SOLVING AMERICA'S HEALTH CARE PROBLEMS

by

Elizabeth L. Bewley

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SECTION ONE: INTRODUCTION

[2008 note: I wrote this paper in 1996 when I was working at McNeil Consumer, part of Johnson & Johnson, as plant manager of one of the three Tylenol factories in the United States. I continue to make it available because demand for it continues. The views expressed herein are my own, and do not necessarily reflect those of Johnson & Johnson, McNeil Consumer, or any other Johnson & Johnson operating companies.]

The current "health care crisis" in the United States is viewed as a trade-off between cost and quality/access. Total health care costs are too high, so treatment must be constrained -- we can not afford to buy as much health care as people want. The people hurt most will be the disadvantaged. "It could be that, ultimately, health care becomes a two-tier market -- quality-oriented care for those willing to pay for it and bargain-basement medicine for the rest." (Magnusson & Hammonds, 1996). You can have *either* "low cost," the argument goes, *or* "high quality and broad access," but you can not have both. (Weitzman, 1990).

My theses are that the major problems with health care in the United States have been framed incorrectly, that the cost/quality dichotomy is unnecessary, and that the solutions most commonly proposed are unlikely to work. Without claiming to address every single issue relevant to health care in this country, I begin by describing executional, decision-making, management, and perceptual flaws that I believe underlie most of the problems with our health care system.

The subsequent section describes why these problems exist. Next, I offer some observations about the shifting locus of power in health care. Then I recommend solutions that I feel would significantly improve costs and quality, and close with concluding comments.

SECTION TWO: THE PROBLEMS

A Definition of Quality

Before discussing the problems, it is important that I define what I mean by quality in health care: favorable impact on mortality and morbidity (disease), certainly, but also on functionality and quality of life as perceived by the patient. Discussions about health care results typically focus on mortality and morbidity statistics because these are most easily obtained from available records.

However, with life expectancies in the 70's (Robert Wood Johnson Foundation, 1995a), many people in the United States are concerned with quality of life, not just at what age they die or whether or not they have a chronic disease. For example, patients may be interested in mobility, freedom from pain, ability to work and engage in other routine activities, and so forth.

These concerns typically have not been formally addressed in assessing quality of care. "Historically, there has been surprisingly little concern about the quality of care provided." (Weitzman, 1990). An author referring to more recent history observed, "Historically, quality assurance meant assuring that providers followed processes of care deemed important by their peers." (Laine & Davidoff, 1996). That is, "quality" care meant that the doctor did things other doctors thought made sense, not that medical outcomes were assessed nor that patients' views of outcomes were surveyed.

My definition of quality reflects current trends in health care thought.

The Problems

The four kinds of problems discussed in this paper are these:

* Executional problems: Assuming that theory and intention translate almost perfectly into practice.

  See the section titled, *Where's Captain Picard when You Need Him? There's No One To Say "Make It So!"*

* Decision-making problems: Assuming that good decisions can be made independent of virtually all the relevant data.

  See: *It's Swamp Gas and Leeches All Over Again!*

* Management problems: Failing to understand the concept of "process", meaning a series of discrete steps that contribute to an outcome, and believing that focusing on just one or two of the steps automatically solves the problem.

  See: *Process? What's a Process? Isn't That Something in the Chemical Industry?*

* Perceptual problems: Failure to understand from whose perspective health care should be framed.

  See: *A Stagehand Once Told Me, "Working in Theatre Would Be Great If There Weren't Any Actors!"*

EXECUTIONAL PROBLEMS

Where's Captain Picard when You Need Him? There's No One To Say "Make It So!"

Captain Picard of the popular Star Trek television series listened to crew suggestions carefully. When he heard one with merit he said, "Make it so!" and it was done. Unfortunately, health care delivery in the U.S. does not work the same way. Tests are often performed incorrectly and medical treatments often fail to conform to standards.

For example, "A gynecologist reviewed the technique used by sixty of his colleagues to take a Pap smear, and found that only fifteen of them performed the test properly. With this amount of slippage in such a simple test, one can only imagine" the problems with more difficult procedures. (Eddy, 1984).

Assume for the moment that the doctor's observations were correct, that improper procedure translates into faulty results, and that these in turn impact care decisions and thence medical outcomes for patients (premises implied but not explicitly supported in the report). If this picture is true, then not only did 75% of the patients believe they had gotten an effective test when they had not, but 75% of the payments for Pap smears in this country are a waste of money because the results are meaningless.

False positives among this 75% would generate unnecessary medical treatment -- more wasted money, unnecessary risk of complications and side effects, emotional distress, etc. False negatives, probably more likely, would result in lack of appropriate medical treatment, and probably higher costs later together with more loss of life. In other words, just saying, "I administered a Pap smear," is not enough. Both quality of care and costs may be significantly worse if the test is not done right.

In a second example, "Most women with highly curable, early-stage ovarian cancer are not meticulously checked during surgery to see if the disease has spread [to the lymph nodes] -- a lapse that could increase their chances of dying, according to a new National Cancer Institute study." (FitzGerald & McCullough, 1996). The authors went on to point out that the above lapse in the standard care regimen for this disease occurred 90% of the time.

That is, while 75% of Pap smears are done incorrectly, 90% of the treatment for early-stage ovarian cancer does not meet appropriate standards. The authors implied but do not yet have the data to show that the omission affects survival rates.

If one accepts their premise, one could hypothesize that both medical costs and loss of life are higher than they need to be. (Of course, if the lives saved by following the procedure are very few, and the costs of the tests are very high, it is possible that total medical costs would be higher if the procedure were followed. No data are provided against which to test this possibility.) The salient point for this discussion is that the fact that a (presumably) effective protocol has been established and published does not mean that that is the care patients actually receive.

Other similar gaps between medical knowledge and practical execution are prevalent. For a third example, "Despite studies of more than a decade ago that showed many physicians were undertreating pain in hospital patients, new research indicates that the undertreatment persists." (Goleman, 1987).

"The typical pattern was the doctor ordered less than was helpful and the nurse gave less than was ordered... 35 to 75 percent of patients did not get adequate pain relief after surgery." (Rosenthal, 1990). "On average, [nurses gave patients] one-fourth the amount permitted by the physician." (Goleman, 1987).

Costs and quality of care are negatively affected by failure to follow appropriate care guidelines: "Myths about pain and its management cause half of the patients who undergo surgery in more than 23 million procedures each year to suffer unrelieved, unnecessary pain" despite the fact that studies have shown that "[hospital patients] with well-controlled pain... tend to be discharged earlier and may suffer fewer chronic pain problems later." (Leary, 1992).

Misleading information about addiction to pain relievers was published 50 years ago, and 20 years ago new studies corrected the error. Yet, as we approach the year 2000, doctors and nurses are still basing treatment on World War II-era myths. (Goleman, 1987; Leary, 1992). Thus, information or knowledge does not necessarily translate into action (pain treatment) and action (Pap smears, treatment for ovarian cancer) does not necessarily match the accepted protocol. Costs and quality are both worse as a result.

In a fourth example, "In a study... of a nationally endorsed guideline recommending decreases in the use of Caesarean sections... 82% [of obstetricians] said they agreed with it, and 33% said they had changed their practices as a result. Nevertheless, only 3% could identify the recommendations correctly... and... actual rates of Caesarean section showed almost no change after the guideline was released." (Leavenworth, 1994a). Again, information and intention do not translate into action. Since Caesarean sections are major surgery with all the usual risks attendant, cost and quality both clearly suffer.

The problem illustrated by all of the above examples is a gap between theory or intention and effective execution of a protocol. That issue is separate from the problem of excessive use of a protocol. Analyses often quoted have suggested that roughly a third or more of common surgery performed is inappropriate to the medical circumstances of the patient. (Drake, 1988).

Further, the percentage of people who undergo common kinds of surgery varies 3- or 4-fold depending on geographic area or practitioner. Researchers have implied that there is no detectable difference in health outcomes to justify the difference in surgical rates. (Brook, 1989; Robert Wood Johnson Foundation, 1995b). A typical report pointed out, "The chance that a man in Iowa with an enlarged prostate will undergo surgery for the problem varies from 15% to 60% depending on the hospital treating him." (Zinman, 1993).

Because this latter point, excessive utilization, has been so thoroughly covered elsewhere in the literature, I do not develop it further in this paper. While ineffective execution and excessive utilization are separate problems, however, both result in higher costs and lower quality.

Before leaving the topic of effective execution, consider a comparison between the examples given and a business operation. I run a Tylenol factory. Not only do we control the manufacturing process very tightly and test every batch of Tylenol we produce to make sure it meets standards, we also recertify all operators at least annually on every piece of equipment they run and every procedure they handle.

They have to get a grade of 100% to pass the recertification tests. That is, we consider it so important that every single person performing every single activity understand 100% correctly how to do it that we are constantly verifying that understanding. Far less than 1% of the product we make is rejected for any kind of quality problem.

In contrast, "An analysis of clinical data from a large hospital chain demonstrated that over a fourth of deaths from cerebrovascular accidents, pneumonia, or myocardial infarction might have been preventable. Sophisticated clinical adjustment for case severity disclosed that mortality from coronary artery bypass surgery varied 20-fold among 16 academic institutions." (Brook, 1989).

One assumes, I think reasonably, that many of the poor outcomes described were a result of less-than-proficient care from some providers. It strikes me as a curious contrast that we are so particular about making headache pills correctly, but people are not equally attentive concerning, for example, Pap smears or coronary bypass surgery.

DECISION-MAKING PROBLEMS

It's Swamp Gas and Leeches All Over Again!

One can look back on the state of medicine 200 years ago and give a little laugh of superiority: people actually thought that swamp gas caused illnesses and that the way to treat practically every medical complaint was through bloodletting, purging, and other violent methods. Medical protocols were unproven and many of them were simply counterproductive.

Are we so much more knowledgeable today? Many of the discussions about quality in health care have appeared to equate quality with uncontrolled access to any services any doctor chooses to prescribe. (Krieger, 1994; Levinsky, 1996). However, there is substantial evidence that much of the care provided is inappropriate and/or irrelevant. (Lamm circa 1987; Drake, 1988; Brooks, 1994; Robert Wood Johnson Foundation, 1995a). These problems are in addition to those caused by poor execution.

While one can hardly argue that medical science has not made huge strides, much of today's care seems reminiscent of that of two centuries ago in the sense that a lot of it is based on unfounded assumptions. "Too often what is described as high-quality care has not been demonstrated to have much of an impact on the health status of the patients. The Congressional Office of Technology Assessment has estimated that only 10 to 20% of clinician practices are supported by randomized controlled trials (Eddy & Billings, 1988). In other words, for most health care practices there is a lack of proof of the efficacy of the treatment." (Weitzman, 1990).

While "lack of *proof* of efficacy" is not the same as "lack of efficacy", lack of proof does raise questions about the validity of the treatment. Another researcher commented, "Our studies indicate that at least one-third of what goes on in the practice of medicine produces little or no health benefit for our patients." (Zinman, 1993). It is not uncommon to find that a protocol once treated as gospel is later shown to be ineffective.

For example, in 1988 after I underwent brain surgery, the surgeon explained to me that he was going to prescribe an anti-convulsive for a year. Prescribing this medicine was standard practice after brain surgery even for patients like me with no history of any convulsive disorder. I complained vociferously because I was concerned about side effects of the drug, and finally after four months the surgeon allowed me to stop taking it.

Several years later I read about a study that concluded that anti-convulsives after brain surgery reduced the incidence of post-operative seizures only in the first *week* after the operation. The standard protocol had required treatment for *50 times* the effective period! Costs and medical risks incurred by thousands of patients each year for over-medication were surely considerable.

A second example concerns treatment of middle ear infections (otitis media) in children. The standard treatment for years was the antibiotic amoxicillin. However, a recent study showed that only one in nine children given antibiotics for acute otitis media actually improved. (Brooks, 1994). Each year, roughly 1.8 million cases are diagnosed ("Day Care, Allergies Linked to Ear Infections," 1996).

If one estimates a conservative cost of $50 for treatment (doctor visit and prescription) per episode, that totals $90 million a year -- of which all but one-ninth, or $10 million, has no positive impact on health outcomes. Again, the costs and medical risks associated with treatment ineffective for the condition are significant.

A third (and anecdotal) example comes from my own experience with repetitive sinus infections. In six consecutive months in 1995, I had six doctor's visits and six sets of similar prescriptions for antibiotics, antihistamines, decongestants, steroid nasal sprays, etc. Clearly, the protocol was not working. When I pointed this out, my primary care doctor referred me to an ENT (ear, nose and throat) specialist.

It took a while to get the appointment, however, and in the meantime in desperation I accepted a suggestion from a friend that I see an acupuncturist. I did not believe acupuncture would work, but I did not feel there was anything to lose. Much to my surprise, the pain and congestion were gone before I even left the acupuncturist's office, and did not recur.

When the time came for my visit to the specialist, he recommended sinus surgery. He explained that I would still have as much congestion as I had historically had, but fewer infections because of better drainage through the enlarged openings the surgery would create. He told me that given my history, the insurance company would immediately approve the surgery with no questions asked.

When I said somewhat sheepishly that I was not sure I wanted to have surgery because I actually was not having any problems since I had had acupuncture treatment, he said, "Oh, well, the difference between standard medicine and acupuncture is that all our treatments are rigorously based on scientific fact, the scientific method, and theirs is purely anecdotal."

It has been almost a year since I first saw the acupuncturist, and with an occasional preventive visit, I have had no sinus infections since then. I did not have the surgery. I ponder the idea that the repetitive prescription drug treatment that did not work was based on "the rigorous scientific method".

Whether this comment referred to clinical trials in the past or management of my particular case in the present, credulity is strained. If referring to the latter, it is worth noting that no one in the health care system realized that I had been treated six times in six months until I pointed out that the protocol was not working.

I realize that sinus infections are notoriously hard to treat, but the sincere belief that many doctors have in the infallibility of medical protocols is cause for concern. The profession seems to have convinced itself that 100% of its actions are based on "rigorous science." I would suggest that in many cases a more appropriate model is "the emperor's new clothes."

A fourth example of decision-making not connected to outcomes is that practice guidelines, a perfectly credible idea, are rendered far less meaningful because they are often simply a codification of professional opinion. They are often not based on objective outcomes analysis. Interestingly enough, AHCPR (the federal Agency for Health Care Policy and Research) has two apparently independent projects underway.

A write-up about the agency notes that two projects in which it is involved are "clinical practice guideline development" and "medical treatment effectiveness studies." (Wilson, 1994). Although one might think that figuring out what medical treatments work might precede telling physicians what treatments to deliver, I observe that in fact of the 20 conditions for which practice guidelines have apparently been developed, only 3 appeared on their roster of medical effectiveness studies. (Wilson, 1994).

A review of the field of practice guidelines confirms the impression that outcomes are rarely formally considered in the development or evaluation of treatment guidelines.

One article reported, "At the present time, there are many more guidelines based on expert opinion than on systematic review.... A review of 59 published evaluations of [clinical practice guidelines] found that... only 11... assessed the impact of guideline use on the *outcomes* [italics in the original] of care. Recently, we conducted our own literature search... [and] found 91 published studies, only 11 of which focused on the outcome of care. Of these, only four studies showed that the use of clinical guidelines produced any significant improvement in patient outcomes." (Worrall and Chaulk, 1996).

Another author commented, "One of the ironies about guidelines is that... they frequently offer recommendations or algorithms that have not been tested themselves." (Roberts, Rosof, and Thompson, 1996). In other words, it appears that outcomes have not been a major factor in determining what is considered appropriate treatment.

While there are some indications that this situation is changing particularly as a result of cost pressures both in the federal budget and in private managed care enterprises (Leavenworth, 1994b; Oss, 1995), it is not changing very fast (Hale & Weiner, 1994; Magnusson & Hammonds, 1996). Note that statistics in 1988 ("10-20% of clinician practices") and in 1996 (11 of 59 studies assessed outcome, 4 of 91 studies showed effectiveness) are not radically different.

Thus, while the idea of "evidence-based" medicine (Worrall and Chaulk, 1996) may be under discussion, studies imply that in eight years there has not been much

actual shift towards using outcomes data to determine appropriate treatment.

