

2005 Medical Director

Colloquy



How Can Medical Directors Have the Greatest Impact On Quality Improvement?

**Based on presentations
at the 2005 Medical
Director Colloquy,
Las Vegas, June 10-11**

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INTRODUCTION

JAMES BRIDGES, MD

Executive Medical Director, Blue Cross Blue Shield of Michigan

The fourth consecutive 2005 Medical Director Colloquy was dedicated to helping the participants to identify trends and review techniques that will allow health plans to continually improve health care quality.

Most Americans would agree that the goals of the health care system should be to keep healthy people healthy and help the chronically ill manage their conditions. Yet, as the National Committee for Quality Assurance (NCQA) has noted, more than 1,000 Americans die each week and thousands more are hospitalized because the health care system does not always deliver appropriate care. Although the quality of U.S. health care is improving, our health care system continues to operate with a large percentage of our population still receiving care that does not meet well-established standards.

In the *State of Health Care Quality 2004*, the NCQA reports that many Americans do not receive appropriate preventive care and care for such chronic conditions as diabetes or hypertension. As a consequence, thousands of patients suffer heart attacks, kidney failure, and osteoporotic fractures that could have been delayed or prevented. NCQA calculates that more than \$9 billion in lost productivity and nearly \$2 billion in hospital costs could be averted through better delivery of standards-driven care for chronic disorders. For example, through better diabetes management, more than 14,000 heart attacks, strokes, and amputations could be prevented each year. Likewise, controlling high blood pressure could avoid 7,600 strokes and 15,900 major cardiovascular events each year.

We have an opportunity, if not the responsibility, to manage the combination of increasing cost and varying performance more effectively. Health plans will need to support, continuously, the use of new tools to engage members, coordinate care, and promote physician quality. Expanded performance measures and accountability throughout the health care system are proven methods of improving quality. It is essential, therefore, that we do all we can to ensure the incorporation of these tools in tomorrow's health care delivery system.

Mindful of the need to balance quality and cost carefully, we hope that the following materials provide valuable insights that can be used to identify and implement effective strategies for improving quality of care. I hope you'll take advantage of the educational opportunity this supplement provides through the sponsorship of The Chatham Institute.

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Care

October 2005

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A CONTINUING EDUCATION ACTIVITY

**Based on the proceedings of the 2005 Medical Director Colloquy
June 10–11, 2005, in Las Vegas**

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SELF-STUDY CONTINUING EDUCATION ACTIVITY

How Can Medical Directors Have the Greatest Impact on Quality Improvement?

Continuing education credit is offered to physicians and pharmacists who read pages 3 through 43 of this publication, complete the post-test on page 44, and submit the evaluation form on page 45. Estimated time to complete this activity is 3 hours.

Target audiences

Medical directors, pharmacy directors, primary care physicians, and health care executives.

PURPOSE AND OVERVIEW

This publication is based on the 2005 Medical Director Colloquy that took place on June 10–11, 2005, in Las Vegas, Nevada.

The content of the 2005 Medical Director Colloquy was derived from an assessment of the target audience members' learning needs related to overall improvement of health care quality, with special attention given to the management of cardiovascular disease and its effects on managed care organizations. The need for this educational activity was based on a review of current medical literature and evaluations from previous medical director meetings.

This year, the United States will spend about \$2 trillion on health care, an amount that represents 15 percent of U.S. gross domestic product. No other industrialized country devotes as great a percentage of GDP to health care. Yet, despite this tremendous investment, the United States lags other industrialized countries in numerous indicators of health care quality.

Addressing the general issue of quality improvement, this supplement presents an argument supporting employers' increased involvement in workplace health-promotion programs, which, properly done, have the potential to improve a company's productivity; an article describing the appropriate use of quality-of-care indicators by medical managers; and an article suggesting ways in which information technology can be used to derive greater value from the extremely high annual U.S. health care expenditure.

With respect to cardiovascular disease, this supplement presents information about the management of heart failure with preserved systolic function (complementing a presentation at the 2004 colloquy on heart fail-

ure with systolic dysfunction); the real world — and highly successful — experience of a large cardiology practice in disease management; and bariatric surgery for morbidly obese patients, which attenuates a range of risk factors for cardiovascular disease and other ills.

Educational objectives

After reading this publication, participants should be able to:

- Determine techniques a managed care organization can use to improve quality of care
- Highlight recent research and advances in the prevention and treatment of cardiovascular disease and related conditions
- Describe current health issues that are affecting health plans' priorities and goals
- Identify issues that medical directors face with respect to challenges, perspectives, and best practices
- Understand how bariatric surgery can address a wide range of comorbid conditions affecting morbidly obese patients
- Gain insights into treatment for heart failure with preserved systolic function

CONTINUING EDUCATION

This activity is sponsored by The Chatham Institute.

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The Chatham Institute is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The Chatham Institute designates this educational activity for a maximum of 4.0 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Pharmacists

The Chatham Institute is approved by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

This activity provides 4.0 contact hours (0.4 CEU) of continuing education

for pharmacists. Credit will be awarded upon successful completion of the post-test and the activity evaluation.

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Digital Medicine and the Managed Care Medical Director: a Look Into the Future

JEFF C. GOLDSMITH, PHD

President, Health Futures, Charlottesville, Va.

The U.S. health care system accounts for about 15 percent of the gross domestic product (OECD 2005). To put that amount — about \$2 trillion — in context, it is the size of a large industrialized nation, approximating the total GDP of Germany. Yet, this gigantic, technologically advanced sector continues to rely on Dickens-era tools for managing its core processes. Building on ideas advanced in *Digital Medicine: Implications*

for *Healthcare Leaders* (2003), this article suggests ways in which information technology (IT) can help us derive more value from the money we spend on health care. One reason the U.S. economy's recovery has been so halting is that health insurance costs have depressed wage growth. American workers fail to understand that it is their money — wages foregone — that funds their health benefits. Contrary to what some people may think, rising health care costs have not been driven by general inflation, wage inflation within the health care sector, rising materials costs, or the aging of the Baby Boom generation. In about 20

years, the Baby Boomers will present a significant problem for the health care system, but they do not yet do so.

Rather, the recent surge in health care spending more fairly can be attributed to other factors, such as cost shifting stemming from the Balanced Budget Act (BBA). The BBA essentially froze Medicare spending for 4 years, inducing providers to shift costs to private employers.

In addition, a backlash against managed care has contributed to rising health care costs. Managed care organizations' efforts to control costs through concurrent review, prior authorization, and other techniques created a sentinel effect — the notion that physicians were being watched. When the sentinel effect diminished, there was a palpable change in physician communities. Perceiving an open cash register, some physicians took advantage of the situation, justifying their actions by pointing to the

need to recover income lost from Medicare payment reductions and from a ruinous increase in malpractice insurance premiums. These were stimuli for physician activism in the form of stunning increases in procedure volume, particularly in imaging and less-invasive procedures like endoscopy and ambulatory surgery. Yet another major component of the problem is the declining cost involvement by patients in this \$2 trillion economic activity. What makes the health care sector unique is that, as of 2003, less than 14 percent of health care costs were borne by individuals out of pocket. That is, 86 percent of total U.S. health spending was covered by other people's money.



JEFF C. GOLDSMITH, PHD

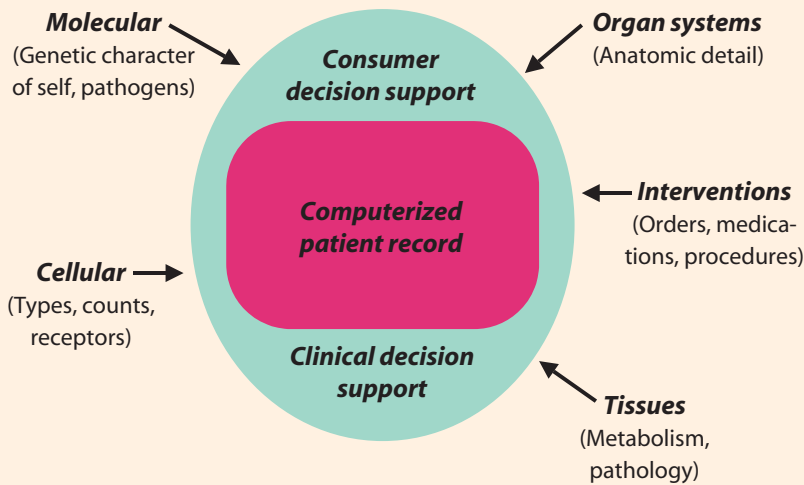
Managed care consequences

In 1980, only about 10 million people were enrolled in managed care plans, and most of them were members of Kaiser Permanente plans. At that time, 24 percent of health care spending was borne out of pocket. By 2001, another 125 million people had been added to the managed care system, although the

share of out-of-pocket health care spending had dropped by 10 percentage points. One reason for this occurrence is that MCOs' marketing departments persuaded employers to encourage enrollment in an HMO or PPO by telling employees that their out-of-pocket expenses would be minimal or nil. That is, during this period when people were being encouraged to try a new way of paying for and managing health care, there was a fire sale on health care services. Today, the cost of that action has become evident. There now is an entrenched sense of entitlement to health care services, as has been made clear by the recent wave of strikes by unionized workers seeking to preserve their benefits.

What was interesting about these strikes is that they carried little political resonance elsewhere, because only 17 percent of privately insured people today still have

FIGURE 1 Digital medicine: converging streams



SOURCE: HEALTH FUTURES 2005

first-dollar coverage in their health insurance plans. Most everyone else has accepted the idea — not necessarily with enthusiasm — that health care is expensive and that we really are obligated to pay a portion of those expenses. But what people fail to realize is how tiny our share of those total expenses really is. We have continued to distort the value of health services by enabling consumers to pretend that the cost of their \$175 physician office visit is only \$10. As a society, we have been wealthy enough to foster the illusion that health care is effectively free to the user.

