organizations; and by medical manufacturers that compete for successful new products and services in the medical marketplace. And they've been intensified by a seemingly insatiable demand by the public for progress and hope in fighting the diseases and infirmities of the day--at any cost.

Without a more effective balance of competition, regulation and voluntary efforts at controlling technology and its costs, the situation will worsen and will reach a crisis point in the next few years. Innovations in medical care are expected with increasing speed in the next decade. At the same time, the region's population will grow older. By the year 2000, the proportion of the population who demand and use the bulk of high-tech health care will increase to an unprecedented level. This shift in the region's age structure, combined with unchecked demand for ever-more-expensive health care, will increasingly strain regional resources, and will make it difficult to satisfy the region's other social needs, such as education, housing, transportation and economic development.

Meanwhile, the ethical dilemmas surrounding an over-emphasis on high-tech medical care will worsen, most particularly the paradox of the haves and the have-nots of U.S. health care--those with all the resources of such health care at their disposal versus those denied access to basic and preventive health care.

The issues surrounding medical technology are regional issues and, in the absence of a coherent federal health policy, demand regional solutions. The Twin Cities constitutes a major medical marketplace in which many decisions affecting the size and shape of the health care system are made locally. One hospital or health plan, taking a more rational approach to the issues of the unchecked adoption and use of medical technology, probably won't make much of a difference in the overall scheme of things, but the Twin Cities health care community, acting in concert with public policymakers, can make a difference.

This investigation has found that an opportunity for reform now exists in terms of the rapid diffusion of expensive medical technology. Health plans and third-party payers face mounting pressure to control costs and ensure high-quality care. To address those concerns, health plans are expected to become more restrictive in the number of providers and types of procedures eligible for payment. Manufacturers of medical technology, who have focused their marketing efforts on providers, must increasingly be concerned that new technology will qualify for third-party payment.

What's needed is a new balance of competition, regulation and voluntary efforts aimed at controlling new and expensive health care technology. This balance must retain the beneficial aspects of competition, yet allow voluntary efforts of providers and consumers to direct the appropriate and timely diffusion of high technology in the region's health care system. The focus of such a new balance should center on a public-forum process for determining a more rational, coordinated system of high-technology programs and services. It should not impede the advance

of beneficial new technologies nor should it involve a return to the "Certificate of Need" process of the 1970s and early '80s.

The Metropolitan Health Planning Board recommends that a forum be established that provides public accountability for the appropriate and timely diffusion of new high-cost health care technology. It would:

- Be regional in focus and influence;
- Involve the voluntary participation of health care providers, payers, buyers, manufacturers and consumers;
- Deal with technologies before they have been introduced to the Twin Cities health care market;
- Employ payer incentives to carry out its recommendations; and
- Be exempt from anti-trust action.

The role of third-party payers is central to the process being recommended. Third-party payment decisions would be used to encourage or discourage the adoption of new technologies at certain locations, based on the recommendations of this forum, and those decisions would be made before, rather than after, providers have committed to the technology. The process would use the latitude payers have in limiting or refusing payment at certain sites for a particular technology, a strategy missing from previous planning and regulatory efforts aimed at controlling health care costs.

The process would require state enabling legislation to avoid issues of antitrust that would be raised by an organized effort on the part of payers to restrict payment. The process established by such "state action exemption" legislation would require active supervision by an appropriate government entity.

Today's Twin Cities health care marketplace presents unique challenges and opportunities for reform. Efforts to control costs, through the rational diffusion of new medical technologies, must be shaped and molded to fit today's circumstances, rather than those of the past. A new and more appropriate balance of competitive forces and regulation, tempered by the voluntary efforts of those involved in providing, purchasing or manufacturing health care products and services, can help ensure an innovative yet affordable health care system for the region's future.

INTRODUCTION

U.S. health care today is increasingly dependent on technology. In many ways, in fact, medical technology is U.S. health care. Each year, hundreds if not thousands of new technologies are introduced into the health care system. Many represent improvements in medical diagnosis and treatment and have, no doubt, contributed to improvements in health care and health status.

The Twin Cities medical community has played a leading role in advancing medical care and medical technology. The Twin Cities was the site for the development and perfecting of the heart pacemaker, the first open-heart surgery, and pioneering work in the field of bone-marrow transplants, among many other important innovations. The Twin Cities is home to many highly regarded hospitals and group practices, as well as numerous medical-technology companies. Their contributions to the progress of medical science continue today.

But advancements in health care technology are proving to be a mixed blessing. The rapid diffusion of new technology into the Twin Cities' health care system exemplifies both the success and the failings of the health care system. The success lies in the prompt development and dissemination of life-saving and life-enhancing methods of diagnosis and treatment. The failings lie in the disproportionate emphasis placed on technological "cure" over preventive care, the inequities in access to beneficial technologies, and in the excessive costs and quality-of-care issues associated with an overabundance of certain technologies.

Concerns have been mounting for several years in public and private arenas about the possible negative effects of the rapid spread of new, ever-more-sophisticated and expensive health care technologies. There's a growing feeling that medical "progress" is taking place faster than society can manage or pay for it. Competition, the major health care policy of the past decade, has been credited by some for stimulating the development of programs and services responsive to consumer demand, and blamed by others for promoting excessive demand for new machines and medical procedures, and the growing costs that accompany them.

What follows is the results of a study of the effects of competition on the diffusion of new technologies into the Twin Cities health care system. The report is qualitative rather than quantitative in its discussion of the issues, relying on interviews with representatives of the Twin Cities health care community and other interested persons for its analysis and the policy recommendations that follow. The study looked at the following questions:

Has a medical arms race ensued among competing health care providers?

Are procedures associated with new technology contributing to high-quality, cost-effective care?

Are hospitals and doctors sufficiently evaluating new technology before adopting it?

Is some type of outside, neutral, third-party monitoring of the adoption of new technology needed in the Twin Cities Area?

If so, what sort of approach or process might be effective?

Definitions. The report deals primarily with what has been called "high technologies," defined by Battista as "advances in biomedical engineering that require major capital investments and coordination of large amounts of human, physical and administrative resources."¹ Bone-marrow transplant programs and magnetic resonance imaging (MRI) are examples.

While the report does not deal with them specifically, "low technologies" are also recognized for the costly effect their repeated use can have on the health care system. Battista defines low technologies as those that don't require mobilization of many human and financial resources, and that can be used easily and directly by health care professionals. Examples include behavior-modification counseling for smoking and other habits, and such technologies as antibiotic therapy.

A third category, medium technologies, should also be recognized, though the report does not directly address them. Medium technologies are defined as the products of intensive technological development but which can be used without an elaborate support system. An example is upper gastrointestinal endoscopy, which can be administered by a clinician without assistance.

HEALTH CARE TECHNOLOGY, COSTS AND QUALITY

Advancements in medical technology over the last two to three decades are so numerous, so complex and so significant that they cannot be summarized adequately here. A sampling of the more spectacular medical developments might include:

- Organ and tissue transplants that now include heart, liver, kidney, pancreas, lung, cornea, skin, bone and bone marrow. Multiple-organ transplants are also being done with increasing frequency, including pancreas-kidney, heart-lung and even some triple-organ transplants. The drug Cyclosporine has dramatically reduced the problem of the body's rejecting newly transplanted organs.
- Significant improvements in the survival rates of premature infants born as young as 23 weeks' gestation, made possible through technologies such as extracorporeal membrane oxygenation and the drug Surfactant, which aids infant lung development.
- Dramatic advancements in the treatment of infertility problems, including in-vitro fertilization and other methods of "assisted reproductive technology" that enable couples who would have remained childless a few years ago to conceive and deliver healthy babies.
- Improvements in the ability to see into the human body and to make earlier and more-accurate diagnoses in a wide range of specialty areas through use of technologies such as the CAT scanner and the MRI scanner.
- Hip and joint replacements, as well as enhanced artificial prosthetics allowing greater mobility for disabled persons who would otherwise be limited in their activities and, in many cases, confined to a wheelchair.
- The use of lasers for a growing number of conditions of the eye, skin, reproductive organs, and other medical and dental conditions. Lasers are proving superior to traditional surgical techniques by causing less bleeding, fewer complications and faster healing.
- Lithotripsy, a therapy employing shockwaves to break up kidney stones and potentially gallstones, eliminating the need for surgery.

Other important technologies and procedures of the last few years appear in Appendix I.

Significant changes have occurred in the treatment of nearly every medical condition, resulting in both major and minor improvements in the quantity or quality of patients' lives. Some of these technologies represent cost savings, particularly those that eliminate the need for surgery or shorten the hospital stay. But most new technologies add to the cost of health care. Inherent in medical progress are facilities, procedures and equipment that are sophisticated and, by definition, expensive.

With improved capacity to see inside the human body, represented by X-ray to computed tomography (CT) to magnetic resonance (MRI) scanning, diagnostic accuracy increases, but so does cost, by 10 times or more, according to Handler.² Advances in cardiology have gone from nitroglycerine and digitalis for coronary heart disease to coronary bypass surgery, with costs increasing a hundred-fold. As McGregor writes, "Inexpensive dying is turned into prolonged living, usually through expensive means."³ Health care costs go up proportionally with each new technology that achieves some new benefit.

The rapid and pervasive diffusion of new technologies is viewed by many as a problem because of the role it plays in the increasing cost of health care, costs that will total \$660 billion in 1990, or 11.5 percent of the nation's gross national product (GNP). That's up from 10.8 percent just three years ago and more than twice the proportion it represented in 1960.⁴ In the Twin Cities, health maintenance organizations have increased their premium rates by 13 to 20 percent and more each of the last three years, and it's expected that double-digit increases will also be true for 1990.⁵ National figures translate into an average \$2,124 per capita in 1988. It's been forecast that total spending will hit 15 percent of the GNP sometime in the 1990s.⁶

New medical technology is just one of many reasons cited for these rapid cost increases. Others include the increasing numbers of elderly people who are sicker but live longer; medical fraud and malpractice; costly treatment for heart disease, AIDs and cancer; unneeded operations; and redundant diagnostic services. The list changes somewhat depending on who's asked, but new medical technology is always on it, whether at the top, bottom or somewhere in the middle.

