RECORD OF SOCIETY OF ACTUARIES
1992 VOL. 18 NO. 1A

MEDICAL TECHNOLOGY – WHERE IS IT GOING?

Moderator: DAVID S. HELWIG
Panelists: DAVID CHERNOF*
PAUL G. SHEKELLE†
ROBERT A. WACLOFF‡
Recorder: JOHN G. FINLEY

- Trends and proliferation of medical technology, including research in genetics and cancer
- What will be the impact?
- What is on the horizon?
- Considerations of containing utilization of various procedures and technology
- Employer strategies to limit exposure

MR. DAVID S. HELWIG: Our topic is medical technology. As we're all aware, health-care costs continue to rise rapidly and much faster than the overall economy, and one of the factors causing health care to be an evergrowing percentage of the GNP as we always hear about in the press is medical technology. Our presentations are going to address what we expect to see in the future for medical technology and what some of the things are that we can do to control those costs. Dr. David Chernof is the senior vice president and corporate medical director at Blue Cross in California. He's responsible for medical policies, physician relations, utilization and quality monitoring programs, and he's going to be discussing the trends in medical technology and what developments are on the horizon. Dr. Paul Shekelle is a staff physician at the Veteran Affairs Medical Center in West Los Angeles and is a consultant in health sciences at the Rand Corporation. He's going to be discussing the appropriateness of medical technology including considerations for containing the utilization. And then finally we'll have Dr. Robert Wacloff who is the chief of medical information and technologies at Southern California Edison, and he's responsible for the evaluation and recommendation of health-care technologies for the company. He's going to be discussing the employer's perspective on the rapid increase of technology and ways employers could limit their exposure. Our recorder is John Finley.

DR. DAVID CHERNOF: I'm going to step a little outside of my role as corporate medical director at Blue Cross and more into the role of a clinician, the role I've played most of my life actually, and talk to you about what I believe to be some of the major

* Dr. Chernof, not a member of the sponsoring organizations, is Senior Vice-President and Corporate Medical Director of Blue Cross of California in Woodland Hills, California.

† Dr. Shekelle, not a member of the sponsoring organizations, is Staff Physician of Veteran Affairs Medical Center in West Los Angeles and a Consultant in Health Sciences of Rand Corporation in Santa Monica, California.

‡ Dr. Wacloff, not a member of the sponsoring organizations, is Chief of Medical Information Technologies of Southern California Edison Company in Rosemead, California.

potential areas of medical progress in the next few years. I'm going to talk about medical technology in a very broad sense: diagnostics, therapeutics, the hardware. Prognostication is a very difficult art in medicine particularly when you're trying to predict the impact of new technologies, so if you do read your journals in a few months, don't hold me too closely to what I've said at this presentation. Following my presentation, I think we'll have a very erudite discussion of how to assess new technologies, their efficacy and their appropriate use, and then I suspect that we will hear the employers lament about the new technologies.

One point in particular that I want to make is that there's been a paradigm shift in the traditional medical model for most of this century and much of the previous century. This model, exemplified by the treatment of acute infectious disease involved the development of relatively low-cost, low-tech technologies and treatments that had a profound effect on the health of individuals and the health of populations. Today we have a different paradigm, that paradigm is the model of chronic disease. The technology is high cost and very complex, benefits a smaller proportion of the population, and produces less dramatic results. In brief, I think we're going to see in the next few years relatively few innovations compared with the penicillins and other innovations of the past century. The innovations are going to be costly and they're going to be incremental developments and innovations, in certain areas. Incremental developments cover a wide spectrum of cost issues and a wide spectrum of technology-impact development issues. The incremental changes are surgery, cardiovascular procedures, established transplants, cancer diagnosis and treatment, radiology, pharmaceuticals, and others. I think you'll also see some quantum changes with respect to entirely new technologies to treat diseases that heretofore have no effective treatment and a marriage of those technologies and those treatments: position emission tomography (PET) scans, stroke management, radiation therapy, biologies, autologous bone marrow transplants for cancer, new transplants, and others. So if you would fasten your safety belts as it were, we're going to move very quickly through the medical frontier today.

In the area of surgery, generally I want to focus on another paradigm that is already upon us. This is typified by the introduction of two new technologies into clinical medicine the past few years: the way they've been introduced and the way they've been disseminated. They are laser surgery and laparoscopic surgery. In both these instances, the perpetrators, if you will, of these technologies, the high-tech companies, have developed them and have cleverly identified the targets, effector organs, for these technologies, and they have heavily marketed those targets. In the process, the manufacturers have bypassed the usual intermediary -- the academic medical center -- where these technologies and new treatments are evaluated and given some order, sense, and prioritization. Instead what has happened is that these technologies have been transferred directly to very distinguished community medical centers, some of the most highly reputed hospitals, and some of the most highly reputed clinicians in our respective communities. But these are people who don't do research, who live at the edge of technology, who have wonderful reputations in communities for always bringing the latest treatments to their patients, and who thrive on having that technology arriving at their doorstep. In turn, these clinicians bring their prestige and the prestige of their institutions to those technologies. For that reason, it's no surprise, for example, that the first eximer laser that was imported into the Los Angeles area was not imported to a university hospital or medical center but to a

private hospital, (a very distinguished private hospital) where one of its chief uses in the first instance may be to treat people who are myopic, the alternative high tech treatment being a pair of glasses.

The other target population, by contrast, is the journeyman practitioner, particularly the proceduralist in the community. This is the clinician who does surgery in suburban areas and inner city areas who is struggling along, looking for some marketing advantage to distinguish himself from all the other journeymen in the community. Along comes a high tech entity which says, I'll take you away to Coral Gables, Florida for the weekend, we'll give you a 12-hour course, to show you how to use this wonderful laparoscope, and you will emerge in your community as the leader with this new technology. It is a very seductive kind of marketing effort, and it works. Now that is not to demean these technologies, they certainly have a place.

Laparoscopic surgery for example has been used for years for certain pelvic conditions in women. It has been used for sterilization purposes, and certainly is, I think, safely the state of the art for the removal of the gall bladder in 1992. But now we're finding people in the community removing portions of the stomach and portions of the intestine, doing appendectomies, and repairing hernias using laparoscope, without these procedures having been evaluated in reputable centers with respect to efficacy and appropriate use. Instead, they have been disseminated into small community hospitals and even ambulatory care centers where peer review doesn't operate the way it does in the major hospitals.

In the realm of surgery, Table 1 shows the number of people waiting for organ transplants in the United States registered with UNOS as of April 1, 1992, which is a 10-35% increase in the numbers of people on the waiting list in one year. There are several reasons for this, one of course, that of the expanding indications for transplants. A few years ago, alcoholic cirrhosis was a contraindication for liver transplant because of the expectation of recidivism. That's no longer the expectation, and transplants are being done in that domain. There's a shortage of organs. On the other hand, there are some new immunosuppressant drugs to be used in a transplant setting that may improve the take of the transplantation and actually prevent rejection of marginal tissue matches. There are a couple of new transplants on the scene, with pancreas-kidney already on board. As a matter of fact, our technology-assessment group at Blue Cross has approved this as a procedure for certain well-defined circumstances. Small intestinal transplants are waiting in the wings as well.