Information technology

IT will have a prominent role in changing that dynamic and fundamentally altering how our health care system operates, all the way down to the molecular level. In a real sense, DNA is digital software, the most complex program found so far in the universe. For 50 years, biologists have been trying to decode this molecule and determine its relationship to disease and disease risk. Although we may wait a long time to discover the genetic basis of complex diseases like cancer, heart disease, and diabetes, we are making important advances elsewhere in genomics. Nucleic acid testing is the fastest-growing segment of the clinical laboratory business. The idea that there is a genetic basis for variation in our response to illness, and that there probably is a way to intervene at the molecular level to deflect the development of illness, will change the pharmaceutical industry in significant ways. In addition, unraveling the variation in patients' ability to metabolize drugs holds the potential for saving lives (by identifying poor metabolizers and thereby avoiding overdosing) and saving money (by not

administering drugs to people who will derive no therapeutic benefit). When a drug costs \$20,000, it will not be unreasonable for the U.S. Food and Drug Administration or a payer to require some evidence that the cell-surface receptors on which the drug acts, in fact, are present.

Information acquired through tools such as Roche Diagnostics' AmpliChip, a microarray that tests for individual variation in the cytochrome P450 family of drug-metabolizing genes, will become part of a patient's electronic medical record (EMR).

As individual patients, we will want to undergo such testing, but MCOs will be challenged to assure people that the information will be protected in a way that does not

adversely affect their insurability. If patients don't trust the health care system to handle that information, they won't permit the testing. In that event, we will have a body of scientific information that enables us to make better decisions about dosing and therapeutic selection, but we will be unable to use it. Some clinicians regard the Health Insurance Portability and Accountability Act (HIPAA) as a waste of money, but they fail to understand the profound lack of trust on the part of many patients. We will need to earn their trust to practice safer and better medicine.

Evolution of the electronic medical record

With patients' trust and continued technological advances, the EMR can evolve far beyond being a static historic record or a digital version of a patient's paper chart. By collecting converging streams of information (Figure 1) and adding science-based decision support tools, the EMR can become a navigational tool that helps the health care team to guide a patient through an episode of illness. Development of such a tool will be constrained by huge knowledge gaps, but the more patient management becomes digital, the more the EMR can be used to determine which clinical interventions add value and which do not. Being able to track patients through the care process will provide a powerful tool for evaluating which clinical interventions lead to good results, as well as which clinicians and institutions do the best job.

If the purpose of the navigational system is to help the clinical team guide a patient through an episode of illness, then the applications that vendors will build on top of the system will enable clinicians to manage not just the patient before them, but all the patients for whom they

are responsible, such as the patients they operated on last week and sent home with medications — and who now are at risk of infection.

The ability to stratify patients who have been seen recently and to communicate with them, whether by intelligent voice-response technology or e-mail, will improve the linkages in the care process, such that a physician who is responsible for several thousand patients will be able to stay in touch with them all, in one way or another.

These IT systems also will be valuable tools for helping clinicians as well as patients to cope with the flood of new biomedical knowledge. Eventually these EMR systems will be intelligent enough to teach physicians how to practice medicine and keep them engaged in new discoveries.

Diagnostic imaging

Among the most sophisticated IT applications currently used in health care are the software programs that help magnetic resonance imaging (MRI) and computed tomography (CT) scanners acquire and manipulate digital images. In a few years, that software will interpret the images, and the first read will be a machine read. Imaging software already has been demonstrated to more accurately identify breast tumors on the basis of digital mammography than do experienced radiologists.

Digital images can be moved anywhere in the world where broadband is available, provided there also is a qualified diagnostician available. It remains a mystery why all these technologies have not materially reduced the cost of imaging. With the imaging volume predicted to grow by 15 to 17 percent annually between now and 2008, one challenge facing health plans is to learn how to use these technologies to reduce the cost of diagnostic imaging.

There is tremendous interest in molecular imaging. Bioluminescent tags eventually will be used to identify malignant cells interoperatively, so that a surgeon will be able to use the image to make sure every cancerous cell is excised. Molecular imaging also will enable scientists and eventually clinicians to see processes such as gene expression taking place inside the cells of individuals.

Remote physiologic monitoring

The convergence of intelligent clinical software with remote sensing technologies will allow large numbers of people who are at risk of being hospitalized for life-threatening chronic conditions to live normal lives. Remote monitoring applications already have been validated for managing patients in intensive care units (ICUs). From one control center, a single intensivist and an intensive care nurse can manage remotely as many as 100 patients in four or five different ICUs. These monitoring tools, which provide a technological answer to variation in cost and risk to patients, have been shown

to reduce substantially mortality, resource consumption, and length of stay. Remote sensing already can inexpensively monitor a person's location, motion and orientation, EKG, temperature, blood oxygen, respiration, sweat (chemical content), speech (content, voice stress), and identity. On the horizon are various devices that will monitor the efficiency of breathing, so as to detect a breathing crisis in a patient with asthma or chronic obstructive pulmonary disease; perform blood counts non-invasively; assess visual acuity; and view internal organs.

In approximately 15 years, intelligent sensor arrays will enable the emergence of a real-time electronic safety net similar to GM's OnStar, only for humans rather than automobiles. We will be able to integrate sensor arrays into modalities that we can wear. We will imbed them in patients' homes and use intelligent software that can evaluate their patterns of behavior and determine whether they are at risk — whether they are sleeping, breathing, eating, or taking their medications. The technologies are available today; the question is about the degree of risk at which it makes financial sense to invest in them for a given patient population. There also will be significant autonomy and privacy issues that constrain the deployment of these technologies.

IT investment by MCOs

Some of the most exciting uses of IT on the administrative side of the health system are found in health plans. IT investment by health plans is far ahead of that by providers. Broadband connectivity is transforming claims processing from an arduous manual process involving telephones, paper, and faxes into a faster electronic transaction that costs vastly less. If MCOs can establish software linkages with providers, enabling true interactivity with them, the \$50 manual claim will become a 10-cent electronic transaction, in which case everyone wins. There is no reason that members of health plans cannot track the status of a medical claim in the same fashion that a customer of FedEx can track a package in transit. It just requires a commitment to IT investment, and MCOs are making those investments.

Without IT, MCOs would be unable to develop consumer-centric health plans, which are IT intensive. Providing decision support for customized health coverage is the core idea behind consumer-directed health plans — the idea that not all subscribers are alike, and that subscribers need the tools that will allow them to select the type of health coverage that best works for them and to determine the degree of economic risk that they are capable of managing.

Predictive modeling — the use of sophisticated algorithms to predict disease risk and disease incidence in advance of illness — facilitates real-time disease management utilizing the tools discussed earlier. (*Editor's note:* See "Evolving Perspectives on Disease Management," by

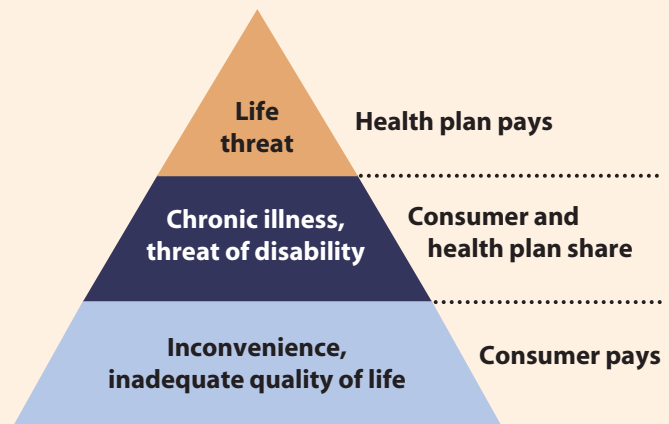
Vincent J. Bufalino, MD, pages 22–26, for an example of IT applied to disease management in heart failure and coronary artery disease.)

Consumer-directed health plans enable us to deconstruct the two functions of health insurance that have become entangled in recent decades — the pure insurance that covers the catastrophic, life-threatening illnesses and the discretionary insurance that covers an astonishing array of services. Through consumer-directed health plans, MCOs are disaggregating these functions (Figure 2). The health plan is the provider of catastrophic coverage, consumers and the health plan share the cost of managing most noncatastrophic conditions, and the consumer pays for services and products that are aimed at the inconveniences related to an inadequate quality of life. We do not want patients to share the cost of insulin or to take money out of their savings accounts for prenatal care; that would be counterproductive and would send the wrong message. Health plans need to promote the activities that not only save money for the patient, but also save money for the health plan.

For decades, a substantial percentage of U.S. health care costs have been concentrated in an extremely small percentage of patients (Berk 2001). A mere 1 percent of patients account for nearly 30 percent of expenditures, the top 5 percent for at least 50 percent of spending, and the top 10 percent for about 70 percent of spending (Figure 3). From another perspective, the bottom 50 percent of patients account for only about 3 percent of spending; the bottom 70 percent of patients, only 10 percent of health care expenditures.