It's been estimated, for instance, that 10 to 20 percent of medical costs increases are the result of new procedures and technologies that weren't available the year before.⁷ Other research suggests that technological advances and more-intensive use of such technologies account for 30 to 40 percent of health care cost increases.⁸

Technology is a culprit in health care cost inflation, not because it doesn't work but because it does work so much of the time. Technology that works has been of great benefit to patients. Tests and equipment unknown a few years ago have replaced many dangerous and expensive procedures. Much technology produces quicker, better results with less pain and upset to the patient. The application of some technologies has improved the quality and length of many patients' lives.

But not all of what is touted as medical progress truly is. Too much medical technology is applied to cases in which a bad outcome is expected regardless of the care provided--cases in which life-support systems are used to sustain a brain-dead patient, for example. Sophisticated technologies have been applied to medical conditions in which simpler and less expensive care would accomplish the same results. Examples of heart disease treatments are often cited. Whether such therapies are effective in doing what they were intended, or whether many constitute overly risky,

over-used alternatives to less expensive therapies, is often debated, sometimes over many years; all the while the procedures continue to be performed.

"Halfway" technologies--technologies that are inadequately tested and prematurely diffused into the medical care system--not only raise cost issues but quality-of-care issues as well. The Center for Biomedical Ethics at the University of Minnesota reports that, with the exception of drugs and medical devices tested by the Federal Drug Administration (FDA) for their safety and effectiveness, only about 20 percent of medical technologies in use are ever rigorously tested for their current uses.⁹ Less than one percent of the nation's annual health care expenditure is earmarked for medical-technology assessment, and most of that went for pre-marketing tests of drugs. According to the Institute of Medicine, the relatively minuscule amount spent on technology assessment can actually be lost in the rounding error for total national expenditures.¹⁰

New health care technology continues to be developed and diffused into the health care system without being evaluated for its efficacy or risk. The effectiveness of half of what the medical profession does is unverified, according to Ellwood.¹¹ This uncertainty has grown as applied to chronic disease, where present-day care, including sophisticated technology, is often of much less benefit than when it's applied to acute disease (pneumonia, for instance) or treating injuries. Experts estimate at least 20 percent of the national health bill--\$125 billion last year alone--is wasted on unnecessary, inappropriate or downright dangerous treatments that lack of verified effectiveness.¹²

Many of these same issues existed long before the decade of the '80s. The emphasis on technology and technological solutions to problems is part of the U.S. way of life. Issues of the effectiveness of medical care and the premature release of new medical technology predate the injection of competition into the health care system and other government efforts at cost control. But the policies of the last decade seem to have exacerbated many of these problems in ways unanticipated when they were adopted.

COMPETITION AND THE COMPETITOR'S DILEMMA

Competition, together with government cost control strategies, has been promoted as a major policy since the early '80s to reign in health care costs. In other industries, competition tends to lower costs. When it comes to health care, however competition is imperfect, and efforts to control costs have by and large been unsuccessful.¹³ Competition, through marketing, advertising and other means, has added to consumers' rising expectations of the health care system, and has increased the system's capacity, through new and expanded programs and services, to satisfy ever-increasing demand. But when it comes to controlling technology and costs, it has fallen short.

According to interviews with numerous Twin Cities health care industry representatives, hospitals and other health care providers acquire new technology for many reasons. Primary among them is to improve patient care, as it should be. But new technology is also adopted for a host of reasons unrelated to clinical need: to keep their physicians satisfied and bringing in patients, to protect themselves from medical malpractice suits, to comply with accreditation requirements, to improve their status and image and, in today's environment, to keep up with the competition. While hospitals have for decades acquired new technology for most of these same reasons, it's the last--"keeping up with the Joneses" in a high-tech era--that has taken on new urgency in the last few years.

Hospitals, clinics and physicians are in competition for patients like never before. To compete and stay in business, they must have the latest in medical technology. The hospital or clinic with the latest in technology--synonymous with good medical care in our society--has the competitive advantage. The resulting proliferation of technology has been called the "medical arms race." The situation in which providers find themselves in such an environment can also be described, from their viewpoint, as the "*competitor's dilemma*:" the dilemma is that while most providers want to make decisions about new technology based on the needs of patients and the community, they are increasingly forced, in a competitive system, to make those decisions on market factors that have little or nothing to do with patients or overall community need.

Another way of stating this is that most health care providers want to do what is best for patients, but competition and the scramble for new technology tend to bring less-pure motives into play. In competition for patients, specialists and facilities must buy the latest equipment. Then they have to use it constantly to pay for it. Unnecessary costs and extra tests and treatments may follow. The injection of competition into the health care marketplace in the Twin Cities has brought with it issues related to both economics and patient care.

Financial incentives have tended to support this way of doing business. Rather than promoting the use of new technologies at the appropriate time, the competitive Twin Cities medical marketplace contains incentives for hospitals and other health care organizations to "hedge their

bets," in a sense--that is, to prematurely adopt and potentially overuse new technologies. The results can be overspending on technology, bringing potential threats to both the health of the patient and the fiscal well-being of the health care system.

The Competitive Advantage

Clearly, the health care system can't survive without technology, since most of today's health care is based on technology that didn't exist even four decades ago. But in today's high-stakes health care, more and more hospitals see the latest technology as imperative to doing business. Beyond patient care considerations, many health care providers feel pressured into offering the latest in technology, whether it's equipment, programs, drugs or procedures, to capture or retain "market share," in too many cases whether the technology has been demonstrated to be either effective in a clinical sense or worth the financial cost involved.

One or more objectives may be involved. Institutional prestige, fed by having the biggest, or the best, or the latest piece of equipment, is one. Another is the perceived need to develop a specialized "product line" or to be a "full-service" institution or hospital system, offering a comprehensive range of programs and services in one or several medical areas. Having the best, or the latest, or the largest helps providers differentiate their services from one another. At many hospitals, the question of what programs or equipment to offer has become so interrelated with these other marketing-oriented needs that they can no longer be separated. Whether full-service or a specific service, it can be marketed to health care purchasers and the public as something better than the competition. According to one local provider, competition in the health care industry is a game of "oneupmanship."

But Twin Cities hospitals are increasingly finding high-cost technology difficult to keep up with. It can be a money-losing proposition if it wasn't needed and is underused. Most hospitals have made poor decisions regarding new technology at one time or another, either getting into a program or service that wasn't needed or investing in more "bells and whistles" than necessary to satisfy patient needs. The incredible rate of technological change contributes to the latter--several generations of the CT scanner were out within five years of the machine's introduction, for example. In just four years, the MRI has gone from being a highly sophisticated new technology to state of the art in diagnosing many diseases.

While third-party payers have been slow to use their clout in restricting payment for unnecessary technology, managed-care plans have started to negotiate contracts in which the costs of technology aren't covered, with the provider absorbing the difference. In some cases, the difference is substantial. And paying the difference has begun to seriously limit other services that can be provided--such as clergy, who have become expendable in some local hospitals. Hospitals use advertising and other marketing efforts to draw in more patients, but the patients needs don't distinguish between profitable and unprofitable services. One provider remarked that what his institution would like to see in an ideal world is the 30 percent of patients outside managed-care plans (that is, with more liberal insurance coverage) demanding more care, and those in managed-care plans demanding less.

The increase in competition from different types of providers providing various medical technologies contributes to quality-of-care issues. A striking example is found in the CT/MRI

expansion of the past decade. With competition in the early '80s came caps on inpatient care in the form of Medicare prospective payment. Those payment caps contributed to the growth of outpatient radiology facilities, an occurrence aided by improvements in technology. For hospitals, the result has been a new and intense competition from radiologists operating their own diagnostic facilities and doctors with their own office-based equipment who have stopped referring patients out.

Numerous outpatient sites with CT and/or MRI capabilities now exist in the Twin Cities, plus inpatient units at all the major hospitals--as it's often been stated, more than in all of Canada. So hospitals not only have to compete with each other, but with a growing number of outpatient sites as well--many of them, according to one article, within "spitting distance" of hospitals.¹⁴ According to several interviewees, healthy competition can easily turn unhealthy when, as in the case of imaging capability, a marketplace like the Twin Cities becomes saturated.

In this case, questions are now being raised about whether primary-care physicians and other specialists carrying out radiological procedures have the specialized training required to correctly read results, and whether unnecessary procedures are being done. The fact that some units are testing patients 24 hours a day may be efficient use of the machines, but it also calls into question whether "Roemer's law" is at work--that is, that a technology's availability promotes its use--and whether all those scans are really needed. The incentives to do more testing seem to be supported by data from the U.S. Department of Health and Human Services and Michigan Blue Cross/Blue Shield that show physician-owned clinical labs perform an average of 6.23 tests per patient compared with 3.76 tests per patient at independent labs.¹⁵

A further example of quality-of-care issues stimulated by overexpansion into new programs is in bone-marrow transplants. The number of transplant facilities in the Twin Cities continues to increase. In Minnesota, the Mayo Clinic and the University of Minnesota Hospitals were pioneers in the area; in the past year, four more Twin Cities hospitals have undertaken bone-marrow transplant programs. While criteria for transplantation will in all likelihood be expanded to include more cases as successful transplants increase, bone-marrow transplants remain an extremely expensive procedure requiring highly trained staff, extensive coordination of a number of medical care services, and a critical mass of patients per program for optimal quality of care. Unless the number of cases rises significantly, an occurrence which is not expected, the quality of the care that can be maintained in these units will be lower than it could be if they had the recommended number of patients.