TABLE 1
Transplant Candidate Waiting List as of April 1, 1992

Organ	Number of Patients Waiting
Kidney	20,217
Heart	24,062
Liver	19,063
Pancreas	675
Lung	749
Heart-Lung	162
Pancreas-Kidney	
Small Intestine	

There's probably nothing more interesting to many of us personally than the developments in interventional cardiology. They all pertain in one way or another to coronary artery disease, which is a disease of middle-aged men. There has been a gradual increase in the number of coronary artery procedures done over time, both the coronary bypass procedures that we're familiar with, and increasingly the percutaneous transluminal coronary angioplasty (PTCAs) or "angioplasty" as it is commonly called. Interestingly enough, in California in 1989, which is the last year that we have good figures, there were 84,000 coronary artery procedures done in California, coronary surgeries of one character or another. Half of those were PTCAs. Now that is good news in a way because, when the procedure is successful, it is much less costly, consumes fewer resources, and results in shorter hospital stays.

But there are a couple of problems associated with this procedure. In the first place, it often is followed by a need for coronary bypass sometime down the stream. The procedures fail sometimes. There's a 5% immediate failure rate, and a 30-40% failure rate in 6-12 months. For that reason, a number of new accessory technologies have been developed to improve the outcome of PTCAs. One of these procedures is the introduction of stents and splints to keep the vessels open. Let me describe the procedure to clarify. The procedure involves threading a catheter that is passed up the groin artery to the coronary artery. A little balloon that's attached to the catheter is inflated with gas. This cracks the narrowing in the coronary artery. The problem is once this narrowing is cracked, it may collapse again, hence the need for mechanical support. On the other hand, a whole new species of bores, corers, and drills have been developed to improve the outcome and reduce the likelihood that it will obstruct after surgery. Incidentally, probably the most promising of these is the eximer laser that I mentioned earlier. It is a very expensive device, several hundred thousand dollars; however it will probably have a great deal of applicability.

I think what's really exciting in the area of coronary artery disease, and I consider this to be interventional coronary treatment or cardiology treatment even though it does not involve the use of a catheter or an instrument, is the refocus of attention on our ability to dissolve blood clots in coronary arteries. We need to take a moment and understand the pathophysiology of a myocardial infarct, or heart attack. The death of heart muscle results most of the time from a coronary artery occlusion which cuts off the blood supply to that heart muscle. That clot usually forms and is superimposed on an area of narrowing in the vessel. There's a moment in time of perhaps 60 or 90 or 120 minutes after this event occurs during which that clot can be dissolved, and the damage to the heart muscle can be minimized. We have had agents to dissolve such clots for a number of years, but they have not been used to the full extent possible. Recently however, the pharmaceutical industry has introduced newer drugs and has heavily marketed to the cardiologists. TPA is the newer drug, and streptokinase is the older drug. TPA is 10 times as expensive as streptokinase but in a head-on-head study, the ISIS III study released in 1991, it became clear that they may both be equally effective. Interestingly enough, many of the cardiologists still use the more expensive preparation. That shows you the impact of up-front, clever marketing on the part of the pharmaceutical industry.

The study has demonstrated that only about one out of every five patients who could be treated with these agents is being treated at the present time. We can expect a very substantial increase in the use of these clot-dissolving drugs in the next few

years. The other finding in this ISIS III study is the fact that aspirin, an interesting low-tech treatment, which is known to reduce the mortality of acute myocardial infarction by 20-30% is seldom used by cardiologists.

What's next in cardiology? First of all, we're going to see head-on-head comparisons of PTCA and clot-dissolving agents for the treatment of acute coronaries. This is going to pose another prototypical problem in medicine: how to evaluate two different technologies. I think what we may see -- and this is not a conclusion, this is just sort of a sense -- is that PTCAs produce better, long-term outcomes in terms of higher functional status, freedom from angina and so forth, but short term they produce a higher degree of morbidity and perhaps a higher degree of mortality; an interesting set of trade offs. The other thing to recognize is that these are very sophisticated and very complex technologies, but they have been packaged very simply, and they can be exported into community hospitals. As a consequence, these procedures are now being done in facilities that have no backup for coronary artery bypass surgery. That's probably not so bad, but what is troublesome, at least to me and perhaps Dr. Shekelle will comment on this, is that these are settings in which there is relatively little peer review, so again, there is less than optimum control over the utilization of these technologies.

I think we'll see the same problem in another area as well as we talk about cancer diagnosis and treatment. There are two new paradigms here in the treatment of cancer. The first one is the retreat from radical surgery for the treatment of various malignancies; we all know that's true for breast cancer as an example. It is also true in less well-known settings such as childhood cancers, lung cancer, and cancer of the head and neck. The minimal surgeries are augmented by a more aggressive use of chemotherapy and radiation therapy.

The other new treatment paradigm is the triplet: it is the combination of (1) very high-dose chemotherapy for malignancies that may have a poor prognosis but may be curable if one could give a large enough dose of chemotherapy; (2) autologous bone marrow transplantation (ABMT); and (3) the administration of marrow stimulating growth factors. Let me explain that to you a little bit. The limiting factor for the administration of many modern chemotherapy drugs is the ultimate toxicity, the irreversible effect on the bone marrow of people who receive that chemotherapy. The bone marrow is the site of production of all of our circulating blood cells: red cells, white cells and platelets. In this triplet, the second piece, the autologous bone marrow transplantation, consists of mechanically extracting the bone marrow from the person who's going to be treated, storing it, and then after the chemotherapy, reinfusing the bone marrow into that individual. Interestingly enough, the marrow cells are reintroduced, find their way back into the bone marrow, and repopulate it. This in turn repopulates the peripheral blood.

The third piece in this triplet is the use of marrow stimulating drugs. Neupogen is one name that you may be familiar with. GMCSF or GCSF and other commonly used names will stimulate the repopulation and replenishment process. Altogether, this is a terribly expensive effort. There is a new wrinkle to this. It is now evident that the cells that have the ability to repopulate the bone marrow, also circulate in the peripheral blood. There are now techniques to harvest those cells from the peripheral blood so that this unpleasant procedure that we do to remove the bone marrow is

unnecessary. That is good news because that should simplify the technology and make it less expensive. In reality, that's what I said in 1991 when I made a similar presentation, but in fact that has not been the case. We're seeing the autologous marrow transplantation as expensive if not more expensive than it was before. The expectation is there will be a rapid shift to using these new peripheral marrow harvesting technologies in preference to the older autologous bone marrow transplantation procedure.

Again, you have this interesting problem because it is a sophisticated, complex technology, but it can be packaged and it can be introduced in the community hospitals that have boutique cancer treatment programs where there is a limited degree of peer review. I see that today as I visit facilities in southern California.

We know that ABMT has a role, there's at least reasonable grounds to identify medical necessity for ABMT for certain categories of breast cancer, for certain childhood tumors, for lymphomas, and certain kinds of testicular tumors. But what we're seeing in the community setting is the use of this very complex, expensive, $120,000-130,000 technology for conditions for which there is no medical necessity. It's a real challenge for us.

