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MEDICAL TECHNOLOGY -- WHERE IS IT GOING?

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- o Trends and proliferation of medical technology
- o What will be the impact on cost?
- o What is on the horizon?
- o Strategies to contain the utilization of various procedures and technology

MR. EDWARD J. WOJCIK: Health care costs have risen dramatically over the past twenty to thirty years from approximately 6% to over 11% of the gross national product (GNP). This is happening in the teeth of cost containment programs such as managed care, preferred provider organizations (PPOs) and health maintenance organizations (HMOs). Average premium increases over the last two years for fee-for-service type health care coverage have been in the range of 15-25% annually, with slightly lesser increases for HMOs.

According to one recent study, medical inflation and increased utilization accounted for about half of the rate of premium increase while improved technology, accounted for slightly over 10% of that increase, or about 1.5-2.5 percentage points of the annual trend a 15-25% total average increase. Thus, improved technology alone may be accounting for an increase in 1989 premium of anywhere from $1.5-$2 billion. Because of these large costs, the of "Medical Technology -- Where Is It Going?" is especially important.

Our first speaker is Cliff Goodman, Ph.D. He's the Director of the Council on Health Care Technology at the Institute of Medicine in Washington, D.C., a branch of the National Academy of Sciences. The Institute of Medicine acts under the Academy's Congressional Charter responsibility to be an advisor to the federal government and at its own initiative in identifying issues of medical care, research and education. The Council on Health Care Technology was established in 1986 to consider matters related to assessment of medical technologies.

DR. CLIFFORD S. GOODMAN: Technology assessment is a comprehensive form of policy research that examines the technical, economic, and social consequences of technological applications. It is especially concerned with unintended, indirect, or delayed social impacts. In health policy, the term has also come to mean any form of policy analysis concerned with medical technology, especially the evaluation of "efficacy and safety." This is an out-of-the-book definition of technology assessment by the Congressional Office of Technology Assessment. It sounds pretty academic and broad, yet this is the kind of thing we started with at the Institute of Medicine.

When one looks at medical technologies one can consider all kinds of uses for and applications of them. In health policy, especially, we're looking mostly at the evaluation of efficacy and safety,

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and that's been a problem. We've looked at the efficacy and safety of medical technologies, but we really need to start looking more at the cost implications. At the Institute of Medicine we took this definition and investigated what people are really doing in the field of technology assessment from a practical standpoint and built a pragmatic framework to help us all understand what the field's about.

There are seven dimensions to consider when assessing medical technologies: technology, application, stage of diffusion, properties, assessors, methods, and purpose of assessment. You must address these because, by the time a technology reaches you, you'll have to ask questions like: Does this fit into a health benefits plan? Is this going to cost us a lot of money to pay for? and so forth.

First, technology doesn't mean just hardware. It means much more, and this broader sense of technology applies to you. Besides the hardware, you're also going to be paying for and considering the costs of health information systems, administrative overhead, support systems, and procedures.

How do you use technology? Usually we think of diagnosis and treatment, but there's a broader spectrum of the kinds of uses of technology. It isn't used just to fix something that's broken. There are other problems as well.

A consideration in technology assessment is the question, how far along is this procedure on the diffusion scale? Is it emerging, new, established, obsolete or outmoded? Most of the questions that have been asked about technology assessment have been directed toward the newer technologies, but established ones are costly, too. You'd be surprised to find that many of the established technologies that apply today, particularly some high cost ones, have never really been exposed to rigorous study. Drugs and devices usually have to go through a screening process by the Food and Drug Administration (FDA) when they're new. But for medical and surgical procedures, there is no really strict comparable regulatory entity to do the screening.

What are we trying to find out about a technology when we assess it? We need to be concerned about safety, efficacy and effectiveness. Efficacy usually means how does it work in a lab or a perfect environment; effectiveness is how does it work in the field. But there's also a whole set of cost-related implications of technologies that you've got to consider: What's the price? What's the real charge? What's the real cost of developing it? Is it cost effective? Is it cost beneficial? Then you get into broader social, ethical and legal implications.

Who does technology assessment? It's a very diffuse field. It is not a clearly linked, cogent, or coherent system. There is no "in-box" for technology assessment questions. Sometimes you don't even know where to go to ask your questions or to find answers. A variety of organizations are involved in it, and each has its own respective agendas. Biomedical research agencies care about certain things. Physician societies care about their bailiwick of surgical and medical procedures. The regulatory agencies usually care about drugs and devices. The policy research institutes might be concerned about other ramifications of technology. There's no one big monolithic system out there, and it's tough to find the answers you are seeking.

How is technology assessment done? There is a whole range of methodologic approaches to answer those questions about safety, effectiveness, cost and so forth. Those approaches can be as simple as putting literature together, literature synthesis, or expert opinion. A lot of the big dollar answers on whether or not to put a new technology into a health benefits plan came about by word of mouth. Many technologies don't undergo a sufficiently rigorous attempt at evaluation. Other methodologic approaches involve simulation/modeling, cost analyses, epidemiological/other observational methods, and laboratory testing. And, finally, we have the so-called gold standard, the randomized controlled clinical trial.

Why is technology assessment done? I think you can probably fit yourself into one of the four major purposes indicated in Slide 1. The first one is usually the concern of the people who make or produce technologies and the people who regulate them. These people must demonstrate or ensure the safety or efficacy of these technologies. The second purpose might apply if you're a hospital procurement manager, trying to decide: Do I buy a magnetic resonance imaging (MRI) unit? Do I buy an extracorporeal shock wave lithotritor? How much do these things cost? What should I invest in them? The third purpose is one which many of us are familiar with on a

personal basis because we've all been patients at one time or another. These are the concerns of physicians and patients, about the effectiveness of a certain procedure/technology. People have different emphases on what's important to them in the field. Finally, in the fourth purpose of assessment, coverage or reimbursement decisions are the concerns of the insurer. So when we ask questions about a technology, we should be aware that different players have different concerns about it. The things that you care about technology might not be the same things that others are concerned about with regard to the same technology.

SLIDE 1

Purpose of Assessment

- to demonstrate/ensure the safety, efficacy, and other properties of health products for public/general use
- to assist in making procurement, investment, and related technology management decisions for health care institutions
- to assist in making patient care decisions, e.g., the appropriateness, indications for using technologies for the patient
- to assist in making coverage (whether or not to pay) and reimbursement (how much to pay) decisions for technologies

I'm going to give you some examples of multiple or different perspectives on technology assessment using the seven dimensions. Medtronic, Inc., shown in Slide 2, is a medical device company. It makes more heart pacemakers than any other company in the world. Medtronic, Inc. has technology assessment concerns that go along those same seven dimensions.

SLIDE 2

Medtronic, Inc.

Technology:	devices, materials, components, fabrication methods, application/implantation procedures
Application:	prevention, screening, diagnosis, treatment
Stage of Diffusion:	emerging, new, established, obsolete/outmoded
Properties:	safety, efficacy, cost-benefit, cost-effectiveness, quality of life
Assessors:	biochemists, physicists, plymer chemists, electrical engineers, cardiologists, orthopedic surgeons
Methods:	laboratory testing, clinical trials, implant registers, surveillance, telephone monitoring, cost analyses, computer modeling, expert opionion, literature syntheses
Purpose:	ensure high quality, reliable products; build knowledge and expertise on which future products are based

Slide 3 lists some examples of technologies that this company has been developing and has to assess. You'll see that those technologies are more device oriented. This company has its own agenda. It makes devices which it wishes to sell.

SLIDE 3

Medtronic, Inc.

examples of assessment topics:

cystic fibrosis screening system
portable blook pressure monitor
cardioversion-defibrillation devices
vascular prostheses
rate-responsive pacing sensors
blood gas monitors
implantable drug infusion pumps
scoliosis treatment devices
spinal cord stimulation devices
synthetic speech sourch device
electrode gels
electro-chemical sensors

Reports provided to FDA to obtain premarket approval for products and to clinicians who will use products.

Slide 4 presents an entirely different organization, the American Academy of Opthamology, which also does technology assessment but in its own way -- a medical specialty society. Look at the kinds of technologies and the properties it cares about, who assesses them, and what their purpose is. Now a days, we see a greater need for third-party payers to consult with these physicians. The third-party payers don't want to make coverage and reimbursement decisions on their own. They want to consult the experts, which frequently means consulting the appropriate physicians' society. The third-party payers want to be able to lean on the expertise of the doctors, but it's not always a strict contractual relationship.

SLIDE 4

American Academy of Opthalmology
Committee on Opthalmic Procedures

Technology:	opthalmic tests and procedures
Application:	diagnosis and treatment
Stage of Diffusion:	new and established
Properties:	safety and effectiveness for specified clinical indications, professional qualifications for use
Assessors:	ophthalmologists and experts in optics, materical science, as appropriate
Methods:	expert opinion, literature syntheses, group judgment
Purpose:	provide recommendations regarding the safety, effectiveness, and indications for use of ophthalmic tests and procedures to the AAO membership, payers, and others

Slide 5 illustrates some of the kinds of procedures, which the organization might be concerned with, some of which have become quite controversial. A good example is radial keratotomy, in which a physician makes little incisions in the cornea that change its shape in order to improve nearsightedness. This medical specialty society, together with one of the institutes of the National Institutes of Health, was sued over that procedure because certain physicians wanted to practice it, and they found out that insurers weren't going to pay for it.

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SLIDE 5

American Academy of Ophthalmology

examples of assessment topics:

laser trabecular surgery for open-angle glaucoma
opthalmic neodymium: YAG lasers
botulinum toxin therapy of eye muscle disorders
automated perimetry

in progress:

radial keratotomy
epikeratophakia
keratophakia and keratomileusis
thymoxamine
cataract surgery (historical review)

Reports published in *Ophthalmology*; distrubuted to government agencies, BCBS, HIAA, others

Another example of technology assessment is the Blue Cross and Blue Shield Association's Medical Necessity Program, shown in Slide 6. This program got started looking not so much at the new and emerging end of the diffusion scale but rather at the older end of the diffusion scale. The Blues began examining some of the technologies that are really outdated or outmoded.

SLIDE 6

Medical Necessity Program

Blue Cross and Blue Shield Association

Technology:	medical and surgical procedures
Application:	diagnosis, treatment, rehabilitation
Stage of Diffusion:	established, obsolete/outmoded
Properties:	effectiveness, indications for use; cost-effectiveness (recently) for selected procedures
Assessors:	medical advisory panel of BCBS plan medical directors; consultation with medical specialty societies
Methods:	literature synthesis, expert opinion, group judgment
Purpose:	provide guidelines to BCBS plans to assist in determining subscriber contractual obligations that require coverage only for necessary medical care

As indicated in Slide 7, they're focusing on a wide variety of laboratory tests and asking, under what circumstances all these batteries of tests are worthwhile. Laboratory tests and intake diagnostic tests cost a lot; many hospitals give the tests to everybody. The Blues are questioning whether that is appropriate.