Corroborating my conclusion by implication are comments from a 1995 meeting of large corporations seeking to develop a strategy to improve quality of care for their employees. The meeting "sends a very clear signal to the health care industry that the basis for market competition will now include outcomes [such as whether a patient's pain was relieved and the person was able to return to work] -- and this implies two sea changes. First... expertise in health education and the psychology of patient behavior will be required... Second, what happens between doctor visits will become just as actively attended to and managed as what happens during doctors' visits and hospital stays. This is a deviation from traditional medicine and it has major implications." (Noble, 1995). That is, the organizations that buy health care have not yet seen medical practice based on outcomes, including those related to patient functionality and quality of life, and would like to.

A fifth example, from another service business, may help illustrate the point that expert opinion about appropriate protocol does not necessarily correlate highly with good outcomes.

Peter Kolesar, an Operations Research professor at Columbia University, described a study he had done for a fire department: "They wanted to increase their effectiveness in responding to fires. They told us that whenever an alarm came in, they immediately sent multiple trucks to the site. We asked what would happen if they just sent one, and then called for back-ups if they were needed. 'Oh, no,' the chief told us, 'We can't do that. Even though most of the calls are false alarms, if it's a really serious fire, every second counts.'"

“We discovered, though, in analyzing what actually happened, that by sending multiple trucks to respond to an alarm, they consistently ran out of trucks and had an empty fire station when new alarms came in. As a result, they weren't sending any equipment at all to a large percentage of the calls. Then they had to get neighboring communities to cover the alarms for which they didn't have any equipment.”

“The delays involved in this process were many times greater than those that would have resulted from sending just one piece of equipment on each call and radioing for backup for the serious fires. We discovered they often ended up with multiple

trucks at the site of a false alarm, and nothing at all at the site of a serious fire. As a result of our study, they changed their protocol and dramatically improved their real response time." (Kolesar, 1987).

Again, plausible theory -- "We have to send multiple trucks because seconds count" -- does not always translate into effective outcomes in the real world, and without methodical feedback loops to analyze what actually happens, the discrepancy is not always obvious to those involved. "Expert opinion" can easily be wrong.

In the early 1800's, standard medical practice relied heavily on cathartics and other "[h]eroic therapy." (Starr, 1982). If there had been practice guidelines 200 years ago, they would have specified bloodletting and emetics. That treatment reflected "expert opinion."

The assumption that one can make good decisions (in this case, establish effective treatment protocols) without reference to most of the relevant data (what outcomes occur when the recommended approach is used) is extraordinary.

As a closing comment, consider the following frank appraisal of the biggest obstacle to using objective data, i.e., feedback about what works best, in making treatment decisions: "The overriding problem is that most providers are very reluctant to look at the outcomes of their treatment and how they compare with the outcomes of other providers." (Boland, 1993).

PROCESS MANAGEMENT PROBLEMS

Process? What's a Process? Isn't That Something in the Chemical Industry?

A process is "[a] series of actions, changes, or functions bringing about a result." (American Heritage, 1992). One of the more serious gaps I see in the health care industry is a lack of fundamental process understanding, and certainly a consequent lack of a process orientation to health care. To make the concept of "process" more vivid, let me draw on a simple example from a previous job with my current employer.

In 1991, among other things I was responsible for the company's [McNeil Consumer's] distribution centers. At the distribution centers orders from customers like drug stores, food stores, etc. are filled. The president of the company asked me to reduce the time it took to assemble and ship orders because he wanted "no more phone calls from customers complaining that orders are late."

The standard time allotted to process an order for shipment was four days. To solve the customer complaint problem, he wanted this time reduced to no more than two days. Uncertain that cutting two days out of the lead time would solve the problem, I reviewed the entire order management *process*.

[2008 note: The gaps described here were typical of the state of the art at the time, across the health care industry and many other industries. Most of these have long since been addressed and should not be construed as indicative of any company's current performance.]

Here are some of the observations:

* Sales people sometimes held orders from customers in their briefcases for several days before they turned them in. Their bonus pay system gave them the motivation to shift sales from one month to another.

* Sales people also occasionally promised customers that they could get new products before the official launch date. We were not permitted to ship before launch. Customers then complained when these orders were "late."

* The order-taking department occasionally made keypunch errors, so sometimes customers did not get what they wanted because their orders were entered incorrectly.

* Computer system problems led to a loss of some orders in electronic transmission from the order-taking department to the distribution centers.

* Forecasts from the Marketing department were often much lower than actual sales turned out to be. Marketing was rewarded for exceeding forecasts, so they had a reason to forecast low. As a result though, Manufacturing, which was authorized to make only what Marketing had forecasted, frequently had not made enough product to meet actual demand. The products simply were not in the warehouse when customers ordered them.

* Response time to get more raw materials into the plants and make more product than planned was several weeks.

* Trucking companies, with their own problems, sometimes missed their commitments to get the product from the distribution center to the customer in the specified amount of time.

* The customer's receiving dock frequently had not been notified of the order by its own purchasing department, and as a result the dock sometimes refused to provide a dock appointment (for unloading the truck) until a day or two after the goods had arrived. Once the truck was unloaded, there were several more steps to be completed, such as recording the transaction in the customer's computer system and actually moving the goods to the store shelves.

In short, I explained to the president that while I would be happy to modify distribution center procedures to ensure that we turned orders around in two days (and I did), that in itself would not guarantee "no more phone calls from customers complaining that orders are late." To achieve that result, we needed to address problems throughout the entire order management *process*.

In attempts to get good outcomes from any even moderately complex process, it is necessary to identify issues with *each step of the process*, and at least equally important, issues with *coordination among the steps*, which typically will require massive communication efforts. In my experience, it is frequently in the interfaces between steps, in fact, that most of the problems lie.

The underlying problem is that while everyone may be making rational decisions for the step(s) in which they are most directly involved, no one is actually looking at the whole process from the outside and considering how it affects its customer -- in my example, the stores buying Tylenol. Recognition of the need for better coordination in the health care process, in fact, has led to the managed care emphasis on the primary care physician. However, as examples below will illustrate, this solution has not accomplished its purpose.

One study of the process of health care concluded that only 25% of emergency room patients studied received adequate care: 67% of those who needed follow-up x-rays actually got them; of those, "38% knew whether they were normal or not; and of those who had abnormalities, 37% received adequate therapy... Some of these disappointing outcomes were the result of lack of compliance on the part of patients, but most of the time the system... had failed. Follow-up appointments were not given because an appointment desk was closed, laboratory slips containing important abnormal results mysteriously disappeared..." (Brook, 1989).

That is, coordination among the steps in the process was poor. Much of the work done, which was costly, did not lead to appropriate care. Many patients may have suffered serious health consequences and engaged the health care system again later, repeating work that had been done already at least once before. As a result, costs and quality of care both doubtless suffered.

Ignoring preventive medicine, an example of the process of health care at its simplest includes at least the following steps:

* Patient or other family member, etc., believes that something is wrong.

* Patient or other decides to pursue medical care based on:

    * Interpretation of how important the symptoms are.
    * Convenience.
    * Cost/Insurance issues.
    * Access to care.

* Patient/other selects a treatment venue, e.g., emergency room or doctor's office.

* Unless it is an emergency, patient/other contacts doctor's office for an appointment.

* Patient/other makes logistical arrangements to keep the appointment.

* Patient/other may engage in palliative care until appointment.

* Patient arrives at doctor's office, checks in, and perhaps waits.

* Patient is seen by nurse, who asks various questions and makes notes.

* Patient is seen by doctor, who asks various questions, makes notes, and makes other comments, e.g., gives instructions.

* Patient makes a co-pay, checks out, and leaves.

* Service provider completes records, billing notes, etc.

* Patient/other may go to a drug store or medical supply store to purchase indicated items.

* Patient implements required actions, e.g., takes medicine, engages in other therapeutic activity, etc. Some of these actions may require changing own or other's daily routine.

* Patient/other may get involved in billing and payment issues.

* Patient feels better/does not feel better.

* Patient starts the process all over again.

Notice that of the dozen or so steps, most of the ones that require initiating action belong to the patient -- deciding to go to the doctor, filling the prescription, changing a daily routine. Very few steps at all belong to doctors, but the entire debate about quality and cost of care focuses on the one or two that involve them. Very little attention is given to the impact of the patient on cost and quality of care.

A common opinion is that doctors' treatments choices should be the focus of cost control efforts because their decisions determine 80% of the costs of health care. I suggest that this emphasis is misplaced. Many of the costs in health care are due to poor execution; decision-making by everyone -- including those who would review doctors' decisions -- that does not correlate to outcomes; and poor process management, due largely to ignoring the patient's role.

Most of the steps in the health care process are fraught with potential difficulty. For example, two issues that cause problems concern patients' comprehension and their compliance. Note that there are typically no feedback loops built into the process to encourage providers to check back with patients to see how the steps in the process are going. ("Are you having any problems taking the medicine?")

Often, feedback occurs only if the process fails and the patient makes the effort to come back. It is inefficient to have the main feedback loop come into play only after the system has failed. It is less costly to have monitoring that allows failure to be prevented. Medical care is also superior if system failure is prevented. If problems with the process are not addressed, costs and quality are likely to suffer. Examples of potential gaps in the process follow.

First, the patient may not make good choices about when to seek care, both overusing and underusing services. Overuse obviously worsens costs and quality; underuse is likely to have a similar effect long term (e.g., women who do not get prenatal care).

Second, palliative care undertaken prior to seeing the doctor may mask symptoms or make a condition worse. For example, analgesics may eliminate fever and thus the doctor may mistakenly conclude that there is no infection when there is. I have never been asked by a physician if I have taken analgesics prior to the office visit. This gap may lead to erroneous diagnosis and treatment, and thus costs are incurred that do not lead to improvement in health. Costs and quality are then both poor.

Third, the patient may not repeat to the doctor all the symptoms he just explained to the nurse, believing that the nurse recorded all the information and that the doctor has read it. This transfer of information has many potential gaps.

Fourth, the conversation between doctor and patient provides fertile ground for misunderstanding. For example, one study involved comparing the answers four doctors got when each asked the same patients about the same set of symptoms. "The variation in the reports of responses to a simple question like, 'Do you have a cough?' was large." The author suggested that responses to more complex questions would, of course, be even more problematic. (Eddy, 1984).

Part of the discrepancy may have its origins with the doctor. It is also true that patients may be imprecise in their answers. When my husband was three years old, he complained that his foot hurt. The doctor examined him and found nothing wrong. Three weeks later, he collapsed after jumping on a chair, and it was discovered that he had in fact a broken leg -- he had just described it imprecisely to the doctor.

Miscommunication can lead to costs for wasted medical treatments and quality problems due to inattention to important health concerns. Higher costs are incurred later to treat medical problems that may have become more serious due to lack of appropriate care in the first place.

A fifth gap in the process of health care delivery is that it is common to find doctors rattling off instructions the patient forgets by the time she walks out the door. It is rare for a doctor even to ask, "Do you understand?" but that question is ineffective anyway -- the patient may think she understands when she does not. One study showed "five minutes after patients left a doctor's office, they remembered only half

of what was told them; and most of what they did remember was at the beginning of the conversation. Yet many doctors give therapy instructions at the end." ("Reading for Your Life," 1994).

In my experience, doctors also rarely ask follow-up questions at the next visit to find out if their instructions were followed. Costs are incurred for medical care, but most of the benefits may be lost because patients forget what they are told. Costs and quality can both suffer.

A sixth gap is that patients may not comprehend health care information they get after they leave the doctor. For example, one study concerning the impact of literacy on patient compliance noted "nearly 30% had inadequate functional literacy." It showed that 41% of the patients "were unable to read directions for taking medication on an empty stomach... 26% could not read information about the next medical appointment." ("Ill Health and Illiteracy: A Highly Dangerous Team," 1995).

If patients cannot follow instructions, once again medical benefits are small and costs are high, because not having improved, they are likely to return for additional care.

A seventh gap in the health care process is that patient compliance with medical regimens is often poor. Consider prescription drug regimens as an example. My company's managed care group explained it this way: "Of every 100 prescriptions, only 70 get filled. Of the 70 filled, 20 go in a medicine cabinet or drawer and are never opened. Of the 50 that are opened, only 25 are taken as instructed -- for example, four times a day with food for ten days."

Thus, if one assumes for the moment that the drugs prescribed are the perfect protocol for the ailment, only 25% of the patients end up with appropriate care -- although costs include doctors' visits for 100% of the patients and prescriptions for 70%. If the patients get better despite the fact that 75% don't take the drugs correctly, then the doctors' visits and prescription costs are a waste because they are unnecessary. If the patients don't get better and therefore go back to the doctor, then for up to 75% of the patients there are unnecessary costs for duplicate medical care.

A corroborating study reported, "In low-income populations, if physicians... ask... about noncompliance, respond... to patient problems[, etc....then] compliance with medications is over 80%, while [otherwise]... it is 15%." (Brook, 1989). In other words, simply making a diagnosis and scribbling a prescription do not result in good medical care -- these actions do not "Make it so!"

An eighth gap in the health care process is that patients may not realize that they have questions until they get home or even until several days have passed. Three examples may help illustrate this point.

I was once given the instruction, "Don't lift anything over five pounds." As days went by, I repeatedly realized I was uncertain how to comply. When I pulled open a heavy door, I wondered how to tell if I was violating the instructions. The door certainly weighed more than five pounds, but I was not lifting it, I was just pulling it. But the force I had to use was more than it would have taken to lift something that weighed five pounds. But it was not lifting...

When I pulled a file out of a tightly packed desk drawer, I did not think until later that while the file itself weighed only a few ounces, I had to exert a lot of force to tug it free. Was that the same as lifting something over five pounds? Was it okay to pick up my big dictionary to check a spelling? I had no idea how heavy it was. (I later found out it weighed seven pounds.) Was stretching okay? It was not lifting, but it used the same muscles.

Thus, what surely seemed to the doctor an unambiguous instruction was not at all clear to me in everyday life.

The next example of difficulty interpreting apparently simple instructions occurred when I was told to call if my fever exceeded 100 degrees. My normal temperature is 97.5, although the average for the population is 98.6. Did the "100 degrees" imply that a fever more than 1.4 degrees above normal merited a call? That would mean I should call if my temperature exceeded 98.9. Or was 100 degrees an absolute measure, regardless of normal temperature? I was not sure. (Neither was the doctor's nurse.)

Another example concerns instructions for drug dosing. If told to take the medicine an hour before meals, what happens if one has a snack, e.g., chips and dip an hour before dinner? Does the instruction mean to take the drug on an empty stomach? What constitutes an empty stomach? If one realizes belatedly that one has just had a snack without having taken the medicine an hour earlier, now what? Is it better to skip the dose or go ahead and take it on a stomach full of chips and dip? Is the drug just 5% less effective or totally ineffective if taken with food?

These may seem like silly little scenarios. But if the medical advice actually matters, it is in the details like these that health care either succeeds or fails. If patients do not know or can not get the right answers, they will be acting at cross-purposes to the doctor. Quality certainly suffers, and redundant care -- an added cost -- may be necessary.

A ninth kind of gap that may occur in the health care process is that patients may understand the instructions but not why they matter. People are given advice constantly, from "Read the instruction book before turning the equipment on," to "Vacuum the refrigerator coils every six months." Most people ignore most of the advice, and frequently nothing very serious seems to happen in consequence. With no explanation about why a drug regimen or other medical protocol is what it is, many people do not take it seriously.

These examples do not exhaust the list. They are simply representative of the gaps that commonly occur in even the simplest of ambulatory health care processes. It is possible to see that any one gap can subvert the system, yielding ineffective treatment and consequently high costs for repeated intervention coupled with poor quality as the patient's condition does not improve and instead deteriorates.

In a process with many steps, any one of which can cause the process to fail, the chances of getting high quality and low cost are slim unless the process is aggressively managed.

More complex health care situations have a correspondingly greater potential for gaps. For example, add to the equation a single diagnostic test. Additional steps include:

* Determine the relevant test to administer.

* Get authorization for and schedule the test.

* Make sure the patient knows when and where to show up.

* Have the patient comply with pre-test instructions (e.g., "Don't eat for six hours before this test.")

* Use proper technique to administer the test (e.g., Pap smears).

* Process the test correctly (e.g., perform lab work properly).

* Record the results accurately under the correct patient's name.

* Report the results effectively to the physician (she gets and reads the report).

* Interpret the results appropriately.

* Discuss the results with the patient.

* Prescribe an intervention if the test results warrant it.

* Etc.