Competition can also be unhealthy when it comes to medical research and training. The role of an institution such as the University of Minnesota Hospitals has traditionally been the creation and dissemination of new knowledge, basic and clinical research, and patient care. According to a hospital spokesperson, this role has been adversely affected by the competitive atmosphere among Twin Cities hospitals. Today the university is viewed by other providers primarily in competitive rather than cooperative terms. The university has been put in a position of having to fight for its share of the market, and thus has grown somewhat more reluctant to disseminate findings to the rest of the medical community.

Physician Pressures

In addition to pure competition, there are more reasons why hospitals find it hard to say no to new technology. Many of those reasons have been around since the days before health care competition, but have been exacerbated by a competitive, survival-of-the-fittest environment. A major contributing factor is the growing number of physician specialists and subspecialists, encouraged by third-party-payment policies that reward technical procedures more richly than cognitive services provided by less specialized physicians. For these specialists, technologies are the tools of their trade.

But more sophisticated technology is increasingly important to less specialized physicians as well. The Medicare system has controlled payment for office services to the point that, to cover costs and make a profit, many physicians have felt it necessary to cut short visits and substitute tests that will be paid for. Third-party-payment rules have encouraged physicians to invest in capital equipment, enabling them to run their own tests for which they are reimbursed. Physician groups are getting into technologies to augment their income, according to physicians interviewed, when in the past they would have used hospital-based equipment. Some of the tests conducted by physician groups may fall into a gray area of questionable need, according to local interviews.

Another factor is physician enthusiasm for innovations that they think will help them do their jobs more effectively. Physicians are taught to test and treat for all possibilities, within the limits of human biology and the pressures of clinical practice. In so doing, the physician must decide how many possible diagnoses need to be tested for, and how much ambiguity in diagnosis and treatment is acceptable. It's been estimated that physicians are certain of the diagnoses only 65 percent of the time.¹⁶ While absolute certainty remains unrealistic regardless of the tests or procedures employed, new technologies that promise to aid in the decision-making process or in the care and treatment of the patient have an almost irresistible lure for the physician.

Defensive Medicine

Though the size of medical malpractice awards has continued its upward trend, the number of cases has actually decreased over the past decade.¹⁷ Nevertheless, the threat of litigation is an ever-present concern for physicians, clinics and hospitals, according to interviews with providers. Providers share a general feeling that more technology and testing helps to reduce the possibility of a lawsuit or provides the necessary defense in case a suit is brought. Medical malpractice is a particular threat in certain specialties, such as obstetrics/gynecology and anesthesiology. The threat of a bad outcome and subsequent malpractice suit has necessitated that the wary health care clinician construct a malpractice defense while caring for each patient. According to Rosenblatt, "No one is sued for obtaining multiple ultrasounds, blood sugars, or biophysical profiles; [but] their absence always violates someone's expert interpretation of the prevailing standard of care."¹⁸

But technology can be used against the health care provider, too, contributing to another dilemma of sorts--one that one physician called the "doctor's dilemma": that in striving for ever-higher levels of certainty, the result can be excessive use of technologies and the problems associated with it, including putting the physician and/or hospital at risk of legal liability for medical

malpractice.¹⁹ The widespread availability of a technology such as MRI, for example, makes the physician legally liable for a missed diagnosis if an MRI scan was not done, because the units are so widely available and, in this Metropolitan Area, MRI has become the standard of care. In fact, according to interviews, an experimental procedure or test performed successfully as few as two or three times has been interpreted as the community standard of care in medical malpractice cases.

The cost of defensive medicine is not known; it's been estimated to account for 10 to 40 percent of all diagnostic exams and to account for the use of more elaborate drugs and therapies than would otherwise be indicated.²⁰ An example is the increasing use of the new non-ionic dyes in radiology, dyes which eliminate the risk of allergic reactions in the small fraction of patients susceptible to conventional dyes. In terms of quality of care, the new dyes are an improvement, but according to several hospital representatives, the conversion to the new dye for 100 percent of patients is costing large hospitals \$750,000 to \$1.5 million more than the old dyes. Though allergic reactions to conventional dyes can be treated, providers are choosing not to risk litigation in case of a significant reaction when the alternative is available and known to reduce such occurrences.

Third-Party-Payment Policies

The major cost containment policy of the '80s was enactment of prospective payment (PPS) for hospitals under the federal Medicare program in 1983. Before that, major payers such as Medicare and Blue Cross reimbursed hospitals retrospectively on the basis of costs incurred, including the acquisition and use of new technology and new procedures, regardless of the associated expense. Under PPS, though, national rates were set for nearly 500 diagnosis-related groups (DRGs), with each DRG including patients with similar medical problems and similar costs. Hospitals were expected to keep their costs within the payment rates. If they spent less per patient, they kept the savings; if they spent more, they absorbed the loss.

PPS has not limited the spread of technology in any significant way.²¹ Besides being adjusted for hospitals in various parts of the country and for inflation, DRG rates are recalculated every few years to keep them in line with changes in technology and practice. While Congress intended capital costs to be included in the rates eventually, they still are not, and are reimbursed on the basis of costs incurred. Because DRG rates cover only inpatients, they have stimulated growth of hospital outpatient services (a result at least partially intended) and the application of new technologies in outpatient settings.

Private payers have also been slow to restrict or limit payment for unproven, expensive or duplicative technologies. Health plans, for all of their built-in incentives to reduce costs, haven't taken the initiative to curtail the proliferation of new technology, interviewees have said. The plans have generally paid a flat per diem rate, regardless of the technology used. The national office of Blue Cross/Blue Shield is in the process of trying to assess technology and to make payment decisions based on their assessments but, according to one insurer, the problem is that the public will perceive such decisions as not in their best interest but as an attempt by the insurer to save money.

Still, when third parties have threatened nonpayment, their actions haven't significantly affected the adoption and use of technology. More often than not, the hospital or clinic has already

purchased or committed to acquiring the new technology by the time they request payment. Clinics interviewed indicated that they either provide the procedure without cost to the patient or charge the patient directly, until the technology has been approved for third-party coverage. Providers have been fairly secure in the knowledge that if some level of efficacy can be demonstrated, it will probably be paid for. Most insurers have no process in place to review coverage for expanded, unproven use of a technology once in place.

Two major barriers exist to a greater role for third-party payers in influencing technology. Both come from the courts. The first has to do with the fact that insurers may be accused of antitrust violations if many insurers exclude a technology from coverage and can be shown to be restraining trade. Second, differences of opinion may occur between the insurer and insured over the provisions of coverage. Insurers may be sued by patients if coverage is denied, and the courts often rule in favor of the patient in spite of evidence that questions the technology's effectiveness.

In Minnesota, the consumer/patient can also complain to the state Department of Commerce, traditionally very consumer-oriented, to force coverage. And, on a larger scale, the state legislature can mandate coverage for a new health insurance benefit. Each of these courses of action, according to insurers interviewed, is "stacked" toward spending money on more technology.

But the days of cost-plus payment policies by public and private insurers may be numbered. Many hospitals fully expect reductions in public subsidies for the purchase of expensive medical equipment in the not-too-distant future, and it has been suggested that some hospitals may have accelerated purchases in anticipation of future cutbacks in reimbursement. Many private insurers are moving in the direction of prospective payment for all hospital patients, and others are considering fee schedules for physicians. Interviews with health insurers, including local HMOs, indicate that they have recently been or are in the process of establishing formal technology-assessment review procedures and criteria. Criteria cover such concerns as the proven clinical effectiveness of the technology and its cost-effectiveness. A feeling continues to exist among traditional indemnity insurers and HMOs that none of them wants to be the "first" to offer a new benefit for fear of adverse selection by high medical users.

Over the last decade, HMOs and other third-party health insurers have tried to control costs through various means, including limiting benefits, increased cost-sharing, and introducing of the concept of managed care. Other changes in the way health care is paid for have included reductions in federal matching funds for Medicaid and relaxation of some of its requirements permitting states to experiment with new ways of providing care. Employers, who provide health insurance as a fringe benefit to most working people and their dependents, have introduced their own cost-containment measures, adding or increasing cost-sharing, encouraging use of HMOs and PPOs, and the like.

These changes, taken together with lower hospital occupancy rates, continuing reductions in length of hospital stays, and increased competition from nonhospital-based providers, may push the industry to look for lower-cost alternatives than the "biggest and best" technology for each institution.

Hospital Decision-Making and Capital Acquisition

Hospitals are capital-intensive. Because they are, hospitals (and other health care facilities) must make difficult choices about where to spend their limited capital funds. Setting priorities and making decisions is becoming more and more difficult as new technologies increase in number and cost. In an effort to keep up, hospitals are increasingly relying on long-term debt to fund assets, as result of declining philanthropic support and inability to generate funds from operations to serve as equity for capital projects.²²

While most hospitals recognize the importance of planning for capital purchases so that resources are there when needed, most hospitals carry out technology assessment on a fairly ad hoc, often haphazard, basis. Hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations are required to develop a three-year capital acquisition plan, yet for many it is little more than a paper exercise. Some limited planning processes are being undertaken to look at replacement high-cost capital needs over a three-to five-year period, but planning for new equipment needs over longer periods lags behind for various reasons, including difficulty in anticipating changing technology.

Rather than making decisions on the basis of a strategic plan that integrates the capital needs of all departments, it was reported in interviews, many hospital committees review projects either on a one-by-one basis, and thus don't have access to other requests before making a decision, or they review them once a year as part of a capital budgeting process.²³ Most funding requests tend to come from radiology, clinical labs, operating rooms and intensive care units. Lower-profile, less glamorous nonmedical items are at a competitive disadvantage, according to one hospital representative.