SLIDE 7

examples of assessment topics:

- o selected laboratory tests
- o medical and surgical admissions batteries
- o respiratory care procedures
- o diagnostic imaging procedures
  - diagnostic imaging for breast disease
  - radionuclide scan and x-ray for bone metastases
  - upper gastrointestinal fluoroscopic study
  - chest x-ray examinations
- o cardiac care guidelines
  - cardiac exercise stress test
  - outpatient cardiac rehabilitation
  - echocardiogram
  - permanent cardiac pacemakers

Guidelines announced in national press conferences, transmitted to BCBS plans. Plans may send guidelines to physicians who provide care to subscribers, and to others.

Slide 8 presents yet another agency that does technology assessment -- the Congressional Office of Technology Assessment (OTA). This agency answers questions posed to it by Congress about technology assessment. The OTA's assessments have broad national policy implications.

SLIDE 8

Congressional Office of Technology Assessment
(Health Program)

Technology:	drugs, devices, procedures, support systems, and organizational/administrative technologies
Application:	previous screening, diagnosis, treatment, rehabilitation
Stage of Diffusion:	emerging, new, established, obsolete
Properties:	safety, efficacy/effectiveness, cost-related, social implications
Assessors:	multidisciplinary staff, consultants including health professionals, biomedical and health services researchers, health administrators, manufacturers, payers, consumers, lawyers, ethicists, economists, and others
Methods:	literature syntheses, expert opinion, cost and other analyses
Purpose:	clarify for Congress the range of technology policy options and potential impacts of adopting them

Slide 9 shows a wide variety of technologies that the OTA has been examining over the last several years, one of which is the artificial heart. Although not too many people really need it and it's costly, it is a great accomplishment. But some people are questioning whether it's worth it.

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SLIDE 9

Congressional Office of Technology Assessment
(Health Program)

examples of assessment topics:

CT scanning
medical information systems
screening for colon cancer
automated multichannel chemistry analyzers
Keyes technique
artificial heart
blood policy and technology
technologies for urinary incontinence
assistive devices for severe speech impairments
nuclear magnetic resonance imaging
intensive care units
Boston elbow
digital subtraction angiography

Reports published by U.S. GPO, available from OTA and National Technical Information Service. Several hundred copies sent to those expected to have interest in topic.

The National Institutes of Health have a program called the Consensus Development Program, shown in Slide 10 and Slide 11. The people involved with this program look at a variety of technologies in terms of safety and efficacy, but cost implications are not one of their concerns. For example, several years ago this program assessed liver transplantation. One of the best experts on liver transplantation said that liver transplantation is safe and effective under the certain circumstances, giving the indications and the contraindications -- all the ingredients of a good assessment. But at the press conference people asked, "Who is going to pay for these liver transplants? Who is going to receive the livers? Where are we going to obtain the livers? Where are these liver transplantations going to be performed? How much is this going to cost the nation?" The National Institutes of Health couldn't answer those questions because they had not addressed those issues. My point is that some assessment programs don't necessarily examine all the issues that are of interest to everyone else. This program handled safety and efficacy for liver transplantation, but it didn't address the cost, availability, and other issues of this very expensive procedure.

SLIDE 10

Consensus Development Program
Office of Medical Applications of Research (NIH)

Technology:	drugs, devices, medical and surgical procedures, facilities, support systems
Application:	prevention, screening, diagnosis, treatment
Stage of Diffusion:	emerging, new, established
Properties:	safety, efficacy, clinical applications
Assessors:	10-12 member panels including biomedical researchers, health professionals, methodologists, public representatives (ethicists, lawyers, economists, patients)
Methods:	literature syntheses, expert opinion, group judgment
Purpose:	assist medical providers in making clinical decisions, inform the public, contribute to scientific thinking

SLIDE 11
Consensus Development Program
Office of Medical Applications of Research (NIH)

examples of assessment topics:

breast cancer screening
supportive therapy in burn care
intraocular lens implantation
fresh frozen plasma
total hip joint replacement
liver transplantation
dental sealants in prevention of tooth decay
drug therapy for depression
lowering blood cholesterol to prevent heart disease
electroconvulsive therapy
adjuvant therapy for breast cancer
management of pain

Findings presented at news conference; statements widely disseminated to health provessionals, researchers, public; published in *JAMA* and pertinent journals.

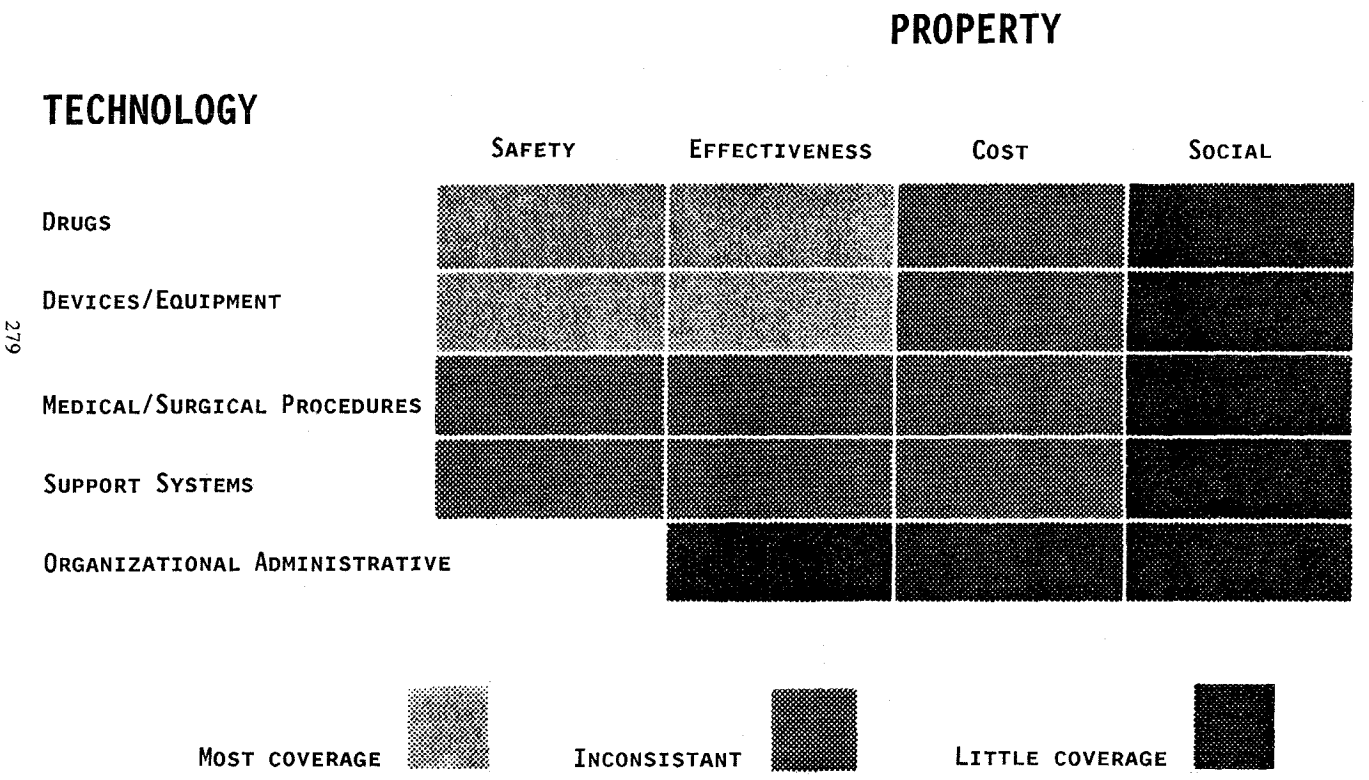
Slide 12 presents a broader view of technology assessment, which shows where the emphasis is and where it's shifting to. The left-hand column lists the main classes of technologies. Across the top are the kinds of properties of technologies that you might have concerns about. Most of the activities in this field have focused on safety and effectiveness for drugs and devices. As one moves to the right or moves downward, the level of activity becomes much less. There has been plenty of activity in the upper left-hand corner because the Food and Drug Administration is pretty systematic about screening new drugs and many new devices, but the assessments that have been done on cost for most technologies are rare. And the assessments that have been done for social, ethical and legal implications of technologies are even more rare. Medical and surgical procedures are beginning to receive a little more attention, but there's no systematic screening for these very expensive technologies. For support systems and organizational administrative systems, the activity level has been relatively minor. What we are seeing then is some shifting of emphasis towards assessing cost and medical and surgical procedures, but it's taking a long time.

What are some of the other considerations for technology assessment that are of use to you and to those who do assessments? Who generates technology assessment topics? Where do they come from? There's no system set up for that. How are assessments done? What's the process? What's the turnaround time? We've got third-party payers who say, "I've got a claim on my desk with a contractual obligation to pay for this claim for a health care procedure and I don't know whether to pay it or not." That person can't wait for a ten-year randomized controlled clinical trial to find the answer. Even though there is a need for a quicker turnaround on that, it's tough to find the answer when the payers need it.

To whom are these assessments reported? What's the impact of the assessments? Does anybody listen if you do them? Are technologies reassessed as they mature? Who pays for technology assessment? We spend about $550 or $600 billion a year for health care in this country, and, very conservatively, we spend maybe $1.5-$2 billion to answer questions like these. If you're running a corporation and you spent only that small percentage to evaluate your operation, you probably wouldn't be in business very long. We haven't been as rigorous as we need to be in examining the medical technologies that we use and pay for.

Slide 13 gives some examples of sources where one can find out about new and emerging medical technologies. The problem is that there's no one place to look. I'm trying to put together information sources about new and emerging medical technologies. For example, in conference proceedings of medical societies, such as the American College of Surgeons and the American College of Physicians, the participants discuss new and emerging procedures. Quite often, the discussants are people who sell marketing research reports and people whose job it is to keep up on these things. On-line databases are another source. There's a directory of on line health care databases. There are databases such as AMA/NET and BMEDDS (biomedical engineering decision

COMPREHENSIVENESS OF U.S. TECHNOLOGY ASSESSMENT



support systems), the FDA bulletin board, HEALTH, MEDIS, and MEDLINE. There's an on-line database for the National Technical Information Service (NITS). There are many sources like that which tell you what's coming over the transom. There are news services on-line like NEXIS and others. There's a whole network of market research, investment, and brokerage firms whose job it is to track information about new and emerging technologies for investment decisions.

SLIDE 13

Examples of information sources for new and emerging medical technologies:

Special publications

Meditrends, Hospital Technology Scanner (American Hospital Association)

Estimating the Impact of Scientific and Technological Advances on Increases in Medicare Costs per Case for FY 1989: Implications for Discretionary Adjustment Factor for FY 1989. (Prepared by Project Hope for the Prospective Payment Assessment Commission)

Health Technology. Published by ECRI, Plymouth Meeting, PA. See especially Vol. 2, No. 4, July/August 1988.

PMA Product Development Updates quarterly (e.g., New Biotechnology, Products for the Elderly, AIDS) Pharmaceutical Manufacturers Association.