Assume a process with twelve sequential events/activities. Assume that each is performed correctly 95% of the time. The probability that the entire process is completed correctly is 54%. (That is, .95 to the twelfth power.) And most real-life health care processes contain far more than 12 steps. It is reasonable to infer that problems with the process of health care delivery can result in dramatically less favorable quality and costs than would be experienced if the process worked as intended.

Just as each step of the order management process needed attention for customers to get their Tylenol on time, each step of the health care process needs attention for patients to get desirable health and quality of life outcomes while costs are minimized.

PERCEPTUAL PROBLEMS

A Stagehand Once Told Me, "Working in Theatre Would Be Great If There Weren't Any Actors!"

Over twenty years ago, I worked on the technical side of both amateur and professional theatre. I remember being bemused when one of the crew made the above comment. It seemed to me her perspective about the point of putting on a play was a little skewed... This example leads to the topic of this section.

From whose perspective should health care be viewed if the intention is to improve quality and costs? For whose benefit should the health care process be designed? (I submit that these are functionally equivalent questions.) Consider an analogy first.

In the distribution center example above, given that the point of the business is to sell Tylenol, most people would agree that the process should be designed so the stores that order Tylenol get it promptly. Having determined that goal, the interests of the groups whose actions help achieve or frustrate that goal can be considered and aligned.

For example, one could change the sales compensation system so that submitting orders within 24 hours was rewarded, and artificial allocations of sales among months was not. One could change Marketing compensation to reward forecasting that most accurately predicts actual sales, rather than rewarding overselling the forecast. Each of these has its own pitfalls and could be the subject of a paper in its own right to review the intricacies of design required to elicit desired behavior.

The starting point, however, is a thoughtful focus on the point of the system: stores that order Tylenol should get it promptly.

(The distribution system itself, of course, is a subset of a larger business with concerns about new product development, competition, profitability, etc. Thus there are larger issues for the company beyond simply getting product to the stores. It is most effective to step back and identify clearly the larger issues and ensure that the distribution system is aligned with larger goals. In the interests of brevity, however, I have presented distribution as if it were unaffected by larger concerns.)

Consider one more analogy before turning to the question of from whose perspective the health care system should be designed to improve costs and quality.

Imagine that there are no private kitchens. Every October, you are handed a piece of paper that describes two or three restaurants, and you have to pick the one in which you will eat all of your meals -- three meals a day, seven days a week -- for the coming year. For each restaurant, the paper lists its street address, waiters' names, and the ingredients found in the most commonly served dishes. You make a choice, hoping for the best.

You are assigned to one waiter for the entire year. This waiter is responsible for nourishing you appropriately. When you get to the restaurant, you find that the waiter to whom you are assigned is often unavailable. The one who takes his place has not generally had a chance to review your nutritional history. It happens, in this world I am describing, that only sometimes can you tell how hungry you are. The restaurant staff has some imprecise ways to assess hunger, and sometimes they tell you their conclusion, and sometimes they do not.

When you go into the restaurant, you do not get a menu. They choose a meal for you. Sometimes they tell you ahead of time what it is, and sometimes they do not. What meal you get depends most of all on what waiter you have. Each waiter serves meals that match his own area of food specialization, whether that food is something you like and feel is good for you or not.

They may give you more or less than you really want, depending on their assessment of your hunger. Even if you tell them you disagree, it is rare for them to change the portions they give you just based on your say-so. If you want some kind of food they never have, occasionally you can get your waiter to give you a voucher to go eat in another restaurant for a few meals. Every time he does, however, they dock his pay.

If you get sick from the food your restaurant serves, or malnourished, or if you just do not like it, that does not necessarily get them to change anything. If you get into an argument with them about it, they might say, "We're running a business here. And no one has proved that it's cost efficient to take consumer preferences into account."

Sound bizarre? Hard to imagine? But that scenario has a lot in common with how health care works, especially in a managed care environment. Health care in the United States is arguably the only trillion dollar industry (Pear, 1996c) in the world that manages to conduct its business in some sense with virtually no reference to its end-user customers (patients) or products (health and quality of life outcomes).

For example, an entire current 600-page textbook, Making Managed Healthcare Work, managed to describe its topic almost exclusively as a proposition that has to satisfy the needs of purchasers (employers), payers (insurance companies), and providers (physicians and hospitals), mainly around cost control and profit protection, with virtually no mention of the patient or of health outcomes. The book's index, 3 columns on each of 12 pages, does not even have an entry for "outcomes," "outcomes analysis," or anything similar. (Boland, 1993).

One might argue that "managed care" is not synonymous with "health care in the U.S.," the topic under discussion, and that thus the above perspective does not fairly describe the whole industry. However, it seems justifiable to view managed care as the up-and-coming dominant approach to health care in the U.S. based on the number of people enrolled and trends in enrollment. In 1995, 120 million people were members of managed care programs (Cafferky, 1995), up from 8 million in 1979 (Starr, 1982) and triple the 1987 enrollment (Ginzberg, 1987).

Common wisdom is that the trend will continue both in employment-based programs (Pretzer, 1996) and in government-funded ones. It is expected that the 38 million Medicare enrollees, only 10% of whom now belong to managed care programs (Iglehart, 1996), will be encouraged to join them through various incentives (Spiers, 1996).

Further, while currently just 23% of Medicaid's 33 million enrollees are in managed care programs (Robert Wood Johnson Foundation, 1995a), additional efforts are underway to increase that number. (Gamino, 1996a; Gamino, 1996b; I. Fisher, 1996). Thus, given current enrollment and trends in both employment-based and government-funded health care programs, the perspective of the managed care industry can plausibly stand as representative of the health care industry in general.

In a typical statement from the managed care text, the author opined, "physicians will continue to have the last word on costs because they control medical resources -- not employers or insurers." (Boland, 1993). Notice that the only players are physicians, employers, and insurers.

The author assumes by omission that there is no role for patients in influencing medical costs -- not in choosing insurance plans, certainly not in participating in treatment decisions, and not in modifying their personal behavior, either in lifestyle elements such as smoking and exercise, or in how they interact with the medical care system, e.g., compliance with prescription drug regimens. Notice also, again by omission, that the author assumes no role for decision-making based on objective outcomes data that could be made available to patients and others.

The doctor makes all the choices. The patient appears to be simply the object upon which action is taken. This point of view is echoed in other essays. "In the health-care marketplace the interests of patients and of society must be represented by the physician, who *alone* [emphasis added] has the expertise and the authority to decide which services and procedures should be used in any given circumstance." (Relman, 1980).

Similarly, another author commented, "Decisionmaking on patient care must be made by those licensed to practice medicine, not by those looking at actuarily sound estimates or bottom-line profit-and-loss statements." (Krieger, 1994). Here again, notice that the only players are doctors and managers/bureaucrats -- the patients are not part of the discussion.

A third explained, "because decisions about procedures are typically made by physicians on behalf of their patients, the physicians must infer their patients' values, and keep them distinct from their own personal preferences." (Eddy, 1984). The author went on to explain the difficulties involved in making value-based decisions for other people. It did not seem to occur to him that an alternative is to provide data to the patients and allow them to make their own decisions based on their values.

Virtually every discussion that suggests allowing others to participate in treatment decisions is talking about a role for managed care reviewers. No change is suggested in the patient's role as the object upon which action is taken. MCOs

(managed care organizations) are in fact making heroic efforts to control physicians' use of resources, but results are mixed at best. "The gatekeeper role is an administrative nightmare, and doctors typically find ways to circumvent insurers' restrictions." (Hammonds, 1996).

Whether it is the managed care reviewer or the doctor controlling treatment decisions, however, patients feel that they are subjected to others' dictates and are not themselves included in the discussion.

So whose perspective should frame decision-making about health care? I suggest that it should be the patient's. The patient is the ostensible reason for the health care system to exist, and I believe that it is only with a focus on the patient and on patient outcomes that big improvements in cost and quality can be achieved.

A recent medical journal article talked about "patient-centered care." "American medicine is in the midst of a professional evolution driven by a refocusing of medicine's regard for the patient's viewpoint. Historically, medicine has been largely physician centered, but physicians have begun to incorporate patients' perspectives in ways that increasingly matter. Some call this shift 'patient-centered' care." (Laine & Davidoff, 1996).

The article then went on to suggest, as part of patient-centered care, the following patient rights:

* To be told what is wrong with them.
* To have treatment options explained.
* To participate in treatment decisions and give informed consent.

The article also suggested that it is appropriate for patients to be permitted to provide feedback from their perspective on outcomes of care.

What radical ideas! In any other arena involving adults who have not been convicted of crimes (that is to say, excepting school children and prisoners), the absence of like attributes would seem simply bizarre. Consider the restaurant scenario. In health care, however, such attributes are considered new and optional.

The article went on to ask, "Will patient-centered care flourish or wither in the current health care climate? On the one hand, prospects for patient-centered care appear

grim... Costs increasingly drive health care decisions, and patient-centered care has not clearly been established as cost efficient.... On the other hand, there are some signs of hope for patient-centered care."

For example, the authors noted, "the current explosion of interest in primary care may support the patient-centered perspective." (Laine & Davidoff, 1996). I am not as optimistic as they are, since the percentage of medical graduates electing primary care specialties dropped from 36% in 1984 to 23% in 1994. Although it had dropped even lower in the early 1990's and the 1994 number thus represents an upturn (Robert Wood Johnson Foundation, 1995a), I do not consider the numbers consistent with an "explosion of interest."

My conception of patient-centered care goes much further than informed consent. It means shaping the entire *process* of care to achieve the intended outcomes: improved health and quality of life for the patient. How does that differ from what happens today?

As a framework for answering that question, consider the experience of Andy Grove when diagnosed with prostate cancer, as described in a lengthy cover story in the business weekly Fortune. (Grove, 1996). A large-print note on the cover of the magazine cautioned, "When Intel's CEO got the chilling diagnosis, he didn't just follow doctor's orders. Neither should you."

Grove read all the original research he could find on the topic, and "talked with more than 15 doctors and half a dozen patients." He discovered that "[e]ach medical specialty -- surgery, cryosurgery, different branches of radiology -- favored its own approach." He also discovered that patients' reports of side effects (impotence, incontinence) were far grimmer than the physicians' reports.

He found that he had to compare the results of different studies himself. "[Physicians] primarily tended to publish their own data; they often didn't compare their data with the data of other practitioners, even in their own field, let alone with the results of other types of treatments for the same condition."

From his research, he discovered that results (survival rates) were as good with a form of radiation therapy as they were with surgery, and with far fewer side effects.

Even given this data, however, virtually all of the doctors with whom he spoke still recommended surgery.

He chose to have the radiation therapy, and commented, "There is no good gatekeeper in this business. Your general internist is not... I concluded that I had to undertake the generalist's job myself... that's the only viable choice any patient has... Investigate things, come to your own conclusions, don't take any one recommendation as gospel."

He quoted, with some irony, from the paper a surgeon wrote about the responsibility of treating patients with this disease. "... [W]hen faced with a serious illness beyond [his] comprehension, [the patient] becomes childlike, afraid, and looking for someone to tell [him] what to do. It is an awesome responsibility for the surgeon to present the options to a patient with prostate cancer in such a way that he does not impose his prejudices which may or may not be based on the best objective information."

None of the surgeons had based their recommendations on objective data.

What does this mean in the context of patient-centered care? Virtually every article I have seen written on the topic of treatment choices argues that only the doctor is qualified to make decisions about treatment options. The rare article that does not take this view argues that cost pressures mandate managed care oversight of these decisions.

Grove's article -- one written by someone outside the health field -- is the first I have seen that suggested that patients might do better if they evaluate treatment options -- using information they get independent of a proponent of one of the options -- and make their own choices.

Getting information about treatment options from the proponent of one (for example, asking a urologist -- a surgeon -- to compare surgery and radiation) is like going to a Christian minister and asking him to help you decide which to embrace: Christianity, Judaism, Buddhism, shamanism, or atheism. It is like going to a Catholic priest and asking him to help you decide whether your chances of life everlasting are better as a Catholic, a Baptist, or a Quaker.

What every article has missed, I think, is that "the doctor" is a meaningless concept -- there is not *one* doctor who objectively evaluates the options and recommends the best one to the patient. Each practitioner recommends his own favorite "which may or may not be based on the best objective information." Bias is reflected even in the recommendations of general practitioners. (Grove, 1996).

The doctors Grove described were not neutral, factual, or unemotional in presenting their opinions. Far from the benevolence implied by the repetitive "doctor knows best, defender of quality" essays, the doctors as portrayed were a tad less objective, a tad more self-serving:

* "[T]he urologist [a surgeon]... told me my options... [and then] gave me the impression that [anything but surgery] would have a lower probability of curing me" and assured Grove that all the side effects from surgery (impotence, etc.) could be treated. The appearance of objectivity is more misleading to the patient than blatant bias: the doctor explained all the treatment options, just as patient-centered care proposes, but then subtly discounted all but surgery, a perspective not supported by data.

* "According to the surgeons who write papers, the side effects are not so bad. But I also read a study that questioned a large group of patients directly, and those results were alarming: the reports of incontinence and impotence were dramatically worse in the second study." So it depends whose view one considers relevant: that of practitioners or of patients who live with the results. The doctors presented only the practitioners' view.

* "I continued with visits to three more well-known surgeons. All were ferociously opposed to... any radiation therapy whatsoever. One, for instance, suggested the likelihood of a need for a colostomy." This argument turned out to be one of intimidation, apparently unsupported by even a single case history. One might consider it a form of emotional abuse. Grove commented that the possibility of needing a colostomy "scared me enormously." One suspects that was the point.

* Another red herring was the argument one surgeon made that antigen levels went to zero only with surgery, not with radiation, so surgery was the only

appropriate choice. Since healthy prostate tissue produces some antigen, and the prostate is entirely removed by surgery, it is technically correct that antigen levels would go to zero only with surgery. But that fact has no medical relevance. When Grove asked about this apparent irrelevance, "The conversation got so heated that my question was never answered."

* Even the leading radiologist with whom he spoke admitted that he himself would opt for surgery if he had prostate cancer. Grove, bewildered, asked him why. The doctor had to stop and think for a while, and then replied, "You know, all through medical training, they drummed into us that the gold standard for prostate cancer is surgery. I guess that still shapes my thinking." This comment was from someone whose own data showed better results in patients he treated with radiation than other doctors' surgical patients achieved. Notice that what was "drummed in" in medical school was not about how to research and carefully interpret data. What was "drummed in" was simply The Answer, as if no improvements in medical therapies might occur in the subsequent thirty or forty years of practice those medical students would experience.

* The surgeons consistently argued that the results of other treatments were not as good as those of surgery. This position was simply not supported by the facts. "The data said that the treatment results were the same -- maybe even better for [radiation]."

Consider the above observations in the context of a comment quoted earlier, "the physician... *alone* [emphasis added] has the expertise and the authority to decide which services and procedures should be used in any given circumstance." (Relman, 1980).

I would also suggest that if Grove were handling his medical needs through a managed care organization, the treatment authorized would probably have been prostate surgery. Practice guidelines based on professional opinion would surely have led to that result. That is, managed care review would probably not have resulted in Grove's getting the superior treatment he did.

If Grove had spoken with only one or two doctors, one might conclude that he just

had bad luck in running across a couple of self-serving ones who did not want to know what the data showed. But he spoke with 15 doctors, and had very similar experiences with virtually all of them.

One could argue that perhaps Grove simply has such an antagonistic personality that no doctor could stand to converse rationally with him. I think that idea is a stretch -- he comes across as intelligent, thoughtful, articulate, and objective in his article -- but even if it were true, that is hardly a defense for "ferociously opposing" treatment that data show to be superior.

Grove did not, in my opinion, experience "patient-centered medicine". The surgeons' perspective was that with surgery, the cancerous prostate would be removed and so that was a good outcome.

Grove, however, was at least as concerned about the possibility of living with impotence and incontinence as he was with destroying the cancer. The surgeons discounted his concerns and focused on the outcome they felt was important, meanwhile ignoring data that said another option got just as good results but with better outcomes in areas that mattered very much to the patient.

Patient-centered medicine, in my mind, would identify the issues of importance to the patient and reflect data that addressed those concerns. Instead, the doctors used their erudition and authority to float impressive-sounding arguments (colostomy, antigen levels, poor results) that appear to me intended to manipulate the patient into selecting a specific treatment despite data that showed another choice to be superior given his concerns.