I want to mention the name Neupogen to you again just to tell you that these drugs that are used to stimulate the bone marrow are also used to augment more standard doses of chemotherapy in the many patients who are receiving chemotherapy for one condition or another. We're talking about 10-14 days of treatment monthly for four to six months as an example. I think if you've not seen this already, what you could expect is a profound cost for every health insurance entity. We estimate this to be in the range of several million dollars for us.

I want to move on to drugs and biologicals, and then new technologies and then I promise to stop. Thirty new drugs were approved by the FDA last year. We can expect at least that many this year. What's more, we're going to see new categories of drugs making their appearance. A drug that has the capacity to inhibit the growth of the prostate gland will be introduced, we can call it a mainstream drug, it will accelerate the trend to less prostate surgery for benign prostatic hyperplasia. Monoclonal antibodies have been around for a number of years for diagnostic purposes. They are now being introduced for therapeutic purposes, and there will be a whole new class of these agents within a year or two. There probably will be only one new cancer drug introduced in the next couple years: Taxall, a very expensive drug extracted from the bark of the yew tree, which happens to be the habitat for the spotted owl interestingly enough. Taxol tells a story about new cancer drugs. Despite all of our technology, and computer modeling, most of our new novel classes of cancer drugs, are developed by screening natural products.

RU486, the very controversial abortifacient, if abortions are not made illegal in the United States, will be available within a year or two. It will have a dramatic impact because it will reduce the need for surgical evacuation of the uterus, or D&C as we know it, to about 4% of individuals. There are five new categories of drugs that have been developed in the treatment of Alzheimer's disease; one of them will be on the market this year, Tacral. Hoescht-Roussel, one of the major pharmaceutical

companies has proclaimed itself the Alzheimer's company, which sort of gives you an idea of how it's going to be marketing.

In 1991, I said gene therapy was on Mars and that it would not be a reality in the foreseeable future. In fact, the FDA and the National Institute of Health (NIH) have licensed 11 treatments for a condition called severe combined immunodeficiency disease. The developers have taken the normal gene, cloned it using recombinant DNA technology, attached it to an innocent retrovirus, removed the normal gene deficient immune cells that circulate in the bloodstreams of the youngsters who have this disorder, and infected those cells with the retrovirus. The normal gene has been deposited in the genome of these cells. The restored cells have been stimulated to multiply in a tissue culture setting, and then reinfused into the kids with the disorder. Lo and behold, the disorder seems to be correcting itself following this treatment!

What about tomorrow? There are 4,000 diseases thought to be inherited; 1,800 disease specific genes have been identified thus far; and 200 companies are in hot pursuit of this kind of therapy. We're going to see some amazing things that are going to be terribly, terribly expensive.

There are candidate technologies, and now we're down really to hardware. One is the PET scanner. The PET scanner provides an entirely different way of imaging the heart, and I rather thought a year ago when it became available, unleashed from the cyclotron and therefore clinically available to the community, that it might very well replace the thallium treadmill test as the screening test of choice for coronary artery disease, and also greatly reduce the number of coronary angiograms that were done for diagnostic purposes. Well, that still may be the case, but there has been such an improvement in computed tomography (CT) technology that we may very well be able to do the same thing with the existing CT technology. So what you may see is either another further explosion in CT usage, or you may see the introduction of $2 million PET scanners, as the alternative, or in everybody's worst nightmare, probably both. I only want to mention the CT scan to bring to your attention that the most dramatic thing that will happen in the next few years is a change in the treatment for stroke. The drugs that I mentioned to you a moment ago that will dissolve clots in coronary arteries have the same capability to dissolve clots in cerebral arteries which are the essential pathogenetic mechanism for strokes. The problem is that the major complication from these drugs is bleeding, and even a little bit of bleeding in the human brain could be catastrophic. We will need some kind of imaging device to monitor and titrate the dose of these clot-dissolving substances. MRI looked like the hot thing in 1991, again another multimillion-dollar device. Now it looks like current imaging technology will suffice. We may be saved with respect to technology but will see a whole new area of treatment evolve.

Radiation therapy devices are only going through generational change. We're advancing from the three to four million electron volt devices to the 18-25 million electron volt devices. That change is already underway. Off in the horizon but actually existing in prototype form in Loma Linda, and I think also in rural Illinois, is the proton beam therapy device. It is a multimillion-dollar device that produces the most exquisite surgical beam of radiation imaginable. It allows one to treat tiny little tumors on the retina, destroy those tumors, and leave the retina intact. It can do the same for inoperable brain tumors, it's an unbelievable device. You have to see it, as it sits

in its three-story gantry. However, there aren't too many malignant tumors on the retina in the United States so the reality is that this device is going to be used for patients who could be treated with simpler and less expensive radiation therapy devices. Again, this is one of the dilemmas and the issues that Dr. Shekelle is going to discuss.

DR. PAUL G. SHEKELLE: I'm on the faculty at UCLA, and I also do most of my research at a place called the Rand Corporation, which is a not-for-profit research organization in Santa Monica that does research in a large number of areas related to public policy, one of those being the health program. I'm a clinician half of the time and a researcher half of the time. And as a clinician who deals in this area and is also a person who stays up on the research of this area, I think that the presentation we just heard was a very lucid and concise explanation of the technologies that we are already facing and will be facing and some of the problems that we've been dealing with in terms of deciding when to use them.

The first thing I'd like to do is start by reviewing the method by which the appropriateness of use of any of these technologies has been made for the past 100 years. It goes something like this. The individual physician sees a patient in his or her own office, the physician conducts a history and physical examination from which a particular medical technology may be indicated. The physician then considers the relative risks and benefits for this particular technology for this type of problem, occasionally compares it to the alternatives if they exist, maybe factors in some kind of implicit patient preferences, perhaps considers cost, perhaps doesn't, then decides on a course of action and gives a recommendation. This all happens in the matter of a couple of minutes within the physician's mind, and implicit in this has been the notion that any decision the physician made was by definition right.

I'd like to now briefly review what has happened to challenge this notion, why we don't necessarily think this way any more. Beginning about 20 years ago, Health Services Research began to document variations in medical practice. One commonly repeated example goes that in neighboring communities in New England, women in one town were many times more likely to have had a hysterectomy by the time they turned age 60 then women in the other town while children in the same town were many times less likely to have received a tonsillectomy by the time of age 20 then in the other town. There didn't seem to be any reason for this, why this should be. The persons in the two towns were of roughly the same ethno-socio-demographic makeup. There didn't seem to be any differences in the underlying rates of disease between these towns. There didn't seem to be any difference in the number of doctors who were available to treat these patients. To make a long story short, Health Services Research has now documented the existence of variations in medical practice between differing geographic areas of the country, for instance the East coast and the West coast, between different towns inside the same geographic area, between different doctors in the same town, between different patients seeing the same doctor, and actually between the same patient seeing the same doctor.

These variations were quite alarming. Research into the causes of these variations led to the startling discovery that when the care that was delivered was critically compared to what might be deemed appropriate care, then by any measure there was a considerable amount of care that was being delivered that was inappropriate. Now

clearly if the same patient sees two different doctors and gets incompatible advice on what is appropriate care, then both doctors cannot be right. Consequently, the method that I outlined earlier for determining appropriateness that has been used for the last 100 or so years cannot always be right. So the question now is, can we improve on this process, can we do a better job of deciding when a medical technology is appropriate?