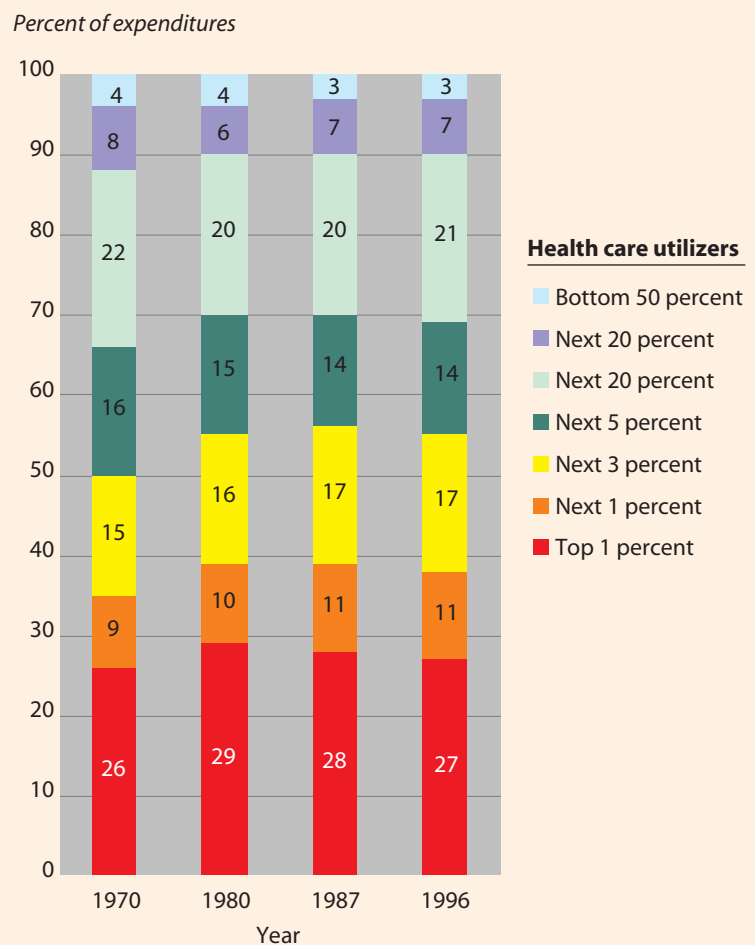
If MCOs do nothing more with their consumer-directed plans than give them to the substantial majority of members who rarely or never use health care in a year, no one is really saving any money. Health plans also are developing predictive tools to help in identifying the small number of members who are likely to incur extremely high costs before they do so, enabling them to work with subscribers and their physicians to avert serious illness. Consumer-directed health plans present an opportunity to open a dialog with subscribers about the economic

FIGURE 2 Deconstructing health “insurance”



SOURCE: KLEINKE 2004

FIGURE 3 Distribution of U.S. health expenditures



SOURCE: BERK 2001

cost of the decisions they make about how to manage their lives. They are not a panacea, however, and many people never will select a consumer-directed plan voluntarily. Nevertheless, consumer-directed plans offer a more realistic and economically healthy way of thinking about the health insurance benefit. It is regrettable that only 3.5 million people currently are enrolled in such plans, and that they are not growing at a far more rapid rate.

Yet, the future of consumer-directed health plans is bright. Even after controlling for selection, I believe we will find sustainable reductions of 30 to 50 percent in cost escalation of care for people in these groups. Thanks to an extremely fine-grained database, we will see marked increases in the accuracy of predicting medical problems. The database will extend beyond claims to a medical occurrence database that is maintained and evaluated on the provider side.

What is worrisome about the way consumer-directed health plans are being approached is that mechanisms have yet to be developed for successfully engaging physicians. The physician still is getting inflationary signals from our health care system: the more you do, the more money you make. We have had a significant reduction in the number of physicians under at-risk contracts during the past 10 years. To take full advantage of this paradigm of engaging consumers to reduce the cost of care, we eventually need to change the way we pay physicians for their activities. To lay the risk solely on them through capitation, as was done during the 1990s, is an incomplete and ineffective solution.

The digital future

Once patients have a continuous relationship with the health care system because of the IT applications discussed previously, it no longer will make sense to continue paying for care on an event-driven basis. Thanks to IT, the future of medicine will be quite different (Table). Patients will have a continuous, low-intensity, permission-based relationship with the health care system. In that kind of environment, it is senseless to pay only for visits. As Donald Berwick, MD, has said, we have been tyrannized by the idea that only the face-to-face interaction is valuable (Berwick 2002).

We should not go the route of paying \$10 for a brief email. Rather, in 10 or 15 years, we will subscribe to health care in the same way that we subscribe for broadband: Once we turn it on, it is always on. Payers will need to decide if there is sufficient health-promoting content flowing through that connectivity to warrant their sponsoring the relationship. Instead of standing between the provider and the patient, the health plan will want to sponsor relationships that are healthy for patients and to be in the position of paying physicians for following the

TABLE Digital medicine: past and future

	Past	Future
Patient-provider relationship	Event-driven	Continuous
Payment mode	Fee for service	Subscription
Records	Separate	Unified
Role of payer	Intermediary	Sponsor
Driver	Provider	Customer
Clinical decision support	"Right stuff"-based	Science-based

practices that constitute effective medicine.

In recent years, some physicians have established boutique medical practices, in which patients are charged a set fee to have a different kind of relationship with the physician — a continuing relationship. Health plans need to explore how they can support and pay for such relationships, because they hold the key to promoting and improving people's health.

Hopefully, we are moving to a customer-driven health care system in which decisions are based on science rather than on the "right stuff." When I am sick, I want the health care system to feel like one big happy family. I do not want to worry about whether my health care providers are burned out because of stress, or looking at the clock because it's time for them to go home, or showing no interest in me because they regard me as somebody else's patient. When I am sick, I am scared and hurting. I want to be taken in by the health system, and I want to feel that people care. We are a long way from that kind of experience, but it is what patients deserve — and it is the care that providers, in their heart of hearts, would like to offer. We must remove the friction and stress from our medical care system if we are to produce the value that \$2 trillion of societal investment ought to be generating in our health care experience.

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DISCUSSION

QUESTION: What is the future of employer-sponsored health insurance?

JEFF C. GOLDSMITH, PHD: If we were designing a health

insurance system from scratch today, we wouldn't go through the employer. A lot of employers would love to get out, but they are unable to determine the way to do so. We are not going to see the political leadership in our country any time soon that would replace that employer-based system with something else. For better or for worse, we're stuck with it, they're stuck with you, we're all stuck together.

QUESTION: Why do payment mechanisms always seem to lag relative to the technology?

GOLDSMITH: Health plans are constantly playing defense. The only leverage that health plans have is to decide whether to cover the new technology — and that's not a position of power. The present payment system does not work any better for the doctors in hospitals than it does for you. There is a tremendous level of frustration. It's time to begin experimenting with physicians and health systems that have reached the point where they realize they can't continue to work the way they've been working to build a different and more rational payment model. It won't happen across a state or a region; it will happen through experimentation. Many of my colleagues in health care are appalled by this boutique medicine idea. They think it's like an effort to grab the wealthiest 3 percent of patients in their markets.

Yet, when you think about the Medicaid population, what you really want is a relationship with somebody in the medical care system who will be a thoughtful, caring fiduciary for the patient. We tried to do that through gatekeeping and got lost in the politics of all the interaction with the specialists. What was missing in the movement toward capitation was a management framework; it was all paper. And when you stop paying claims and just start writing people checks for a month — most of them didn't have the data systems to evaluate whether they were making or losing money and whether they were making any difference in the lives of the patients.

The IT infrastructure created on the provider side through the adoption of electronic records provides the framework for managing population-based risk. The technology really does change the game. It will enable risk to be managed in a thoughtful and responsible way. We can't continue with event-based payment for another 10 years, because we're going to run out of money.

QUESTION: Genomic testing is extraordinarily expensive. Do you see any change in the costs of those tests?

GOLDSMITH: There is a two-part answer to your question. Because it is wedded to microchip technology, we will see the cost come down, but there are some categories of knowledge that we will need to acquire only once. Then, the question will be: How do we use that knowledge in a responsible and thoughtful way?

One reason that the tests are so expensive is that you can use the microarrays just once. It costs several thousand dollars to buy a microarray. There obviously are tremendous benefits to be accrued by having point-of-care microarrays that can be reused. So there are technological barriers that will be surmounted in the next 5 to 10 years, which will dramatically reduce the cost of acquiring genetic information.

For determining an individual's drug metabolizing characteristics, my strong suspicion is that you are going to need to do it just once. The question is: What benefits can be derived from paying for it once? A lot of thoughtful research needs to be done to validate whether that is a good investment. It strikes me intuitively that this is something I'd like to know as a patient. And I think eventually you will, too.

QUESTION: Who should bear the cost of bringing electronic health records to the private community physician, who frequently isn't willing to supply the money and would like the health plan or somebody else to pay for it?

GOLDSMITH: One could argue that when you study the flow of funds from reducing medical errors, reducing excessive testing, and all the rest of it, MCOs are the ultimate beneficiaries. The use of electronic health records really doesn't help the provider. If we just leave it to the state of nature, physicians will take 20 years to do this. Health plans will be able to procure the technology more economically than the physicians will. It isn't the clinical component where the biggest benefits will come from, it's going to be in the ability to build out the trackage to their payment system, so that physicians don't need two or three FTEs in their office who spend time jousting over whether the bill is complete and accurately documented. That's where the huge waste is. If you can tell doctors that the software will enable them to repurpose those individuals to do patient education or clinical work, your credibility with them will increase when you are able to help them reduce their operating costs. Their savings will accrue more from handling the administrative flow of transactions in an intelligent way than from having electronic medical records in their office.

QUESTION: Do you have a vision of what the physician will become, in terms of the management of relations and being digitally connected?

GOLDSMITH: A significant fraction of the physicians for whom IT is painful and anguishing will leave practice in the next 5 to 7 years, and there will be a transition of leadership in our medical communities to young people for whom computing and thinking in systematic terms about using clinical data will be as natural as breathing. A generational transition will take place in the next 7 to 10 years, and we need to be ready for that when it occurs.

A View of Preserved Systolic Function and The Approach to the Heart Failure Patient

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In discussions of heart failure, the term *diastolic dysfunction* is being replaced by a new phrase: *heart failure with preserved systolic function* (HF-PSF). This change in terminology serves to heighten awareness of the fact that patients who appear to have heart failure indeed may have heart failure even if their systolic function is more or less normal. Unlike systolic heart failure, no guidelines exist for diagnosing and managing patients with HF-PSF, and its optimal treatment has yet to be defined. Nonetheless, this condition is common (sometimes occurring together with systolic dysfunction), especially among the community-dwelling elderly. About 40 percent of all cases of heart failure can be classified as left ventricle (LV) diastolic dysfunction (Dougherty 1984). Once the symptoms of heart failure are present, the patient's prognosis is limited (Table 1, page 10).