Hospitals receive more requests for capital equipment than can be accommodated by the approved capital budget. The task of determining priorities is difficult for local hospitals. It should involve assessing many factors, including clinical effectiveness, potential obsolescence and compatibility with the hospital's strategic plan, but most hospitals don't look at them all. These factors are often not quantifiable; thus individual opinion and political power play an important role. Financial factors--including startup and ongoing costs, revenue forecasts, capital availability and return on investment--are generally the most thoroughly analyzed by Twin Cities hospitals. According to interview findings, other factors considered (which vary by facility) include: market potential, projected volume of use, availability of alternative technologies, physician retention and attraction, efficacy, space and staffing needs, impact on health outcomes, and competition for the service. The technology's expected obsolescence seems to be less considered. It's difficult to say from the interviews what degree of weight is given to any of these factors other than the financial.

Institutional decision-making regarding new technologies is often a political process involving negotiation between an institution's administration and the health professionals, usually physicians, who want the new equipment or program. Who gets what within an institution is also directly related to the power held by individual departments, and according to one hospital spokesman, it is not uncommon for "turf wars" to develop between hospital departments during the budgeting process. It was acknowledged that, in general, those who ask for a new technology first and are the most vocal, get it. While tension has always existed between physicians and administrators over these matters, this tension has increased in an era of efforts to control costs, on one hand, and to continue to attract patients and satisfy physicians, on the other.

It's been suggested that most hospitals need to do a better job of developing and using a comprehensive set of criteria for evaluating requests for new technology, thereby also reducing the political leverage exerted by individuals or departments in the decision-making process.²⁴ It has also been suggested that hospitals and other facilities develop long-range plans to replace existing and acquire new technology, as defined within the broader framework of their strategic plan. And in light of shrinking capital resources--including pending proposals to fold Medicare capital reimbursement into its prospective-payment system--it has been suggested that hospital resources be pooled to share expensive technologies so that each hospital becomes highly specialized in only a few, rather than many, medical areas.

Antitrust Enforcement

The sharing and pooling of hospital resources is complicated by the relatively recent application of antitrust law to the health care industry. The possibility of antitrust action is an effective barrier to cooperative action, according to Twin Cities health care representatives. Before 1975, it was generally believed that health care professionals were engaged in the "learned professions" and therefore exempt from antitrust laws. Further, many if not most hospitals were nonprofit and were thought to be incapable of anticompetitive behavior.

But beginning in 1975, the Supreme Court held that professionals, including those in health care, were subject to antitrust, and since then, the Department of Justice and the Federal Trade Commission have used the same guidelines as for other industries to decide instances of antitrust in health care. According to this view, anticompetitive acts by hospitals, physicians and other health care organizations are illegal, even when motivated by the desire to improve the quality of care or the efficiency of the health care system.

Antitrust law is based on the premise that competition produces the best mix of quality goods and services at the lowest cost and is in the best interest of the consuming public. Hence, antitrust law prohibits conduct that unreasonably restrains trade and significantly reduces competition in an industry or particular market. Since 1975, numerous antitrust cases have been brought against health care organizations. Court decisions have found providers in violation of antitrust for agreeing not to compete through restrictions on advertising; for efforts to raise or fix the price of their services; for excluding competitors; and for forcing third-party payers to deal with them only on specified terms.

All these cases have made clear the fact that the courts, in their interpretation of antitrust law, will not allow private agreements among competitors to substitute for market forces, even in cases in which it can be shown that certain forms of competition result in threats to patient care or higher costs.²⁵ But states can supplant competition with cooperative action or regulation under the "state action" doctrine if they clearly articulate their intention to do so and provide for adequate supervision of the intended process.

Marketing from Medical Technology Companies

Medical technology companies are a potent force in the Minnesota economy and in Minnesota medicine. Medical Alley, a trade association, represents 165 such companies in the state. Part of

the industry is heavily regulated; the Federal Drug Administration tests drugs and implantable medical devices, ensuring both types of technologies for their safety and effectiveness. New medical technologies that don't fall into either of these categories, however, are not regulated and often not rigorously tested.

Many medical manufacturers are doing conscientious jobs of ensuring the safety and effectiveness of their products before they're widely marketed. The central mission of a well-known local manufacturer, for example, is to significantly improve people's lives through its medical products, and it goes to great lengths to ensure the efficacy of its products. Profit-making falls further down on its list. But other manufacturers and distributors of medical devices promote the use of their products, not always with regard to proven efficacy. The pressures of having to show a profit and the lack of research and development funding for new products also contributes to companies' drive to get their products into the marketplace, resulting in the marketing of "halfway technologies," technologies that haven't been adequately tested and shown to be effective.

Medical-technology companies must be able to document some level of effectiveness, because they won't stay in business if their products don't work, especially if they're harmful. But recent reports of the General Accounting Office said that makers of medical devices routinely fail to notify the FDA of problems with their products.²⁶ And there are sometimes conflicts of interest between manufacturers and clinical researchers that influence the outcome of research projects.²⁷ Even when research shows a new product to do some good, the larger question must be raised whether the incremental benefit it provides is worth the often-increased cost. Many companies don't ask that question.

In a competitive environment, medical manufacturers and hospitals have accommodated one another in the spread of innovations. Manufacturers solicit hospitals as research sites for their new developments, and hospitals have been, for the most part, happy to take on experimental machinery and protocols because of the competitive edge it could provide the hospital. In the past, the threat of nonpayment by a third-party payer for new technology has been minimal. But that will change with more restrictive payment policies for new technology; thus, the medical-technology industry will need to work more closely and earlier with payers in determining appropriate research sites for medical innovations in the future.

Public Demand

The expectations of the public for medicine cannot be overstated as a factor influencing health care providers' adoption and use of new technologies. According to one hospital administrator, ill people are desperate for hope, and technology offers hope. U.S. culture has fostered faith in progress, often defined in terms of technology. There's also a strong emphasis--some would say too strong--on the needs and the rights of the individual, to the exclusion at times of the larger social good. These typically U.S. outlooks manifest themselves in the demand for new medical technology, including unproven halfway technologies. One example, is the demand for experimental AIDS treatments of the last few years.

But the public places the health care industry and policymakers in a quandary in regard to its attitudes. A Health Insurance Association of America (HIAA) survey of 1,500 U.S. households each year for the last decade reveals the conflicting views held by most citizens in relation to

health care: that is, they are enthusiastic about expanding health benefits but don't know how to pay for them.²⁸

- Over 50 percent believe we do not spend enough on health care, while only 10 percent believe we spend too much.
- Most believe we should not ration technology to limit costs. By a 71 to 26 percent margin, they agree with the statement that "health insurance should pay for any treatments that will save lives even if it costs one million dollars to save a life."
- Only a third of the public find it reasonable that some health plans cover some treatments and medical procedures while others do not.

On the other hand, when survey participants have gone through a series of questions requiring them to make choices among competing technologies, many have come to accept that health care has limits and concede that health insurance cannot pay for all available technologies, according to a poll conducted by Louis Harris and Associates for the Loran Commission in 1987. An example is living wills. Eighty-four percent of the public believe the law should allow doctors to honor living wills, even if it means allowing the patient to die.

The news media help fuel public expectations of medical technology by reporting on "breakthroughs" and "cures" that haven't been proven, and by generalizing the benefits of legitimate new developments to the many rather than to the few who might actually benefit. One health care industry representative reported that his organization has received as many as 6,000 phone calls for information following a news story about a new medical treatment or procedure. Responsible media coverage occurs when stories emphasize costs and side effects of new technology; report background studies and their results, in addition to the most recent development; emphasize preventing the problem rather than only fixing it; and avoid making new treatments sound more effective, more conclusive, or applicable to more people than they really are.

Conclusions

Competition, combined with government cost controls, has been promoted as a major policy since the early 1980s to control health care costs, but in that respect, it has failed. Unlike other industries in which competition tends to lower costs, in health care, it is imperfect. True competition in Twin Cities health care has not been possible because:

- 1) The entry of providers into market has not been free, that is, certain health professionals are limited by state practice laws despite evidence of their effectiveness in a broader role.
- 2) Buyers are not well-informed. Buyers, whether individual patients or corporations, still don't have the information to make critical decisions. Many decisions remain with the provider.
- 3) Government has assumed a greater rather than lesser role in the "market," primarily through its Medicare and Medicaid programs.
- 4) Many consumers are left out of the system altogether. No one competes to serve people without insurance coverage.

To be fair, the injection of competition into Twin Cities health care hasn't caused all the problems facing today's health care system, including the too-rapid diffusion of medical technologies. Most of the problems existed before, to a greater or lesser degree, under a more-regulated health care system. But the pressures of a competitive marketplace have tended to magnify many of the problems of old. Competition, through marketing, advertising and other means, has served to increase consumer wants and expectations of the health care system; and has increased its capacity, through new and expanded programs, services and technologies, to satisfy those desires. Rather than containing costs, competition as manifested in the widespread diffusion of health care technologies has contributed to continuing escalation of health care costs. Spectacular patient billings created by high-tech offerings are almost commonplace--liver transplants at \$150,000 and up; premature babies at \$500,000 and up.

While most interviewees did not want to eliminate healthy competition, many more expressed reservations about certain aspects of competition and its impact on the nature of the Twin Cities health care system. Many medical providers expressed a concern over the industry's shift from serving patients to making money, and they expressed a desire to regain the service mission of the industry. It was often stated that competition has displaced cooperation, and that the sharing of costly technology has become the exception rather than the rule. In its place, the competitive environment has led local hospitals to feel the need for more equipment and programs than are needed, a situation that has resulted in unnecessary and expensive duplication of services among hospitals and outpatient facilities. Some procedures are of marginal use for some patients, and the availability of technology leads to overuse in those cases. Under-use results in difficulties in meeting overhead costs and a weakening of the health care facility financially.

The fear was expressed that duplication of technologies will increase in the future. It was strongly questioned whether the Twin Cities needs, for example, five lithotripsy units, two heart transplant programs, six neonatal intensive care units, or five bone marrow transplant units. It was stated that most Twin Cities hospitals will be self-designated cancer centers within the next two years. Many people said the problem will grow worse in future, with technological change speeding up and successive innovations more costly. An oft-stated example of an expensive new technology just over the horizon is the PET scanner. The question was asked: how many does the Twin Cities Area really need? At this point, no satisfactory means exists to answer that question.