First, we need to look at the reasons why inappropriate decisions are made. Contrary to what many people may believe, the reason behind most of the inappropriate decisions is not that there are a lot of ignorant doctors out there who are making all of the inappropriate decisions. For instance, in some of these variation studies, researchers have noticed these wide variations in the use of bypass surgery between the doctors at Harvard and the doctors at Yale. It's very difficult to assume that one set of those doctors is that much smarter than the other.

The other reason that is probably not the cause for most of the inappropriate decisions is that doctors are deliberately overutilizing medical technologies for their own financial gain.

Again to make a long story short and not to go through the research that underlies this, it's now felt that the leading cause of the practice variations that have been seen is that there's great uncertainty over the appropriate way to treat many conditions, and this is because much of medicine, although it's called a science, rests on a very, very scanty scientific base, leaving physicians to practice according to rules of thumb or their own anecdotal experience or that of a few peers around them, and most of that experience is guided by their most recent patient encounters. To improve the medical decision-making process then, we need to improve the scientific basis upon which those decisions are made.

Now ideally, we'd like to have our scientific evidence in the form of randomized control trials of the technology in question as applied to the patient populations and the clinical situations we are interested in. This gets at a lot of what Dr. Chernof was talking about. A lot of these new technologies have not been subjected to the appropriate randomized control trials for anything, even for efficacy in any target population. Unfortunately, for many technologies this kind of information doesn't exist. There are very, very few clinical questions that have been definitively answered. Even for those technologies that have been examined by randomized control trials, frequently the patient population that we are interested in may differ in some crucial aspect from the patient populations that were enrolled in the trial, making it difficult to generalize the results from one study to the patient in our room.

I'd like to give you an example of that. Perhaps one of the best studied medical technologies now is coronary artery bypass surgery that has now been the subject of over 17 randomized control trials. My alma mater, Duke University, kept a registry for many years of all patients who had undergone coronary angiography. Now coronary angiography is a prerequisite to undergoing coronary bypass surgery in order to visualize the coronary arteries preparatory to bypass surgery. Well, when one investigator decided to look through this registry to definitively determine the appropriateness of bypass surgery for each patient on the registry by taking each registry patient and then trying to match that patient to one of the clinical types of patient

populations that had been studied in a randomized control trial, he found that the number of patients for whom such a decision could be made was surprisingly low. In only about 10% of the cases at Duke of the patients who had undergone coronary angiography could the personal physician have made a definitive recommendation for whether that patient should have subsequently undergone bypass surgery based on the result of a randomized control trial, and this is for one of the best studied technologies.

For this reason, I believe that we may not be able to make all the decisions regarding the appropriateness of many technologies based solely on the results of randomized control trials. I don't mean to diminish their importance; I think that they are crucial, and I think that we should be undertaking many more randomized control trials than we are, but I think that much of the current focus on what's called outcomes research will not solve all the problems that need to be solved.

So the question is, what are we to do? Should we just let the system continue to run as it is, try to undertake the scientific studies that we can to shore up the knowledge base in critical areas, acknowledging that we're going to leave some gaps in the fabric? Well, these randomized control trials usually take several years to complete, and I believe that this choice is indefensible because it continually exposes patients to procedures that are being performed now, that are unnecessary, possibly harmful, and certainly costly.

Another question is do we consider the cost effectiveness of each technology as applied to everyone in general such as what has been happening in the state of Oregon? For those of you unfamiliar with that, Oregon has been revamping its Medicaid program where it has gone through a very exhaustive process that has ultimately led to a rank ordering of medical technologies and procedures, and an estimation of how much it would cost for the population of interest. Then the legislature said this is how much money it will pay and it has drawn a line. Everything above the line, people get, everything below, people do not get.

Now there's much in Oregon's deliberations which I admire, but this is also not the choice I favor. The reason is that there are certainly effective therapies below the line, and that means that these therapies will not be covered for the patients who could benefit from their use. The other thing is that the therapies that are above the line are going to be covered for anybody who is eligible for coverage, which again leaves the final decision of appropriateness on an individual basis to the physician at the bedside, and that method as I've previously outlined we know will certainly lead to some inappropriate uses. What we really want is for patients who are likely to benefit from a technology to receive it, while those patients who are certainly not going to benefit from the technology to not receive it. This will require making decisions about appropriateness as they would apply to different clinical situations.

The alternative I favor then is the development of appropriateness criteria for clinically specific situations using the available scientific literature and using expert clinical judgment to help fill in the gaps. Such criteria are already being developed and are sometimes called practice guidelines. Let me briefly describe to you how one such methodology for this works and is used at Rand.

Our method involves a systematic literature review to first capture all of the available literature. We then perform a literature synthesis and a mete analysis where appropriate. We develop an exhaustive series of clinical scenarios for patients who might undergo the procedures, say CT scanning of the head. We then select a panel of experts who will then grade or rank the scenarios based on their own clinical expertise and what's available in the literature for appropriateness using a formal judgment consensus method that does not force the lowest-common-denominator-type of agreement.

Now this method includes features of both a delphi, which is an iterative process of anonymous ratings with feedback of group results to individuals, and a round table, which involves a face-to-face discussion.

Critical to the process, of course, is the selection of the panel of experts. The general criteria covering the selection of the panels of experts we use at Rand is that they are of nine members, which is the size that we have found is about the largest that you can get to work cohesively around a table. They are a mix of academic physicians and private practitioners. They include at least one member from the different geographic regions of the country again because of practice variations, and they include a mix of those who do the procedure and those who do not.

This last point is crucially important since no medical specialty sees all the patients with a given clinical problem. For instance, all the patients with coronary artery disease do not end up in the cardiovascular surgeon's office. Many of them are seen initially by cardiologists, internists, family practitioners. The input from these practitioners is important as they may see a different spectrum of the disease than does the cardiovascular surgeon. Additionally, there's always the problem with the inherent bias toward doing a procedure that a proceduralist has.

The results of this process is a set of clinically specific indications for the procedure, each of them labeled as being appropriate, inappropriate, or of uncertain appropriateness. Now there are other methods that perform a similar function that have been used by the specialty societies; some have been promoted by David Eddy, some have been developed by local health plans such as Kaiser and the Harvard Community Health Plan.

Now is any one method perfect? Well, we don't know right now what the best way is for any of these methods to take. We need to do further research on refining the prospective validity of these methods. Are these methods preferable to the current system? I believe the answer to this is unequivocally yes. Retrospective and prospective evaluations of the use of medical technologies with criteria developed in these manners has shown that a large amount of care delivered or proposed to be delivered is for reasons that are thought to be medically inappropriate.

Based on my personal experience with the Rand method and with David Eddy's method and with the Harvard Community Health Plan Method, I think that the key elements of any such method include both an exhaustive literature review as I mentioned, a multidisciplinary group of experts to consider the problem at question, some kind of group judgment method, and clinically specific criteria. For instance, statements such as, "A CT scan is not indicated in headache," are not helpful

because clearly as a clinician, we know that CT scans are helpful for some patients with headache. What we need to know is which types of patients with headache they are helpful for and which types of patients they are not helpful for. Implicit in this is specific statements about when not to do the technology.