Conference proceedings

Medical professions, providers, engineering/scientific

Online databases (see, e.g.: *The Directory of Online Healthcare Databases, 1989* published by Medical Data Exchange, Los Altos, CA)

AMA/NET
BMEDDS
BRS/SEARCH
FDA Bulletin Board
HEALTH
MEDIS
MEDLINE
NTIS

News services

NEXIS
F-D-C Reports, e.g., NDS Pipeline, Prescription and OTC Pharmaceuticals, and Health Policy & Biomedical Research
Pharmaprojects
Scrip

Market research/investment/management sources

Some special publications are yet another source of information. There's a journal called *Health Technology* which is published by Emergency Care Research Institute (ECRI) in Plymouth Meeting, Pennsylvania. That journal's market is hospitals and the people who buy medical devices and equipment for hospitals. In the July/August 1988 issue, the journal included a list of new and emerging technologies that hospitals ought to be interested in buying; some of them are very expensive. The American Hospital Association publishes *Medi Trends*, which just came out again in 1989. It's a compilation or consolidation of information from many medical journals and experts in the field of health care technology, which attempts to briefly summarize all the new things one needs to look for in medical technologies, diagnosis, treatment, rehabilitations, screenings, and so forth.

The Prospective Payment Assessment Commission (Pro PAC), in order to make decisions about adjusting the diagnostic related groups (DRGs), needed to know about the new technologies. Its members did a comprehensive study that looked at new and emerging medical technologies with respect to their cost implications for the Medicare Program. The work was done by Project Hope in Washington, D.C., and the report can be obtained through Pro PAC in Washington, D.C. While

this is a very good source, it does demonstrate, though, that it isn't always easy to find out the information you need.

Finally, what are the criteria that generally make a technology important for consideration? The first criterion is a high unit cost such as MRI or a position emission tomography (PET) scanner, or a lithotripter. The second criterion is the frequency of use. Does the technology get used a lot? Even if a technology isn't terribly expensive, it can become costly if it gets used a lot. These little nickel-and-dime laboratory procedures that are given to a hundred million people a year are going to add up. The third criterion is a potential for significant benefit or risk. If a technology isn't going to make much difference in someone's health or if it doesn't pose a significant risk, it's less likely to be assessed; but if it can make a big difference in health or it poses a significant risk to the person, then that's something that bears assessment. A fourth criterion is the variation in use. A lot of medical procedures especially are subject to wide variations of use. Jack Winberg has built a career around this; he started to look at prostatectomies by region. For example (and I don't have the exact numbers), he'll look at a county in New Hampshire or part of another state, and say, roughly 20% of the men might need and use this procedure in one area while a similar group of men, adjusted for age and other demographic variables, might utilize the same procedure twice as much. So when you're seeing the same procedure being applied very differently in two different areas, you start asking questions about it.

Let me summarize then four reasons why it's important to assess the technology: (1) high unit cost, (2) high frequency of use, (3) significant benefit or risk, or (4) variation and use in practice.

MR. DAVID TENNENBAUM: I'd like to share with you some of my thoughts from the third-party payer perspective on the role that technology plays in contributing to rising health care costs and describe some of the thought process that the Blue Cross and Blue Shield Association is involved with in evaluating technologies. We define technology fairly broadly to include any drug, device, or procedure -- just about any kind of clinical service that a provider may offer. Our focus is also fairly broad, encompassing not only well-established technologies but new technologies and existing technologies addressing new applications. They all contribute to costs. Our focus includes both the big ticket technologies and the smaller ones, which may also be significant.

As payers we face two different types of fundamental clinical questions with regard to technology. One is a question of efficacy. The other is appropriateness. With regard to efficacy, that question gets predominantly directed to new technologies. Appropriateness or medical necessity gets devoted to existing well-established technologies. When we talk about efficacy in looking at new technologies, the fundamental question is whether or not a given technology has progressed from some definition of investigative procedure. From the perspective of the third-party payer, investigative generally means it's not eligible for coverage. At what point does the technology pass through a certain threshold to then be considered safe and effective?

The Blue Cross and Blue Shield Association has its own set of review criteria, which we employ to evaluate new technologies. One of the ways in which we serve our member Blue Cross and Blue Shield plans is by providing guidance and advice to them about these emerging technologies. The ultimate coverage decisions, however, rest with the member plans. The principles that guide us are twofold. One, there should be a sufficient amount of authoritative evidence in the peer review medical literature, and two, that there should be some evidence that there's an impact on health outcome. In other words, it's not whether a particular device has been able to take a pretty picture but rather, in fact, whether that pretty picture has had a significant effect on patient management.

The five principles that guide us in reviewing technologies are as follows:

1. The technology must have a final approval from the appropriate government regulatory body. From our standpoint that basically means it must have FDA approval. This is only an initial criterion that a technology must meet.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. The technology must improve the net health outcome.

3. The technology must be as beneficial as any established alternatives.

4. The improvement must be attainable outside the investigational setting. It does us little good if the one generator of the procedure is able to do it while nobody else can.

5. There must be some evidence that the provider community, at large, is also able to perform the procedure.

The Medicare program just recently made public, and more explicit, the proposed criteria that it will use to evaluate technologies. One provision that has received much attention and interest is that for the first time Medicare is going to make some effort to incorporate cost effectiveness as a criterion in its review process. We commend Medicare for this tack. It's a bold but reasonable step. Medicare is going to be fairly selective in deciding which technologies it will choose initially in considering cost effectiveness. I believe that we are still in the beginning phases of being able to employ cost effectiveness analysis in technology assessment, and we look forward to Medicare's doing it.

Let me now highlight some of the pressures and forces from the provider community which we, as third-party payers, perceive as challenging us. Third-party payers are increasingly facing pressure to pay for experimental or investigative procedures. The old debate or the one that we're perhaps more familiar and comfortable with, was trying to assess whether a new technology, in fact, had passed that threshold from being investigative to being safe and effective or standard medical practice. The emphasis is now evolving to where the provider community is increasingly willing to concede that this is, in fact, an investigative procedure, but nevertheless, it wants us to pay for it. Coincidentally, at the very time that the provider community is requesting payment for investigative treatments, our own capacity as third-party payers to assess whether a given service is investigative has increased. There was a time when most third-party payers simply didn't know what they were paying for. Nowadays, with the increased benefits management and managed care programs in place, we have access to better data. We have become increasingly aware that we are paying for investigative treatments for which we had never intended to pay and have explicit contractual exclusions not to pay. This pressure to pay for investigative treatment is coming from a number of fronts, not the least of which is a revision in some of the FDA's drug policies.

The FDA is routinely criticized for taking too long to review and approve drugs, thus lengthening the time before those drugs are available on the market. The FDA has made some effort to be responsive to that criticism and has made some fairly significant policy decisions over the past few years to do that. Efforts have been made to speed up the review process, through the various phases of evaluation and, in some cases, to actually eliminate some of the end stages of investigation. Sometimes, in order to get the drug on the market sooner, the FDA has even allowed for concurrent data collection and analysis while the drug is on the market. For such a drug, having what is referred to as a premarket approval (PMA) to market, most third-party payers have little choice but to pay for it. A similar kind of FDA policy is one in which the FDA has said, basically, that an individual can bring an investigative drug in from outside the United States for his or her own personal use, provided that it is not sold to other people. Again, third-party payers question whether or not we should be paying. A perhaps more contentious point is what we refer to as the treatment IND. This refers to a drug/device/procedure, which the FDA readily acknowledges is investigative but makes available to the general public under certain circumstances, on condition that the provider and the subscriber will provide data to the manufacturer regarding its efficacy. The drug manufacturers do not typically charge for these drugs, since there's some implied warranty of efficacy if they charge for it, and I think they're happy to give it away at these early stages. But the questions that we face as third-party payers are with respect to the ancillary services and hospitalizations associated with the provisions of these investigative services.

Another major force pushing for us to pay for investigative services comes from the cancer community. The National Cancer Institute (NCI) estimates that there are about 50 thousand individuals who are in some control trial for cancer treatment, and its goal over the next five years is to double that number. There was a time when the federal government would subsidize the hospital and patient care costs associated with such trials, but those days are gone. The NCI will usually just provide payment for the investigative drug, and some monies to do the research and data collection, but the hospital and patient care costs are largely left to the patient, or increasingly, to the payer. We are hearing increasingly from the provider community reasons why we should be paying for this. The principal argument is that, yes, one knows it's investigative, but

if it's a life and death situation, or if there are no alternate therapies, then this is, by definition, the state-of-the-art technology, and third-party payers should be paying for it.

Another major thrust we're seeing more of from the provider community concerns "big ticket" technology items. Two such examples are organ transplants and in vitro fertilization. About five years ago, we as a country went through a great debate about whether or not we should be paying for heart and liver transplants. Practically every Blue Cross and Blue Shield plan, at least, has the capacity and willingness to offer benefits for heart and liver transplants. Not all accounts may elect to have it, but at least the willingness to offer it through some special rider generally exists. There is a greater percentage of our plans, which also offer benefits for heart, lung, and pancreas transplants, although, again, the percentage is something less than heart-lung. I believe that in the future the big transplant issue will be over bone marrow transplants, a procedure that will cost $100,000 to $200,000. Currently, the procedures are still being used for relatively rare conditions, such as various hematological bone marrow disorders and bone marrow cancers. Yet, there is an emerging body of evidence to show that bone marrow transplants will be used as an adjunct to various cancer treatments for advanced cancer. There's a large amount of evidence building that it should be or can be used for metastatic breast cancer. When bone marrow does pass that threshold and is shown to be effective as an adjunct for cancer treatment, we're going to be seeing a huge proliferation of these procedures.

Another interesting example of a big ticket item is in vitro fertilization. Here we find an interesting dilemma. The question is not whether the procedure is efficacious or not. We are looking at a general population in which 16% of married couples between the ages of 18 and 40 are infertile. An estimated one million women would be considered eligible for in vitro fertilization. These one million couples currently have no chance of conceiving without the in vitro fertilization procedure. At best, we're looking at about a 20% success rate after perhaps four or five tries over a year's time; at $4,000 or $5,000 a shot, that's an average of some $20,000-$30,000 before the procedure is successful.

I highlight these two technologies as examples of what we're increasingly seeing with the new technologies. For very costly and expensive technologies, third-party payers are increasingly offering these services as a rider rather than offering them under the basic package. They will offer it to the account if the account is willing to pay the additional special premium for that service.

The other interesting facet that these technologies represent is that one cannot look solely at the efficacy of a technology. One has to also look at the provider of the service. Generally, the more complex the procedure, the more sophisticated the provider needs to be. We as third-party payers are increasingly putting ourselves or finding ourselves in a position of being provider evaluators, as well as technology assessors -- looking to various experience, volumes of procedures, and successful outcomes associated with these procedures before we will, in some cases, encourage our subscribers to utilize these services.