As Miller concludes:

"The record of technological successes, failures, and uncertainties is sufficiently checkered to indicate that the matter of technological transfer deserves fresh approaches. Little about experience to date suggests that providers, either physicians or hospitals, will establish monitoring or evaluative procedures to exercise self-constraint on the application of new technologies. On the contrary, it has been demonstrated that medical centers will compete for patients on whom to use new and expensive procedures as well as for physicians to provide them. Allowing institutional rivalries and competition among hospitals to accelerate a medical arms race raises profound concerns. Allowing consumers to establish priorities by means of market demand presumes knowledge beyond credibility for most patients. Promoting procedures of high prestige or profitability will not necessarily assure that the resultant priorities protect the public interest.²⁹

IMPLICATIONS OF THE MEDICAL TECHNOLOGY ARMS RACE

The rate at which innovations in health care technology come out is projected to increase in the next decade. In the field of computer technology in the years to come, it will become increasingly common to send information on a patient across town, across the country or around the world for expert consultation. New drugs will alleviate illnesses such as cancer, diabetes, Parkinson's disease, arthritis and ulcers, to name a few.

Organ transplants will be more successful in the future, and there may be breakthroughs in nerve regeneration and catheter-based procedures to take the place of traditional surgery. Diagnostic equipment will continue to be improved; the next major development will be the PET (positron-emission tomography) scanner which will offer higher speed, and higher quality image resolution than CT and MRI. The use of lasers will become more widespread and more treatment options will be available for infertile couples. Earlier therapies are anticipated for preventing heart attacks, and more aggressive therapies for patients in the acute phase of cardiac disease.

Dramatic breakthroughs are forecast for the field of biotechnology and are projected to have profound effects on society.³⁰ Genetic engineering will become increasingly sophisticated, with research advancing that will help the body heal itself. A program is planned that will map the human gene. If funded and successful, it would determine the order, content and locations of seemingly countless number of genes on human chromosomes and would provide a detailed map of the system that makes individuals what they are. Such a map would allow doctors to create a genetic printout of a baby at birth, allowing predictions about the medical future of the life of the infant--and the ethical dilemmas that would bring with it. It would also dramatically influence the treatment of lethal diseases such as leukemia and AIDS.

In short, in the field of medicine, as in other fields, our love affair with technology will continue and everything that is technically possible will be done.

Many of these innovations will improve quality of care and health outcomes, but they will also have far-reaching implications that extend well beyond the health care field. Besides affecting individual lives and medical, legal and economic structures, new technologies will challenge fundamental societal beliefs. Social effects of new technologies include the direct and indirect effects of medical technology on the institutions and relationships considered important by society; ethical issues have to do with benevolence, justice and respect for individuals. These larger social and ethical issues have been largely ignored in the past in determinations of the costs, benefits and ultimate need for a new technology. In the future, questions such as the following will need to any considered:

- Who benefits from the application of a new technology and who does not?
- Does the new technology improve the quality as well as length of life?
- What are the unintended or negative consequences that result from use of a new technology?
- What will a new technology cost society? Do the costs require that tradeoffs be made with other important societal needs?
- What is the actual need for a technology, and how much of it is enough?
- Does the technology raise other ethical and legal issues?³¹

An Aging Population

Questions of this sort are particularly relevant because of the changing demographics of the region. The demand for new medical technologies promises to increase in the next 10 to 20 years to a point never before seen, and it threatens to overtake the region's capacity to respond to its health and non-health care needs. A key factor is the aging of the region's population.

The Twin Cities in the 1990s will see a huge increase of people in their 40s and 50s, the age at which the average person starts making greater demands on the medical care system. By the beginning of the 21st century, adults in this age group (the "baby boom" generation) will be the largest age group in the Twin Cities. It will make up over 30 percent of the region's population, compared with only about 20 percent in the '70s and '80s.³²

The fastest-growing segment of the Twin Cities' population is the elderly--people 65 years of age and older. It is the age group that makes the most intensive use of and heaviest demands on the medical care system. By 2010 the 85+ crowd will more than double from its 1980 level of 21,000 to an estimated 44,000. Such shifts in age structure in the Twin Cities, as elsewhere in the nation, are unprecedented and, combined with the high expectations of this generation, will result in enormous strains on the region's health care resources and on society in general. Competition for health care resources, without changes in those expectations, will intensify to unprecedented levels. Health care needs will demand an ever-increasing proportion of the region's resources, taking away from the resources available to meet equally important regional needs, such as education, housing, transportation and economic development.

Health Outcomes

The probable explosion in health care costs is particularly troubling in light of health outcomes. Health outcomes aren't keeping up with increasing health care costs; and as those costs go up, we're getting less and less for our money. U.S. national health care expenditures--in terms of percentage of GNP--exceed those of comparable western democracies by a significant margin. Yet, morbidity and mortality rates in other Western democracies are equal to or better than U.S. rates.

The U.S. ranks equal to or lower than some third-world countries in many indicators of children's health and quality of life. The U.S. ranks only 19th in infant mortality and 21st in mortality of children under five. Almost one in four U.S. children under six lives in poverty. Not only are indicators lower in the U.S. than the dollars spent would indicate, but the public perceives the quality and availability of care in most of these other nations to be superior to that in the U.S.³³

The U.S. trails its neighbor to the north, Canada, in many of these health status indicators, in spite of Canadian health care expenditures per person that are significantly less than in the U.S. Perinatal and neonatal mortality and overall longevity are all better in Canada than the U.S. Canada has no waiting list for prenatal or child care or pediatric operations. Neonatal intensive care units in Canada use less technology than American units. And the instance of premature births in Canada is declining, primarily because of a national emphasis on preventive care.

Prevention

It's the preventive focus that tends to get the short end of the stick when technology takes center stage. Yet, health care technology is a relatively small part of good health. According to estimates by the Centers for Disease Control, only about 10 percent of premature deaths are the result of inadequate health care services.³⁴ The degenerative diseases, accidents and other leading causes of death are often self-inflicted, the result of the way people choose to live their lives and structure their environments. Lifestyle and environment together account for an estimated 70 percent of all premature mortality.

The irony (often stated in interviews with community representatives) is that, with all that is spent on health care, many health problems could be avoided in the first place with healthier habits and a cleaner environment. Yet the diagnosis and treatment of illness continues to be emphasized in the region, through more sophisticated and specialized medical technology, while much less is done than might be to prevent the conditions that necessitate use of that technology.

A case in point is perinatal care. Millions of dollars continue to be invested in sophisticated neonatal intensive care for babies born prematurely with medical problems that might easily and less expensively have been prevented with better care of the mother before and during pregnancy. The nation's and the region's infant mortality rates are worse than those of many other industrialized nations, yet relatively few people (some of the few were local physicians) see anything incongruent about the six neonatal intensive care units in the Twin Cities Area competing to care for very ill infants. Rosenblatt describes one aspect of what he calls the perinatal paradox as follows: "The NICU is perhaps the most vivid example of the lack of balance in a system in which high-risk mothers cannot receive public subsidies for their prenatal care, yet neonatal intensive care is an inalienable right once the baby arrives in the NICU."³⁵

Many of the most dramatic improvements in health over the last 70 years have been the result of sanitation programs and overall improvements in living conditions. And they have come with rising educational levels. It has, in fact, been shown that a woman's educational level is the strongest predictor of a newborn's health, for the simple reason that with increasing education comes greater awareness of the need for, and the means to achieve, adequate nutrition, prenatal care and the other factors that contribute to a healthy newborn. Several people representing the health care industry and public interest groups said it would make more sense to spend more of the region's resources on improved housing and working conditions, on improving education and reducing poverty and other societal failings, all of which would most likely have a greater impact on the overall healthiness of the region's population than would unlimited investment in medical technology.

Access to Care

Closely related to the issue of preventive care is the overwhelming ethical issue of access to care of any sort--basic and preventive or high tech--for growing numbers of the region's population. According to Callahan,

"We congratulate ourselves on having the best medicine in the world--not related to our health status or health outcomes data, but based on the development and use of high tech medicine, just

one aspect of our health care system. But there's a huge inequity here, between the best that is available for some, and little or nothing available for others. The combination of too much care for some, and too little for others, together with costs increasing at unacceptable rates, calls into question the basic tenets of the American health care system³⁶

The restructuring of the economy to include a growing number of service jobs together with layoffs and other worker dislocations, the tightening of Medicaid coverages, cost-saving cutbacks in employer-provided coverage, and a general increase in the number of people covered with inadequate insurance all portend an increase in people without health care insurance and without access to care unless dramatic steps are taken to rectify the issue. Several state proposals are currently being considered or have been proposed.³⁷

Beyond the uninsurance issue, a recent study found evidence that the type of insurance also affects a person's care once they're in the medical care system, especially as it relates to high-tech medicine.³⁸ Specifically, it found that high-tech medical treatments go more often to privately insured patients than to people with public insurance or no insurance. Researchers found that the odds that a privately insured patient would receive angiography were 80 percent higher than the odds for an uninsured patient. For bypass graft surgery, odds were 40 percent higher for the privately insured, and for angioplasty they were 28 percent higher. Odds for Medicaid patients were similar to those for the uninsured.

According to local interviews, communities of color are hit disproportionately hard by issues of access to both basic and high-tech health care, in spite of health problems and living conditions that are often worse than those of white people. A recent report by the U.S. Department of Health and Human Services said Blacks needing a kidney transplant must wait nearly twice as long as whites--more than a year--to receive a donated organ.³⁹ The same basic issues apply to communities of color when it comes to other organ transplants as well. Other studies have documented similar disparities in the application of medical technologies to minority groups.⁴⁰

Health insurance will eventually be expanded to cover more of those currently without financial access to care. If it is "business as usual" regarding new and ever-more-expensive medical technologies, the added demand will escalate the upward spiral in health care costs to the point that the region cannot meet its other physical and social needs, needs which--if they go unmet--will threaten the health and well-being of the region's citizenry as surely as the lack of accessible health care does.