Heart failure of all kinds affects about 4.9 million patients in the United States (AHA 2004), with 400,000 new cases being diagnosed annually. Its overall prevalence is 2.3 percent, but prevalence rises sharply with age, from 1 percent among people aged 50 to 59 years to 10 percent among those within the age range of 80 to 89 years. In general, the mortality of patients with HF-PSF varies from 1.3 percent to 17.5 percent, depending on the source of the published report (Vasan 1995). Nonetheless, the 5-year mortality rate among all people with heart failure is about 50 percent (Levy 2002).

The mortality rate among patients with preserved systolic function generally is somewhat lower than among patients with systolic dysfunction (Gottdiener 2002). In patients with HF-PSF, the 1-year mortality rate is about 5 percent to 8 percent, compared with 10 percent to 15 percent among patients with systolic heart failure (and 1 percent in age-matched controls), but for patients over

the age of 70, mortality rates for systolic heart failure and HF-PSF are nearly the same (Zile 2002a). If coronary artery disease (CAD) is not the underlying cause of HF-PSF, patients have a better prognosis, as the 1-year mortality rate in this group is 2 percent to 3 percent.

Heart failure also is attended by substantial morbidity. Hospital discharges increased by 157 percent between 1979 and 2002 — rising from 377,000 to 970,000 (AHA 2004). During 2005, direct and indirect costs of heart failure are expected to reach about \$28 billion, with more than half that amount devoted to hospital care.

About 75 percent of patients with heart failure have antecedent hypertension. A smaller proportion develops heart failure subsequent to myocardial infarction (MI); about 20 percent of MI victims develop heart failure within 6 years after the MI. Some heart failure patients, of course, have a history of both hypertension and MI. Partly because of the prevalence of hypertension in

the United States and the number of patients who survive MI, heart failure is the only cardiac diagnosis whose prevalence and incidence continue to rise.

Although cardiac output may not significantly drop, the increase in LV and left atrial pressures stimulates abnormal reflexes, primarily in the sympathetic nervous system, followed by activation of the renin-angiotensin-aldosterone (RAA) system and increased levels of catecholamines and atrial natriuretic peptide. According to the neurohormonal hypothesis, salt and water retention ensue primarily from such neurohormonal activation.

No distinguishing feature of HF-PSF

Diastolic dysfunction has been defined as impaired LV filling at normal left atrial pressure (Gaasch 1994). That is, a much higher pressure is required for the LV to fill.



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TABLE 1 Prevalence and worsening prognosis of HF-PSF increase with age

Age (years)	<50	50-70	>70
Percentage of all heart failure patients presenting with HF-PSF	15%	33%	50%
Mortality rate, 5-year	15%	33%	50%
Rate of hospital admission for heart failure, 1-year	25%	50%	50%

HF-PSF=heart failure with preserved systolic function.

SOURCE: ZILE 2002A

Thus, to maintain normal LV filling volume, which is the true definition of preload, higher pressures are required. Filling pressures are high in patients with preserved systolic function, and the cardiac index can be normal or low. An echocardiogram would show that the ejection fraction (EF) is preserved (e.g., LVEF >40 percent). In such a patient, the pressure-volume curve would show that, compared with the normal curve, the pressure is higher for every milliliter of volume; for every increase in volume, the pressure rises more rapidly than normal (Figure 1).

Although LV systolic dysfunction can be ascertained via noninvasive calculation of the LVEF, it is difficult to determine diastolic dysfunction noninvasively, and a normal EF should not be used to exclude a diagnosis of heart failure in the face of clinical evidence that suggests otherwise (Vasan 2000).

Vasan and Levy have proposed criteria for classifying patients according to the degree of certainty about a diagnosis of HF-PSF (diastolic heart failure, in their terminology) (Table 2). Under these criteria, a diagnosis may be upgraded from *possible* to *probable* if the patient had markedly high blood pressure (systolic pressure >160 mm Hg or diastolic pressure >100 mm Hg) during the

episode of heart failure; echocardiographic evidence of concentric LV hypertrophy without wall-motion abnormalities; tachyarrhythmia with a shortened diastolic filling period; onset of congestive heart failure after infusion of a small amount of intravenous fluid; or clinical improvement in response to treatment aimed at the presumed cause of diastolic dysfunction.

In terms of signs and symptoms, patients with HF-PSF resemble those with systolic dysfunction (Table 3, page 12); during the physical examination, there really is no distinguishing feature of HF-PSF (Zile 2002a). About 85 percent of these patients are short of breath on exertion, and they may be short of breath at rest. They tend to complain of extreme shortness of breath more than fatigue.

More than half the patients have nocturnal symptoms identical to those of patients with low ejection fractions, and they complain of orthopnea. Owing to interstitial fluid, about one third have some edema. They also have neck vein elevation, crackles, a displaced point of maximum impulse, and an S3 and an S4 gallop.

Their chest X-ray may show an LV that looks prominent, owing to LV hypertrophy. In hypertensive patients, hemodynamic load probably is the most common reason for LV hypertrophy, but trophic factors (e.g., angiotensin II [AT-II], catecholamines, insulin) and environmental and genetic factors (e.g., age, gender, race, other illness) also play roles. In the future, genetic markers may point to the patients who are most likely to develop LV hypertrophy, and who are likely to respond well, or not at all, to various therapies.

In addition to an increase in the diameter and length of cardiac myocytes, LV hypertrophy is associated with an increase in the amount of connective tissue in heart muscle. Perivascular fibrosis also occurs, particularly noted in microvasculature. In the Framingham study, in both young and old subjects, LV hypertrophy was associated with a significantly higher incidence of heart failure. In older men and women (ages 65 to 94) with LV hypertrophy, risk for heart failure in-

FIGURE 1 Pressure-volume curves

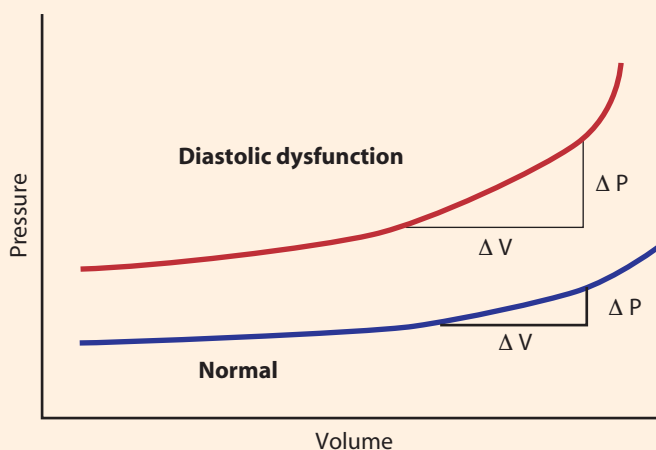


TABLE 2 Proposed criteria for degree-of-certainty diagnoses of HF-PSF

Criterion	Evidence
Definite	
• Definite evidence of heart failure <i>and</i>	Clinical signs and symptoms, lab tests (e.g., chest X-ray), typical clinical response to diuretics, with or without documentation of elevated LV filling pressure or low cardiac index
• Objective evidence of normal LV systolic function in proximity to heart failure event <i>and</i>	LVEF ≥ 0.50 within 72 hours of heart failure event
• Objective evidence of LV diastolic dysfunction	Cardiac catheterization showing abnormal LV relaxation, filling, or distensibility indices
Probable	
• Definite evidence of heart failure <i>and</i>	Clinical signs and symptoms, lab tests (e.g., chest X-ray), typical clinical response to diuretics, with or without documentation of elevated LV filling pressure or low cardiac index
• Objective evidence of normal LV systolic function in proximity to heart failure event <i>but</i>	LVEF ≥ 0.50 within 72 hours of heart failure event
• No objective evidence of LV diastolic dysfunction	
Possible	
• Definite evidence of heart failure <i>and</i>	Clinical signs and symptoms, lab tests (e.g., chest X-ray), typical clinical response to diuretics, with or without documentation of elevated LV filling pressure or low cardiac index
• Objective evidence of normal LV systolic function but not at time of heart failure event <i>and</i>	LVEF ≥ 0.50
• No objective evidence of LV diastolic dysfunction	

EF=ejection fraction, HF-PSF=heart failure with preserved systolic function, LV=left ventricular.
SOURCE: VASAN 2000

creased approximately fivefold, compared with subjects with no LV hypertrophy.

These structural changes are driven by the neurohormonal cascade that characterizes heart failure. Due to elevations in AT-II, norepinephrine, and aldosterone, patients develop an increase in afterload. Angiotensin-converting enzyme (ACE) mediates the conversion of angiotensin I into AT-II, hence the utility of ACE inhibitors in treatment of heart failure. AT-II increases the level of catecholamines, which also are indirectly upregulated through the sympathetic nervous system. In addition to promoting sodium reabsorption and potassium excretion, aldosterone is a powerful fibrotic agent.

Most patients with preserved systolic function are women over age 65, and they may have atrial fibrillation and a history of hypertension. A typical patient might develop pulmonary edema after a sudden load of sodium,

resulting in a trip to the emergency room and occasionally resulting in the need for mechanical ventilation. In this instance, gentle diuresis is extremely effective. If a large dose of diuretic is given, however, the patient can become hypotensive and then develop renal dysfunction, necessitating a longer hospital stay.

Treatment of HF-PSF

The general principles guiding the treatment of patients with HF-PSF are to manage the presenting symptoms and to make the patient comfortable; define the etiology; plan long-term therapy — which entails discussions with the patient and education about the benefits of pharmacologic and nonpharmacologic therapy (e.g., exercise, treatment of sleep apnea); maintain atrial contraction; and avoid positive inotropic agents (e.g., dobutamine, milrinone, dopamine).