Another general trend that we see as third-party payers is the increased use of screening procedures. I'm talking about the fairly well-established technologies: mammogram, pap smears, colon cancer diagnostic procedures, cholesterol testing, etc. We are absorbing a tremendous increase in the demand for these services from a number of fronts, not the least of which are state mandates. Last year there were at least ten states mandating that mammography be offered by third-party payers, and this year alone we're aware of at least ten additional states that are considering such legislation. The demand is also coming from accounts to some extent. Although faced with some 20-30% premium increases, accounts are not as enthusiastic about offering additional benefits at this time. Interestingly, the push to offer these benefits is actually coming from the providers themselves. Traditional benefit programs find themselves competing with HMOs and generous PPO packages and in order to avoid continuous adverse selection, those programs must offer benefits, which are going to attract the younger, healthier persons.

Much of the debate about these technologies is concerned not with whether they should be offered but rather what the right frequencies are. The main debate we observe now with mammography, for example, is the appropriate age. Should it be 35, 40, or 50? We have some fairly powerful organizations lining up with differing opinions about that based on various cost effective measures and assumptions which we employ. The American Cancer Society and the American College of Radiology are advancing the argument of baseline at 35 and annual screening at 40.

The American College of Physicians and the National Task Force on Health Promotion is advocating 50, while the Blue Cross and Blue Shield Association, through its own review, is also advocating starting at age 50. Similarly, we have debates on whether pap smears should occur every year, two years, or three years. There seems to be a growing body of evidence to show that perhaps every two or three years is now considered more appropriate than yearly.

I bring up this point because I think we can anticipate that in the coming year there will be a great initiative from the government pushing and promoting screening services. A U.S. preventative task force, which has been in existence for several years doing extensive research analysis, is making its findings public, and the government is calling upon payers, providers, and various groups to begin to implement some of these recommendations. You will soon be hearing a greater emphasis to pay for these services.

We are also observing a fundamental change from the insureds themselves as to the kinds of technologies and services that are being demanded. Consider acquired immune deficiency syndrome (AIDS), for example. It's expected that by the year 1991, there will be some 400,000 people diagnosed with AIDS. That will be generating some estimated $37 billion in health expenditures. With alcohol and substance abuse, we're expecting 1.5 million people by 1992 to be admitted just for the explicit diagnosis of alcohol or substance abuse.

Pro PAC, the Prospective Payment Assessment Commission, tries to be the guiding force behind Health Care Finance Administration (HCFA) and the Secretary of Health and Human Services in terms of adjusting the DRG rates. One very important aspect that the people there look at is the role that technologies play in providing services and to what extent the DRGs need to be adjusted. Pro PAC released its report to Congress in March 1989, making some interesting recommendations. It recommended that for 1990 the allowances for scientific and technological advancements be zero. Pro PAC had looked at some 13 technologies, which it had defined as cost increasing and quality enhancing technologies, and which would generate costs of about $242 million alone. Yet, Pro PAC argued for no additional increase in DRG rates associated with the technology. The rationale is that most of the technological advancements are expected to improve the efficiency and the cost effectiveness of providers providing those services. This is somewhat in contrast to last year. In 1988, Pro PAC had looked at 29 different sets of emerging technologies for 1989, encompassing over $300 million of additional expenditures and had recommended a .5% increase in the adjustment.

I tell you these numbers because a major issue is the extent to which technologies affect the cost of inpatient care. It appears to me that most experts and prognosticators, with respect to technology proliferation at least on the inpatient side, are emphasizing cost effectiveness. The issue is not so much offering something new and different, but rather, offering something proven to be cost effective to the provider, to keep the cost for that DRG at the same rate.

The following are some of the different technologies which we, at Blue Cross and Blue Shield Association have observed over the past year and which we think can become big ticket items. These include services and drugs and such as aerosolized contamidine used prophylactically to treat pneumocystis carinii in people with AIDS and whose cost is estimated at $1,200-$1,500 a year; AZT prophylactic, also for people with AIDS, is estimated to cost $800 a year; and Inteferon, which is having an increasingly wider set of applications, estimated to cost $1,500 a week to treat Kaposi's sarcoma, a condition which is commonly found in people with AIDS. We are also looking at human growth hormone which is estimated to cost $20,000-$30,000 a year. The new generation of cholesterol lowering drugs are suspected to cost from $200,000-$300,000 a year. The new factor eight drug used for hemophiliacs raises an interesting question in that most hemophiliacs, by virtue of being exposed to so many blood byproducts, are human immunodeficiency virus (HIV) positive. The thrust now is to try to give the hemophiliacs a factor eight blood derivative that is much more highly refined and doesn't contain the HIV antigen and which is eight to ten times more expensive than the original factor eight. We're looking again, therefore, at something on the order of $15,000-$30,000 a year. Consider TPA versus streptokinase -- here we are looking at a technology that promises some advantage over streptokinase and is offered at $1,200-$1,500 a shot for TPA compared to a very nominal cost for streptokinase.

These drugs are simply part of an increasing trend that we are observing. As the drug industry develops more sophisticated capacity to develop drugs, as biotechnology capacity improves, we're going to be looking at whole new generations of very expensive drugs heretofore unseen.

Consequently, third-party payers must become aware of particularly expensive drugs and will need to scrutinize these closely to determine their effectiveness.

I'll briefly mention some of the technologies, which we expect will be used and paid for in the near future. These would include gall bladder lithotripsy, which will eventually, if proven to be successful, replace choleocystectomies. We're also seeing chorionic villi sampling, a technology coming to maturity that will be replacing amniocentesis in the near future. Five years ago a PET scan was a futuristic concept, and yet we're seeing in the near term the increasing acceptance of the PET scan in the evaluation of dementia and Alzheimer's disease. Although they appear now to be more of a long-term futuristic technology, we are beginning to wonder and worry, too, about the various predictive genetic screening procedures under which, at infancy or early adulthood, one might have one's genes analyzed and, from that analysis, predict the likelihood of developing cancer, hypertension, or other diseases. That technology will be problematic in terms of the various policy and coverage implications.

MR. WOJCIK: Dave, you mentioned technologies like the lithotripsy and the PET scans, which replace some technologies, for instance, the surgical procedure for a gall bladder or a CAT scan respectively. Would you think that lithotripsy will lower the cost of a gall bladder operation in the long run, or is it going to make it more expensive? I believe that now the PET scan is much more expensive than the CAT scan. Can we assume that the original costs that I have stated in the introduction are going to go much, much higher, because of some of these new replacement technologies?

MR. TENNENBAUM: Let me give you two interesting examples. One is in the area of lithotripsy. We have a lot more experience with kidney lithotripsy. Gall bladder is now the next generation of technology, but two interesting scenarios got played out with kidney lithotripsy. One, although the average invasive operative procedure to remove a kidney stone was something like $3,000 or $4,000, we found that, when kidney lithotripsy came on the market, we were seeing a tremendous variation in the expected costs, some twofold and threefold differences among providers. Many were making the interesting argument that they should be paid at the same level as the invasive procedure itself. We took great exception to that and said, "Although you are treating what historically has been considered a surgical procedure, you are essentially employing medical technologies, if you will, and, therefore, the cost should be much more medically cognitively oriented rather than surgical." So, in the example of kidney lithotripsy, we were able to effect a significant reduction in cost.

With the issue of CAT scan/MRI/PET scan, we were unfortunately initially seeing that, because the MRI/CAT providers were uncomfortable with the MRI, they were doing both scans in order to have some point of comparison. So I don't think that we were seeing any cost savings there. Now, there's an increasing delineation between what a CAT can do and what an MRI scan can do. We definitely want to know in advance what's truly unique and different about the PET scan that the MRI and the CAT scan can't do. Payers will be primarily interested in encouraging payment for a PET scan only for those truly unique conditions requiring it. For all other conditions not needing the more sophisticated capacity, payers will pay only for either a CAT or MRI, based on the need.

MR. MARK F. HOWLAND: I'm interested in the fast track approval of certain drugs by the FDA on an experimental basis. How are insurers reacting to that? Are we as a group paying for them, or are some paying for them and some not?

MR. TENNENBAUM: There's a great diversity of response. All payers, including all Blue Cross and Blue Shield plans, are feeling the pressure to pay. Some plans have adopted the policy of saying, "we will look at the particular drug in question or the particular procedure in question, and we will try to evaluate its merits or efficacy. If there is evidence to show that it's effective, then we will go ahead and pay for it." For example, I believe Independence Blue Cross (formerly Blue Cross of Philadelphia) has a fairly elaborate review process where it will review a drug that's not yet FDA approved but that the provider community wants to offer, and make an individual case-by-case determination as to whether or not Independence Blue Cross will pay. Currently, I think that's the response that most payers will be giving to this type of question.

MR. LESLIE D. MICHELSON: I shall be discussing what I consider to be among the most complex services provided in our economy, the delivery of health care. One of the reasons that health care is an incredibly complex service is because of the technology associated with it. My thrust is that,

in order to control health care and to manage the service and health care delivery, one needs to implement a set of strategies and modalities that are at least as complex as the service delivery itself. One of the main reasons why a health care cost problem exists is because people have not been as comprehensive in their approach to solving that problem as is necessary. So the thrust is putting together a comprehensive framework for managing care.

I want to illustrate as graphically as I can the extraordinary step up in health care costs. As Slide 14 illustrates, many employers across the country are now looking at health insurance premium increases on the order of 20% annually. What's so shocking about this, in light of the relatively low level of inflation in the economy, is that this is on top of a base, which is approximately 100% higher than it was in the early 1980s when employers first got hit with 20% increases.