A regular updating of these guidelines or these criteria is needed as new knowledge becomes available. Now by whatever method these are created, how they are best to be implemented is not well understood. This has been an area that has been very insufficiently studied, and I predict will be the focus of a substantial amount of research throughout the rest of this decade.

Certainly one method that does work is capitating physicians by making them risk responsible for the cost.

The question is what to do for the fee-for-service physician. Since our goal is to increase the medical scientific information and the knowledge base upon which physicians make these decisions, you might be led to believe that, if we publish these kinds of criteria in reputable and well read scientific literature or mailed these criteria to all the individual physicians, we might improve the number of appropriate decisions that are being made. The results of physician education programs and their capacity to improve the appropriateness of decisions, though, has been very disappointing, and I do not feel that this method will achieve the goals that we want.

This is going to leave us with some form of utilization review as the method to achieve these goals. As this has been laid out, this by necessity seems to be on a case-by-case basis, and individual cases are needed to be evaluated for their appropriateness before they're allowed to proceed. For very expensive technologies, or very important technologies, it may continue to need to be done in this manner.

However, I can envision as private physicians link up into multigroup physicians so that you have a large enough patient population base upon which to make statistical prognostications. It would then be possible to use some less expensive and less intense technologies and to create profiles of what the expected use of these technologies might be within this population. Then have limits on that above or below, which if the physician group practices within those limits, no utilization review on a case-by-case basis would be needed. But, if the group practices above or below these limits, that would trigger an in-depth review of its continued utilization of these technologies.

MR. HELWIG: After listening to those last two, it sounds like technology is going to be expanding a lot faster than was previously believed. Dr. Wacloff is going to give us some perspective on what the employers can expect and what they can do.

DR. ROBERT A. WACLOFF: It was very interesting to get the invitation to come to speak on medical technology to a group of actuaries, and in fact I enjoy speaking about it to any group. This is something that I've been working on now for about 12 years, and I find technology has been changing quite rapidly.

Where is it going? Through the roof! In the event that people do not get a hold of it very shortly, the cost will undoubtedly bankrupt many of our corporations and

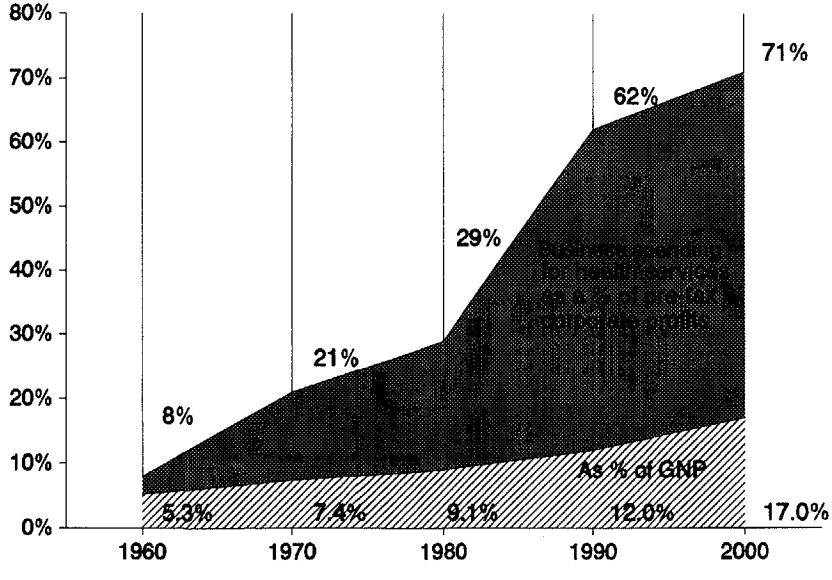
probably our own health-care system. I do a lot of contracting for corporations, and particularly Southern California Edison has been one of my major clients. I'd like to start out by introducing that company.

Southern California Edison is a public-utility corporation. It is not a health-care company. However, Edison has internalized the majority of the aspects that we all consider about health care into an internal environment, thereby achieving a system where it can control some costs. I'd like to provide a little bit of a background both on Edison and the existing system at Edison, and try to help you to understand how changes occurred at Edison.

In fact, if we look at health care in general, many people have used the analogy of a balloon: you punch in one side, and all it does is pop out in another. Well, unfortunately, when the system isn't controlled from one perspective or one payor, that does often happen. It's a very dynamic system, and when one part of a system is changed, another part will change. It might not happen right away, there are time lags involved. At the point that this can occur, change needs to be implemented and at the point that it's implemented, it needs to be monitored and then modified as things go on. So we'll start out with the health-care strategic issues for the 1990s and beyond for Southern California Edison.

Why is health care an issue, why does Edison care, why does anybody care at this point? Half the GNP growth will be in health care by the year 2000. In 1990 we had $264 billion of the GNP growth, about 23% by the year 2000, over $623 billion of the GNP growth will be associated with health care. As a percentage of GNP (Chart 1), the bottom of the chart goes up to 17% in the year 2000.

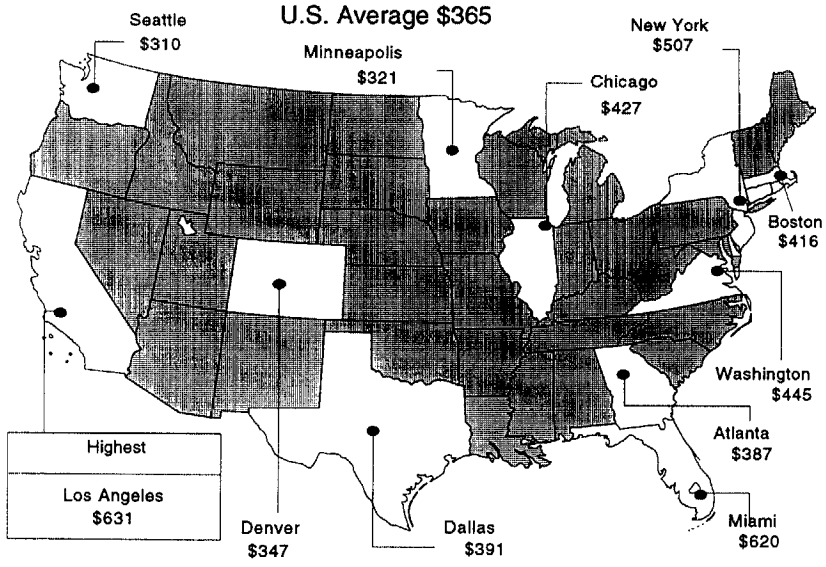
CHART 1
Impact of Rising Health Care Costs



This is why it is that Edison and other corporations are very concerned about health care. Some 71% is the business spending for health services as a percentage of pretax corporate profits. We have gone from 8% in the 1960s up through 29% in the 1980s, 62% in 1990, and it is expected to be over 71% as of the year 2000.