Life and Death Dilemmas

For some there is too little care, for others too much. The latter poses its own ethical dilemmas. The availability of too much technology, too much care, can make health care tech a mixed blessing in those cases in which it saves lives, but does not and cannot assure the quality of those lives. Medical technology can achieve miraculous cures and recoveries for patients and their families, but it can also cast families like those who were interviewed, along with the medical

team, into the anguish of no-win medical dilemmas, forcing life and death decisions.

Some are immediate decisions that take place in the operating room. Others, like severe head injury cases, can stretch out over weeks or months or years and are the most agonizing. They raise questions such as, if the kidneys fail, should dialysis be started? If the blood pressure drops, should medications be given to support it? Should the respirator gradually be turned down, even withdrawn? When is a patient allowed to die?⁴¹ Physicians are not trained to deal with families in crisis situations and to provide the kind of support and information to help them make such final decisions. It's easier to show medical residents how to start an IV or operate a new piece of machinery than it is to teach them how to talk with families, and medical education and residency training don't do a very good job of it.

Medical technology developments--those that fall in the gray area between a true advance and a questionable development--increase the number of complicated cases where traditional medical moral choices are unclear. An overriding ethic among physicians, reinforced by the demands of patients and families, is that everything, regardless how marginal in its potential effectiveness or illusory its benefits turn out to be in the end, be done for the individual patient. Life-support technology makes it possible to keep a body alive long after there is hope for recovery. This situation results in technologies being applied to medical conditions for which they were not indicated, resulting in no improvement in patient condition, or in a worsening of the condition, if iatrogenic effects are introduced.

One of the ironies of modern medicine is that for the past 20 years, physicians have convinced the public of the marvels of medical technology, only now to be caught in the uncomfortable position of having to persuade the same public that in too many cases technology only prolongs death. According to a recent article on life and death issues in health care, "...Because society is mostly unwilling to face death, patients are becoming prisoners and physicians the servants of technology."⁴²

Not everything that is new in health technology is good, and not all that is good is needed, according to Tanneberger.⁴³ If not everything should be available to everyone, it raises the ethical question of who makes those choices and how. The ethical dilemma involves the issue of premature versus delayed versus no introduction of costly, complex technologies. Not only do questions about safety and effectiveness need answers, but so do questions about the affordability, cost-effectiveness, and social impact of new technology. It is unethical to widely introduce a technology that the health care system cannot afford and which is introduced at the expense of other more useful programs.

In today's medicine, doctor and patient must decide whether "the mere presence of a medical technology is affecting their decisions. The same life-saving science that has made resuscitation, trauma care and transplantation commonplace can force physicians and patients through a maze of choices and possibilities, where the fact that something can be done might overshadow whether it should be done."⁴⁴

Rather than allowing technology to drive medical decision-making, appropriate decision-making must drive the use of medical technology. Making this unnecessarily difficult is the overwhelming availability of many new technologies needing to be paid for and thus begging to be used.

POSSIBLE SOLUTIONS

According to a local hospital representative, a long deliberative process regarding new technology isn't the usual way in this country. Instead of waiting till it's proven beneficial, we seem to adopt do it as long as its not proven harmful. Yet, a new and more effective strategy than the current policy of unrestrained technology diffusion is needed. The challenge to developing a thoughtful system for more rationally controlling the diffusion and use of new technologies is to construct a system that is truly in the public's interest, a system that encourages the development and appropriate use of safe, beneficial, cost-effective medical technologies without unnecessarily discouraging innovation.

Varying Interests

A strong sentiment has been expressed in Twin Cities health care circles for a more rational, considered approach to technology diffusion. Interest is strong among payers as well as health care providers and policymakers. The reasons for groups' interest vary based on their differing perspectives, but many overlap. The main (though not exclusive) interests of particular groups can be summarized as follows.

- The patient and provider are both concerned with the safety and efficacy of the procedure they're considering use of.
- The employer and other major health care purchasers, including HMOs, want to be able to determine which extensions of coverage are the most worthwhile.
- Hospitals and HMOs (as providers of care) look at new technologies as major investments and need to know about a technology's feasibility, including but not limited to financial feasibility.
- Third-party payers need to determine coverage and payment policies regarding new technology.
- Medical manufacturers need to know a new technology's potential market size and how well a new product will compete in the marketplace.
- Medical associations need to respond to practitioners' and third-party payers' inquiries about new technologies.
- Professional societies want to improve medical practice and service delivery.
- Government makes decisions regarding payment based on the economic efficiency, safety and efficacy of new technologies.
- Legislative bodies need to consider the broader economic, social and political impacts resulting from the application of scientific knowledge.

Government's interest deserves special mention because of the pivotal role it should play in the issue. Government at all levels should be concerned about the spread of technologies because of its overall role in protecting the public health and its more specific role in encouraging the development of, and using and paying for, medical technology. Government is the largest single payer for health care, financing over 40 percent of the national health care bill. Government ought to be getting its money's worth, while protecting the well-being of its citizens. Costly, unnecessary, ineffective medical technologies infringe on that well-being and are an extra burden on the taxpayer.

Professional associations, including the American Hospital Association, the American Medical Association, and the American College of Physicians have assessment programs. Locally, some health insurance companies and HMOs have begun, or are considering, limited programs of technology assessment to aid them in making decisions regarding claims. Other programs of assessment and information on health technologies are listed in Appendix II.

Possible Strategies for Controlling Technology Diffusion

For high technologies, the following possible strategies employing a strong government role, a combination of government and private roles, and private responsibility have been suggested over time and from different sources, including from some local interviews.

1. Strong government role by various means, such as.....
 - a) Assignment of global budgets to health care institutions, as is done in Canada, to control costs and, indirectly, to control adoption and use of new technologies. Not politically acceptable here.
 - b) Central planning also used in Canada, an approach probably not acceptable here.
 - c) Reinstatement of Certificate of Need or some modification as was tried in the 1970s and early '80s in Minnesota. See below for fuller discussion of merits and shortcomings.
2. Public/private strategies, such as.....
 - a) Regionalization of specialty/tertiary services, in which institutions would be encouraged to share expensive new technologies. This approach was tried to some degree under the National Health Planning and Development Act of 1974, and some modification might be made to work now through selective payment to preferred providers by insurers. The theory behind regionalization says that even when sophisticated new procedures have been found to be efficacious, not all potential providers are equally qualified to render them. Medical literature continues to support the contention that the medical outcomes of complex procedures are better if they are performed in centers with high volumes of those services, and that economies of scale come with higher volumes.
 - b) Creation of an information body on health technologies, to provide more information on emerging health care technologies. To some degree, the National Institutes of Health and the federal Office of Technology Assessment play the role of central information source on some (though not all) technologies, but they function less adequately when it comes to disseminating that information at the local and regional level and to advising policy- and decision-makers regarding the appropriate diffusion of those technologies.

- c) Third-party payment incentives, by which insurers would be more discriminating in paying for both big-ticket and small-ticket services. Payment decisions are critical points in the diffusion of many technologies. One possible national model is the Prudential Insurance Co. which, in 1988, began a process to designate "institutes of quality" around the country, to which they send Prudential HMO or indemnity plan beneficiaries needing high-technology care. It's an effort to control insurance costs while, at the same time, achieving the best medical outcomes for the patient. Thus far, Institutes of Quality have been designated for organ transplants, lithotripsy, and allogenic bone-marrow transplants.
3. Private strategies, such as.....
- a) Reorientation in training health professionals, to teach health professionals to weigh the benefits, risks and costs of medical technologies so that they use technology where it can make a difference.⁴⁵
 - b) Control over the number of professionals and specializations, so that there are not more specialists (who tend to use high technology) than are needed.
 - c) Limitations on private-market financing of new health care facilities and equipment.

Government's Recent Role in the Diffusion of Health Care Technology

Health planning and Certificate of Need (CON) programs were instituted at the federal and state levels in the 1970s, but largely disbanded by the mid-'80s. The National Health Planning and Development Act of 1974 set up a system of state and local planning agencies with broad responsibility for planning and guiding the development of the health care system. But the legislation gave them little power other than public persuasion and the requirement that every state establish a CON program to approve major capital spending and introduction of new hospital and nursing home services. The federal health planning law was repealed in 1986 and the State CON law was sunsetted in 1984, both in favor of a competitive approach to health care cost containment.

Planning and CON programs are widely regarded by most policymakers and health care providers to have been less than successful in controlling the diffusion of technology and the costs of health care. Some successes associated with regional planning can be pointed to, however. Newborn intensive care in U.S., and in the Twin Cities Area, is the best in the world; the U.S. has the lowest mortality rate for low-birthweight infants anywhere in the world. This result has been attributed to regionalized programs, strongly encouraged by regional planning programs. The flip side of this success may be CT. The need for CT scanning, which came on the medical scene at about the same time as federally sponsored health planning, was significantly underestimated by health planners at the time, and has since become an essential diagnostic tool.

All in all, planning in the 1970s and early '80s was supported only halfheartedly, without an overall national health policy, and without resources at the local level to truly shape and influence the health care system. It also made the mistake of trying to cut back on programs, units and equipment after they were essentially committed to by their sponsoring health care organizations. CON offered health planning its only teeth and it proved to be relatively easy for applicants to establish "need" for their proposals, reviewed one by one as they were by the health planning agency and State Department of Health. Totally missing was any financial incentive for health care providers to limit acquisition of machinery or expansion of programs; all the financial incentives in place at the time encouraged them to do just the opposite.

Health planning and CON were replaced by federal and state policies encouraging development of competitive market forces in health care. As described in preceding sections, these policies have also been unsuccessful in either controlling costs or limiting the diffusion of expensive health care technologies.