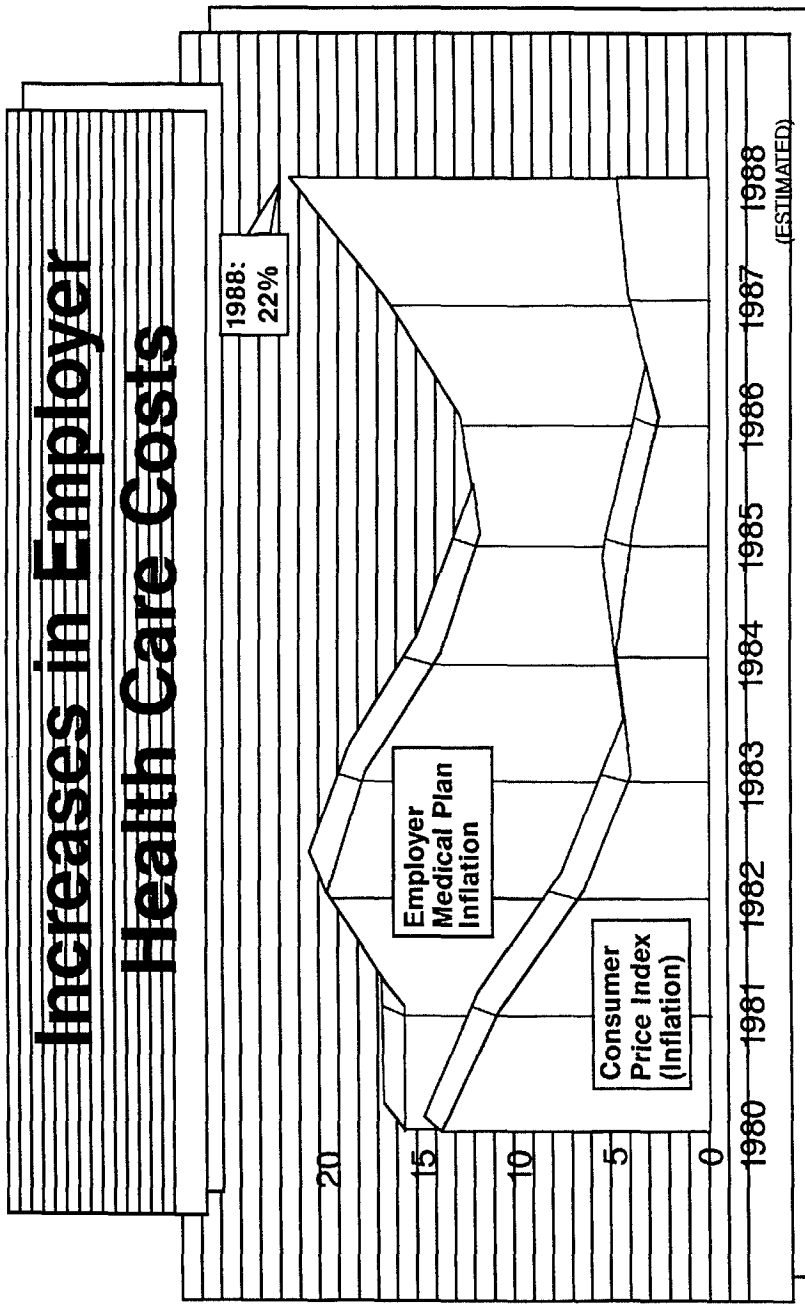
Many people are attempting to analyze the problem and parcel out the causes for these extraordinary increases. *The Wall Street Journal* recently published a pie chart trying to parcel out the causes down to the first decimal place. I'm not sure that anybody can do that in any reliable and scientifically valid way. The causes of increased health care costs shown in the pie chart were as follows: malpractice, 1.4%; catastrophic cases, 8.8%; technology, 11.2%; utilization, 16.3%; cost shifting, 29.5%; medical inflation, 32.6%. It suggests that much of the increase in health care costs is due to new technologies, increasing utilization, the shifting of costs from player to player, and an extraordinary increase in catastrophic cases and the technology that's available to handle those cases. I am not suggesting that we turn back the clock and do away with all these marvelous technological innovations. That's not my position at all.

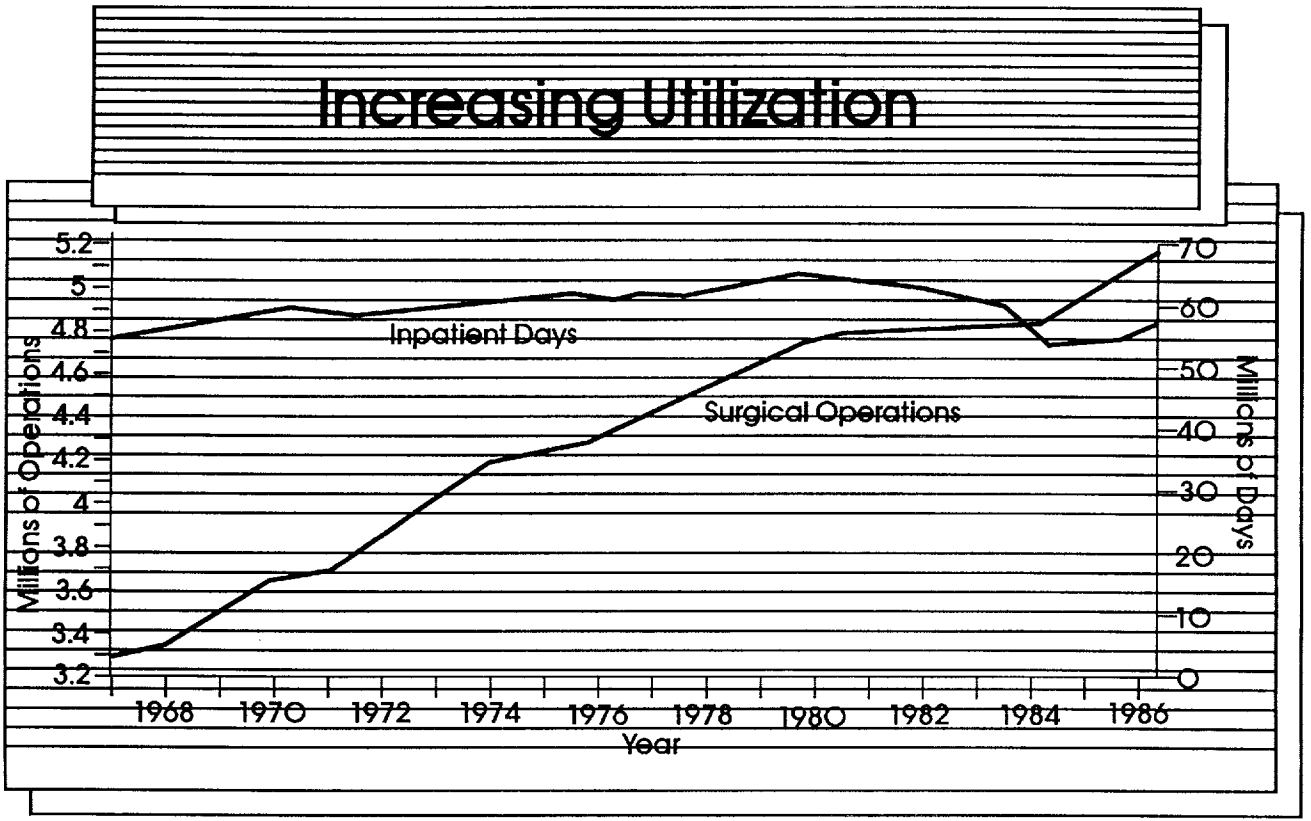
I think there have been extraordinary and marvelous medical technologies that have been developed and are currently being utilized to great effect throughout the health care delivery system. There are wonderful imaging technologies, which make it much easier to diagnose difficult problems. There are wonderful treatment modalities, such as intraocular lenses, which when properly implanted give people who are virtually blind the opportunity to see again; or the implantation of artificial hips, which give people who are crippled by arthritis the opportunity to be mobile again; or technologies like organ transplants, which extend people's lives. There have also been truly extraordinary developments in neonatal care, which give very tiny babies a chance at life. There are other modalities such as coronary artery bypass surgery and angioplasty, which can now give people whose lives would be shortened as a result of coronary artery disease an opportunity to live longer, fuller, lives.

The problem with many of these technologies, in my view, is that they're initially evaluated using the very best doctors in the country on specific types of patients, without regard to the costs associated with the utilization of those technologies. Once they get out in the community, though, they're used by every doctor on virtually all types of patients and, given the dynamics of the third-party reimbursement system, are used without regard to the increasing marginal cost associated with those technologies. That represents a key problem. I'd like to put that problem in a larger perspective of what I believe is going on in the health care delivery system and then illustrate to you some ways in which we can respond to that type of problem.

Although I think it's difficult to put together pie charts explaining the factors resulting in the increase in health care costs, it's not very difficult to look at some of the trend lines. Slide 15 illustrates the consistently increasing use of surgical procedures. There's a point of inflection in about 1984; no one's quite sure why that occurred. Many of those surgical procedures have traditionally been done on an inpatient basis, but what the inpatient-days line on Slide 15 illustrates (graphed using the scale on the right-hand side) is that, notwithstanding the very significant increase in the number of surgical procedures, the number of inpatient days has been declining, although there's been a recent reversal in this decline. This decline is a result of utilization review programs, which have been reducing the average length of stay for typical inpatient procedures and which have been shunting to an outpatient setting procedures that had previously had been done on an inpatient basis. Extraordinary developments in medical technology now make it possible to do things in an outpatient environment that which previously had only been possible and safe in an inpatient environment, but it's not at all clear that there has been a cost saving change in the health care delivery system. My view is that outpatient surgical procedures probably have saved some costs but not nearly as much as many people think because the focus has been too narrow.

SLIDE 14


Increases in Employer Health Care Costs
1988: 22%
Employer Medical Plan Inflation
Consumer Price Index (Inflation)
20
15
10
5
0
1980
1981
1982
1983
1984
1985
1986
1987
1988
(ESTIMATED)



SOURCE: Division of National Cost Estimates, Office of the Actuary: National health expenditures, 1986-2000. *Health Care Financing Review*. Vol. 8, No. 4. HCFA Pub. No. 03239. Office of Research and Demonstrations, Health Care Financing Administration. Washington. U.S. Government Printing Office, August 1987.

Slide 16 illustrates the increasing utilization of outpatient visits. Again, there's a point of inflection in 1984, which occurs at about the same time that the number of inpatient days began its decline at a somewhat increasing rate. People have begun to use outpatient procedures much more frequently than they've used inpatient procedures. You sort of punch in on the punching bag on one side and it comes out on the other side. When one looks at what has happened to the average cost for an outpatient visit during the same period, one sees that there have been extraordinarily large increases over a period from about 1982 to 1986, on the order of 70%. So the shift from an inpatient procedure to an outpatient procedure has been associated in time with a tremendous increase in outpatient utilization and a tremendous increase in average cost for outpatient procedures. It is questionable whether or not this strategy has accomplished the cost containing objectives that were initially set out for it.

This suggests a particularly difficult dilemma for everyone who's concerned about developing appropriate health care management techniques. The dilemma is how does one in this environment contain costs without restraining innovation or denying people high quality health care? In response to that, I'd like to first examine some of the strategies that have been employed to date and then describe and try to persuade you of the validity of a more comprehensive framework that I think is appropriate.

What's happened to date on cost containment efforts? There's been a lot of shifting going on and I will admit that this tends to simplify, somewhat unfairly, what's happened, but it illustrates the point that I think is fundamentally true.

1. The first shift has been a shift of risk to providers. DRGs are a Medicare shift of the risk of the cost of a particular case to hospitals. HMOs are essentially a shift of the financial risk to the doctors or to the business people who've put together the HMO. Capitation programs of all sorts are nothing more than shifts of risk to providers as opposed to payers.

2. The second shift has been the shifting of care to discounters. PPOs are essentially discounted networks. Exclusive provider organizations (EPOs) are discounted networks in which the providers have agreed to discount their typical fees in exchange for an increase in volume. What has happened in many of these circumstances is that on a total cost basis they've more than made up for the discount in fees.

3. The next strategy has been a shift in the location of care. A reduction in length of stay occurs from a shifting in location of care from an inpatient facility. Home health care is a shifting of the location of care from an inpatient facility to home. Discharge planning is basically the same thing, i.e., shifting of care from an inpatient facility to a nursing facility or to home. Outpatient mandates, which require a procedure to be done on an outpatient basis that had previously been done on an inpatient basis, are also a shifting of location.