Grove clearly has the resources -- the intelligence, persistence, habit of research and scientific thought, sense of personal autonomy and authority, even an apparently stay-at-home wife to go to the library for him -- to wrest a patient-centered result from the health-care system. It seems likely to me that less than one half of one percent of the population is similarly equipped.

If the health care system in the U.S. were actually patient-centered, I think everyone would get what Grove ultimately got -- objective information from which to make personal choices. However, they would get it without the extraordinary effort Grove

had to make. As he concluded, "I think we have a long way to go to reach this ideal." (Grove, 1996).

Patient-centered care implies making the patient the focus, rather than focusing on the doctor, on an episode of care, or on some theoretical abstract. Patient-centered care has perhaps always been suspect in the medical profession. "A professional who yields too much to the demands of clients violates an essential article of the professional code: Quacks, as Everett Hughes once defined them, are practitioners who continue to please their customers but not their colleagues." (Starr, 1982).

An article on patient-centered care referenced earlier noted, "Historically, quality assurance meant assuring that providers followed processes of care deemed important by their peers... By the late 1980s, outcomes of care began to be widely emphasized over process measures, but providers remained the ones who evaluated the outcomes." (Laine & Davidoff, 1996).

Note that I did not find similar evidence of widespread outcomes-based evaluation. The article also said, "Incorporating patient-based measures of outcome such as functional status and quality of life into research will help to ensure that investigators deem interventions successful only when they result in meaningful benefit to patients... On moral grounds, patient centering is the right thing to do since medical care is, after all, intended primarily for the benefit of patients." (Laine & Davidoff, 1996)

What is astonishing is not these sentiments themselves, but that in 1996 they are considered novel enough to command prime space in one of the country's premier medical journals.

Four personal examples may help to illustrate the distinction between today's standard approach and my concept of patient-centered care.

When I had the recurrent sinus infections noted earlier, my primary care doctor referred me to an allergist in addition to the ENT doctor mentioned before. My primary care doctor's approach was to continue to prescribe antibiotics, etc. The allergist had his whole regimen of allergy testing and treatments. And the ENT offered surgery.

At no point after the referrals did my primary care doctor discuss with me the three different perspectives (including test results) of the three different doctors to help me sort through the options and choose an approach that best fit my needs. Nor has any mainstream doctor ever asked me about any alternative care I have pursued. In this case, for example, my primary care doctor does not realize that I had acupuncture or that it seemed to work.

The term "managed care" seems curiously inappropriate -- my care is not being managed at all. There are simply episodes: "I've been here six times in six months for sinus infections. Would you send me to a specialist?" "Oh, sure, that makes sense. You'll get the referral letter in 7-10 days." Period. That was the end of the discussion; he never raised the topic again. I chose to make my own decisions; but I certainly did that without any assistance from the practitioner who was theoretically responsible for managing my total care.

Another example of care that is not patient-centered in my recent experience is that I have had three different primary care doctors in the last year -- not because I have ever requested a change, but because they keep leaving the practice for reasons unknown.

Apparently the record-keeping is spotty as well, or perhaps the doctors do not have time to look at the charts. The doctor I see rarely has any idea at all of my recent medical history. I have found myself several times explaining that some proposed treatment was contraindicated for some compelling medical reason that should have been obvious to him from the records. Again, the impression created is that the focus of attention is something other than the patient.

In a third example, the primary care doctors in my managed care organization seem alarmed at the very concept of women. For example, during my first visit to the practice after my employer changed insurance plans, I asked for a standard referral to an ob/gyn for an annual check-up.

The doctor put up his hands in front of his face as if to ward off attack. "Don't talk to me about women's health. I don't have anything to do with that. You don't need to talk to me about that. You don't need a referral from me. Just pick someone from the list and go. Anything to do with women's health, I don't get involved in."

His reaction did lead me to wonder how "managed" my care was: anything to do with being female, he didn't want to know about. Again, it seemed clear that I, the patient, wasn't the focus of attention -- the doctor was adamant about dealing with only a fraction of me.

For a final example, I draw on an experience I had in college. Due to multiple food allergies and problems with the dorm food, I had gotten a medical waiver excusing me from the meal plan even though I was living in a dorm. However, I did not have good alternatives because I could not afford to eat in restaurants, there were no kitchen facilities available to students, and the college had a strict policy prohibiting hot plates, refrigerators, etc. in student rooms.

In one visit with the local doctor, the topic of nutrition came up. He handed me a brochure and told me I should eat meals like the ones pictured therein. I stared at the brochure -- it showed elaborate 3-course meals, broiled meats and fish, steamed fresh vegetables, etc. I was living on things like Carnation Instant Breakfast. His advice was flawless -- it was just entirely beyond my reach. His advice did not have anything to do with me.

I suspect I am not the only person who has experienced a profound disconnect in talking with a doctor whose advice may be clinically perfect but entirely unexecutable by the patient. It is a rare doctor, I believe, who conducts conversations with patients interactive enough even to discover the disconnect, much less works with them to modify the advice or to come up with alternatives they can handle.

The above examples, Grove's and mine, suggest that care is not currently patient-centered. Practitioners have their own favorite treatments, and patients are not provided with information about outcomes, either medical or quality of life, to help them sort through the options and choose. And in fact, most doctors, insurers, and MCOs view the decision about treatment choices as theirs to make. The patient's perspective may carry little weight.

The health care system frequently operates with attention to individual episodes of care and not with a long-term, coordinated, outcomes-oriented framework. The *process* of care is unmanaged, and many good intentions are derailed as a result.

In addition, much of the care rendered is inappropriate, irrelevant, or poorly executed. These are some of the problems with health care delivery in the United States, and they contribute significantly to high costs and low quality of care. The next section discusses why these problems exist.

SECTION THREE: WHY THE PROBLEMS EXIST

To offer effective solutions, it is important first to understand where the problems came from. Most commentators believe that cost problems are due to traditional fee-for-service and third-party payment arrangements. While this view has merit, I believe that one might solve those problems without getting a significant improvement in both costs and quality. In fact, there is some evidence that HMOs may control costs but that quality of care declines. (Dao, 1996; Schine & Hammonds, 1996).

I suggest instead that both cost and quality issues arise substantially because of four types of problems discussed above: executional flaws, decision-making not based on outcomes, process mismanagement, and perceptual flaws concerning patient-centered care. This section identifies key sources of problems in these areas.

Why Problems Exist with Execution

I believe these problems arise for at least three reasons: the style of medical education, the private nature of doctor-patient interaction, and the lack of performance feedback for physicians.

First, medical education is conducted as a "passive-learning, teacher-centered" proposition, which encourages rote memorization rather than active problem solving. (Jonas, 1990). As a result, medical students may feel they have no opportunity to ask questions for clarification or to better understand whether particular features of a protocol are critical or peripheral.

In my experience, when people do not understand whether something matters or why it does, they are less likely to be meticulous about adhering to it. They are also less capable of adapting it to address subtle problems or contingencies.

Second, physicians essentially practice medicine individually, one-on-one with the patient. They typically do not have peers in the room with them as they treat patients. Thus they may have limited opportunities to get informed feedback about their techniques, and over time may drift from the ideal protocol without realizing it.

Third, although this situation is starting to change, practitioners typically have not gotten feedback about the outcomes of their interventions in any methodical fashion compared to any standard (or average) or compared to other practitioners. Consequently they may not be aware that anything is amiss.

When the information is provided, improvement is likely to occur. For example, one program in New York led to a "41% decline in risk-adjusted operative mortality" for one procedure while national mortality for the procedure dropped 18%. (Chassin, Hannan, & DeBuono, 1996). That is, unrelated improvements led to some of the decline, but most of it appeared to be correlated with corrective action prompted by methodical reporting of outcomes.

Why Problems Exist with Decision-Making

Decision-making about what, if any, medical procedure or protocol to use in a given situation is frequently not based on validated data about medical or quality of life outcomes patients experience when that procedure is used. I believe this gap arises for at least three reasons: confounding uncertainties in data collection and interpretation, the approach to protocols taught during medical education, and the logistics of disseminating new findings.

First, a gap arises because uncertainties are endemic to medical care. "Uncertainty creeps into medical practice through every pore. Whether a physician is defining a disease, making a diagnosis, selecting a procedure, observing outcomes, assessing probabilities, assigning preferences, or putting it all together, he is walking on very slippery terrain." (Eddy, 1984). Factors that make it difficult to evaluate outcomes properly include:

* Skill in executing a procedure varies widely among practitioners and across institutions. (Eddy, 1984).

* Protocols may be used on patients for whom they are inappropriate.

* Patient compliance with medical regimens may be highly variable.

* Patients themselves vary widely in their characteristics -- age, size, health habits, confounding additional medical conditions or health histories, etc.

* Some outcomes take years or decades to manifest. (Eddy, 1984).

* Randomized trials are sometimes impossible to arrange -- for instance, one often cannot randomly assign patients to different doctors or randomly assign them to smoke (Naylor & Guyatt, 1996), have children, experience high stress levels, etc.

* Outcomes related to quality of life and functionality are hard to capture. (Eddy, 1984). Patients' views are not typically part of the medical record, which is the basis for most studies of outcomes.

Second, medical education appears to teach specific protocols rather than teaching how to interpret original research and evaluate alternative or new protocols. (Grove, 1996). As a result, even when new results are available and new protocols published, practitioners may be uncomfortable discarding the protocol they learned and adopting a new one based on their independent analysis.

One author concluded, "In the end... a physician will have to do what is comfortable... The applicable maxim is 'safety in numbers.' A physician who follows the practices of his or her colleagues is safe from criticism... This tendency to follow the pack is the most important single explanation of regional variations in medical practice." (Eddy, 1984).

Consequently, even when outcomes data are available, many physicians may continue to use procedures or protocols that do not deliver the best outcomes. This phenomenon may also partly explain why studies have indicated that so much of the surgery performed is inappropriate to the patient's circumstances. Or, as someone once said, "When all you have is a hammer, everything looks like a nail!"

Third, it is possible that there are logistical problems involved in disseminating new research results and practice guidelines (protocols) to practitioners. A current *New England Journal of Medicine Article* implied that there are about 650,000 physicians in the U.S., with over 500,000 of them in patient care. (Rivo and Kindig, 1996). Logistical problems may occur on both ends -- results may not reach all the relevant physicians, and physicians may be bombarded with too many to absorb. (Roberts, Rosof, and Thompson, 1996).

Why Problems Exist with Process Management

The process of health care delivery for any individual patient in the United States is fragmented and uncoordinated. Pieces of the picture are not brought together, loose ends are not tied up, and continuity of care is limited. I believe these gaps exist for four reasons: lack of ownership of the process, the content of medical training, the style of medical training, and insufficient motivation for change.

First, as with many processes, no one owns the entire picture. In health care, pieces are owned by patients, practitioners, insurers, employers, ancillary service and product providers (e.g., laboratories, pharmaceutical companies), managements and administrators of managed care organizations and of Medicare and Medicaid programs, Congress, state legislative bodies, etc.

Each of these understandably has its own area of expertise, a limited understanding of the total picture, and its own interests to protect. Given this situation, what is surprising is not that the process does not work as well as it might, but that it works as well as it does.

Second, the content of medical education tends to emphasize acute care, and the tertiary-care hospitals in which most training takes place offer far more opportunities to deal with patients in crisis than to learn how to ensure continuity of care and good follow-up.

The curriculum in medical school tends to focus on specific medical data -- anatomy, pharmacological effects, etc. -- and addresses what decisions and actions the doctor should execute. That is, it focuses on the doctor's physical intervention. It does not focus on, or place these actions in the context of, the total *process* of health care delivery. Similarly, the example medical students see in hospitals does not focus on the comprehensive long-term needs of the patients.

A third reason for gaps in process management in health care is related to the style of medical education. Physicians are likely to treat patients as they themselves were treated -- that is, they are likely to adopt a one-way communication style, simply providing the "official answer" to patients without engaging in much interactive dialogue.

Since medical education typically does not include any courses that explicitly teach how to communicate with patients, there is nothing in the curriculum to offset the example students experience. The resulting barrier makes it harder for patients to ask clarifying questions and reduces the probability that they will comply with instructions. It also makes it less likely that physicians will ask questions to confirm patient understanding. The feedback loops and continual interactive communication so critical to effective process management are thus missing.

A fourth reason that process management problems exist -- or at least why they endure once developed -- is that they have not yet become painful enough to solve.

In contrast, in consumer goods businesses in the early 1990's, cost pressures so profoundly buffeted both manufacturers and retailers that industry councils got together and started developing the concept of "supply chain management" (Drayer, circa 1991), which means coordinating closely the activities of raw material suppliers, manufacturers, wholesalers, retailers, and ancillary service providers (e.g., trucking companies) to meet consumer needs far more rapidly and with far lower costs than had been the case. (Byrnes & Shapiro, 1991).

The estimate of the savings opportunity available in the grocery industry, for example, was $30 billion per year. (Kurt Salmon Associates, Inc., 1993). In businesses with profit margins of 1-2%, continual bankruptcies, and fierce market pressures, cleaning up the supply process was so attractive an opportunity that opposition to giving up turf melted away. Boundaries between legal entities became less important than solving mutual problems.

For example, it is not uncommon for a trucking company to have a permanent office inside a manufacturer, the better to coordinate both inbound and outbound shipments. Similarly, leading manufacturers may gain agreement to design the layout of store shelves for entire categories of products (all analgesics, for example) including those of its competition, by showing that its layouts result in higher sales and profits for the retailer. Both of these boundary-crossing practices occur where I work.

The tone among participants is less, "Do it my way or I'll take my marbles and go home," than it is, "Let me show you how I can help you achieve your goals better --

and simultaneously reach mine as well."

Notwithstanding all the news stories about a health care crisis, I believe that health care has not yet reached sufficiently dire straits to make similar cooperative efforts appear compelling. The people who are desperate -- those without health insurance, for instance -- have little voice.

For example, in the last few months, I have found over one hundred articles related to health care in the newspapers and magazines to which I subscribe. Although many reports on health care mention the 40 million uninsured (Zaldivar, 1996), only three of the articles had as a main topic health care for the poor or uninsured.

Those with a voice -- physicians, Medicare enrollees, etc. -- have a lot to say but are not pushing for greater cooperation and coordination throughout the health care process. They are pushing for greater "freedom," meaning the ability to operate autonomously, not the ability to work with other players to jointly solve system-wide problems. While I realize my point of view may be unconventional, I believe it is also accurate.

Why Problems Exist with Perceptual Issues Concerning Patient-Centered Care

Even the AMA's own publication, *The Journal of the American Medical Association*, contained an editorially-supported blurb that said, "Historically, medicine has been largely physician centered..." (Laine & Davidoff, 1996). That is, even the doctors' own organization acknowledges that medicine has typically been practiced with the doctor as the central character, not the patient.

The gap -- the lack of constant awareness that patient well-being is the purpose of the health care system -- is epitomized by the apocryphal story of a hospital patient being awakened during the night to be given a sleeping pill.

Paul Starr's 500-page epic portrayal of the forces that have shaped American medicine and of the rise of physicians' authority covers the ground quite well. (Starr, 1982). A few of the factors included are the rise of science and technology; the medical profession's control over education and licensing, control over access to hospitals and medicines, and increasing dependence on colleagues for success (for referrals, for consultation, for defense against malpractice claims, etc.) with a

corresponding decrease in reliance on patients for success; and a pluralistic society with no strong central government to offset the concentrated power of physicians. (Starr, 1982).

SECTION FOUR: THE SHIFTING POWER IN HEALTH CARE

This section makes a few observations about the declining power of physicians, the ascendancy of insurers and managed care organizations, and the countervailing forces of legislation. It points out problems caused by using legislation to address specific medical conditions and protocols for treatment, and goes on to mention limitations of several approaches often proffered in discussions about improving health care costs and quality.

Physicians, the AMA, and medical education administrators run the risk of making themselves largely irrelevant to health care in the United States. For example, many people prefer untested alternative therapies to mainstream medicine. "A national survey... found that one of three Americans used unconventional therapies." (Kolata, 1996a).

Even within the mainstream, however, doctors are losing credibility and exclusive control over medical practice. They are losing this control because of the increasing perception of a mismatch between patient needs and what the medical profession offers. Two examples follow.