Neither CON nor the competitive strategy has worked in the Twin Cities to restrain new technologies at the level necessary for high-quality patient care or at costs the region can reasonably afford. Each of these policies has been imposed from above, from the federal and state levels of government. It is time for a new approach, specifically a regional strategy that might serve as a model for other areas of the state and nation.

A REGIONAL FOCUS

The Twin Cities Metropolitan Area represents a major medical marketplace in which most of the health care required by Twin Citians is provided. Together with the Mayo Clinic at Rochester, it is also the referral center for specialty medical care for a large proportion of the residents of Greater Minnesota and parts of surrounding states. According to statistics from the Council of Hospital Corporations, nearly a quarter of Twin Cities hospital inpatients were from outside the Twin Cities in 1989.

Besides providing for the patient-care needs of the population, health care has taken on a vital role in the region's economy. According to Medical Alley, a trade association with 165 members, the majority of whom are based in the Twin Cities Area:

- Health care represents approximately 15 percent of Minnesota's economy and is its fastest-growing segment. Over the last seven years, the number of jobs in the medical device industry has grown faster than any other industry. Between 1978 and 1986, gross state product increased by 88 percent, while the health care gross product increased by 143 percent.
- More than 190,000 people are directly employed in Minnesota's health care industry. The payroll for the industry totals over \$4 billion. Health care's share of the state's employment is 30 percent higher than the national average.

- Minnesota ranks 10th in the number of medical devices registered with the FDA. Minnesota exports 50 percent more health care goods and services than health care organizations nationwide.⁴⁶

Local Decision-Making

While the influence on the region's health care system of decisions made in the nation's and the state's capitol regarding Medicare and Medicaid cannot be underestimated, neither should the decision-making that goes on locally regarding health care priorities, programs, and technologies. Local health care professionals are persuaded to adopt new technologies through many different channels, some formal, some informal. Greer has researched the influence of the local organization of medical practice on the diffusion of new medical technologies. She emphasizes the finding that local professional communities are medically closed systems, in spite of their links to an international medicine, and that the diffusion of new technology is "anchored in the norms and relationships of local practice."⁴⁷

In the absence of certainty as to patient response to disease and to a host of other factors affecting the use of technology, and in the absence of medical literature that tells the whole story about the benefits, risks and appropriateness of a new technology, practitioners tend to rely on local opinion and consensus as to whether a form of treatment is effective. Innovations, according to Greer, are adopted locally as a result of "individual innovators," are promoted by "idea champions," and as results of the technology become available, are assessed by local "opinion leaders." Thus, structures of local participation, according to such findings, are more effective in relating research and innovation to practice than are external forces, such as the medical literature.

The diffusion of new technology has been described as having its own lifecycle--it is developed, comes into use, becomes obsolete, and is dropped from use.⁴⁸ Many factors influence the diffusion of technology. Some are objective, others subjective. Among the more objective are the following:⁴⁹

- Prevailing theory--how closely an innovation "fits" with accepted explanations for empirical phenomena.
- Attributes of the innovation--whether it "fits" physician style of practice in terms of being fairly easy to learn and use, having an economic payback, and no better alternatives being available.
- Features of the clinical situation--whether it solves an important clinical problem.
- Presence of an advocate--whether someone in a position of influence strongly supports the innovation and encourages its adoption.

The above are not very likely to be influenced by pressure from policymakers.

Factors more amenable to influence include:

- Practice setting--whether group practice, hospital size and teaching status, etc. (Group practices, for example, tend to innovate more quickly than do solo practices.)
- Decision-making process--whether an individual decision, group decision or institutional

decision is needed. (A process involving more people requires a longer time to reach a decision, for example.)

- Characteristics of providers who potentially adopt new tech--differences in physician skill levels, attitudes toward innovation, and socioeconomic and demographic characteristics may or may not influence receptivity to new technology. (As an example: specialty physicians may be more receptive to innovations in high-tech than nonspecialty physicians.)

Factors most amenable to influence include:

- Outside factors--these include regulatory agencies and third-party insurers that can influence technology diffusion, either constraining it or encouraging it, by decisions about coverage or by setting standards for its use.
- Conduct and methods of evaluation--evaluations of technology can influence physicians, other potential adopters, other experts who exert influence in the health care system, or third-party payers and regulators who set policy for the system.
- Communication channels--how physicians learn about new practices; medical journals, discussion with colleagues, continuing education are important sources, though vary significantly depending on characteristics of physicians, type of innovation (drugs vs. procedures, for example), stage of diffusion the technology is in, etc.

RECOMMENDATIONS

It's safe to say complete information will probably never exist on the efficacy, safety, and broader economic and social effects of medical technologies, because they are so varied, complex and in a constant state of flux. But it is also not unreasonable to demand some sort of public assessment of expensive new technology before it is widely adopted and put into use. On the contrary, it is wrong to squander resources on technologies that are unneeded, ineffective or inadequately tested. Reigning in unnecessary, expensive technology is a necessary part of achieving needed balance between preventive and curative health care and between the region's health and nonhealth care needs.

Needed is a more systematic process for monitoring and directing the appropriate and timely diffusion of high technologies in the Twin Cities health care system. Provider decisions to acquire new technology have traditionally been internal to the institution or facility, and have more recently been subject to the pressures of the competitive marketplace. While the healthy aspects of competition should not be eliminated--those forces that push health care providers to innovate in creative and beneficial ways--a public forum for jointly determining a more rational, coordinated system of high technology programs and services is also needed.

Before any recommendations are made, it's important to clarify what's **not** being proposed:

It is not being proposed;

- That the advance of new beneficial technologies be stopped or reduced.

Those that are beneficial in terms of patient outcome and quality of life are to be encouraged.

- That CON be resurrected.

CON didn't work very well in the '70s and would not be supported now.

- That competition be eliminated from the region's health care system.

The beneficial aspects of competition are to be encouraged, such as the provision of better and more complete consumer information on health care alternatives and more than one provider competing to provide a particular program or service.

- That a new large bureaucracy be created to oversee and direct the diffusion of health care technology among Twin Cities health care providers.

The expense of a new bureaucracy could not be politically supported, nor is it needed.

- That a system of provider haves and have-nots be created.

There are plenty of health care programs and services to go around, without denying particular providers the opportunity to serve.

- That a "Minnesota FDA" or a Minnesota Office of Technology Assessment be established to approve new technology.

The proposed process will not test the safety, efficacy or cost-effectiveness of new technologies.

- That a technology "think tank" be established.

The proposed process will not attempt to come up with answers to all issues of medical technology.

- That health care decisions be removed from providers.

The ultimate decision to acquire or use new technology will remain with the provider under the proposed process.

- That Minnesota's health care technology industry be crippled.

Innovations in medical care that improve patient care outcomes will continue to be marketed and sold in the Twin Cities and elsewhere under the proposed process.

- That all problems facing the area's health care system will be solved by the proposed process.

The proposed process takes a focused look at technology issues and the difference it can make in that issue area. By itself, it will not solve the many other issues besetting health care.

It is being recommended that a forum be established providing public accountability for the appropriate diffusion of new high-cost health care technology with the following characteristics. The forum should:

- Be regional in focus and influence;
- Involve voluntary participation of health care providers, manufacturers, payers, consumers and others;
- Be focused on technology issues, but address issues of access, cost and quality as they relate to technology;
- Deal with technologies before they have been introduced to the Twin Cities health care market;
- Employ incentives for payers to carry out its recommendations;
- Address the issue of consumer demand;
- Have exemption from antitrust laws; and
- Periodically evaluate the process and outcome of its own efforts for their effectiveness.

Regional focus. The Twin Cities is a major medical marketplace which serves as the center for high-technology medicine for a large portion of the Upper Midwest. It has been shown that patterns of use and diffusion of new technologies are determined at the local and regional level. Thus the potential exists for dealing with the issue of the rapid spread of medical technology at the regional level. Successfully doing so might serve as model for the rest of the nation.

Voluntary participation of providers, manufacturers, payers, consumers and others.

Accountability for the appropriate application of new technology has to be a cooperative effort with regulators and policymakers, consumers, providers, medical-technology companies, business/labor, and third-party payers. It won't work if anyone is left out because decisions cannot be made unilaterally. It needs to be voluntary because the process, as proposed, cannot force any group to participate. The process is dependent upon the timely and effective pooling of information regarding innovations and developing a process by which they can be reviewed and a

common decision arrived at.

Technology before the fact. To avoid some of the shortcomings inherent in the CON and regional health planning process of the '70s, decisions made in the public forum about the appropriate diffusion of a technology should be made when it is new, before health care facilities have acquired or committed to the technology, rather than after the fact. It is very difficult for either the third-party payer or the provider to say no to a technology that is already in place, or already committed to.

Payer incentives. The role of third-party payers, including traditional indemnity insurers and HMOs, would be central to this process of controlling the spread of new technology. Third-party-payment policies, based on the recommendations of this forum, would be used to encourage or discourage diffusion of new technology in the Twin Cities health care market. In instances of a sophisticated technology requiring a high level of staff training and expertise and/or capital investment, and high volumes of patients, such a process could be used to discourage a technology's widespread and premature adoption. The latitude payers have in limiting the widespread adoption of new technologies is significantly greater than what they have traditionally practiced, and greater use of payment policies would go a long way in helping more rationally direct the distribution and diffusion of new technologies. It could also be used to make the provider accountable for the use of technology and quality of care by setting provider qualifications for the technology.

Antitrust exemption. An organized action by payers to limit or refuse payment, even to achieve the goals of cost control and patient welfare, would be viewed by the state attorney general's office as unreasonable restraint of trade and a violation of state antitrust laws. To make the recommended process possible, new state legislation to provide a "state action exemption" will be necessary to pre-empt competitive activity in health care in the Twin Cities, and such action, in turn, requires active supervision by a government body such as the Metropolitan Council or an agency in state government. Policies and recommendations regarding the appropriate distribution of new technologies will involve the process of negotiation among competing groups. Government can provide the arena in which such negotiations can take place, as well as negotiating as a major purchaser of health care itself.