TABLE 3 Similarity of signs and symptoms in systolic heart failure and HF-PSF

	HF-PSF (ejection fraction >50%)	Systolic heart failure (ejection fraction <50%)
Dyspnea on exertion	85%	96%
Paroxysmal nocturnal dyspnea	55%	50%
Orthopnea	60%	73%
Jugular venous distension	35%	46%
Rales	72%	70%
Displaced apical impulse	50%	60%
S3	45%	65%
S4	45%	66%
Edema	30%	40%
Cardiomegaly	90%	96%
Pulmonary venous hypertension	75%	80%

HF-PSF=heart failure with preserved systolic function.
SOURCE: ZILE 2002A

It is important to learn the history of the patient's hypertension, including its duration, the drugs that have been used to treat it, how long those drugs have been used, and whether those drugs have been effective. If the hypertension is not controlled, treatment needs to be modified or initiated. If the blood pressure is controlled, left atrial pressures will come down. Likewise, if the patient has ischemic symptoms that have not been fully explored, it is important to investigate further, starting with a noninvasive assessment. Ischemia needs to be treated, and the progression of CAD must be prevented. CAD always should be considered when designing treatment strategies. For some heart failure patients, revascularization or statin therapy, or both, may be part of the treatment.

Echocardiograms are a most important tool for determining essential parameters related to heart failure, such as the presence of mitral regurgitation and the degree of remodeling. A noninvasive test to detect ischemia or coronary angiography may be warranted to rule out the presence of coronary disease as an etiology for HF. Myocardial biopsies are rarely needed, being reasonable only when the information will guide treatment decisions. The possibility of pericardial constriction or restrictive cardiomyopathy may need to be considered.

More specific goals for the treatment for HF-PSF are to reduce the congestive state, maintain atrial contraction when possible, reduce the heart rate, prevent progression of CAD, control hypertension and promote regression of hypertrophy, attenuate neurohormonal activation, and prevent fibrosis and promote its regression. Enhancing ventricular relaxation, though an appealing concept, has been less well proven as a treatment goal.

Relief of congestion. Reduction of congestion is pursued to make the patient comfortable. This is achieved through sodium and fluid restriction, diuretics as needed, ACE inhibitors, and dialysis or ultrafiltration when diuresis alone is not achieving the goal or if the renal function is impaired.

Atrial contraction. Atrial contraction should be maintained through direct current or pharmacologic cardioversion. If a pacemaker is required, it should be a sequential atrial ventricular (AV) pacemaker, because symptoms of HF may worsen if patients with HF-PSF receive a ventricular pacemaker alone (Wilkoff 2003).

Heart rate. Because tachycardia reduces diastolic filling time and reduces the time for coronary filling, patients with HF-PSF fare better in general with

lower heart rates. Bradycardia reduces oxygen demand and improves coronary perfusion, lowers diastolic pressure, increases the ventricular filling time, improves the force-frequency relationship, and enhances the coronary flow reserve. Beta blockers or non-dihydropyridine calcium channel blockers can be used to slow the heart rate, as can an AV pacemaker in conjunction with aggressive rate control medications or AV junctional ablation.

CAD. If patients have CAD, they should receive the usual treatments to prevent its progression, including statin therapy. If active ischemia is suspected, a noninvasive workup may be needed, followed by coronary angiography if the noninvasive testing is abnormal.

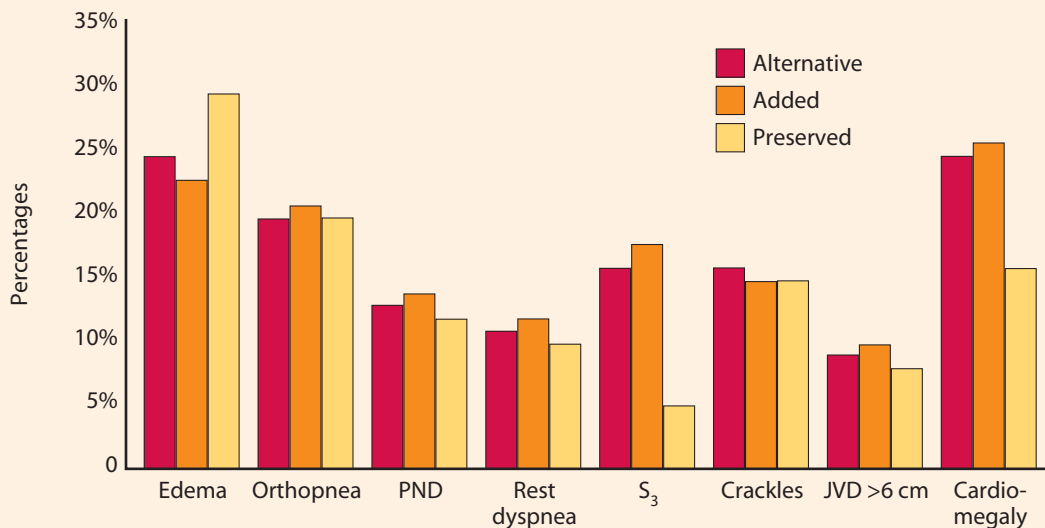
Hypertension. Control of hypertension is critical, especially in patients with diabetes. Often, patients with heart failure have blood pressures that are not well controlled and far beyond the guidelines issued by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure in its seventh report (JNC-7). Patients with diabetes should have their blood pressure controlled to less than 130/80 mm Hg. Some would say that CHF alone is justification for a lower target for BP control, although this more definitively applies to CHF with a low EF.

Hypertrophy. If the patient has LV hypertrophy, then therapy targeted at reversal of hypertrophy is warranted. Both ACE inhibitors and AT-II receptor blockers (ARBs) have been proven to reverse LV hypertrophy.

Neurohormonal activation. Attenuation of the neurohormonal cascade is important not only to control symptoms, but also to prevent disease progression. Beta blockers and ACE inhibitors are useful in this regard.

Fibrosis. This is an active process associated with ventricular remodeling. The activated neurohormonal sys-

FIGURE 2 CHARM trials: baseline signs, symptoms, and radiographic findings



JVD=jugular venous distension, PND=paroxysmal nocturnal dyspnea.
SOURCES: GRANGER 2003, MCMURRAY 2003, YUSUF 2003

tem is greatly responsible for interstitial fibrosis and collagen deposition. Aldosterone has been linked to increased fibrosis.

Drug therapy for HF-PSF

Patients being treated for heart failure typically take three or four drugs for their heart failure alone, beyond those they might require for diabetes, hypercholesterolemia, or other conditions. Eighty percent of heart failure patients are on two or more drugs for heart failure. Drugs employed in management of HF-PSF are similar to those used to treat systolic dysfunction and include ACE inhibitors, ARBs, beta blockers, calcium-channel blockers (which are not used in systolic heart failure), digoxin (for atrial fibrillation), diuretics, and spironolactone. The use of positive inotropic agents is discouraged, because they provide little or no benefit if the EF is preserved, and because long-term use may worsen the pathophysiological processes underlying diastolic heart failure (Zile 2002b).

ACE inhibitors. ACE inhibitors lower end diastolic pressures and, along with ARBs, have been proven to reverse LV hypertrophy. Unfortunately, ACE inhibitors still are underutilized and underdosed, primarily because physicians have the same fears today as they did when the first trials of ACE inhibitors were published in the early 1990s: that ACE inhibitors will result in overly low blood pressure, cough, or irreversible renal failure.

Beta blockers. Evidence that beta blockers are effective in reducing mortality among patients with New York Heart Association (NYHA) class II and class III heart failure comes primarily from patient populations with low

ejection fractions. Data are scarce for patients with preserved systolic function. Beta blockers, which slow the heart rate and treat ischemia, if present, are good antihypertensive agents. Although beta blockers must be titrated slowly and carefully in patients with systolic heart failure, this precaution usually is not necessary for patients with HF-PSF (Zile 2002b).

Diuretics. In general, diuretics are overused and overdosed in the treatment of HF-PSF. For a hospitalized patient, low doses given intermittently may work best to make the patient comfortable. Subsequently, the patient should be sent home on a flexible diuretic regimen.

Unless a patient is noncompliant with sodium restriction, diuretics are not always needed on a daily basis. Instead, patients can be instructed to follow the “rule of threes”—if they gain 3 pounds in 3 days, they should resume taking their diuretic.

Once patients have been hospitalized with acute pulmonary edema and have experienced a sudden sense of drowning, which is very frightening, they may become highly motivated to monitor their weight and to comply with diuretic therapy and restriction of sodium.

Prospective data from CHARM-Preserved. CHARM-Preserved is the only clinical trial that has generated prospective data for the HF-PSF population. CHARM (Candesartan in Heart failure Assessment of Reduction in Mortality and Morbidity) was a set of three randomized, placebo-controlled clinical trials enrolling a broad population of patients with symptomatic heart failure. Both the CHARM-Added and CHARM-Alternative trials enrolled patients with a depressed LVEF (≤ 40 per-

cent), while CHARM-Preserved enrolled patients whose LVEF was >40 percent. (The trials involving patients with systolic dysfunction are called Added and Alternative, because in the former, candesartan was used in addition to standard treatment, including ACE inhibitors, while the latter enrolled patients who could not tolerate ACE inhibitors.) Baseline signs, symptoms, and radiographic findings were similar for all three studies (Figure 2, page 14).