Why in particular does Edison care rather than other corporations? Well, Chart 2 shows the average monthly insurance premiums per employee. Southern California and Los Angeles are peaked at the highest per capita expense. Obviously, there are some others that aren't too far behind, Miami, Washington, D.C., and New York.

CHART 2
Average Monthly Insurance Premiums
Per Employee of Small Firms

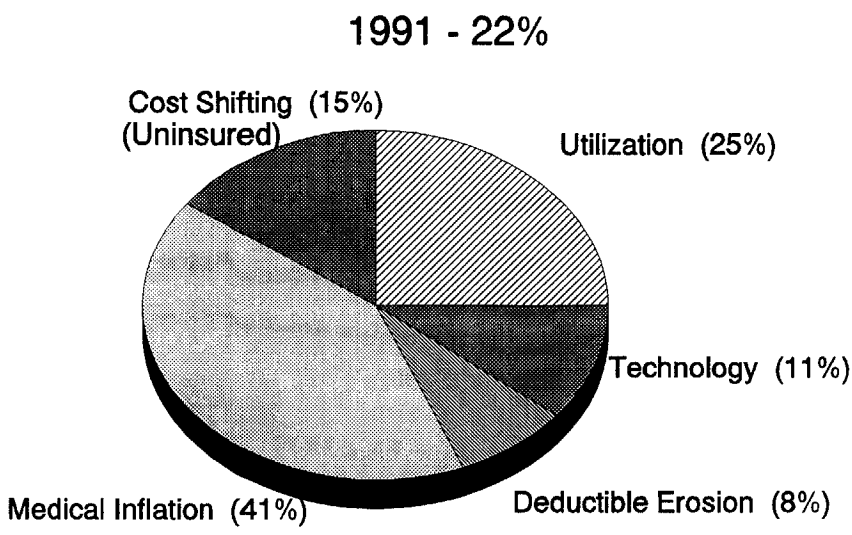


Why are corporate medical-benefit costs increasing (Chart 3)? The costs may be a little bit different than what insurers are seeing, maybe a little different than what the rest of the economy is seeing. If we look at technology, that's what this particular talk is supposed to be about, we're only at 11%.

I would like to challenge Chart 3 though and maybe some of your thinking in that what we heard from the other speakers is direct cost associated with medical technologies that we would foresee in a physician's office. From a corporate perspective and from a perspective of somebody looking at technology in general, there are a lot of technologies that are being used now. There are computers that are being pushed on physicians from a management perspective. There are mainframe systems and local area networks. There are new technologies from managed care and everything else that if we take a look at the medical inflation and the

utilization, that additional 66% I think is also going to be tacked on for where technology is increasing.

CHART 3
Why Are Corporate Medical Benefit Costs Increasing?



Dr. Chernof mentioned the cost of angioplasty. We found in particular certain hospitals where if a patient presents into the emergency room with chest pain, he is almost guaranteed to receive angioplasty. Obviously, this is an instance where we would like to know about those hospitals ahead of time, and possibly try to do some negotiating to not have those hospitals on if, in fact, the procedures are being done inappropriately.

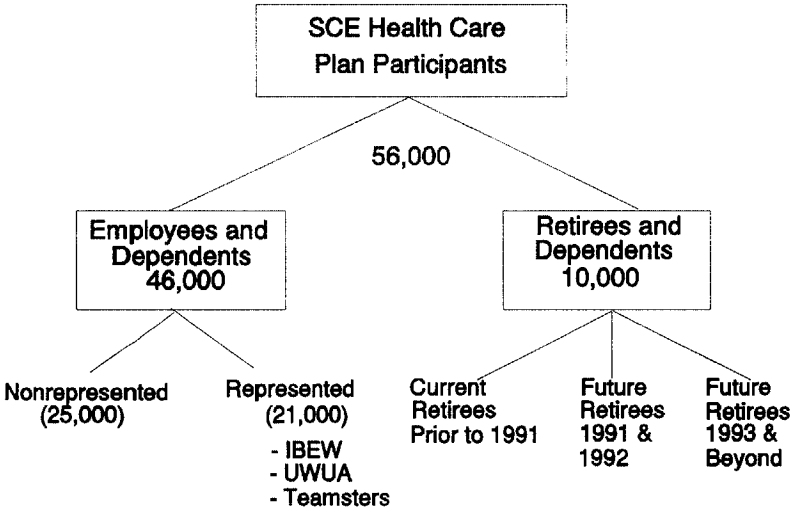
In regard to the cost of additional imaging, there was also a comment made about taking something and having a substitute versus a complement. These are technologies that we would just as soon have a lot closer look at. It used to be where a physician would see a patient who was going into surgery. The physician would examine the patient and the patient would go into surgery. Nowadays, the patient will go from an exam to an X-ray to another exam to an ultrasound to another exam to a CT scan, to another exam to review the CT scan to an MRI to another exam and finally surgery for the same procedure. It's no wonder our costs are increasing at the rate they are.

Edison decided approximately four years ago that one of the ways that it was going to address all of these issues is to go through a total quality management approach. One of the ways of the corporate commitment to quality was for the health-care department within Southern California Edison to achieve joint commission accreditation. It did that and we're quite proud of that event. Edison has an internal group of

eight clinics of which the Rosemead facility is the largest, it has 16 physicians who are full-time physicians that see Edison's patients.

Obviously, one of the goals is quality, the other is monetary. The health-care cost-containment potential between 5-, 10- and 20-year savings for Edison is as much as $6.4 billion by internalizing the health-care system within the corporate environment. Take a look at what Edison has internally (Chart 4). The Edison health-care-plan participants comprise approximately 56,000 individuals: 46,000 employees and dependents, and 10,000 retirees and dependents. That's a fairly large population for whom to provide services. The system itself is the HealthFlex system with flexible benefits, different deductible options, and preferred provider networks.

CHART 4
Health Care Plan Population

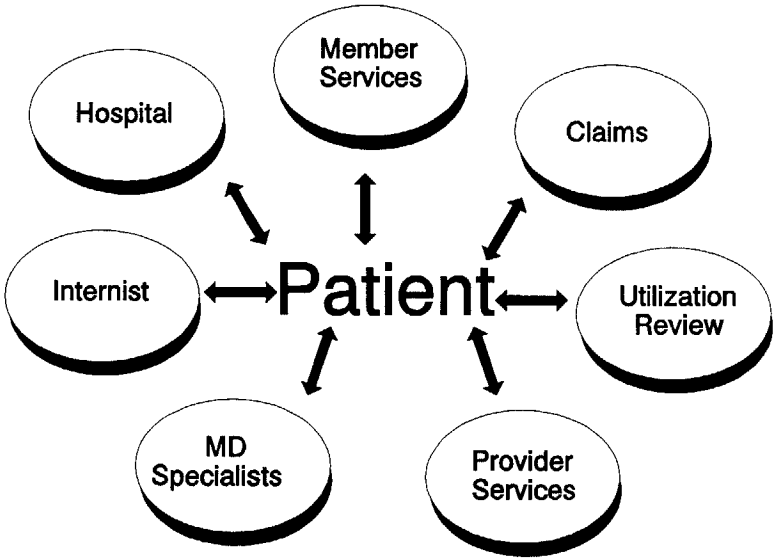


What can be done? Managed care is one of the first options that Edison chose to be able to put in the utilization review. To try to track down the HMO pricing, what we were finding is that HMOs were shadow pricing the Edison health-care plans. Future retiree plan changes and preventive health also are directly related to the technologies that we were implementing. As far as the performance from 1989 through 1991, how well did we do with the implementations? Well, in looking through the three-year period, we've achieved a $66 million savings. Some $32.5 million of that came from the managed care aspects changing what was previously an unmanaged system and making it a lot more managed. It's not at 100% efficiency yet but we're trying. The cost-containment expenditure forecast for this as we look from 1987 through 1992 has achieved $159 million in savings this year from the implementation of those programs.