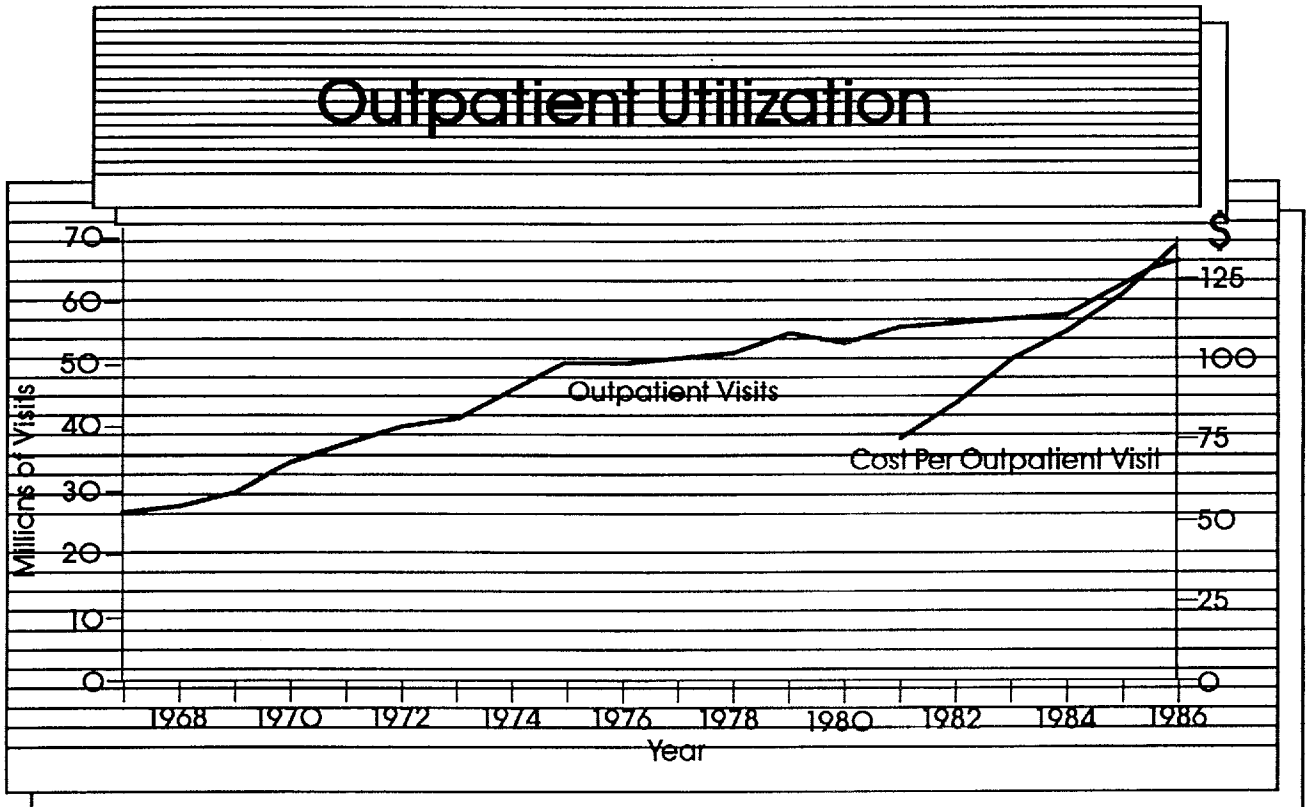
4. Another strategy is case management in which case managers do more than just shift location, by attempting to find more appropriate settings for care. It is not clear to me nor to anybody else exactly what the overall cost containing results are of this type of shift. Clearly there are some, but I wonder how much.

5. The final factor in existing cost containment efforts is the shifting of costs to patients in terms of increased deductibles, copayments, and caps.

I suggest a more comprehensive framework, which I think would be far more successful in managing care. That is a framework which focuses not on containing cost, but on maximizing value. That's what it's all about in the final analysis. Value in health care, as in any commodity, consists of basically two components, total cost and quality. What has been lacking is that the thrust of the focus has been on containing the cost side with entirely too little focus on the quality side.

Cost consists of two parameters: the unit cost and the volume. Merely focusing on unit cost without focusing on volume isn't going to result in successful management on the cost side of the equation.

Quality in health care consists of a number of different components. The first is appropriateness. Does this modality, procedure, or technology need to be used for this patient at this point in time?



SOURCE: Division of National Cost Estimates, Office of the Actuary: National health expenditures, 1986-2000. *Health Care Financing Review.* Vol. 8, No. 4. HCFA Pub. No. 03239. Office of Research and Demonstrations, Health Care Financing Administration. Washington. U.S. Government Printing Office, August 1987.

The second component of quality is the process of care. How good is this surgeon? How good is this radiologist? Are their readings accurate? Do they follow appropriate practice patterns? The third component is patient satisfaction. Patients have very distinct and significant reactions to the process of care they receive. These are important considerations, and in my view, they are ignored much too often. Finally, the fourth component of quality is the outcome. Our research has shown that there are dramatic differences in outcomes from provider to provider.

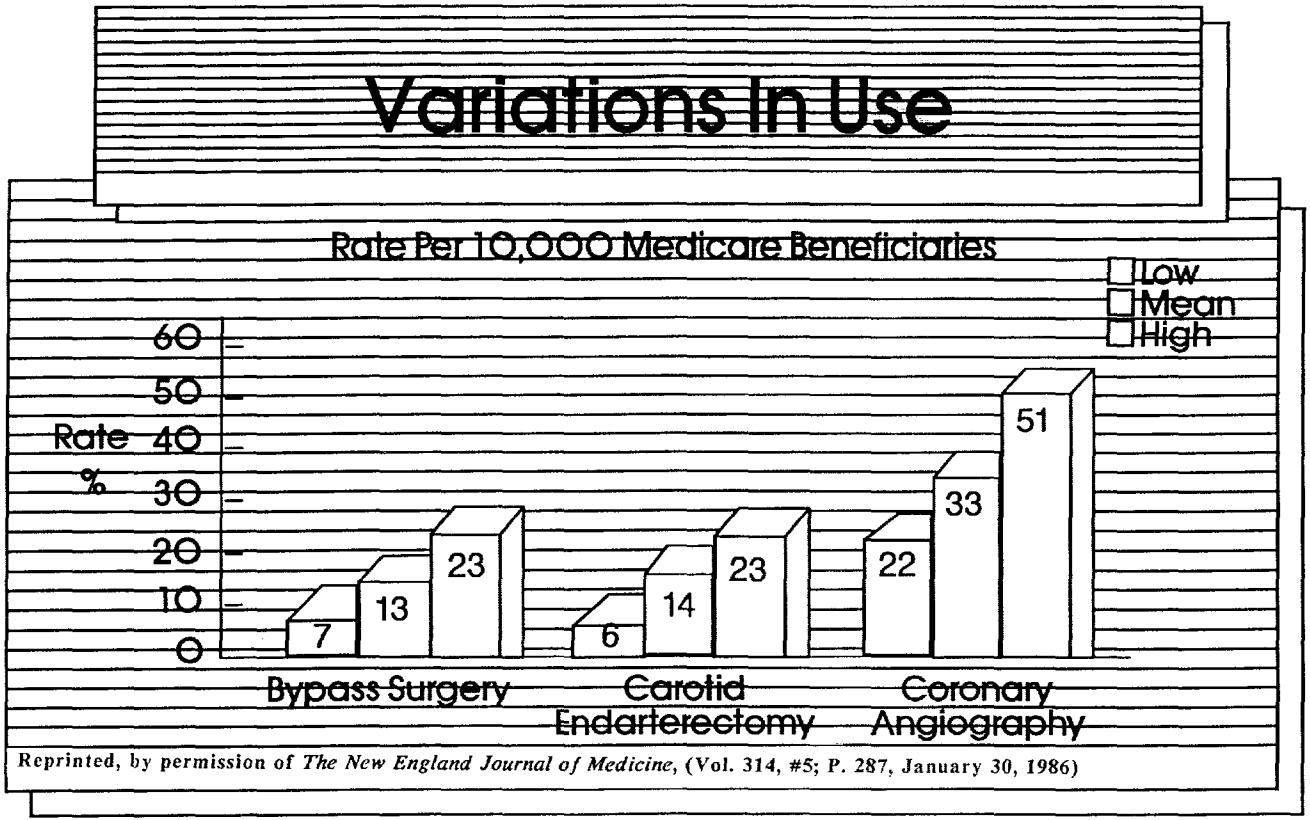
Just in case you believe that one needn't look at all these other factors because they have been taken care of already, I'd like to disabuse you of that view by sharing some of the results of the research that my colleagues have performed and published. The first is variations in use. There is an entire school of analysis of health care data, which has demonstrated extraordinary variations in the per capita utilization of a variety of different procedures. Slide 17 illustrates three procedures (bypass surgery, carotid endarterectomy, and coronary angiography), indicating the per capita utilization in the Medicare population and showing variations in these procedures from two to four times for populations who are otherwise indistinguishable. It really causes one to ask what in the world is going on?

A second thing to look at is a variation of process. One of my colleagues did a careful study of sixteen academic primary care practices to look at deficiencies in what's happened in those practices. Slide 18 summarizes some of the results which she found and published. The bars illustrate the percentage of patients in these practices who did not receive necessary health care -- running the gamut from administering flu and pneumococcal vaccines (pneumonia vaccines) to the teaching of breast self-examination and the discussion of birth control. The bars on the left indicate the percentage of patients who did not receive these services. The center bars indicate the mean, and the bars on the right indicate the high rank order in these practices. You can see that in some of the practices (flu vaccine as an example), the variation is from 4-83%. In discussing birth control, it is from 0-82%. This suggests that from medical practice to medical practice there are wide variations in the quality and in the process of care being provided.

Another illustration, shown in Slide 19, which I think is even more startling, is from a recently published study of twelve hospitals, done by Dr. Robert DuBois, in which he demonstrated that between one-fifth and two-fifths of certain types of deaths (strokes, pneumonia and heart attacks) in hospitals might have been prevented had the providers used more effective intervention techniques. When one looks at those preventable deaths and arrays them by hospital, within that group of 12 hospitals one sees wide variations among hospitals. Slide 20 shows that for strokes, between 1.2-5.8% of all admissions, depending on the hospital, resulted in preventable deaths. The pneumonia and heart attack examples illustrated the same point. If one makes a careful hospital-to-hospital comparison on the basis of the criterion, of preventable deaths, one will find extraordinarily wide variations.