CHARM-Preserved enrolled patients with a mean age of 67 and a mean LVEF of 54 percent (Yusuf 2003). Forty percent of the subjects were female — twice the usual rate in a heart failure study. Sixty percent had NYHA class II heart failure; 38 percent had class III. Their medical histories included hypertension (64 percent), MI (44 percent), atrial fibrillation (29 percent), and diabetes (28 percent). Their baseline therapies included diuretics (75 percent), aspirin (58 percent), beta blockers (56 percent), lipid-lowering agents (42 percent), calcium channel blockers (31 percent), digitalis (26 percent), ACE inhibitors (19 percent), and spironolactone (12 percent).

Patients were randomized to placebo (n=1,509) or candesartan (n=1,514) at an initial dosage of 4 mg or 8 mg once daily, at the study physician's discretion. The dose was doubled every 2 weeks until a daily dose of 32 mg was attained. Patients were followed for a median of 37 months, with the primary outcome being cardiovascular death or hospitalization for heart failure. The primary outcome was reached by 24.3 percent and 22.0 percent of the placebo and candesartan groups, respectively, a relative risk reduction of 11 percent ($P=.51$). This benefit was due entirely to a reduction in the hospitalization rate in the candesartan group (Table 4, page 14), reflecting the relatively low cardiovascular mortality in

this population, compared with patients with systolic dysfunction. To put the CHARM mortality data in context, annual mortality rates in the general U.S. population for people ages 55 to 74 would be about 0.6 percent for cardiovascular causes and 1.7 percent for noncardiovascular causes.

Discontinuation that was due to any adverse event occurred in 17.8 percent of those patients who were receiving candesartan versus 13.5 percent of patients in the placebo group, with discontinuations occurring at a higher rate in the candesartan group as a result of hypotension (2.4 percent vs. 1.1 percent), increased creatinine (4.8 vs. 2.4 percent), and increased potassium (1.5 percent vs. 0.6 percent).

Conclusion

The CHARM-Preserved study provides the best prognostic information available to date about current therapy for HF-PSE. In this study, mortality generally was low, possibly because many patients were using lipid-lowering agents and beta blockers. That is, the CHARM-Preserved population may have been better medicated than the patients reported in various heart failure registries. This is purely speculative, however.

CHARM-Preserved provides the rudiments for developing guidelines for HF-PSE, but it is insufficient in itself for guiding therapy. The contribution of CHARM-Preserved is to show that blockade of the RAA system with the ARB candesartan reduces the rate of hospitalization in patients with HF-PSE. It does not clarify the utility of beta blockers, ACE inhibitors, or spironolactone in this population.

The usefulness of ARBs in this population will be further explored by the Irbesartan in Heart Failure with Preserved Systolic Function study (I-Preserve). In addi-

TABLE 4 Annualized incidence of deaths* and annual hospitalization rates in CHARM

	Total mortality	CV mortality	Non-CV mortality	HF hospitalizations (n=episodes)
CHARM-Alternative (N=2,028)				
Candesartan (n=1,013)	10.0 (n=265)	8.2 (n=219)	1.7 (n=46)	7.3% (n=207)
Placebo (n=1,015)	11.5 (n=296)	9.8 (n=252)	1.7 (n=44)	10.0% (n=286)
CHARM-Added (N=2,548)				
Candesartan (n=1,276)	9.8 (n=377)	7.9 (n=302)	2.0 (n=75)	7.1% (n=309)
Placebo (n=1,272)	11.1 (n=412)	9.3 (n=347)	1.8 (n=65)	8.2% (n=356)
CHARM-Preserved (N=3,023)				
Candesartan (n=1,514)	5.5 (n=244)	3.8 (n=170)	1.7 (n=74)	5.2% (n=241)
Placebo (n=1,509)	5.4 (n=237)	3.9 (n=170)	1.5 (n=67)	6.0% (n=276)

*Per 100 person-years.

CV=cardiovascular, HF=heart failure.

SOURCES: [MORTALITY DATA] SOLOMON 2004; [HOSPITALIZATION DATA] GRANGER 2003, MCMURRAY 2003, YUSUF 2003

tion, the National Heart, Lung, and Blood Institute has a trial in progress to evaluate an aldosterone inhibitor: Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist (TOPCAT). The goal of TOPCAT is similar to that of CHARM-Preserved — to determine whether spironolactone reduces the risk of cardiovascular death or hospitalization for heart failure. While the results of these trials are awaited, clinicians should continue to aggressively treat hypertension and ischemia and attempt to reverse LV hypertrophy in patients with HF-PSE.

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Multiple Benefits of Bariatric Surgery

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Bariatric surgery may be the most powerful surgical intervention developed in the last 50 years. It is the only surgery that can treat 15 different comorbidities associated with morbid obesity. Bariatric surgery also may prevent or delay the need for other surgeries, such as joint replacement or coronary artery bypass graft (CABG).

The comorbidities of severe obesity essentially run from head (stroke, pseudotumor cerebri, diabetic retinopathy) to toe (diabetic neuropathy, infections, venous stasis disease), and they affect every single organ in between. For any given organ, a comorbidity secondary to severe obesity can be named. Almost every one of these comorbidities can be completely reversed or significantly improved, however, if the patient's excessive weight can be shed.

The solution to the obesity epidemic afflicting this country is prevention, not surgery, but patients who already have developed severe obesity are beyond prevention and rarely achieve substantial weight loss through diet, exercise, or drug treatment. In the same sense that total hip or knee replacement is appropriate for a person with a dysfunctional joint, or that CABG is appropriate for a person with coronary artery disease, a morbidly obese person has a "broken" body in need of surgical repair. There is no study showing that any nonsurgical treatment for severely obese patients has long-term efficacy. Through bariatric surgery, however, severely obese patients can achieve dramatic weight loss while simultaneously resolving or improving comorbid conditions, as shown in a recent meta-analysis (Table).

Weight-loss surgeries may be divided into two broad categories: The malabsorptive procedures, which achieve weight loss purely or primarily via decreased small intestine absorption, and the restrictive procedures, which rely purely or primarily on decreased stomach capacity. The jejunoileal bypass was the first widely used weight-

reduction surgery, but it is no longer performed, because of severe complications that result from the blind loop constructed when the upper small intestine is joined to the lower small intestine. To avoid these problems, newer malabsorptive procedures have been developed—the biliopancreatic diversion (BPD) and the BPD with duodenal switch, but they are performed at relatively few centers. Nonetheless, these malabsorptive procedures may offer the best control of diabetes, the greatest weight loss, and perhaps the least long-term recidivism, attributes

that may make them appropriate for patients with supermorbid obesity (body mass index [BMI] >50.0).

The purely restrictive procedures include vertical banded gastroplasty and the laparoscopic adjustable gastric band (LAP-BAND, Inamed Health). The advantages of laparoscopic procedures are that they are cosmetically appealing and are associated with less pain and a lower rate of wound-related complications, such as severe infections and incisional hernias. On the other hand, surgeons have a steep learning curve before they become adept at laparoscopic procedures (Schauer 2003). Few surgeons perform all procedures well. A patient should select a

procedure on the basis of a thorough discussion of its risks and benefits, being mindful that the best procedure for the patient is the one in which the surgeon is the most competent—and that the surgeon may be unable to offer an unbiased assessment of his or her own skills. As in other surgeries, the greater the surgeon's experience with a given bariatric procedure, the lower the mortality and complication rates (Courcoulas 2003, Flum 2004, Liu 2003, Schauer 2003).

The greatest cause of mortality in bariatric surgery is a leak at the junction of the stomach and the small intestine, resulting in peritonitis. Such a leak requires immediate surgical treatment, but it often evades early diagnosis. One great advantage of a laparoscopic approach is that it facilitates detection and correction of the problem.



HARVEY J. SUGERMAN, MD

TABLE Risks and benefits of bariatric surgery

	Purely restrictive procedures		Primarily restrictive	Primarily malabsorptive
	Gastric banding (adjustable and nonadjustable) (%)	Gastroplasty (vertical banded gastroplasty) (%)	Gastric bypass (Roux-en-Y) (%)	Biliopancreatic diversion or duodenal switch (%)
Operative mortality (≤ 30 days)	0.1	0.1	0.5	1.1
Weight loss (mean change in percentage of excess weight)	47.5	68.2	61.6	70.1
Diabetes resolution	47.9	71.6	83.7	98.9
Hypertension resolution	43.2	69.0	67.5	83.4
Hypertriglyceridemia improvement	77.0	72.4	91.2	100.0
Hyperlipidemia improvement	58.9	73.6	96.9	99.1
Obstructive sleep apnea resolution	95.0	78.2	80.4	91.9

SOURCE: BUCHWALD 2004

The second leading cause of death in bariatric surgery is a pulmonary embolus. Super-obese males with venous stasis disease are at such high risk of pulmonary embolism that they probably should have a vena caval filter inserted. Although all these patients should be given anticoagulants, it is unknown if or for how long such therapy should be continued after discharge, because some of deaths occur after discharge.

Complications vary from procedure to procedure. With the duodenal switch, steatorrhea and malodorous stools are common. Concerns about the loss of fat-soluble vitamins arise with any malabsorptive procedure and lifelong supplementation is required. Inadequate calcium absorption, bringing with it the risk for osteoporosis and secondary hypothyroidism, is a problem with both the gastric bypass (GBP) and the duodenal switch, but it is not a concern with the adjustable gastric band, and nor is iron-deficiency anemia or vitamin deficiency. Weight loss may not be as great with the laparoscopic adjustable band, but the surgery is an extremely low-risk procedure. Persistent vomiting can be a complication of the laparoscopic adjustable band, along with gastroesophageal reflux. Reversal of gastroesophageal reflux occurs in almost all patients undergoing gastric bypass.

The risk of operative mortality from bariatric surgery needs to be placed within the context of the risk of mortality for severely obese patients who do not undergo weight-loss surgery. In a Canadian study, 1,035 severely obese patients who had bariatric surgery between 1986 and 2002 were followed for up to 5 years and compared with 5,746 severely obese patients matched for age and gender who did not undergo bariatric surgery (Christou 2004). The mortality rates were 6.17 percent and 0.68

percent in the control and surgery groups, respectively — a relative risk reduction of 89 percent. This study has been criticized on the grounds that the surgical patients may not have been appropriately matched with the controls, but this study is 1 of 3 to show a mortality benefit from weight-loss surgery.