What did the system look like (Chart 5)? The patient was in the middle; the patient had the choice; the patient was able to go to the hospital, to member services, to

claims. The patient was free to choose where he or she would go. Chart 5 is an effort to help individuals understand the system the way it was, and maybe see if there are ways that we may be able to improve or achieve additional cost savings. Obviously, the M.D. specialists are a lot higher cost than our internist. There are certain areas of hospital life that are considerably higher. There may be some other member services, home health care, home infusion therapies that might benefit us. So there might be more incentive systems that we might want to implement. The way we are moving is toward the primary-care physician, again a gatekeeper system, very similar to what many people have had for years, moving toward a patient-care management team who would most efficiently and most appropriately determine both for the patient, for the primary-care physician and for the company how to best utilize the resources that we have, which are limited.

CHART 5
HealthFlex Physical/Patient/Health Plan Interaction

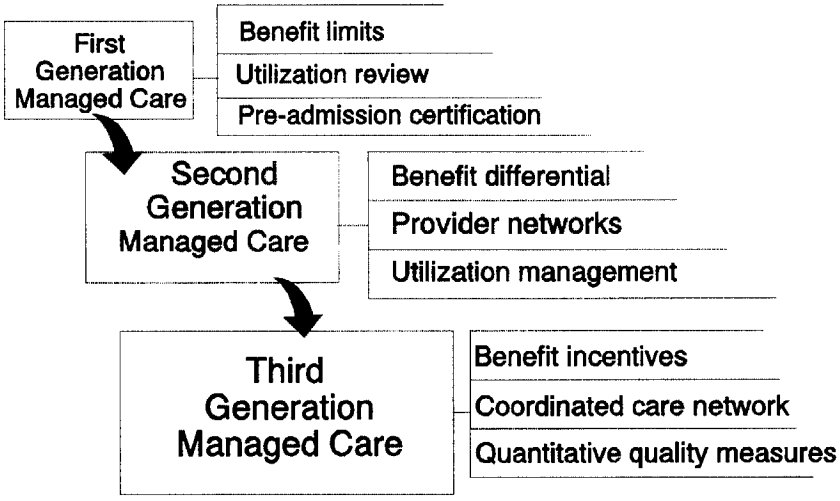


We started out with a first-generation managed care (Chart 6). We're now moving toward a third generation of managed care. We now are providing benefit incentives to individuals, coordinated care networks and quantitative quality measures. We're trying to put a number on the individuals who are achieving success.

The third generation that we've moved to from our current system is a large preferred provider network. The future is a tighter coordinated-care network of exclusive providers. I said we had approximately 16 full-time physicians working for Edison, we also have approximately 7,500 other providers who do contracting services for Southern California Edison. The tighter coordinated-care network will help us achieve even a much tighter control over the additional services whether that be through choice of which hospitals, which external facilities whether it's a particular cardiac facility, etc.

What we'd like to be able to do is maximize the number of individuals who are going to receive the highest quality care. We'd rather not have 10 people going here, 10 people going there, we'd rather have 20 people going to the highest-quality system and then try to reduce the cost based on negotiated fees. We've gone from multiple HMOs to integrated self-funded HMOs, patient-driven administration (currently) to a seamless administration.

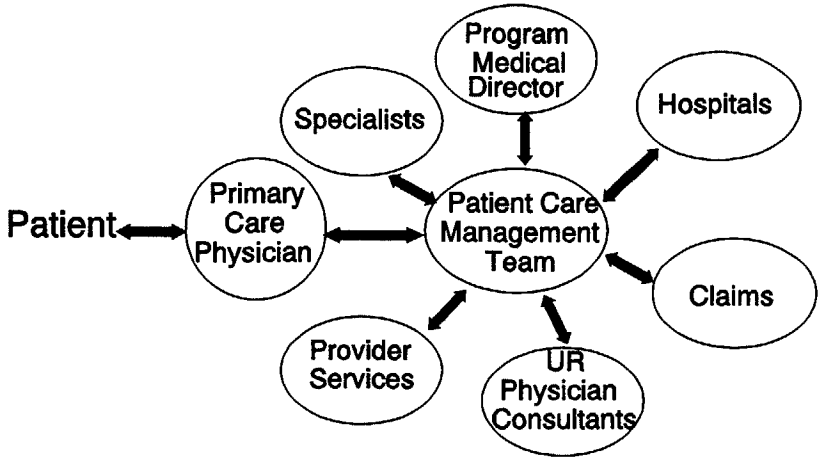
CHART 6
Managed Care



Mr. Brophy, from the Travelers, I believe also gave a statement in regard to the card systems and moving toward a paperless society within medicine. Louis Sullivan is also trying to approach that, and the Institute of Medicine has suggested that by 1997, we move toward a fully computerized medical record. I would also suggest that these are technologies that we need to be aware of. The cost associated with converting the current medical system over to a computerized medical system is not insignificant, again going from case management to outcomes management as well. Outcomes research as mentioned earlier is not a panacea but will help as an adjunct to everything else.

Where do we feel the future health-plan, cost-management performance will be (Chart 7)? We know where we are right now. We know that in 1992 we have achieved with HealthFlex the same cost that the HMOs have. In fact, we have even developed an incentive for the individuals where based on an actuarial cost, our costs are lower than the HMOs. Our employees now have to pay to go to an HMO where in previous years, the HMOs were much less expensive, and in fact the HMOs were free to the patients, they had to pay for the Edison plans. We believe that the future plan will in fact reduce the increase. We're not saying the increase is going to stop, it will still increase, but we're going to try to change the rate at which the change occurs.

CHART 7
Future Health Care Plan Interaction



The building blocks for health-care reform, another way that Edison and other corporations are trying to stem the costs associated with medical technology is to try to work through Washington. We believe that health-care reform does have to occur. At the point at which 71% of profits for a corporation are being placed into health care, corporations would no longer be able to be in existence. We believe that health-care reform does have to occur, and we believe that these are the blocks that have to be in place: the National Health Care Council, payment reform, waivers of antitrust restrictions, capital spending, standardized claim reform and technology assessment, all of which have part of medical technology or technology assessment associated with them. The National Health Care Council is needed to monitor health-care spending. The keeping-up-with-the-Jones' attitude that the hospital down the street is able to have the MRI that we don't have I think is going to be a thing of the past.