Another illustration, and one that I think is critical and central to everything that we are doing as an organization, looks at the appropriateness of care. That is the extent to which people are getting health care that they simply don't need and that is counterproductive in light of their medical circumstances. We've studied a number of different procedures and have documented the levels of inappropriateness illustrated in Slide 21. Between 14-64% of some of these procedures which people have received, are simply unnecessary and counterproductive; this conclusion is not based on cost but is based exclusively on the medical facts and circumstances. After having studied this chart and having considered just the lower portion of each of these bars on the chart, our actuaries estimate that the clearly inappropriate use of these four procedures alone in the United States account for over $3 billion in one year. Those are expenses which could be saved without damaging anybody's access or health status. Indeed, forgoing the procedures would enhance the health status. This is all the more disturbing in light of the extraordinary increase in the utilization of particular modalities such as bypass surgery and angioplasty. Angioplasty is a less invasive alternative to bypass surgery. Over 75,000 angioplasties were performed in 1979 compared to over 225,000 done in 1986. Notwithstanding an enormous amount of literature and dialogue about the egregious overuse of this procedure, the volume of bypass surgeries continues to increase year after year. Over 50,000 bypasses were performed in 1970, and by 1986 the number of bypasses increased to over 300,000.

Referring back to the managed care framework, I hope I've now persuaded you that there are variations in all these parameters in health care that need to be addressed.



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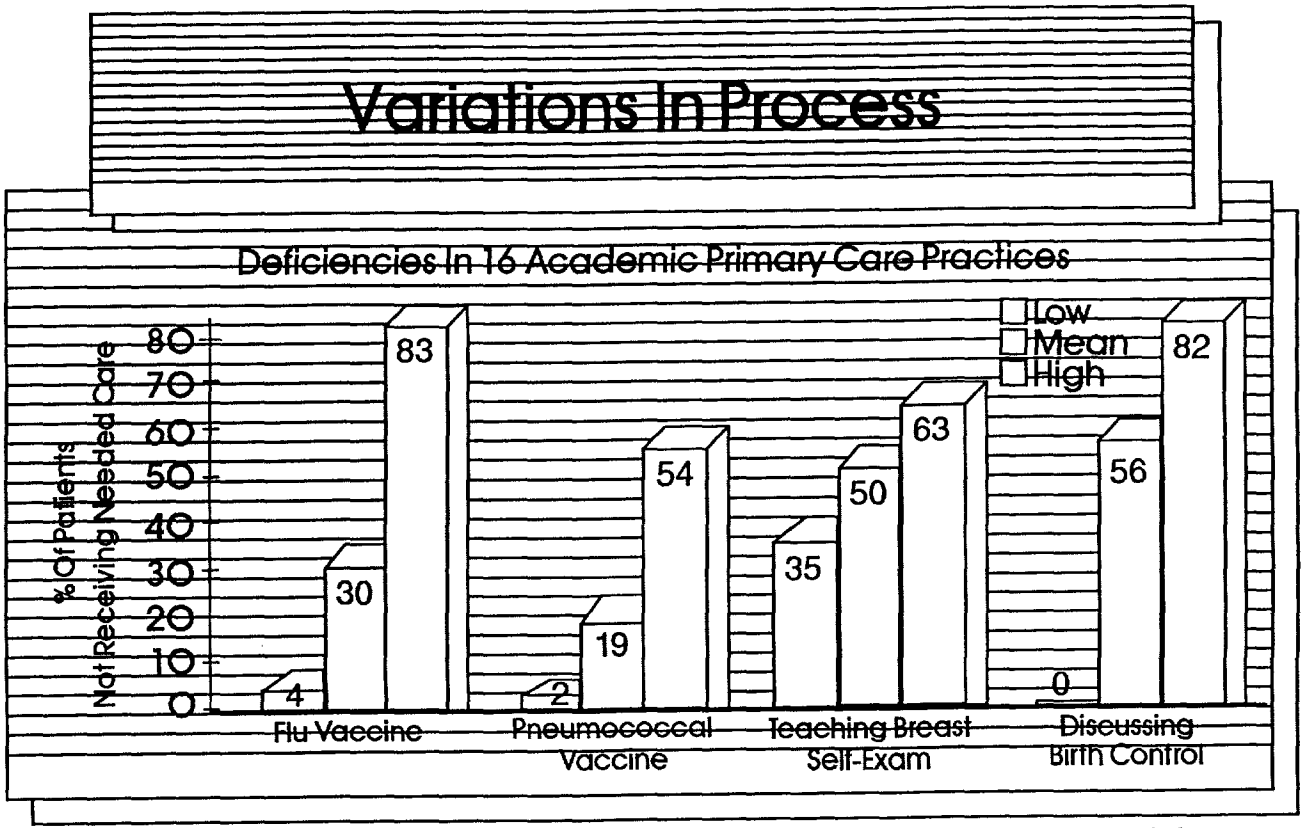
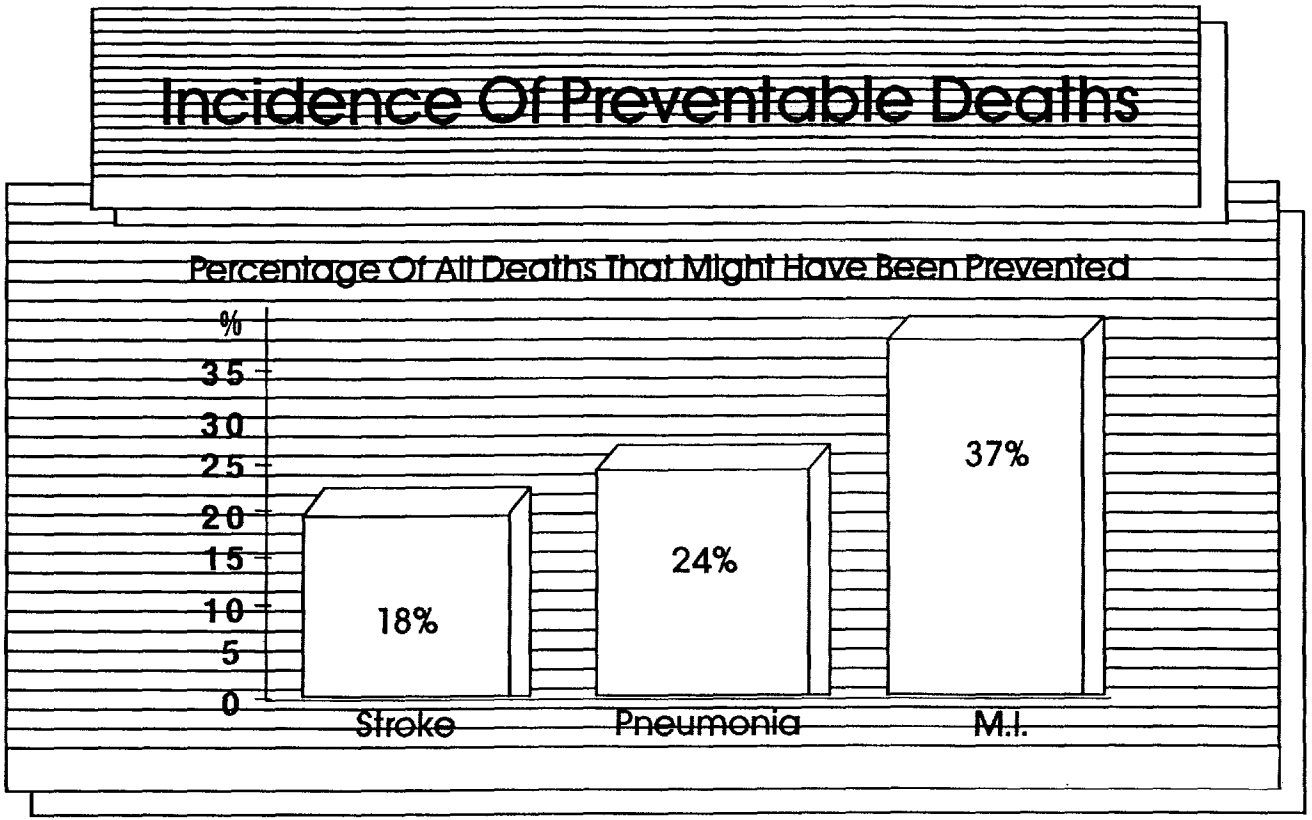
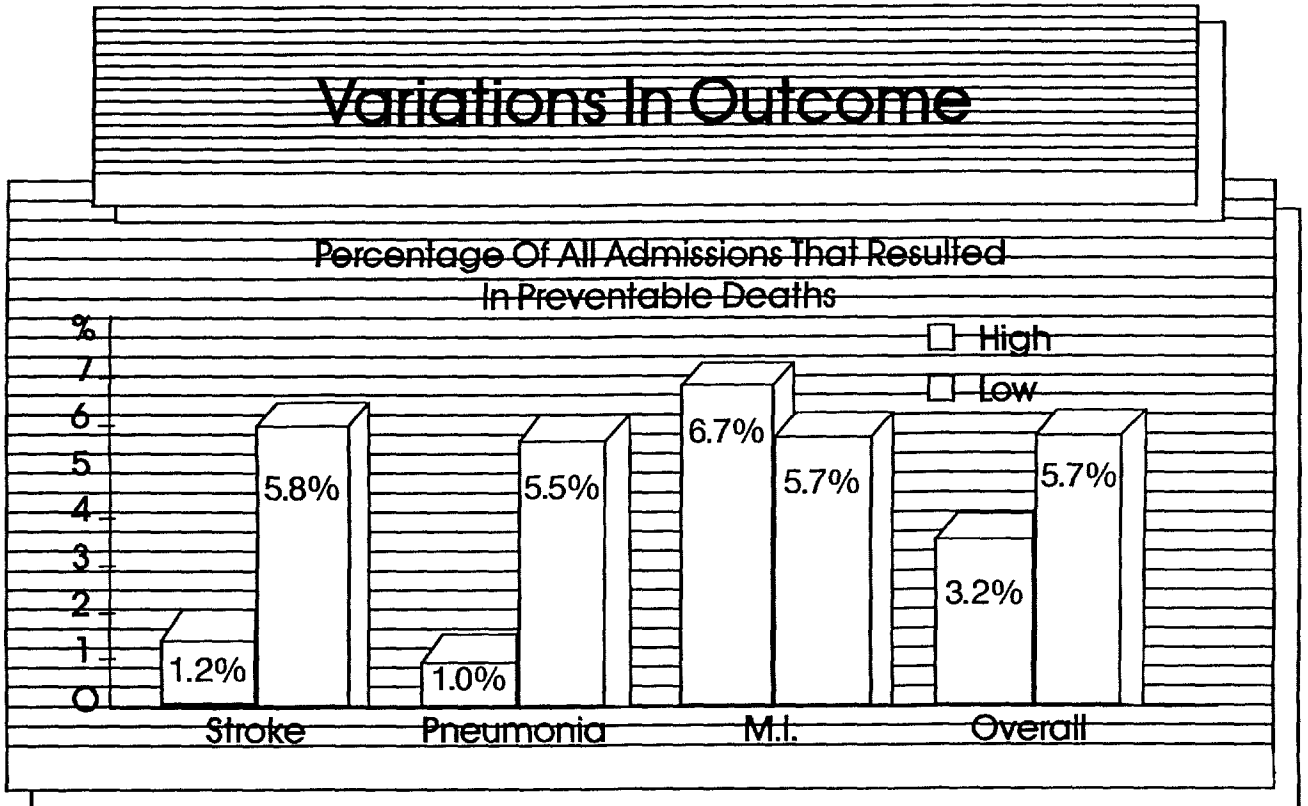