First, recall the research on pain management that shows that most doctors continue to treat patients based on myths that are 50 years out of date. Second, it is generally accepted that more primary care physicians are needed; instead, fewer are being produced. (Robert Wood Johnson Foundation, 1995a).

One is reminded of Detroit's response to consumer concerns in the 1960's and 1970's -- automakers were very powerful and could call the shots about what cars would be sold. The gap between consumer needs and the offerings grew. When alternatives entered the market in the form of cars from Japan, U.S. automakers were disdainful. It was only long after they started losing substantial market share that they started to change their offerings.

The medical profession seems unresponsive to the fact that patients will actively seek other sources for information and care if they view their doctors as unable to address their needs. For example, if patients feel they cannot get objective, relevant information from their doctors, they will go elsewhere.

The president of one commercial venture on the Internet noted, "The United States has a wonderful health care system, but we have very little access to information about it, and as consumers we do a terrible job of purchasing health care... Our goal is to be the largest site on the Internet not only for health and wellness information, but also qualitative information on physicians, nurses, hospitals, H.M.O.'s and P.P.O.'s." (L. Fisher, 1996).

Another health care web site proprietor was quoted as saying,, "We get about 40,000 visitors a month." (L. Fisher, 1996). One can easily envision a business opportunity: perform the kind of research for individuals that Andy Grove performed for himself.

One doctor plaintively said, "Today, hospitals and many other entities... are structuring health care delivery around, through, or completely without the medical staff." (Krieger, 1994). "Medical staff" refers to physicians who practice in a hospital and excludes other health care providers such as nurses.

One author noted that many organizations, including managed care offices, are using other care providers who have relevant training but starting salaries in the $50K's, about half what doctors earn. These include physician assistants and nurse practitioners, who "do 70-80 percent of what a general practitioner does without spending 10 or 11 years... in medical school." (Hopper, 1996).

It appears that much of medical school/residency training is not about teaching doctors skills they need to have to be effective in patient-centered medical practice. It does not require much imagination to picture a managed care office staffed with one physician and half a dozen physician assistants or nurse practitioners. I think that outcomes are likely to be just as good or better with this staffing configuration, given management that emphasizes effective execution, treatment choices based on medical outcomes and patient functionality and quality of life, a process orientation, and a focus on the patient.

Then most physicians could end up unemployed. The tragedy there is that the talents of hundreds of thousands of intelligent, well-educated, and for the most part well-meaning individuals would be wasted. That situation would represent a misuse of human resources that borders on the criminal.

To avoid it, however, I suggest that individual physicians, the AMA, and those responsible for medical education would need to align themselves far more clearly and effectively with the goal of achieving superior patient outcomes. There are few indications that this realignment is likely to occur in the foreseeable future.

While the locus of power in health care is starting to change, it appears to be moving toward other groups with concentrated power, not toward patients. One can tell the tide is changing by noting how doctors are fighting back. For example, one author noted that doctors are starting to unionize to offset the power of HMOs (Kilborn, 1996), and another reported, "With huge mergers changing the face of the health care industry, the Federal Trade Commission plans to make it easier for doctors to band together, coordinate prices and form networks to compete with insurance companies and health maintenance organizations." (Pear, 1996a).

Other news articles paint a similar picture of increasing power in the hands of large organizations, but not necessarily to the benefit of patients. "Attack of the Health-Care Colossus," talked about a hospital group's clout (Stodghill, May 20, 1996). "Aetna to Buy U.S. Healthcare in Big Move to Managed Care," (Eaton, 1996) and "Managed Care Empires in the Making," (Freudenheim, 1996b) both reflected insurance company and H.M.O. consolidation. "Big Hospital Chain Makes a Bid to Buy Blue Cross of Ohio," described an attempt to combine a hospital chain and an insurer (Freudenheim, 1996a).

"Big", in fact, seems to be the operative word: "Big Wellpoint Deal Creates a Health Provider and 2 Charities," (Sterngold, 1996), "$2.3 Billion Deal Creates Giant in Managing of Doctors' Offices," (Freudenheim, 1996c), and even, "Big H.M.O. Guilty in Antitrust Case," (Freudenheim, 1996d).

Besides the responses from doctors, other reactions to the growth of insurers and managed care organizations are coming from legislators. The problem with what one is tempted to call "sound-bite legislation," however, is that it focuses on outlier situations -- in some cases, resulting in legislation by anecdote. Therefore, it can easily worsen both costs and quality. This situation is discussed below.

Doctors are quick to point to tragedies wrought by what they see as heartless penny-pinching managed care bureaucracies interfering in their care decisions, e.g.,

a child whose health deteriorates and whose parents both lose their jobs as a result of an HMO ruling that the gravely ill child could be treated only at a site hundreds of miles from home (Weston & Lauria, 1996).

With a tone that says, "Oh, yeah, you think you're so great at quality?" consumer watchdogs are quick to point to tragedies wrought by grossly incompetent doctors, e.g., amputating the wrong foot, falling asleep during surgery and thus having the patient die, etc. (Gavzer, 1996), and so argue that doctors should be subject to greater review by outsiders.

While both ends of the spectrum doubtless exist (brilliant doctors whose cures are so successful that they seem almost magical, finding their hands tied by ignorant managed care clerks; alcoholic surgeons whose hands shake so badly during surgery they can not hold the instruments), I would argue that these extremes should not be the focus of national and local policy. The problem with health care costs and quality/access does not reside in this 1% of health care transactions. It resides in the mundane 99% that make it into the news far less often.

Unfortunately, however, legislation often seems designed to address the 1% of the cases that are outliers and does so in excruciating detail. Managed care organizations have lost credibility around their ability to manage the quality of care (Dao, 1996; Protos, 1996a; Protos, 1996b; "Give Newborns 48 Hours," 1996; Schine & Hammonds, 1996; Golz, 1996; Weston & Lauria, 1996) and are thus being subjected to very detailed legislation.

For example, 30 states have recently passed laws regulating HMOs over issues such as guaranteeing maternity patients at least a 48-hour hospital stay after birth (Schine & Hammonds, 1996), similar federal legislation is pending (Pear, 1996b), and newspaper editorials have lauded this regulation. ("Give Newborns 48 Hours," 1996). It is worth noting, however, that there is little evidence that the 48-hour requirement is necessary or appropriate for most patients.

Proponents of alternative health care tout the advantages of a rapid return to home and provide glowing reviews from happy parents. No less an icon of female self-determination than the venerable The New Our Bodies, Ourselves suggested that home birth or childbirth in a birthing center provides substantial advantages over

hospital births with no greater risk for most patients (Boston Women's Health Book Collective, 1992).

A typical birthing center noted that it provides "six hour postpartum care" before mother and baby leave for home (Austin Area Birthing Center, 1995); a midwife who oversees home births reported, "I stay two to four hours after the birth..." (Kraft, 1995).

One could argue that for a fraction of the cost of an extra day's hospital stay, one could provide superlative home nursing care after every birth with the added advantage of being able to help the mother make the transition from the artificial environment of the hospital to her home. HMOs may no longer have options like home visits, however, because of the very specific medical care protocols that have been written into law. As a result, both costs and quality may suffer.

For managed care organizations to avoid similarly heavy and detailed regulation in the future, they would have to clean up their poor quality image very quickly. I believe they could achieve this goal by focusing on outcomes of care. Without such a shift, they run the risk of losing control of their operations and miring the country in mountains of counter-productive legislation.

Thus, a struggle ensues over where the power in health care will lie, and it is not clear what the balance will be between physicians, insurers and managed care organizations, and legislators in the debate about costs and quality. The voices of employers, who often buy the care, and of patients are not so clearly heard.

Several solutions currently popular to address the "health care crisis" seem to me to be incomplete and in some cases counter-productive to the goal of improving costs and quality. For example, insurance coverage for the uninsured is a laudable idea. However, without addressing the issues raised in the first half of this paper, the costs would be prohibitive and quality problems significant.

Similarly, single payer coverage may be an idea with merit. However, while it has the potential to reduce administrative costs by as much as $100 billion annually (Robert Wood Johnson Foundation, 1995a), that change alone would not improve the quality of care.

The concept of managed care is also constructive. However, as currently executed, while costs are sometimes contained, care often suffers. The section that follows includes extensive recommendations that I feel can more effectively address both cost and quality issues.

SECTION FIVE: SOLUTIONS

Four problem areas were discussed above: executional flaws, decision-making that is not based on outcomes, process mismanagement, and perceptual deficiencies concerning patient-centered care.

While hundreds or thousands of suggestions to address these can probably be generated, this section focuses on four arenas. In order of priority, these are:

- Outcomes analysis
- Process improvement for MCOs (managed care organizations)
- Physician training and education
- Individually tailored care

Because the solutions proposed are many, each section begins with an outline that briefly summarizes the recommendations to follow. Comments about feasibility and evaluating effectiveness complete each of the four parts.

Part One: Outcomes Analysis

1. **Refine protocols for outcomes research**

    a. **Include functionality and quality of life components as well as clinical outcomes**

    b. **Require comparison of data and results to those of other researchers for the same disease/condition, whether same protocol or not.**

2. **Develop a format for writing clinical practice guidelines that includes outcomes**

3. **Expand funding for outcomes research**

4. **Make outcomes research more accessible**

    a. **Encourage Internet use**

    b. **Encourage publication of comparative outcomes (doctors, hospitals)**

    c. **Encourage employers to provide support for employees to research outcomes**

    d. **Encourage links between academics and clinicians**

5. **Legislate, lobby, and educate funders, users, and certifiers to demand outcomes data**

    a. **Legislate S.E.C.-like disclosure of past outcomes by providers to employers and employees**

    b. **Educate employees to ask for outcomes data when discussing treatment options**

    c. **Expand informed consent forms to include outcomes data**

d. **Vary Medicare/Medicaid reimbursement depending on outcomes history**

e. **Require (via JCAHO) medical staffs to review care relative to outcomes within the hospital and across hospitals within the community/region**

Part One: Outcomes Analysis

The health care system in the United States has tremendous resources. To get the benefit of those resources, it is important to apply them in a way that results in desirable medical and quality of life outcomes for patients. Making decisions about what medical interventions to use is a critical task.

Patients, doctors, insurers, and others currently have limited assistance to help them make these decisions well. Specifically, there is limited information available about the outcomes of various treatments. Suggestions to address this gap appear below.

It should first be noted that "outcomes analysis" is commonly used to mean two different things. First, it may mean determining what happens when a particular protocol is used, e.g., "xx percent of patients live tt years after procedure yy." Ideally, researchers would also note, in this example, what percent of patients live tt years after procedures zz and ww as well. That is, one would like to be able to *compare* protocols to choose the one with the most promising results. In fact, this comparison is rarely provided.

Second, "outcomes analysis" may mean, "What happens when patients undergo procedure xx at hospital (or with doctor) pp compared to those who undergo it at hospital (or with doctor) qq?"

One immediately notes the confounding difficulties that arise. One protocol may get better results than another protocol *when performed by certain practitioners or at certain sites* but worse results when performed by others or at other sites.

My view is that we will be "bailing while sailing" for a number of years. That is, feedback about outcomes of different protocols will lead to improving some and eliminating others, while feedback about outcomes of different practitioners' execution will have similar results for them -- some may learn to improve their technique and some may stop performing the protocol.

One would like to think that over time the result would be effective protocols performed by skilled practitioners. For the moment, though, it is important to realize that "outcomes analysis" may refer to protocols or to practitioners, hospitals, etc.

Recommendations to increase the availability and use of outcomes data appear below.

1. Refine protocols for outcomes research

AHCPR (Agency for Health Care Policy and Research) *[2008 note: this federal agency was subsequently renamed AHRQ, Agency for Healthcare Research and Quality]* could develop guidelines for identifying and analyzing patient-centered outcomes data, i.e., functionality and quality of life.

Protocols already exist for handling data about medical outcomes. AHCPR could also develop a format for researchers to report the full range of outcomes -- medical, functional, and quality of life -- in a standardized way that would permit meaningful comparisons across treatments, doctors, facilities, patient populations, etc.

Further, AHCPR could set a standard for reporting on research that would require comparing the researcher's results with those published by other researchers addressing the same disease/condition. This idea follows Grove's comment that this comparison is uncommon in medical research in his experience, making it very difficult for a layman to draw conclusions about the meaning of different outcomes of different studies.

Not incidentally, this omission also makes it difficult for medical practitioners to understand how to interpret the reported results. Related to an idea Eddy mentioned, one could encourage medical journals to require this sort of comparison in articles they publish. (Eddy, 1984).

2. Develop a format for writing clinical practice guidelines that includes outcomes

I suggest that AHCPR recommend a disclosure to be included in clinical practice guidelines that would explain exactly how the protocol was derived. That is, was it based on expert opinion? Did it take outcomes into account? What outcomes? Were patient perspectives included? How? Eddy made a related recommendation about policy statements, suggesting that policies should identify the medical and economic outcomes considered in their

development and what the policy maker estimates would happen to each of those outcomes in the future if the policy were adopted. (Eddy, 1984).

My suggestion is not that clinical practice guidelines *must* include outcomes analysis (nor predict the future); it is that the reader should be able to *tell* if outcomes analysis drove the protocol's development or not, and if it did, what kind of outcomes were taken into account. AHCPR could lobby medical organizations and publications to champion the use of this disclosure statement.

3. Expand funding for outcomes research

Increase federal funding for outcomes research 100-fold to $5 billion a year. Here is my rationale. Outcomes research consumes about a third of AHCPR's annual budget (Zinman, 1993). In 1994, that amount would have been about $50 million of its $150 million budget (Wilson, 1994).

Government spends about $420 billion a year on health care (Pear, 1996c); the vast majority of this spending comes from federal sources. It has been widely reported that some significant fraction of care -- often quoted as a third (Zinman, 1993) -- results in no improvement in health or other outcomes for the patient.

That is, the government spends as much as $140 billion a year -- a third of $420 billion -- to no effective purpose, and spends about $50 million a year to figure out what actually works. In other words, the government spends about four one-hundredths of one percent as much to figure out what works as it wastes on ineffective care each year. My proposal is to increase that funding to 4%.

Similarly, I recommend a proportionate increase in funding for clinical practice guideline development. These guidelines would be based on the outcomes analyses funded above. AHCPR "has issued 17 sets of clinical practice guidelines in the past four years." (Roberts, Rosof, & Thompson, 1996).

Given that various organizations have published over 1800 set of guidelines,

most based on expert opinion rather than outcomes (Worrall and Chaulk, 1996), it is clear that the AHCPR efforts to date, while valiant, are simply not adequate to meet the need.

4. Make outcomes research more accessible

Encourage the dissemination of outcomes analyses and practice guidelines on the Internet. This solution implies that patients and doctors are, or can become, computer literate. Internet use is already spreading rapidly and may not require much encouragement.

Encourage widespread publication of *comparative* outcomes research. For example, one might compare the outcomes at all the hospitals in a metropolitan area for the ten most common kinds of surgery. This kind of reporting occurs today in pockets; the idea is to make this kind of information as readily available as stock quotations. The JCAHO (Joint Commission on Accreditation of Health Care Organizations) could play a key role by setting guidelines for compiling such data and requiring hospitals to publish it annually.

Through a lobbying campaign to be devised by AHCPR, encourage employers to support literature searches about outcomes to help their employees identify the best care options. This idea would help address the problem that any given doctor may not have the best data upon which to make treatment recommendations.

At least one employer, in fact, already provides this support. "[Pacific] Bell's award-winning Health Information program has an 800 hotline that links a counselor for people covered by the company to the National Medical Library in Baltimore and the latest medical information... One [employee]... had an unusual cancer. Her doctor wanted to wait before prescribing treatment, but the Health Information staff researched the obscure disease and discovered that without immediate surgery the woman would likely die within two years. She had the surgery." (Chambliss, 1996).

Encourage "meaningful linkages between academic researchers and

community clinicians." (Scott, 1994). I believe that the intent of this recommendation is to get real-life data into the discussion of outcomes, not just theoretical or controlled studies. That is, while controlled clinical studies are compelling, the results do not always translate perfectly into real-life settings.

Further, this cross-fertilization represents an additional way to encourage the inclusion of outcomes relevant to the patient, not simply clinical outcomes, in research projects. I suggest that one might create some incentive for academics to register their research projects with AHCPR, which could function as a clearinghouse to provide this information to interested MCOs (managed care organizations).