There's going to have to be additional cost sharing and resource sharing as well. Proposed are nonenforceable expenditure targets, with reports annually to legislatures on causes of excessive spending and proposed solutions. There's going to have to be payment reform, and in particular, the elimination of cost shifting and the improvement of access for the uninsured. There are multiple projects throughout the country, many of which are trying to move towards card systems and many of which are trying to form a tiered system whereby some of the more expensive technologies are controlled. What we'd like to be able to do is provide as much access for the uninsured as possible, but possibly the additional high-cost technologies would not be available.

Waivers of antitrust restrictions are needed. The community multipair consortium negotiates with providers. This has been upheld both in courts for some time as well as within labor negotiations. There's been a large health-care consortium within Memphis that has made *The Wall Street Journal*, and in fact is very lucrative in one

respect and at the same time it has been very successful in reducing costs. Large groups of employers banded together to form a consortium to buy services from particular hospitals. They were no longer specific individuals who had no clout to be able to do the contracting negotiations. The larger the groups the better the cost. Unfortunately, right now this is still being held up.

Capital spending needs to be monitored. Databases are needed on significant health-care capital purchases, and I mentioned the computers earlier. If we look at many other service industries, health care is very far behind with regards to management technologies. We may be very far ahead and we may be the furthest advanced in the world with regard to specific medical technologies in an operating room, with the use of a PET scanner or another system. When it comes to being able to understand where the costs are going, most of the time we don't have a clue. We're trying to achieve national databases and national database projects that will be able to significantly address where our health-care dollars are going. We want to obviously reduce the costly duplication of resources. We don't want multiple clinics having the same resources. We'd like them to be able to share something.

Improving the geographic distribution of resources is needed. Obviously, within Edison's population, we have a very diverse group of individuals. Edison is a corporation that often has suggestions from the womb to the tomb as to where it should follow its patients. There are multiple generations within the Edison corporation. We have younger populations closer to some of the sites, and we have our retiree populations who move into specific retirement communities. We want to improve the geographic distributions. We probably are in a position where within the next year, we will be moving another facility closer toward some of the retirees. We want to make sure that those individuals who need specific resources have easy access, and at the same time improve the geographic distributions. There is no sense in having a facility in an area where it's not going to be as well used.

Standardizing the claim form is needed. This comes in from some of the work from the American National Standards Institute as well. You want to find something that's used by all third-party payers. Many corporations are printing their own forms for some things, using multiple forms for this insurance company and that insurance company. Right now the amount of paperwork that's being generated is driving most people nuts. To be quite honest, at this point we've been told computers are great, you got to implement this, that and everything else. I am a computer advocate, I do advocate a lot of automation but by and large, most people are finding that the implementation of a computerized system increases the paperwork, increases the amount of paper flow through offices. So keep that in mind when you're buying that system and they say, oh, this is so much more efficient. We want to be able to provide the data for integrated health-care databases. When things are not standardized, there's no comparison, it's very difficult. The mete analysis that was mentioned earlier is needed because things aren't standardized. We've got to place things between various applications. Overall we want to reduce the administrative cost. One of the ways of doing that obviously is to reduce the paperwork, and to standardize the claim forms will help. The American National Standards Institute has recently sent out the latest in the draft for that particular form, and I hope we'll be voting on that probably sometime in June or July 1992. So I hope we're not too far off from a national standard form that can be used.

In regard to technology assessment, we need an agency to coordinate the efforts, and to determine the efficacy of new procedures and equipment. It's mentioned that there are agencies out there, many of which corporations, such as Southern California Edison, do use. We are by no means finalizing or making the determination of what is appropriate or not appropriate medical care. We do have physician staff and for a particular patient, we will determine what is most appropriate for that patient. By and large for overall technologies to be seen as acceptable that will be paid through our insurance portion of our corporation, we look to outside agencies. We read articles that come out of Rand. We look for things that have come out of other groups as well.

Publishing guidelines for insurers is also helpful in assessing technology. In particular the Academic Medical Center consortium released a group of guidelines that will be used for just that. Doctors can determine the best, most economical and thereby one can hope the most appropriate course of treatment in using some of these guidelines.

We rationalize the introduction of new technologies. Is the technology a substitute or a complement? Do we want to go toward a new drug? Edison has also internalized pharmacy, lab and x-ray. Dr. Chernof mentioned the pharmacy in particular. I'd like to give one way that we've addressed that and that's through antidetailing. I hope there aren't any pharmacists in the room or drug company representatives for that matter, but we've had to quite literally go back out after we heard, and quite often we do hear, that the physicians want to try some new medication, that they just heard is the best and greatest. There might be one study and of course, that study was funded by the drug company itself, but there was a study that proved efficacy and safety or tried to show it at least. What we're finding is that we then are spending a lot of our time and effort to antidetail or to counterdetail or to reeducate those physicians who have had this type of drug detailing which occurs on a regular basis. Again, internalizing the pharmacy has allowed us to have pharmacists on staff who can balance between the cost toward the corporation, the best things for the patient, and possibly to have a much better understanding of the drugs themselves and to have a better working relationship with the physicians.

To reduce the inappropriate care and associated costs with that care. We need to be able to monitor and address what is inappropriate. We've discussed retrospective analysis. Dr. Shekelle mentioned that a lot of retrospective studies are going on. A lot more now are going prospective. I would suggest that in a lot of the inappropriate care what is being found now is it's all retrospective. We're finding it out after the fact. What we need to do is move toward prospective analysis, and prospective adjustments so that at the point that the physician wants to provide care that is inappropriate, he is stopped prior to that care being given. One of the ways of that being done are through additional information systems. Granted here come the computers, but I'm referring to these as a system by which additional information is given either to the provider, to the nursing staff, or to the group that is providing the service to the patient. Technologies to reduce paperwork in general have been available to many outside service organizations. Health care as I said earlier is probably 10-15 years behind. Again, this is moving more away from the specific medical technology and more toward the medical management technology. But in fact when we look at administrative cost associated with the increasing cost for

health care, that is an area that we can begin to make the system more efficient. Managed care moving towards a fourth and fifth generation will also help us.

In conclusion what I'd like to at least address is the balance between the quality of health care and the cost savings. Edison is a corporation; it is in business to make money and to provide additional revenues for its shareholders. However, it's also in the business of making sure that its employees are in the best of health so that they can provide those services for not only the shareholders but also all of the individuals that Southern California Edison, a utility company, provides electricity.

What I'd like to do then is go back to the point at which you try to understand the system, determine where areas of change can be determined, modify those areas, find out where the weak links are, and then monitor them and see if change needs to occur again. One of the things we're trying to do is constantly go through that. It's a total quality management approach, and again it's just back to the point of trying to address quality. It means different things to different people, but if you try to take as many different opinions and as many different definitions of it, if you can address as many as you can, then you're moving in that direction.

The methods or points that I'd like to address or at least leave you with are to think about the substitute versus complement technologies. These are areas that are going to adversely effect where costs are going. One of the things that Edison has done and that many other corporations are doing is internalizing. Internalize that which is practical or feasible. Shift to a prospective rather than retrospective thinking. We can stop things prior to them happening which means we don't have to pay for them. Going towards consortium at the point that these are seen as legal entities is a help. Larger groups buying larger amounts of services are going to be able to negotiate reduced fees. You want to increase the knowledge and information, not necessarily data overload.