In the Canadian study, patients in the treatment group also had a significantly reduced risk of cardiovascular disease, cancer, endocrinological disorders, infections, musculoskeletal disorders, and respiratory disorders. These multiple benefits also carried a financial benefit: the cost of surgery was amortized at 3.5 years.

Sleep apnea. In *The Pickwick Papers* (1837), Dickens described the character Joe as a “fat and red-faced boy in a state of somnolence.” Joe was wont to fall asleep while driving his master around, and once fell asleep while knocking on a door. Borrowing from Dickens, Sir William Osler coined the term *Pickwickian Syndrome* in 1918 to describe obese, hypersomnolent patients. Joe has real-life counterparts, most famously a rotund 51-year-old business executive who fell asleep during a poker game — while holding three aces and two kings, a full house. Standing 5 feet, 5 inches tall, he had gained considerable weight during the past year and weighed 260 pounds at the time of this incident. Thus, his BMI was 43. (A BMI of 18.5 to 24.5 is considered normal, 25.0 to 29.9 is considered overweight, and 30.0 and above is considered obese. According to NIH guidelines, a person is eligible for bariatric surgery at a BMI of 35 to 39 if a comorbidity is present or at a BMI ≥ 40 even without a comorbidity, which rarely occurs.)

He previously had experienced brief episodes of fainting and had developed persistent edema of the ankles, but it took this kind of grievous misfortune at the card table

to prompt him to seek medical care. In the hospital he was found to have hypoxemia, hypercarbia, and heart failure in addition to daytime somnolence, a constellation of signs and symptoms that in a famous case report was referred to as the Pickwickian Syndrome (Bickelmann 1956).

In my practice I have had a similar case, a cab driver named Greg. In 1981, Greg was 6 feet 2 inches tall and weighed 580 pounds (BMI of 74). As a result of his daytime somnolence, he had wrecked five taxis. When I met him, he was on a ventilator in the intensive care unit. He had obesity hypoventilation, extremely high pulmonary artery and wedge pressures, and sleep apnea. Had I not performed gastric bypass surgery for Greg in 1981, he no doubt would have died within 1 or 2 years. Today, 24 years after his surgery, he weighs 211 pounds — and he no longer falls asleep at the wheel of his taxi.

In general, patients with mild to moderate sleep apnea (respiratory disturbance index [RDI] <40) experience complete resolution of sleep apnea within 6 months of GBP, and patients with severe sleep apnea (RDI >40) experience significant improvement within 1 year of the surgery (Charuzi 1985, Sugerman 1992).

Pseudotumor cerebri. A condition that is underdiagnosed among the morbidly obese is pseudotumor cerebri (PTC), characterized by pulsatile tinnitus and constant severe headaches, which are worst on awakening. Definitive diagnosis of PTC necessitates a spinal tap, the only way to measure the pressure of cerebrospinal fluid (CSF).

PTC also is known as idiopathic intracranial hypertension, but the condition no longer need be considered idiopathic, because we have established its probable etiology as increased intra-abdominal pressure associated with central obesity (Sugerman 1999). Because of pressure on the cranial nerves, many patients also have cranial nerve palsies (e.g., visual field cuts, Bell's palsy, tic dolo-reux).

After surgically induced weight loss, cranial palsies diminish due to reduced CSF pressure, and there is a significant decrease in pulsatile tinnitus (Michaelides 2000) and headache (Sugerman 1999).

Type 2 diabetes. The longer patients are severely obese, the more likely they are to develop type 2 diabetes. The longer the diabetes is present, the less likely the patients are to respond favorably to surgery and the more likely they are to develop diabetic complications such as neuropathy, retinopathy, nephropathy, and peripheral vascular disease. Numerous studies have documented the efficacy of bariatric surgery for type 2 diabetes, and a meta-analysis has found that diabetes was completely resolved in 77 percent of patients and resolved or improved in 86 percent (Buchwald 2004). No other therapy is as effective in achieving control of type 2 diabetes and as complete and long-lasting (Pories 1995).

Hypertension. Weight-loss surgery has been shown to lead to resolution of hypertension or a significant decrease in medications for systemic hypertension in two thirds to three quarters of patients (Carson 1994, Foley 1992). In the Swedish Obese Subjects Study (SOS), control of hypertension was lost after 8 years, but in that study 94 percent of patients had some form of purely gastric-restrictive procedure. Among the 6 percent who had a gastric bypass, significant reductions in both systolic and diastolic blood pressure were retained after 8 years. After 10 years, control no longer was evident (Sjöström 2004), but the lead author of the study believes it was because of a type 2 statistical error, as only 34 patients who had undergone a gastric bypass were available for 10-year follow-up.

Dyslipidemia. Bariatric surgery, notably gastric bypass, leads to dramatic improvements in the control of dyslipidemia, and the effects are long-lasting. Triglyceride levels decrease and HDL-cholesterol concentrations increase while LDL levels decrease, resulting in an improved HDL:LDL ratio. In one study, 38 of 151 consecutive patients undergoing bypass had elevated serum total cholesterol or elevated triglycerides, or both, and lipid profiles were normal in 32 of these patients (84 percent) 6 months after surgery (Brolin 1990). In another study, sustained improvements in lipid profiles and other coronary risk factors were noted 5 to 7 years after Roux-en-Y gastric bypass (Gleysteen 1990). In the SOS, sustained triglyceride and HDL improvement after 2 years was noted (Sjöström 1999), but cholesterol control was not significant after 10 years (Sjöström 2004), probably due to the low percentage of patients (6 percent) in this study who had undergone gastric bypass, the most effective procedure for improving lipid levels.

Polycystic ovary syndrome and pregnancy complications. Bariatric surgery enables women to resume menstrual regularity, and it increases their fertility. Patients are instructed to avoid pregnancy during the first year after bariatric surgery, as pregnancy during a time of rapid weight loss is inadvisable. Women who become pregnant after bariatric surgery experience decreased rates of pregnancy complications (Bilenka 1995, Dixon 2001, Richards 1987).

GERD/asthma. Bariatric surgery improves gastroesophageal reflux disease (GERD) (Frezza 2002, Smith 1997), even in patients who are less than morbidly obese (Jones 1998), and asthma (Dixon 1999, Macgregor 1993), the latter most often being a complication of GERD.

Joint pain and lower back pain. Compared with conventional obesity treatment, bariatric surgery makes it more likely that obese patients will recover from joint pain and have a reduced long-term risk of developing work-restricting musculoskeletal pain (Peltonen 2003). Because of excessive weight, morbidly obese patients are poor candidates for joint replacement. Yet, patients who

have lost weight through bariatric surgery can undergo total hip and knee arthroplasties with excellent outcomes and acceptable complication rates (Parvizi 2000).

Lower back pain is another complication of morbid obesity. Weight-loss surgery can diminish lower back pain and even lead to its disappearance (Melissas 2003).

NALD/NASH. Nonalcoholic fatty liver disease (NALD) is very common in morbidly obese patients, and a significant subset of these patients also have non-alcoholic steatohepatitis (Ong 2005), which has the potential to advance to cirrhosis. Whereas early malabsorptive procedures led to weight loss but often worsened steatohepatitis and fibrosis, contemporary bariatric procedures been shown to cause regression of NASH (Luyckx 1998, Ranlov 1990, Silverman 1995) and even reverse liver fibrosis (Kral 2004).

Quality of life. Numerous studies have documented an improvement in quality of life (QOL) following bariatric surgery, and it has been argued that improved QOL by itself justifies bariatric surgery for severely obese patients (Kral 1992). In some instances, patients who have had successful weight-loss surgery even exceed the normal population in some QOL measures (Choban 1999).

Improvements become apparent within a few weeks after surgery (Dymek 2002), and they tend to persist. In the SOS after 2 years of follow-up, the greater the weight loss, the greater the improvement in QOL (Karlsson 1998). In a group of patients who had undergone gastric bypass a mean of 13.8 years previously, QOL was significantly better than that in a control group and most of the bypass patients' subscales were similar to most U.S. norm values (de Zwaan 2002).

Centers of Excellence

Because of anecdotal reports of bariatric surgery deaths, the American Society for Bariatric Surgery (ASBS) has established a Centers of Excellence program through the independent, not-for-profit Surgical Review Corporation (SRC). A board of governors representing stakeholders provides oversight of SRC. The board comprises up to 15 members and currently consists of four bariatric surgeons, two nonsurgeon professionals practicing in the health care industry, two members of the health insurance industry, a former bariatric surgery patient, and the current president of the ASBS Corporate Council.

Any surgeon, surgical practice, or hospital in the United States or Canada that provides bariatric surgical services may submit applications. Thus far, more than 500 centers and 900 individual surgeons have sought provisional approval and 150 centers and 225 surgeons have sought full approval. For provisional approval, the application fees are \$5,000 and \$500 for a hospital and a surgeon, respectively. Full approval requires an addi-

tional fee of \$10,000 by the center and \$1,000 by the surgeon.

Among the criteria for provisional approval as a Center for Excellence is the expectation that an applicant institution will perform at least 125 bariatric cases per year and that a bariatric surgeon will perform at least 50 cases per year. The applicant also must provide a full complement of consultative services and immediate availability of in-house critical care services. The applicant must have monitoring and tracking systems in place to provide follow-up for 75 percent of patients at 5 years.

The granting of provisional status indicates that the SRC is confident that an applicant possesses the resources to provide safe and effective bariatric surgery; full approval indicates that the SRC believes an applicant possesses the experience to do so, on the basis of a review of outcomes, which includes a site visit. The first centers will be granted full approval in the summer of this year. Contracts are being developed between the SRC and health insurance plans.