While some scientists prefer to keep their work secret until it is published, one might generate enough interest to make this information-sharing worthwhile. Researchers might gain access to data from large populations of patients by partnering with an MCO. MCOs might gain some sophisticated help in interpreting the data they already have. Thus, the joint efforts could be mutually beneficial.

5. Legislate, lobby, and educate funders, users, and certifiers to demand outcomes data

Require by federal law that MCOs and insurers publish outcomes data as part of the bidding process for corporate health contracts and during enrollment for employees. This idea is similar to S.E.C. (Securities & Exchange Commission) requirements for disclosure of past performance and other data before investors are allowed to purchase mutual funds.

That is, both the idea I am suggesting and the S.E.C. requirements call for reporting of historical performance -- outcomes -- in terms relevant to customers before they commit to buying.

In the absence of legislation or before it takes effect, lobby employers to encourage them to demand outcomes data from their insurers and MCOs. "For better or worse, most people still get their medical coverage through their job, so it's the responsibility of Corporate America to become far more vigilant about enforcing standards." ("Health Care Is Looking Healthier," 1996).

The lobbying effort I propose would be an educational effort run by AHCPR to explain the potential cost savings and quality benefits of insisting on outcomes data. Some employers already do require this data and have success stories to tell (Magnusson & Hammonds, 1996).

Educate consumers to ask questions about outcomes when service providers propose various treatment options. AHCPR could develop the materials (brochures, videos, etc.). Avenues for distribution include:

* Through employers.

* Directly to Medicare and Medicaid patients.

* Public service messages on television, to encourage consumers to lobby their employers to push for this data as well as to ask questions of their doctors.

* Through MCOs, which have a vested interest in ensuring that patients get the most effective care.

* Through state agencies dealing with the uninsured poor.

Upgrade the JCAHO requirement that hospital medical staffs (physicians) have a committee to review quality, adding a requirement for outcomes analysis including a comparison among practitioners and across facilities in the community/region.

While the requirement for quality review already exists, "little is known about the activities of review committees or their impact on the quality of services provided." (Weitzman, 1990). The JCAHO currently requires simply that the medical staff "[help] ensure" that all its members "are clinically competent and that clinical care rendered is appropriate." (JCAHO, 1995).

Expand informed consent forms for medical procedures that cost more than a chosen threshold, e.g., $1,000, to include information about outcomes. The information provided would include three parts.

The first would be a disclosure similar to the one I suggested AHCPR develop for inclusion in clinical practice guidelines. This disclosure would explain what outcomes of the procedure have been researched -- medical, functional, and quality of life -- and what those *procedure*-specific findings were.

The second part of the form would report the *facility's* outcomes experience with this procedure compared to those of other facilities in the area.

The third part would report the *practitioner's* outcomes experience with this procedure either in absolute terms or compared to a relevant standard, perhaps the average of other practitioners in the facility or region, etc. Since very little of this information is currently available, a phase-in period would clearly be required.

Vary Medicare and Medicaid reimbursement to practitioners and hospitals depending on their outcomes data. This idea is a take-off on, "afoot in New York are plans to link outcomes to the state's payments to hospitals, with the highest reimbursements going to centers giving the best care." (Zinman, 1993).

I suggest that practitioners and hospitals with no data be reimbursed at the lowest rate. Those with data but poor outcomes would be reimbursed at the second-lowest rate. The graduated scale would lead to those with the best outcomes getting paid the highest rates.

The analyses would have to conform to AHCPR requirements, and patient-centered outcomes (functionality, quality of life) could gradually be phased in. Eventually, these might be weighted 50% or more in the reimbursement calculation.

One advantage to a plan that stipulates variable payments for variable outcomes is that it creates a motivation for MCOs and other large health care organizations to do outcomes analysis themselves, thus avoiding some of the need for federal funding.

This plan might also help MCOs sell the idea of outcomes analysis as a basis for care to physicians who work in their organizations. The MCO could point out that the federal government required outcomes analysis to justify higher payment rates, which in turn would affect how much the MCO could pay doctors. The idea of reimbursing based on outcomes has the advantage of directness and simplicity -- it does not control for intermediate steps but for end results (risk-adjusted, of course).

Analysis of feasibility and comments on evaluating effectiveness of outcomes analysis recommendations:

I believe that all of the above ideas are eminently feasible, with the exception of dramatically increased funding for outcomes analysis and practice guideline development.

Most of my recommendations for AHCPR would have it devising standards, developing communication campaigns, and serving as a clearinghouse; these are high leverage activities. The legislation proposed is conservative, simply mandating disclosure. It would address many of the problems that are leading to growing legislation of H.M.O.s around the country, but is a much more elegant solution than mandating specific protocols.

The proposal to vary Medicare and Medicaid reimbursement based on outcomes would take some thoughtful work to implement. For example, since patient-centered outcomes are not generally available today, some kind of gradual phase-in would be necessary. Further, the potential for fraud exists; an audit program would need to be developed.

One advantage, however, is that doctors and insurers are used to changes in federal funding schemes, e.g., payment for Diagnosis-Related Groups in 1983 and by Resource-Based Relative Value Scale in 1992 (Robert Wood Johnson Foundation, 1995a), and the change I am proposing is certainly no more complex than those. Similarly, JCAHO as an accrediting agency already has the clout to set standards; modifying them as I suggest, of course allowing for phase-in, seems reasonable.

The funding increase for outcomes analysis is problematic. While I find the logic compelling, it seems unlikely that Congress could be convinced to appropriate these additional funds. Consequently, I reluctantly conclude that this alternative is unlikely to succeed.

The best chance for success might be a bootstrap approach: AHCPR would get a modest amount of additional funding and direct it to outcomes analysis and subsequent informed practice guideline development for conditions for which the federal government (Medicare) has high medical bills each year. Incentives could then be created to encourage Medicare providers to use the AHCPR practice guidelines, which would be based on outcomes analysis, to treat these conditions.

As the government saw medical costs drop for the conditions addressed, AHCPR would be given a portion of the savings. It would use this money to fund outcomes analysis and then protocol development for the next set of conditions that cost the government a lot each year. And so forth.

Effectiveness of components of the above program would be assessed through quantitative feedback loops -- what percentage of employers rate outcomes data as "important" or "very important" in selecting MCOs and insurers for their employees? What percentage of employees report asking their physicians about outcomes data for proposed treatments? What percentage of Medicare reimbursements are at the "outstanding outcomes" level vs. the "no data" level?

Effectiveness for the program as a whole could be assessed through longitudinal studies that review the appropriateness of medical treatments rendered, the average costs per patient for various diseases/conditions, etc. These studies could compare Medicare patients treated by "no data" practitioners or MCOs and those treated by "outstanding outcomes" practitioners/MCOs.

Having more information about outcomes would solve many problems. I believe costs and quality would both improve significantly. Not only would patients and others have objective data upon which to base treatment decisions, but I believe that many of the executional and process management flaws would get addressed as well.

I say this because if practitioners and MCOs faced broad publication of data suggesting that they were not very good at what they did, they would be highly motivated to figure out where the gaps were and to fix them. Professional survival would depend upon this response. And many of the problems, I believe, could readily be fixed if physicians and MCOs chose to do so.

Part Two: Process Improvement for MCOs (Managed Care Organizations)

1. **Computerize all patient records to address data gaps**

2. **Engage patients in the process of their health care**

    a. **Educate patients -- prepare training materials and incentives**

        (1) **When to engage the health care system**

        (2) **About the process of care -- what to expect, roles and responsibilities**

    b. **Prepare patients for office visits**

    c. **Improve the information transfer process**

        (1) **Provide clipboard and form to take notes during visit**

        (2) **Provide binder to file each visit's notes at home**

        (3) **Convert practitioners from jargon to simple English**

        (4) **Educate practitioners in listening skills and asking questions**

        (5) **Provide comprehensible documents and generic tapes**

        (6) **Provide audiotape or videotape of each doctor's visit**

3. **Encourage compliance by setting up aggressive support processes**

    Example is prescription drug regimens

    a. **Set up an on-site pharmacy or arrange for home delivery**

    b. **Dispense prescriptions in a pill organizer that clarifies what pill to take when**

    c. **Call on Day 2 to address questions/concerns**

4. **Ensure feedback opportunities**

    a. **After/between visits**

    b. **At the start of each subsequent visit**

5. **Process control**

    a. **Research problems (asthma example)**

    b. **Research patient behavior and modify systems accordingly**

Part Two: Process Improvement for MCOs (Managed Care Organizations)

Health care is a complex endeavor. To get the good outcomes desired, all of the steps in the process of health care delivery need to function optimally themselves and also be tightly coordinated with other steps. MCOs, insurers, and Medicare/Medicaid can analyze and redesign as much of the process as they control or influence. Both the extent of the problems and the opportunities for improvement are huge.

In the interests of brevity, the discussion below is limited to opportunities for MCOs to improve simple ambulatory care. Note that it may be easier for HMOs to make these changes than for less integrated organizations to do so.

1. Computerize all patient records to address data gaps

MCOs could improve record keeping tremendously by installing computers in every treatment room and having all patient information recorded on the spot into a computerized record. Of course, this improvement would require an investment in hardware, software, and training.

Right now, in all the health care offices with which I am familiar, each visit generates several sheets of paper that get added to the file and essentially lost: there are so many of them, they stick together, they're hard to read, no one knows which ones are going to matter, etc.

The computer system could be designed with fields that would make it easy to check on data in a variety of dimensions. If one wanted to review all the information from a previous visit -- vital signs, symptoms noted, tests run, instructions given, drugs prescribed -- one could query the system to display the entire visit record.

If, alternatively, one wanted to see one kind of information over time -- blood pressure, cholesterol level, all the drugs that had been prescribed for this patient in the last year, or anything else -- one would simply ask for that field's data for the last 12 months to be displayed.

In addition, MCOs could work with labs and other service providers to

transmit test results electronically, keyed to social security numbers. That way, lab results could immediately update the patient's record.

Further, the addition of new lab results to the patient record could trigger the patient's name to appear on a list to call with an "all okay" message if the results are normal and on the doctor's to-do list to review if the results are not normal. (If the doctor wanted to review all results before patients are called, that could be designed into the system as well.)

When the doctor reviewed the lab results electronically on a computer in her office, she could indicate the next action to be taken and the computer could route the information where it needed to go, e.g., to the appointment desk to call the patient to come in for a follow-up visit, to a nurse or clerk to call the patient and tell him that the results were normal and that he need do nothing further, to the doctor's own list of phone calls to make if she needed to talk directly with the patient, etc.

One the indicated action were taken, that fact would be entered into the computer system and the patient's record would be updated accordingly.

2. Engage patients in the process of their health care

The discussion of problems with the *process* of health care delivery included the observation that patient is the one who is expected to take most of the steps and make most of the changes. Yet the patient is provided with far less information than most of the other players in the health care system.

For example, her doctor has her medical records; she does not. Her managed care organization knows the cost of the various tests administered to her; she probably does not even know what all the tests she has had are, much less what they cost. Her pharmacist probably knows how to interpret "take one hour before meals;" the patient does not know what happens to the drug's effectiveness if she has a snack before dinner.

Thus, the central player, the one for whose benefit the entire health care system theoretically exists, is ignorant of most of the information she needs to make good decisions.

An article on "the thousands of [Internet] Web sites offering health information" comments, "The proliferation of health sites in cyberspace reflects a deep hunger for information that will help people make more informed choices about their own care... People want specific information." (L. Fisher, 1996). Logic would suggest that increasing the information the patient has could dramatically improve both costs and outcomes.

One article notes, "A growing body of evidence suggests that patients who actively participate in their own care have more favorable clinical outcomes." (Laine & Davidoff, 1996). I suggest that an excellent way of engaging patients in their own care would be to provide them the opportunity to understand more about the health care process.

One could take advantage of patient interest by create training materials and incentives. For example, if patients completed six out of eight training modules offered in the course of the year, they would get a $100 reduction in health insurance premiums the following year.

A first step would be to educate patients so they understood when to engage the health care system rather than simply care for themselves, and what to expect when they did interact with the system. Part of this education could cover what constitutes an "emergency" and justifies going immediately to the hospital rather than calling the primary care physician.

Other education in triage could be provided, e.g., what symptoms warrant a call to a nurse, what symptoms warrant a visit to the doctor, etc. Education could probably be done at the employer's site in large group meetings -- the employer is motivated to keep employee health care costs down through appropriate use of the health care system, and so might be willing to provide a venue for educational efforts.

Communication approaches could include group role plays about how to handle quasi-emergencies; videos; handouts including laminated, magnetized guidelines to post on home refrigerators; etc.

Another part of the education could explain to patients how the professionals

in the office work together and what their roles and responsibilities are. For example, do they need to repeat to the doctor the same things they just told the nurse? Why? What is the process for getting a referral? And so forth.

A second opportunity to help the patient become more engaged in his own care would occur when he called for an appointment. He could be prepared for the visit in a manner appropriate for the problem he had.

For example, suppose he said, "My knee hurts and I don't know why," and his appointment were set for three days away. He could be asked to start noticing if it hurt more in the morning or in the evening, whether any other joints hurt or not, if any particular activities or motions seemed to hurt it more, etc. He could be asked to write down the names of any analgesics or other over-the-counter drugs he was taking for the problem. Then when he came in to see the doctor, he would be able to provide much better data for the doctor to use in making a diagnosis.

A third and tremendous opportunity for engaging the patient more in his own care would be to dramatically improve the information transfer process between the patient and the doctor. Six specific suggestions for MCOs appear below.

First, provide patients with an easy way to record important information. Patients rarely walk into the doctor's office with paper and pencil, yet they are invariably given instructions, frequently with multiple steps or activities to follow.

When they arrived in the waiting room, they could be given a clipboard with a preprinted form on it with several sections: "Symptoms or other things I want to tell the doctor," "Questions I want to ask the doctor," "Prescriptions to fill," "Over-the-counter drugs or supplies to buy," "Things to do," "Test results," "When to call back," etc.

The MCO could prepare several versions of this form and based on the patient's medical history, hand him the one most likely to be appropriate. While the patient was waiting for his appointment, he could note symptoms

and questions to ask. He could fill out the rest of the form as he was talking with the doctor, thus giving both of them records to complete.

It is curious that most of the actions to be taken belong to the patient -- fill the prescription, make changes at home -- but the doctor is the one taking all the notes.

The approach suggested has the overt advantage of helping the patient remember what to do. It has the more subtle advantage of putting the two players on more equal footing: both have important notes to take because both have important roles to play. The patient would be no longer simply a passive object waiting while the doctor takes notes; he would be more likely to feel engaged in the process of his own care.

Second, provide the patient with an easy way to organize the forms on which he would have taken notes during office visits. The forms could be on three-hole-punched paper and the patient on his first visit could be given an attractive binder in which to file them at home.

Thus the patient could have a record for reference, making him far more able to be an active partner in his own care, and far more capable as well of providing important information to other service providers.

A third way to improve communication between the doctor and the patient: shift from medical jargon into simple English. This change would doubtless require retraining for many physicians.

One study gave the example, "Instead of saying, 'To stage your malignancy, we need to perform diagnostic scans. Then, once we know the etiology, we can discuss some of the various chemotherapy treatment options,' a doctor could say, 'You have cancer. I need to know where it has spread. A CAT scan should tell us. Then we'll know if drugs can stop it.'" ("Reading for Your Life," 1994).

While some doctors deliberately obscure information to enhance their power (Starr, 1992), it is reasonable to suggest that patient comprehension should take priority. The MCO could arrange training and feedback for doctors.

Fourth, train doctors in other basic communication skills specifically geared to ensuring that patients and doctors understood each other during doctors' visits, and that obstacles to compliance were removed. One component of such training would be listening skills, including asking productive questions. One of these questions might be, "What do you feel is contributing to this problem?"

My own experience provides an example of the point of this question. After a business trip to a developing country overseas, I found myself unusually tired for an extended period. When I told the doctor I was tired, he immediately told me that people my age needed to get more exercise. I did not have a chance to tell him I was concerned that I had picked up something overseas -- nor that I was already swimming many hours a week.

A second useful question for the doctor to ask might be, "What have you tried already to address this problem?" This would allow the doctor to hear about alternative medicine, home treatments, etc. The patient might be doing helpful or harmful things, and it would be useful to know. For example, he might be using ice to treat a condition for which heat is a better choice, thus aggravating the problem. Without asking, the doctor would never know.