Recommended Structure and Process

Details of the structure and process of a technology forum remain to be worked out with community representatives. In general, however, it is proposed that such a forum include representatives of the various sectors of the Twin Cities health care marketplace, as well as consumer and government representation. The forum might be under the supervision and oversight of the Metropolitan Council, granted state action exemption under enabling legislation. It would meet regularly to determine the appropriate new technologies for study. With the assistance of a small staff, it would study and issue reports, including recommendations for the appropriate diffusion of three to six new technologies per year.

To carry out each study, the forum would put together an ad hoc committee of experts in each technology to do the study and issue a report for review and approval by the technology forum. Each study would require approximately three months to produce, and would cover the need and demand for the technology in the Twin Cities Area and for the relevant population, required provider training and qualifications, third-party-payment policies regarding the technology, and the appropriate number and type of local providers of the technology. It would also include a timetable for reassessment if necessary. Opportunity for a minority report at the committee and forum level would be provided. Each report's recommendations would be extensively publicized through the media and through provider channels to generate public support. Payers, who would be represented on the forum, would be encouraged to use the findings and recommendations of the studies to make payment decisions.

Many legal, organizational and operating questions remain to be answered about the forum, including the scope of the state-action-exemption legislation required; the relationship of the forum to the Metropolitan Council; the relationship of a forum covering the Twin Cities Metropolitan Area to the rest of the state; the possible use of the forum's recommendations as quality-of-care standards; the impact of the data practices act on the forum; how forum members are selected and appointed; how the forum is funded and at what level; and many other important issues.

BACKGROUND TO THE REPORT

The impetus for this report comes from several places. During 1988-89, the health planning board of the Metropolitan Council invited representatives of the local health care industry in to talk about issues they saw developing in Twin Cities health care. Several identified the growth and spread of expensive technology as an issue that should be looked at closely. Also in 1989 the influence of technology on human services was identified by a Metropolitan Council strategic planning process as one of several major areas that should be of interest to the Council in the future. All the while, health care premiums continued their rise, with many employers perceiving that large portions of those increases were due to the growth in, and demand for, more-expensive health care technologies.

In October 1989 the health planning board approved a charge to a board subcommittee to explore issues that may be developing with the adoption and use of medical technology in the Twin Cities Metropolitan Area. The charge to the subcommittee was fairly broad and general. It was:

to assess whether major issues are developing, or may develop in the near future, in terms of the adoption and use of health care technology that significantly increase costs, and if so, what those issues are/will be and what, if anything, ought to be done about them.

The goals of the study were defined as follows:

- To better understand what is happening locally with the adoption and use of health care technology, including information that can be shared with regional and state policymakers;
- To determine whether or not the marketplace is providing for the appropriate adoption and use of health care technology, or whether the need is developing for some type of neutral, third-party monitoring and possible intervention into the adoption and use of new technology; and
- In general, to make a contribution to the overall goals of high-quality, cost-effective health care and improved health status through the appropriate use of health care technology.

Process Used to Conduct the Study

Half the members of the health planning board made up the subcommittee appointed to carry out the study on medical technology. Members of the subcommittee are:

Roberta Davis, chair, technology subcommittee, Metropolitan Health Planning Board;
Instructor, Inver Hills Community College
Benjamin Aune, President and CEO, Interhealth
Christine Gibson, Market Manager-Health Care, US WEST Communications
David Lutes, chair, Metropolitan Health Planning Board; Employee Benefits/Risk
Management Administrative Assistant, Minneapolis Public Schools
Gayl Madigan, Supervisor, Shakopee Women's Reformatory
Jerrald Olson, Vice President, Hammel Green and Abrahamson
John Oswald, Senior Researcher, Group Health, Inc.
Dean Randall, retired
Molly Sullivan, Legal Assistant/Claims Representative, Health One

Ben Fuller and Barbara Colhapp also served on the subcommittee until their resignations because of time constraints. John Coleman, a retired physician, has also followed the deliberations of the subcommittee from its start and has contributed information, insights, and assistance with both the substance and the process of the study.

The subcommittee began meeting in October 1989 and met biweekly through June 1990 and again from September through November 1990. At the outset, the subcommittee decided it would use a two-part process for dealing with the subject of medical technology:

Step 1: Interview persons from the community and health care industry for their opinions of what types of technology should be looked at, issues or problems that have developed or may be developing regarding its adoption and use, and possible solutions, if they are needed.

Step 2: Hire a consultant to interview key decision-makers from hospitals, outpatient medical facilities, HMOs and health insurance companies on the process they use to adopt new medical technologies, as well as representatives of public-interest groups for their views on health-care-technology issues. Thirty interviews were conducted by the consultant, with findings and conclusions summarized in a report to the subcommittee.

As part of its process, the subcommittee interviewed (listed alphabetically):

David Adams, Business Manager, St. Paul Radiology
Earl Bakken, Founder and Director of Medtronic, Inc.
Paul Bowlin, Director of Medical Affairs, Fairview Southdale Hospital
Lewis Cope, health and sciences reporter, *Star Tribune*
Robert Dickler, Director, University of Minnesota Hospitals
James Ehlen, M.D., President, Physicians Health Plan
Sue Klein, Director of Quality Management, Mercy Medical Center
Barbara Leonard, Director of Maternal Child Health Program, School of Public Health, University of Minnesota
Elizabeth Lincoln, Vice President of Risk Management, Midwest Medical Insurance Co.
Nicole Lurie, M.D., Hennepin County Medical Center
Becky McIntosh, Clinic Manager, Model Cities Health Center
Ann Ogden, Vice President of Development and Marketing, United Hospitals
Del Ohrt, Vice President and Medical Director, Blue Cross and Blue Shield of MN
Richard Palahniuk, Head, Department of Anesthesiology, University of Minnesota Hospitals
Kathleen Flynn Peterson, attorney, Robins, Kaplan, Miller & Ciresi
Reinhard Priester, Fellow, Center for Biomedical Ethics, University of Minnesota
Helen Rubenstein, Special Assistant Attorney General, state of Minnesota
Norine Smith, Executive Director, Indian Health Board of Minneapolis
Gordon Sprenger, President and CEO, Lifespan, Inc./Abbott-Northwestern Hospital
James Toscano, Executive Vice President, Park Nicollet Medical Foundation
Barbara Veath, Medical Affairs Consultant, Blue Cross and Blue Shield of Minnesota
Harry Wetzler, M.D., Senior Scientist, Interstudy
Three patients or members of families of patients who have received various forms of high-cost, sophisticated medical technology

Subcommittee members also toured St. Paul Radiology, United Hospitals and Children's Hospital in St. Paul to visit and see first-hand the CT and MRI diagnostic areas, the neonatal intensive care unit and coronary angiography rooms. They witnessed, and discussed with hospital personnel, tapes of laser surgery and coronary bypass surgery.

The report and its policy recommendations are based on the findings and conclusions of this process.

FOOTNOTES

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APPENDIX I

Significant Technologies, Procedures

Endoscopy, arthroscopy (fiber optics)
Fetal monitoring
Mammography
Echocardiography
Computerized tomography (CT)
Digital subtraction angiography (DSA)
Magnetic Resonance Imaging (MRI)
Positron Emission Tomography (PET)
Single Photon Emission Computerized Tomography (SPECT)
Ultrasound
Pacemaker implant
Coronary angiography
Balloon angioplasty, laser angioplasty
Implantable defibrillator
Ventricular assist. device
Coronary artery bypass graft, heart valve replacement
Artificial heart
Organ transplants (heart, lung, kidney)
Bone-marrow transplant
Thrombolytic drugs (tissue plasminogen activator (TPA) streptokinase)
Carotid endarterectomy
Genetic testing, infertility studies
In vitro fertilization
High risk - premature birth prevention and support
Specialized intensive care units (coronary, neonatal)
Parenteral/enteral nutrition therapy
Intraocular lens implants, cataract extraction
Lithotripsy (ESWL)
Laser surgery
Joint replacement, transplant
Radiation therapy
Nuclear medicine studies
Linear accelerator
Dialysis (acute and chronic)
Hypertensive drugs
Biotherapeutic agents
Immunosuppressive drugs
Intravenous therapy, infusion pumps
Implantable drug metering
Home health services, treatments
Ambulatory surgery
Chemotherapy
Respiratory therapies, ventilator support
AIDS treatment, infection control

Source: Abbott-Northwestern Hospital

APPENDIX II

Profiles of 20 Technology Assessment Programs

Joint American College of Cardiology/American Heart Association Task Force on Assessment of Cardiovascular Procedures
American College of Physicians Clinical Efficacy Assessment Project
American Hospital Association Hospital Technology Series Program
American Medical Association Diagnostic and Therapeutic Technology Assessment Program
Battelle Memorial Institute Human Affairs Research Centers
Blue Cross and Blue Shield Association Medical Necessity Program
Blue Cross and Blue Shield Association Technology Evaluation and Coverage Program
ECRI
Institute of Society, Ethics and the Life Sciences (Hastings Center)
The Permanente Medical Group, Inc., Division of Health Services Research
Medtronic Inc.
National Center for Health Services Research and Health Care Technology Assessment Office of Health Technology Assessment
National Heart, Lung and Blood Institute
National Institutes of Health Office of Medical Applications of Research Consensus Development Program
National Library of Medicine
Congressional Office of Technology Assessment Health Program
Prospective Payment Assessment Commission
Smith Kline & French Laboratories Cost-Benefit Studies Program
University of California at San Francisco Institute for Health Policy Studies
VA Cooperative Studies Program

Source: Clifford S. Goodman, National Academy of Sciences, Washington, D.C.