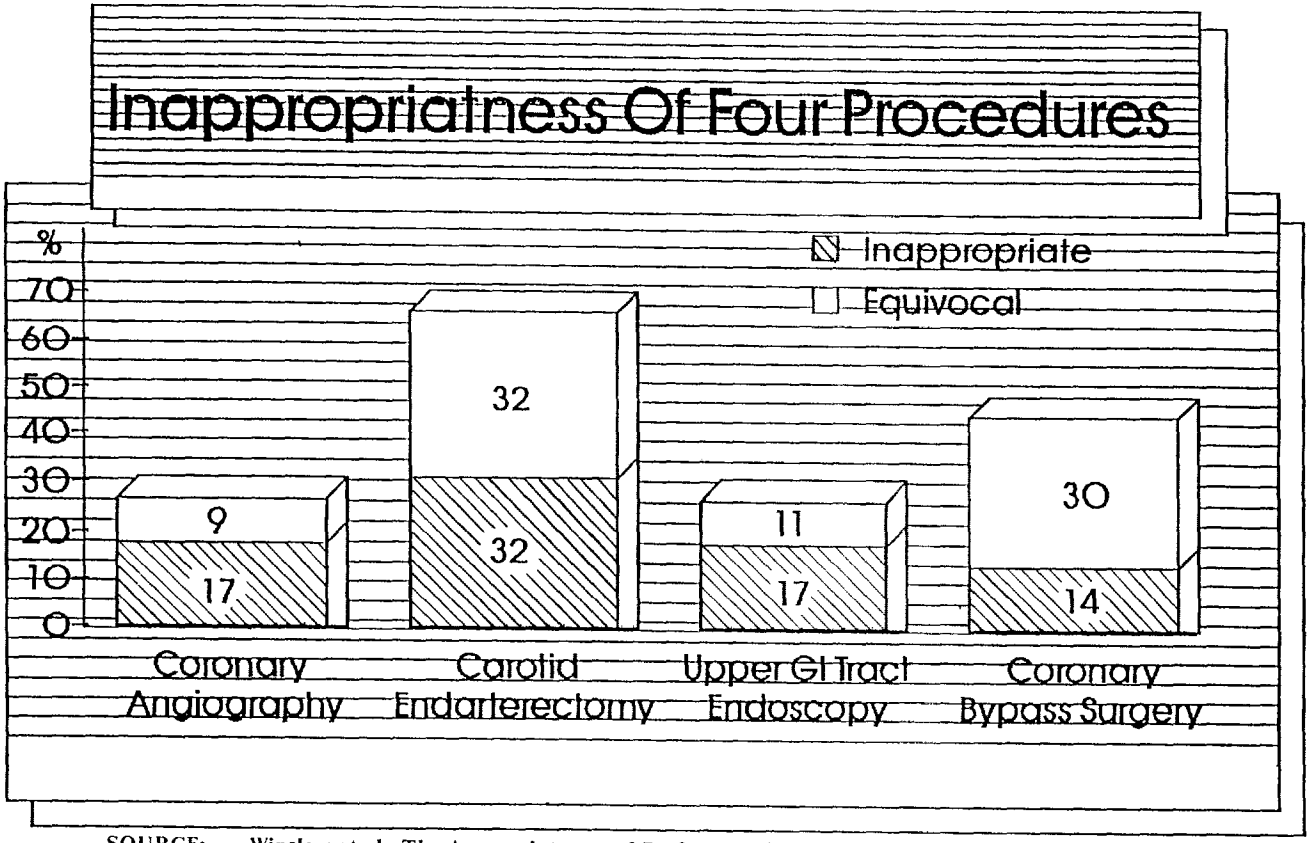
SOURCE: Kosecoff et al; General Medical Care and the Education of Internists in University Hospitals; *Annals of Internal Medicine.* 1985; 102:250-257.



SOURCE: Dubois and Brook; Preventable Deaths: Who, How Often, and Why? *Annals of Internal Medicine.* 1988; 109:582-589.



SOURCE: Dubois and Brook; Preventable Deaths: Who, How Often, and Why? *Annals of Internal Medicine.* 1988; 109:582-589.



SOURCE: Winslow et al. The Appropriateness of Performing Coronary Artery Bypass Surgery. *Journal of The American Medical Association*; July 22/29, 1988; Vol. 260, No. 4, 505-509.

Chassin et al. How Coronary Angiography is Used. *Journal of The American Medical Association*; November 13, 1987; Vol. 258, No. 18, 2543-2547.

I will talk now about one particular modality that is currently available and that is quite important for responding to these variations -- the use of appropriateness standards. Appropriateness standards can encompass, to varying degrees, aspects of unit volume, process of care, outcomes, and patient satisfaction. What do I mean by appropriateness standards? Appropriateness standards are scientifically developed, clinically detailed statements of when particular procedures should or should not be used. They take a procedure, which basically has been through the regulatory process and which is now being used in the field, and set up specific guidelines for the types of patients who are good candidates for the use of that procedure. As I mentioned earlier, what often happens, once a procedure is in the field, is that it is used not only for patients who are good candidates for it but also, to a large degree, for patients who are not very good candidates for it. This is how Pro PAC viewed appropriateness standards: "Carefully developed guidelines for appropriateness can play a highly constructive role. Practice guidelines may be unique among available methods to contain costs in that they can increase the quality and efficiency of care in the process of slowing increases in expenditures." In that sense, I think these standards can be very valuable.

In summary, there are really five applications of appropriateness standards.

1. Physician credentialing process -- This includes two pieces. One is board recertification for physicians, and the other is providing physicians admitting privileges in a hospital. Physicians whose practices are consistent with the appropriateness standards should be recertified and should be given admitting privileges.

2. Selective contracting -- If you're putting together a preferred provider network or an HMO or if you're entering into an exclusive contracting relationship with a hospital, it would be reassuring to be entering into a relationship with people who you knew were using procedures appropriately and not using them inappropriately.

3. Indemnity programs -- The precertification of medical care based on appropriateness is a new and emerging area and one that I think can be integrated quite easily into existing indemnity programs. This can result in significant reductions in cost and significant improvements in quality by eliminating medical care that simply shouldn't occur and is counterproductive.

4. Provider education -- This can be done in two ways: actually using it in medical schools in the training of physicians, as well as using it in continuing education programs (particularly for providers who have had appropriateness problems identified through some of these new modalities).

5. Consumer education -- There's a trend of patients becoming increasingly more involved and more demanding in connection with the provision of health care. Patients can be educated on benefits of appropriateness standards in two ways. First, they can try to understand those standards themselves and see how they apply to their particular cases. Second, if there are enough data collected, they can be published and made available to patients to form the basis for appropriateness ratings of particular providers, similar to the way that HCFA has begun to publish data about death rates in hospitals. Consumers can then, over time, make more informed choices about whom they select to provide health care.

In summary, there are extraordinarily wide variations in both usage and quality of care. A comprehensive and complicated set of solutions will be required to solve some of the health care problems. Any tendered solution that focuses exclusively on one dimension of health care is inevitably going to result in failure because it's not as comprehensive as the problem is itself. I would suggest, as perhaps a first step in the development of such a comprehensive solution, the development and incorporation of appropriateness standards because they have the unique ability to contain costs and improve quality without denying anybody access to care.

MR. JOSHUA JACOBS: I want to ask the panel for any suggestions on how to use the technology portion of the trend of increasing costs as a breakout. I've seen so many people with different estimates of how much technology is increasing costs.

MR. MICHELSON: The pie chart came from *The Wall Street Journal*, which is a highly respected publication in the business world. I don't know how people estimate the percentage with such fine

detail. Frankly, the reason I used the slide was my frustration that *The Wall Street Journal* published something to the one decimal place level of accuracy; I simply don't know how it's done.

MR. JACOBS: I don't mean to interrupt, but I think that chart was done by one of the consultants and they show a tremendous amount for what they call cost shift, something like 30% of the total. I think that's a controversial question of conceptual nature as to how much the cost shift really was. I've seen other charts developed that are quite different from that.

MR. TENNENBAUM: I would only add a comment that, again, it depends on how you define technology. You can probably legitimately define technology as we have, as everything but room and board. I've read other estimates that say anywhere from 30-50% of the rising costs are attributable to the increased use of new technology, so there is a tremendous variation, and it depends on how you want to define it.

MR. WOJCIK: You'll note that in the pie chart from *The Wall Street Journal*, the author stated that improved technology rather than all technology accounted for 11.2% of the increase in trend. I agree that whether one calls it enhanced or new technology, this is most difficult to measure accurately. It's really always going to be controversial, but now that we know so much more about the magnitude of cost for this new technology, we ought to perhaps consult with experts such as these to answer the following questions: (1) what's on the horizon, (2) how is this new technology going to impact on costs, and (3) how is this going to affect our rating for the coming year?

DR. KENNETH LAPENSEE*: It struck me, in listening to Dr. Goodman, that Pro PAC, is doing exactly what Mr. Jacobs might be trying to find out. In fact, it's saying that technology is going to contribute so much to the prospective payment system (PPS) and it's even assigned percentage increases to the PPS. Maybe Pro PAC is recommending less of an adjustment than their trend would indicate might be necessary, but at least Pro PAC is doing that kind of research. Isn't that right?

DR. GOODMAN: That's right. It's funny that the laws that provide for what Pro PAC can do authorize it to put a ceiling on the correction factor allowable for technology. There's something called the Discretionary Adjustment Factor (DAF), and a component of that is allowable for technology. Believe me it doesn't account for your concerns insofar as the relative magnitude of the technological contributions in total health care costs. I think Pro PAC can't give you a very useful bottom line, but it can help identify the technologies that it thinks might affect Medicare costs. It's a pretty good barometer, but it isn't a good bottom line measurement for a total.

While we are very concerned about the costs of technology, there are many people who are very concerned about the legitimacy of asking questions about the costs of new technology. Dave mentioned that he was encouraged that Medicare, in its recent statutes, is making it explicit that it would like to consider costs when it comes to coverage and reimbursement for health care providers under Medicare. After that was announced in the draft regulations, four well-known national health care organizations protested directly to the secretary of the Department of Health and Human Services. I believe that these were: the Health Industry Manufacturers Association, which is the consortium of the major medical device and equipment makers from the whole country, the American Medical Association, the American Hospital Association, and the American Association of Retired Persons. Those are four powerful organizations that were objecting to the explicit consideration of cost in coverage and reimbursement decisions by the biggest third-party payer in the world. So this kind of concern, which you all have regarding costs, is not necessarily widely shared.

* Dr. LaPensee, not a member of the sponsoring organizations, is Director of Health Strategy/Research at State Mutual Life Assurance Company in Worcester, Massachusetts.