A third question might be, "What else do you think I should know about in order to treat you?" This question might elicit information about collateral medical issues affecting the current complaint. A fourth question (or statement) might be, "To make sure I've communicated clearly, please tell me in your own words what the next steps are that we have discussed."

A final question might be, "What can you think of that might keep you from doing all of the things we talked about?" The doctor could then work with the patient to come up with solutions to the issues raised. For example, if the patient said, "Gee, my stomach always hurts when I take antibiotics, so I really don't like taking them," the doctor could review the importance of taking the drugs at the end of a meal instead of on an empty stomach.

I think the above five questions would elicit far more useful information than

the doctor usually gets, yield far better diagnoses, and result in much better compliance from patients. Doctors might be evaluated by the MCO partly based on whether patients understood them or not. Patients with chronic conditions, for example, could be surveyed -- perhaps while waiting for the doctor before their next appointment -- to see how much they understood about their diagnosis, treatment options, etc.

A fifth way to improve information transfer is to ensure that patients get information in a medium and at a level they can deal with.

"A 1990 study... [found that] only 14% of the public-clinic patients and 55% of the private patients were reading at or above an 11th grade level. Yet virtually all the educational materials, hospital forms and letters from physicians were written *several levels* [italics in the original] above the 11th grade. 'Patient education materials and hospital forms are given to patients with little regard for their ability to read them,' the study concluded." ("Reading for Your Life," 1994). Written materials could be redesigned, and audio-visual materials could supplement them. (Ibid).

A sixth opportunity to enhance communication is a take-off on the above idea. While the article quoted was suggesting generic educational videos, it seems to me one could also make available to patients the option of having an audio or video tape made of the doctor's visit. In the beginning, one might offer these options for complicated situations (e.g., brain tumor, breast cancer).

The cost of taping is negligible compared to the cost of having the patient forget or misunderstand key parts of the conversation, a highly likely event in any case but certainly even more likely when the patient is seriously ill.

One counter argument is doubtless that doctors may resist being recorded because of potential future liability. However, it seems a poor perspective to have to think one can defend oneself by saying, "With no recording, no one will ever be able to prove what I said."

Potential technology problems could be addressed so no third party needed to be in the room, etc. Audio and video tapes have two advantages: for patients with limited literacy skills, they could supplement or supplant written notes. For all patients, they would capture nuances that did not make it into the notes.

Patients are more likely to engage in the process of their own health care if they feel heard and understood; if they feel that their questions are viewed as legitimate; and if they receive information in a way they can absorb, remember, and act on.

3. Encourage compliance by setting up aggressive support processes

I believe that it would usually be far less expensive and far more effective for MCOs to invest in getting patients to comply with treatment regimens than to keep treating medical conditions that exist because patients do not comply. As an example of how such efforts might work, consider compliance with prescription drug regimens.

As mentioned earlier, many people do not even fill their prescriptions; those who do often do not take the drugs as prescribed. I suggest that this problem could be substantially eliminated by taking three steps. First, ensure that patients get the drugs in the first place; second, make sure it is easy to remember when to take the pills; and third, help resolve any concerns that contribute to non-compliance.

A number of managed care organizations are addressing the first problem by having a captive pharmacy. That is, it is in the same building as the doctors' offices. This geography makes it easier for people to get their medicine before they go home.

I suggest a further enhancement to this arrangement, which would be to call either the captive pharmacy or any authorized drugstore before the patient leaves the treatment room, and arrange either for the prescription to be ready when the patient got there (most doctors will do this now *if asked*), or for it to be delivered to the patient at home.

By making it standard practice to arrange for 100% of the prescriptions to be filled before the patient even walked out the door, the first hurdle would be overcome. MCOs might even find it cheaper to pay the total cost of the prescriptions and home delivery themselves rather than run the risk that patients will not comply.

Many people simply do not remember if they have taken their pills or not, and then give up part way through a drug regimen because it is too hard to remember. To address this second issue, MCOs with captive pharmacies (or a few designated public ones) could arrange for prescription drugs to be dispensed in a container more likely to support compliance than the current pill bottle does.

For example, for pills that must be taken 4 times a day with food, a standard translucent plastic box with 44 separate cavities (11 rows of 4) could be designed. Easily affixable labels could be produced listing the days of the week; and "breakfast" "lunch" "dinner" and "bedtime" could be preprinted on the cover, one over each of the four cavities in each column.

The pharmacist then could arrange the labels and fills the cavities so it is clear when each pill should be taken. For instance, if the prescription were being filled Wednesday morning, the pharmacist would label the first column "Wednesday" and put pills in the "lunch" "dinner" and "bedtime" cavities.

The cost of the containers would be negligible compared to the cost of a repeat doctor's visit necessary because, not taking the medicine, the patient did not get better. One would have to address the CPSC (Consumer Product Safety Commission) requirements for child resistant packaging, but this issue would not be insurmountable.

To address the third issue, a nurse could call the patient on the second day after the office visit to confirm that the patient is taking the medicine and not having any side effects, and to address any questions or concerns about the drugs that the patient might have.

4. Ensure feedback opportunities

The MCO could arrange for feedback opportunities after one office visit and before the next. A nurse could call the patient a few days or a week after the office visit to ask if the patient has had any subsequent difficulty taking the medicine, locating other supplies or equipment recommended, performing the exercises prescribed or completing other activities, etc. The nurse could also elicit questions from the patient and address them on the spot or arrange for the doctor to answer them.

It goes without saying that the nurse would be sitting in front of a computer terminal as she spoke with the patient, entering any relevant information and follow-ups required. The computer system, as described earlier, would distribute the follow-ups to the appropriate people. Until an entry had been made indicating that the follow-up had been completed, the computer would flag it as an open issue in the patient's record.

In addition, the doctor could open each visit with a brief review of the previous one. ("Two months ago, you came in to see me because of a problem with your knee. Were you able to take the medicine and do the exercises we talked about? Are you still having trouble with your knee, or has the pain gone away?") He could then enter feedback into the computer system both for the patient's record and to build a database about real-life outcomes of various protocols.

5. Process control

Control mechanisms need to be built in to ensure that the system is performing as intended and does not drift over time. This step is essential. It would be easy to evaluate the effectiveness of process control by checking medical records and surveying patients.

One employer noted, "We found in a study of 6,600 adult asthmatics that people didn't feel they were getting the care they needed... for a variety of reasons, the health plans were not giving them the right tools to help themselves." (Noble, 1995) Given feedback like this, one would then need to backtrack and find out where the process had broken down.

Information is process control's best friend. The enemy of good process control is fallacious assumptions that are never checked. Suggestions for improving the process of health care delivery have been made above, using a simple ambulatory care environment as a framework. To expand the options and to address more complex processes, it would be reasonable to research patient behavior and identify gaps or misunderstandings and then design solutions to address them.

I do advise caution, however. Some authors believe they understand patient behavior, but what they observe, I think, simply reflects that patients have not had meaningful information about outcomes of care and about the health care system and so have had to improvise.

One author advised, "Most consumers purchase healthcare services on the assumption that the quality of care is essentially the same. Therefore [in marketing the program] the differentiation for a provider is a function of service, price and program package." Service, the author explained, includes office location, appointment lead time, courtesy, waiting-room time, etc. Program package referred to what doctors, hospitals and procedures were included in the plan. (Boland, 1993).

Notice that outcomes of care are not considered relevant in marketing health care plans to consumers.

Another author noted, "... most patients tend to focus on interpersonal aspects of care in assessing quality..., the amenities of care... [and] how many services they received." (Weitzman, 1990). Notice that once again there is no suggestion that patients are concerned with outcomes of care in their assessment of quality.

If patients focus on the courtesy of the office staff and the number of services they receive, it is not because, as Weitzman claims, they lack technical expertise. In my opinion, it is because real information about outcomes is not readily available to them. Having the "technical expertise" to order leeches -- or caesareans -- would not be helpful.

Patients may have focused on the periphery in the past because information about the core was conspicuously absent, so they had nothing else to go on. This state of affairs does not mean that patients are not interested in medical, functional, and quality of life outcomes or that they are so naive that comfortable chairs in the waiting room are more important to them than whether they get better.

It means they need legitimate information so that they can be effective partners in managing their own health and their use of the health care system.

The interpretation of patient behavior by the two authors quoted above provides a cautionary note for anyone managing a process. Data collection and interpretation are critical steps. Done mechanically, they can lead to irrelevant conclusions and prompt an inappropriate focus in response.

Those managing segments of the health care process do have an advantage to help them avoid straying from reality: if they keep paramount the focus on medical and quality of life outcomes -- and objective measures of these -- they should be able to recognize both excursions from the process and process steps that are not contributing to good patient outcomes at a reasonable cost.

Analysis of feasibility and comments on evaluating effectiveness of process improvement recommendations:

I believe that all of the above ideas to improve the process of health care delivery are highly feasible. Many managed care organizations are large enough to make the investment in computer systems realistic, and to have the management resources available (or procurable) to manage the detailed design, training, and implementation of the other process improvements.

The recommendations do not require outlandish amounts of money, nor do they need broad political support or consensus in order to be implemented. They do require some changes in physician behavior, but MCOs and particularly HMOs are increasingly in a position to mandate such changes. None of the changes recommended interfere with physician choice of treatments, which is a much more explosive issue for doctors.

With the statistics showing the high percentage of medical interventions that are ineffective because of failure to follow through on the system's side or failure to understand or comply on the patient's side, it seems to me that the opportunities to improve both cost and quality would be sufficiently attractive to gain the attention of MCOs.

Effectiveness of components of the program could be measured by comparing various statistics against control groups or over time. Information could be gathered through medical record reviews and patient surveys.

For example, how many inappropriate emergency room visits per thousand enrollees are there among people who have completed training in when to use the emergency room compared to the rate for those who have not completed the training? What are compliance rates with prescription drug regimens for patients provided with aggressive support compared to those of patients who are not?

What level of understanding do patients with chronic conditions have about their condition and treatment options if they are being seen by doctors who have completed communications training compared to those being treated by doctors who have not?

In an MCO with many offices, it would be easy to evaluate the effectiveness of the entire program by using half of the offices as a control group and comparing costs and medical and quality of life outcomes across offices. As always, such studies need to be risk-adjusted.

Part Three: Physician Training and Education

1. **Use federal funding as leverage to modify the content of medical school curricula and medical residencies.**

2. **Include recertification with a performance component in Board certification**

1. **Use federal funding as leverage to modify the content of medical school curricula and medical residencies**

   Find a way to tie federal funding for medical schools to specific curriculum requirements. Similarly, tie federal funding for hospital residencies, currently $70,000 per resident (Mullan, 1996), to specific requirements for training. Rather than legislating the exact requirements, I would suggest legislating that the federal AHCPR (Agency for Health Care Policy and Research) review and modify the federal requirements every five years. One would need to limit the percent of the curricula and of residency time that the federal government could dictate.

Some of the ways in which physicians may contribute to problems in health care delivery have been discussed above. Education and training modifications would be designed to reduce or eliminate these issues. Topics to cover would include:

a. A definition of health care as a process with the patient as focus and both medical and quality of life outcomes as the purpose.

b. How to participate effectively in a complex process, with special attention to hand-offs and feedback loops.

c. The concept of outcomes analysis and why it is important, including the idea that many clinical practice guidelines have been established without explicitly considering medical and quality of life outcomes.

d. How to evaluate research results, determine whether to adopt new protocols, and learn to execute new protocols effectively.

e. Communication skills to enhance transfer of information to and from patients.

f. How to avoid inappropriate use of protocols. Presumably this effort requires either sharper diagnostic skills or a more critical evaluation of clinical practice guidelines.

g. Issues to consider in managing long-term primary care. Ideally, this item would be addressed partly by modifying residency requirements to include one year of primary care practice.

h. Models for improved decision-making and how to manage trade-offs. This topic is described more extensively below.

One author suggested that doctors are not well-prepared to make the decisions and handle the trade-offs that confront them in their practice every day.

He commented, "There is ... a strong tendency to oversimplify. One of the easiest ways to fit a large problem in our minds is to lop off huge parts of it. In medical decisions, ... a physician can... draw on a number of simplifying heuristics. Anyone uncomfortable dealing with probabilities can use the heuristic, 'If there is any chance of (the disease), the (procedure) should be performed.' If one cannot estimate the number of people to be saved, one can use the heuristic, 'If but one patient is saved, the effort is worthwhile.' If one cannot contemplate alternative uses of resources that might deliver a greater benefit to the population, there is the heuristic, "Costs should not be considered in decisions about individual patients.' There is a general all-purpose heuristic, 'When in doubt, do it.' ... Unfortunately, a large number of incentives encourage simplifications that lead to overutilization... The losers are patients, consumers, and taxpayers -- anyone who has to undergo a valueless procedure or pay the bill." (Eddy, 1984).

It is possible to teach decision-making models, and I believe doing so would help.

2. Include recertification with a performance component in Board certification

Expand the Board certification process to include periodic (e.g., perhaps every five years) recertification including a performance component. The advantage to this route is that many of the most prevalent protocols are specific to a particular specialty, e.g., coronary bypass surgery. The process could include testing awareness of current protocols and their performance.

Analysis of feasibility and comments on evaluating effectiveness of physician training and education recommendations:

The probability of getting curricula or residency programs modified to include some or all of the above suggestions may be remote. The AMA violently opposes strings attached to federal funding. However, I think this idea merits further review. Current funding practices work at cross purposes to the country's health care needs, yielding excess specialists. (Starr, 1982). I think the federal government has the right to attach strings to its grants -- it does in many other arenas.

On the assumption, however, that the above recommendations would get snarled in political tangles with the AMA, I think it more likely that MCOs (and possibly even Medicare/Medicaid programs) would simply impose additional training requirements on physicians as a requirement for their participation. Eventually, if enough doctors resented having to get more education after they just completed eleven years of college and medical training, they might lobby within the AMA to get the curricula and residency programs modified.

An effective evaluation process would require half the students to follow the new training regimen and half the old. Outcomes of the two groups could then be compared. However, the logistics of this arrangement might prove impractical. In addition, results might be confounded by the fact that physicians who did not receive this training in their medical education might end up getting it from their MCO employers.

Increased requirements for continued licensing such as recertification would probably be similarly hard to sell since it is physicians who control that process. To start, one might try to get the requirement in place for future graduates, and then work on how to address existing practitioners. For the latter, one might start by

having a less frequent recertification, e.g., once every 10 years, and gradually shorten the interval.

One limitation of the Board route is that it would only address practitioners who are Board certified in the first place. Further, this approach would not necessarily address the more generic protocols, e.g., pain management. Evaluation of effectiveness would include studies tracking rates at which protocols were executed properly over time. Another measure of effectiveness might be the distribution of scores on the recertification exam over time.

Part Four: Individually Tailored Care: "Star Trek" Research and Technology

1. **"Hospital in a watch"**

2. **Nanotechnology**

3. **Individual DNA blueprint**

4. **Individual biochemical risk management**

5. **"Smart card" medical record**

Part Four: Individually Tailored Care: "Star Trek" Research and Technology

Currently, much health care advice is based on population averages. It is not customized for each individual. If one wants to talk about care that is truly patient-centered, however, one would want that care to be tailored to the specific individual, not based on what is good for most people most of the time.

The problem with applying models that approximate average reality is that they are always inaccurate when applied to individuals. Think of statements such as, "the average family has 2.3 children". One thing one knows for certain is that no one actually has 2.3 living, breathing children.

Similarly, a simple example from medicine is that drug pills are designed to provide the right amount of medicine for the average patient, but any specific individual may actually need more or less than that for optimal treatment.

One of the more thought-provoking perspectives from the alternative medicine movement is a "reject[ion of] the principle... that in any scientific investigation of a medical treatment, the treatment must be applied to each patient in exactly the same way...[instead believing that alternative] therapies are supposed to be individually tailored..." (Kolata, 1996b). Thus, a point of view frequently considered outlandish today may in fact hint at the best of treatment frameworks for tomorrow.

The ideas presented below to tailor care to the individual would require extensive additional research and development before they could be implemented. The first four ideas were taken directly from a session called "Best of Health Care Futures" at the World Future Society annual conference in June, 1993.

1. "Hospital in a watch"

One idea is to develop advanced technology small enough to wear all the time that would perpetually monitor critical indicators such as blood pressure and alert the wearer if any condition merited attention.

2. Nanotechnology

Scientists envision tiny machines just a few molecules big that could be ingested and roam the bloodstream looking for specific problems, e.g.,

cholesterol blocking an artery. When a machine found a problem, it would manufacture on the spot the appropriate drug to eliminate it.

3. Individual DNA blueprint

This idea is to be able to recommend the combination of food, medicines, behavioral changes, etc. most constructive for the individual based on her unique DNA blueprint. For example, for some people reducing salt intake is important while for others it is irrelevant. Some people, to function optimally, need more protein than others. And so forth.

4. Individual biochemical risk management

Right now, the FDA approves drugs as "safe and effective" based on the population in general. If there is a drug that solves a critical medical problem for 40% of the population but causes serious side effects in the other 60%, the FDA would not now approve it for sale.

If it were possible to be *certain* to which group an individual belonged, one could picture marketing the product to the 40% for whom it would be safe. Such an idea would clearly require massive patient education to avoid sharing drugs or other medical regimens that had been specifically tailored to one person.

5. "Smart card" medical record

More recently, one article suggested, "In fact, it could be possible within 10 years -- and certainly within 20 -- for you to carry around a smart card containing your complete genetic makeup. You would bring it with you when visiting the doctor, and the doctor would use it to prescribe medications or other treatments to meet your own specific needs." (Millett and Kopp, 1996).

Analysis of feasibility and comments on evaluating effectiveness of individually tailored care recommendations:

While the hospital-in-a-watch and nanotechnology ideas may see commercial development, the DNA-based projects would require massive funding. It is not clear

that any private organizations have sufficient resources to fund these, nor that government-funded organizations would see these efforts as a priority.

These are appealing ideas, though. *One could evaluate their effectiveness by comparing the treatments delivered as a result of these technologies to those that would have been delivered without these technologies, and estimating the differences in outcomes thus achieved.*

For example, assume the record showed that 10% of the people who try to quit smoking succeeded with current approaches. Then assume that the third idea above allowed regimens tailored specifically to individuals, and that 25% of the people succeeded in quitting with those regimens. That would suggest that the new technologies had in fact improved medical outcomes.

SECTION SIX: CONCLUSIONS

The commonly accepted view is that in health care in the United States there is an inherent conflict between improving costs and improving quality/access. In this paper, I have suggested that this dichotomy is false, that the accepted frameworks shaping the discussion are flawed, and that solutions different from those commonly proposed are both necessary and eminently feasible.

A raging debate today concerns physicians' autonomy to decide on treatment versus the right of managed care organizations to review or limit their treatment choices. I suggest that that entire debate becomes irrelevant if one instead makes the patient -- rather than the physician -- the center of attention and concentrates on achieving beneficial results that are important to the patient including medical, functional, and quality of life outcomes.

To highlight critical gaps in achieving that goal, this paper has discussed four types of problems. These include executional flaws, decision-making without relevant outcomes data, process mismanagement, and perceptual deficiencies concerning patient-centered care.

Having the patient make treatment choices based on objective data about the outcomes that typically result could rapidly cut both costs and poor quality care out of the health care system. Poor outcomes related to irrelevant or inferior treatment options would probably decline rapidly since patients would rarely choose a treatment known to get poor results. Poor outcomes caused by poor execution and poor process management would be likely to be too damaging to physicians' and MCOs' reputations and bank accounts to continue unaddressed.

In short, by reviewing current issues from a different perspective, it becomes clear that practical and effective changes could be made to address many of the current problems in health care in the United States. There is ample room for improvement.

Most of the changes required are not intellectually difficult to understand nor unreasonably complex to implement. They would require primarily a constant focus on the purpose of the health care system -- patient outcomes -- and some persistence and common sense. Health care costs and quality can be improved simultaneously.

SOURCES CITED

American Heritage Dictionary of the English Language. 3rd ed. Boston. Houghton Mifflin, 1992.

Austin Area Birthing Center. Brochure. “Creating an Ideal Birth for You and Your Baby,” 1995.

"Best of Health Care Futures." Conference workshop. World Future Society, June 27-30, 1993.

Boland, Peter. Making Managed Healthcare Work: A Practical Guide to Strategies and Solutions. Maryland: Aspen Publishers, 1993.

Boston Women's Health Collective. The New Our Bodies, Ourselves. New York: Simon & Schuster, 1992.

Brook, Robert H. "Health Services Research: Is It Good for You and Me?" Academic Medicine 64 (1989). Reprinted in The Nation's Health. 3rd ed. Ed. Philip R. Lee and Carroll L. Estes. New York. Jones and Bartlett Publishers, 1990. 339-346.

Brooks, Adrienne C. "Middle Ear Infections in Children." *Science News*, 146 (1994): 332-333.

Byrnes, Jonathan L. S. and Roy D. Shapiro. Working Paper 92-058. "Intercompany Operating Ties: Unlocking the Value in Channel Restructuring." 1991.

Cafferky, Michael E. Managed Care & You: The Consumer Guide To Managing Your Health Care. New York. McGraw-Hill, Inc.: 1995

Chambliss, Lauren. "The 10 Healthiest Companies for Women." *Working Woman*. June 1996: 61+.

Chassin, Mark R., Edward L. Hannan, and Barbara A. DeBuono. "Benefits and Hazards of Reporting Medical Outcomes Publicly." *New England Journal of Medicine* 334 (1996): 394-398.

Dao, James. "New York Bill Offers Wide Range of Protection for H.M.O. Clients." *New York Times*, May 09, 1996: A1+.

"Day Care, Allergies Linked to Ear Infections." *Austin American-Statesman* June 16, 1996.

Drake, Donald C. "Medicine's Jagged Edge: Volumes of Unnecessary Care." *Philadelphia Inquirer*, September 19, 1988: 1-A+.

Drayer, Ralph. "The Emergence of Supply Chain Management in North America." Speech. Undated: early 1990's.

Eaton, Leslie. "Aetna to Buy U.S. Healthcare in Big Move to Managed Care." *New York Times*, April 02, 1996: A1+.

Eddy, David M. "Variations in Physician Practice: The Role of Uncertainty." *Health Affairs* 3:2 (1984). Reprinted in The Nation's Health. 3rd ed. Ed. Philip R. Lee and Carroll L. Estes. New York. Jones and Bartlett Publishers, 1990. 347-355.

Fisher, Ian. "U.S. Offering Some Support for Pataki's Medicaid Plans." *New York Times*, June 28, 1996: A13.

Fisher, Lawrence M. "Health on Line: Doctor Is In, and His Disk Is Full." *New York Times*, June 24, 1996: C1+

FitzGerald, Susan and Marie McCullough. "Study Finds Lapse in Optimal Care of Ovarian Cancer." *Austin American-Statesman*, May 22, 1996. Reprinted from *Philadelphia Inquirer*.

Freudenheim, Milt. "Big Hospital Chain Makes a Bid to Buy Blue Cross of Ohio." *New York Times*, March 30, 1996: 1.

Freudenheim, Milt. "Managed Care Empires in the Making." *New York Times,* April 02, 1996: C1+.

Freudenheim, Milt. "$2.3 Billion Deal Creates Giant in Managing Doctors' Offices." *New York Times,* May 15, 1996: A1+.

Freudenheim, Milt. "Big H.M.O. Guilty in Antitrust Case: Small Insurer Gets $1.2 Million Award." *New York Times*, May 23, 1996: C3.

Gamino, Denise. "Texas' Medicaid Switch Falters." *Austin American-Statesman* May 18, 1996: B1+.

Gamino, Denise. "State-Local Impasse Stalls Medicaid Reform in Texas." *Austin American-Statesman*, May 28, 1996: A1+.

Gavzer, Bernard. "When Doctors Are the Problem." *Austin American-Statesman* April 14, 1996: *Parade Magazine* cover + 4-6.

Ginzberg, Eli. "A Hard Look at Cost Containment." *New England Journal of Medicine* 316 (1987). Reprinted in The Nation's Health. 3rd ed. Ed. Philip R. Lee and Carroll L. Estes. New York. Jones and Bartlett Publishers: 1990. 246-252.

"Give Newborns 48 Hours." Editorial. *Austin American-Statesman* May 20, 1996: A10.

Golz, Earl. "Humana HMO Eases Admissions Requirement." *Austin American-Statesman*, May 31, 1996: C1+.

Goleman, Daniel. "Physicians Said to Persist in Undertreating Pain and Ignoring the Evidence," *New York Times*, December 31, 1987: B5.

Grove, Andy. "Taking on Prostate Cancer." *Fortune,* May 13, 1996: cover + 55-72.

Hale, Judith A. and Robin B. Weiner. "How Managed Care Measures Up: Few Managed Care Plans Link Procedures to Health Outcomes, Despite Some Efforts to Measure the Level of Preventive Screening." *Business & Health*, January, 1994: 34+. CD-ROM. Medical Economics Publishing Company. May, 1995.

Hammonds, Keith H. "Oxford's Education." *Business Week*, April 08, 1996: 108-110.

"Health Care Is Looking Healthier." Editorial. *Business Week*, April 08, 1996: 146.

Hopper, Leigh. "Assistants Lend Hand to Overworked Doctors." *Austin American-Statesman*, June 24, 1996: A1+.

Iglehart, John K. "Health Policy Report: The Struggle to Reform Medicare." *New England Journal of Medicine* 334 (1996): 1071-1075.

"Ill Health and Illiteracy: A Highly Dangerous Team." *New York Times*, December 6, 1995.

Joint Commission on Accreditation of Health Care Organizations. "Standards, Scoring Guidelines, and Aggregation Rules." 1995.

Jonas, Steven. "Health Manpower: With an Emphasis on Physicians." Health Care Delivery in the United States 4th ed. Ed. Anthony R. Kovner and Steven Jonas. New York. Springer Publishing Company,1990. 50-86.

Kilborn, Peter T. "Devalued by Growth of H.M.O.'s, Some Doctors Seek Union Banner." *New York Times*, May 30, 1996: A1+.

Kolata, Gina. "On Fringes of Health Care, Untested Therapies Thrive." *New York Times*, June 17, 1996: A1+.

Kolata, Gina. "In Quests Outside Mainstream, Medical Projects Rewrite Rules." *New York Times,* June 18, 1996: A1+

Kolesar, Peter. Conversation. 1987.

Kraft, Ashley Hill. "The Informed Choice Agreement of the Association of Texas Midwives: Ashley Hill Kraft." Resume. May, 1995.

Krieger, Gary F. "Medical Staff Must Answer Challenges of the '90s." *American Medical News*, March 21, 1994: p. 37+. CD-ROM.

Kurt Salmon Associates, Inc. "Efficient Consumer Response: Enhancing Consumer Value in the Grocery Industry." Preliminary Draft. December 30, 1992. 120 pages.

Laine, Christine and Frank Davidoff. "Patient Centered Medicine: A Professional Evolution." *Journal of the American Medical Association*: 275 (1996): 152-156.

Lamm, Richard D. "The Ten Commandments of Health Care." Paper. Undated. (He gave it to me in November 1987.)

Leary, Warren E. "U.S. Urges Doctors to Fight Surgical Pain (and Myths)." *New York Times*, March 06, 1992: A1+.

Leavenworth, Geoffrey. "Quality Costs Less: Reduction in Inappropriate Care Lowers Costs, but also Improves Quality and Outcomes." *Business & Health* March 1994: S6+. CD-ROM. Medical Economics Publishing Company. May 1995.

Leavenworth, Geoffrey. "Case Studies: After Reviewing Past Procedures, Three Hospitals, an HMO, and an Employer Found Compelling Reasons to Use Guidelines." *Business & Health* March 1994: S13+. CD-ROM. Medical Economics Publishing Company. May 1995.

Levinsky, Norman G. "Social, Institutional, and Economic Barriers to the Exercise of Patients' Rights." *New England Journal of Medicine* 334 (1996): 532-534.

Magnusson, Paul and Keith H. Hammonds. "Health Care: The Quest for Quality." *Business Week*, April 08, 1996: 104-106.

Millett, Stephen and William Kopp. "The Top 10 Innovative Products for 2006: Technology with a Human Touch." *The Futurist*, July-August, 1996: 16-20.

Mullan, Fitzhugh. "Graduate Medical Education and Water in the Soup." *New England Journal of Medicine* 334 (1996): 916-917.

Naylor, C. David and Gordon H. Guyatt. "Users Guides to the Medical Literature: X. How to Use an Article Reporting Variations in the Outcomes of Health Services." *Journal of the American Medical Association* 275 (1996): 554-558.

Noble, Holcomb B. "Quality is Focus for Health Plans." *New York Times*, July 03, 1995: 1+.

Oss, Monica E. "Shawnee Hills: A Case Study in Outcomes Assessment." Behavioral Health Management May/June 1995: 31. CD-ROM. Medquest Communications, Inc. May, 1995.

Pear, Robert. "Doctors May Get Leeway to Rival Large Companies." *New York Times*, April 08, 1996: A1+.

Pear, Robert. "A Bill Lengthens Hospitalization Coverage for New Mothers." *New York Times*, April 18, 1996: A8.

Pear, Robert. "Cost of Health Care Is Increasing More Slowly, Report Says." *New York Times*, May 28, 1996.

Pretzer, Michael. "The Managed Care Juggernaut: Explosive Growth Nationwide." *Medical Economics*, April 15, 1996: 64-74.

Protos, John. "Ten Things Your HMO Won't Tell You." *Smart Money*, March, 1996: 134-144.

Protos, John. "Loopholes in the Safety Net." *Smart Money*, July, 1996: 100-105.

"Reading for Your Life." *Philadelphia Inquirer* ,circa January 07, 1994.

Relman, Arnold S. "The New Medical-Industrial Complex." *New England Journal of Medicine* 303 (1980). Reprinted in The Nation's Health. 3rd ed. Ed. Philip R. Lee and Carroll L. Estes. New York. Jones and Bartlett Publishers: 1990. 94-103.

Rivo, Marc. L. and David A. Kindig. "A Report Card on the Physician Work Force in the United States." *New England Journal of Medicine* 334 (1996): 892-896.

Roberts, Richard G., Bernard M. Rosof, and Robert S. Thompson. "Practice Guidelines: Coping with Information Overload." *Patient Care*, February 29, 1996: 39-57.

Robert Wood Johnson Foundation, "Annual Report 1994: Cost Containment." 1995.

Robert Wood Johnson Foundation, "Guidelines for Grant Applicants." 1995.

Rosenthal, Elisabeth. "Powerful New Weapons Change Treatment of Pain." *New York Times*, February 11, 1990: C1+.

Scott, Miriam Basch. "Data Should Be Shared, Not Competitively Withheld, Researchers Say." *Employee Benefit Plan Review*, January 1994: 56-57. CD-ROM. #00815384 ProQuest. Abstract.

Schine, Eric and Keith H. Hammonds. "In California, It's 'Hell No, HMO!'" *Business Week*, May 20, 1996: 38.

Spiers, Joe. "Medicare's Bad Prognosis." *Fortune*, May 27, 1996: 57-58.

Starr, Paul. The Social Transformation of American Medicine. New York. Basic Books, Inc, 1982.

Sterngold, James. "Big Wellpoint Deal Creates a Health Provider and 2 Charities." *New York Times*, May 21, 1996.

Stodghill, Ron. "Attack of the Health-Care Colossus." *Business Week*, May 20, 1996: 40.

Stokes, Jean Elizabeth. "The Informed Choice Agreement of the Association of Texas Midwives: Jean Elizabeth Stokes." Resume. 1995.

Weitzman, Beth C. "The Quality of Care: Assessment and Assurance." Health Care Delivery in the United States 4th ed. Ed. Anthony R. Kovner and Steven Jonas. New York. Springer Publishing Company, 1990. 353-380.

Weston, Brent and Marie Lauria. "Patient Advocacy in the 1990s." *New England Journal of Medicine* 334 (1996): 543-544.

Wilson, Anne. "AHCPR Agency Review." Internet: <CLEARINGHOUS@delphi.com> January 24, 1994.

Worrall, Graham and Paul Chaulk. "Hope or Experience? Clinical Practice Guidelines in Family Practice." *Journal of Family Practice* 42 (1996): 353-356.

Zaldivar, R. A. "1 in 5 Go without Insurance for a Time." *Austin American-Statesman*, June 24, 1996: A5.

Zinman, David. "Keeping Score: The New Trend toward Evaluating Medical Care." *American Health*, April 1993: p. 56 (5). CD-ROM. RD Publications Inc.