Barriers to bariatric surgery

As the benefits of bariatric surgery have become better understood, and as surgeons have increased their skill and experience levels with laparoscopic procedures, the number of bariatric surgeries has increased by 40 percent annually in each of the past 5 years. During the 5-year period ending in 2002, the number of bariatric surgeries performed in the United States increased by 436 percent, from an estimated 13,386 to 71,733 (Encinosa 2005). During this period, outcomes improved substantially as surgeons gained experience and overall quality of care associated with bariatric procedures improved: the length of stay declined by 24 percent, from 4.99 to 3.80 days, and the inpatient mortality rate declined by 64 percent, from 0.89 to 0.32 percent. In a nationwide sample of patients with employer-sponsored health insurance, the 2002 average total payment for bariatric surgery, including hospital, physician, and the patient's out-of-pocket payments, was \$19,346, of which 97 percent was borne by health plans.

The 2002 surgeries were performed in only 6 percent of the 11.5 million adults clinically eligible for bariatric surgery, so there is substantial room for increased utilization. Yet, despite the numerous benefits of bariatric surgery, some health plans still erect barriers for patients considering weight-loss surgery. In Texas, a 6-month to 1-year weight-loss program supervised by a physician or a physician assistant is mandatory before bariatric surgery can be performed. Some health plans require riders for bariatric surgery, while others deny coverage, claiming the procedure to be dangerous, ineffective, or experimental. They apparently place no stock in studies that find bariatric surgery to be clinically effective (Buchwald 2004, Maggard 2005) or even cost-effective (Chris-

tu 2004, Clegg 2003, Craig 2002, Fang 2003). Nonetheless, these same health plans provide coverage for numerous other surgeries that, in my view, are clearly inappropriate in severely obese patients — Nissen fundoplication for GERD, bladder suspension for urinary incontinence, lumboperitoneal shunts for pseudotumor cerebri, uvulopalatopharyngoplasty for sleep apnea, split-thickness skin graft for venous stasis ulcers, lumbar disc surgery for lower back pain, and joint replacement for degenerative joint disease.

Conclusion

Bariatric surgery saves lives, decreases comorbidities associated with severe obesity, and improves patients' QOL. Through the ASBS Centers of Excellence Program, we hope to obtain data on 40,000 patients per year to determine which procedure is best for which patient. Health plans that deny bariatric surgery for their severely obese members prevent these patients from receiving the single treatment that is most likely to lead to substantial improvements in all realms of living.

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Evolving Perspectives On Disease Management

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Disease management is one tool for improving the quality of health care. This article will focus on cardiovascular disease management, citing the experience of a large Midwestern practice after first placing it in the context of general recommendations for improving health care and specific recommendations for pursuing disease management.

In *Crossing the Quality Chasm*, the Institute of Medicine issued six broad recommendations for improving the quality of health care in the United States (Table 1). More recently, the American Heart Association (AHA) drew up a set of nine principles to enhance disease management (Table 2), which provide a tool with great potential to improve health care for chronically ill patients. In general, the AHA's principles for disease management expand on the six characteristics of an improved health care system as mentioned in the Institute's second recommendation — that a health care system offer health care that is safe, effective, patient-centered, timely, efficient, and equitable.

The AHA defined disease management as “multidisciplinary efforts to improve the quality and cost-effectiveness of care for selected patients suffering from chronic conditions” (Faxon 2004). The AHA noted: “Disease management strategies may address any aspect of the full spectrum of prevention and treatment options for cardiovascular disease and stroke, including primary prevention, secondary prevention, and rehabilitation.”

The AHA's interest in disease management was spurred by the success of heart-failure programs around the country, in which non-physician-centric care facilitated improvements in the delivery of health care to this important high-cost subpopulation. The desire to control costs while improving quality appeals to both the

public and private sectors. Congress has authorized several demonstration projects and pilot programs, including the Medicare Capitation Disease Management Demonstration, the Medicare+Choice Benefits Improvement and Protection Act (BIPA) Disease Management Demonstration, the Medicare Coordinated Care Demonstration, and the Chronic Care Improvement Program.



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Chronic care improvement program

The Chronic Care Improvement Program (now called Medicare Health Support) is a pilot program authorized under Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Disease management lobbyists were extremely effective in making the case for this program to members of the House Ways and Means Committee in an effort to have it included in the MMA. Nine sites nationwide have been selected for phase 1, a 3-year trial of the concept (Table 3, page

24), after which nationwide expansion of the program or successful components may begin in phase 2, as the Secretary of Health and Human Services sees fit.

Phase 1 is essentially a set of randomized, controlled trials in which 180,000 Medicare beneficiaries with heart failure or complex diabetes, or both, will be randomized to an intervention or control group. These conditions were selected because they account for a disproportionate share of costs in the Medicare population. Heart failure accounts for about 43 percent of Medicare spending, but the condition is found in only 14 percent of Medicare beneficiaries. Likewise, diabetes accounts for 32 percent of Medicare spending but is found in only 18 percent of beneficiaries. Among the goals of the program are to reduce unnecessary hospitalizations and emergency department visits; to reduce the rate of costly and debili-

tating complications; and to promote evidence-based care.

Participating organizations will receive a monthly fee for each beneficiary, but their fee will be at risk if the organization fails to meet agreed-on standards for quality improvement, patient satisfaction, and savings to Medicare (contractors are required to demonstrate net savings of at least 5 percent). Medicare Health Support ultimately will help determine whether the disease management techniques employed in commercial populations also are effective in the Medicare population, where beneficiaries are more likely to be poor, frail, and cognitively impaired.

Experience at Midwest Heart Specialists

With 56 physicians, Midwest Heart Specialists (MHS) is one of the largest private-practice cardiology groups in the country. Our cardiologists work from 7 main offices and 12 satellite offices in suburban Chicago and are affiliated with 11 hospitals. As cardiology has evolved during the past 15 years, we have assumed a significant burden of managing the chronic diseases surrounding our patients' cardiovascular conditions, be they hypertension, hyperlipidemia, or diabetes. We also pay increased attention to early detection and primary prevention of these conditions.

In 1996–1997, MHS participated in the Quality Assurance Program, a nationwide study sponsored by Merck and involving a review of the records of 48,807 patients with diagnosed coronary disease at 140 medical practices (cardiology, 80 percent; primary care, 20 percent). The study determined whether the LDL-cholesterol level was recorded in a patient's chart, whether the patient was on a lipid-lowering drug, and whether the patient was at goal. The nationwide results were dismal: only 44 percent of patients had a documented LDL-C level, only 39 percent were on a lipid-lowering drug — and only 11 percent were at goal. At MHS, where we prided ourselves on the quality of our care and where we thought we were doing a good job, the numbers were not much better than the

TABLE 1 Recommendations for improving quality of health care

1. Health care system should adopt as its explicit purpose the continual reduction of the burden of conditions for the people of the United States
2. Health care system should pursue safe, effective, patient-centered, timely, efficient, and equitable health care
3. Congress should authorize and appropriate funds for monitoring and tracking processes to evaluate health systems against these criteria
4. Health care system should redesign itself, incorporating concepts such as patient empowerment, evidence-based decision making, shared knowledge, and cooperation among clinicians
5. Agency for Healthcare Research and Quality and National Quality Forum should convene stakeholders to develop strategies, goals, and action plans for achieving substantial improvements in quality in the next 5 years for 15 priority conditions*
6. Congress should establish a Health Care Quality Innovation Fund to produce a public-domain portfolio of programs, tools, and technologies of widespread applicability.

*Cancer, diabetes, emphysema, high cholesterol, HIV/AIDS, hypertension, ischemic heart disease and stroke, arthritis, asthma, gall bladder disease, stomach ulcers, back problems, Alzheimer's disease and other dementias, and depression and anxiety disorders.

SOURCE: IOM 2001

TABLE 2 American Heart Association's guiding principles for disease management initiatives

1. The main goal of disease management (DM) should be to improve quality of care and patient outcomes.
2. Scientifically derived, peer-reviewed guidelines should be basis of all DM programs. Guidelines should be evidence-based and consensus-driven.
3. DM programs should help increase adherence to treatment plans based on the best available evidence.
4. DM programs should include consensus-driven performance measures.
5. All DM efforts must include ongoing and scientifically based evaluations, including clinical outcomes.
6. DM programs should exist within an integrated and comprehensive system of care in which patient-provider relationship is central.
7. To ensure optimal patient outcomes, DM programs should address complexities of medical comorbidities.
8. DM programs should be developed for all populations and should particularly address members or underserved or vulnerable populations.
9. Organizations involved in DM should scrupulously address potential conflicts of interest.

SOURCE: FAXON 2004

national averages: 47 percent with LDL-C level in the chart, 51 percent on lipid-lowering therapy, 22 percent at goal (Brown 2003). Nevertheless, in a lipid clinic that we maintained for high-risk patients, the performance was far better (best in the country, in fact): 97 percent with documented LDL, 97 percent on lipid-lowering therapy, and 71 percent at goal.

Unfortunately, we could not hire the additional 70 nurses who would be needed to help manage the other 35,000 patients in our practice who were on lipid-lowering therapy. Hence, we turned to the computer for assistance, using the electronic medical record (EMR) as the tool to make it easier for the point-of-care physician to care for the patient. We began installing our information technology infrastructure in 1997 and have been improving it ever since. In early 2000, we began developing virtual specialty clinics for cholesterol, hypertension, and heart failure. In addition to integrating hospital records into the system, we are in the midst of developing a process to allow monitoring data collected in patients' homes to be incorporated into their EMRs.

During the first year that our new EMR system was in operation, we tracked 11,263 consecutive patients, of whom 81 percent had a documented LDL, 72 percent were on lipid-lowering therapy, and 54 percent were at goal. At the 20,000-patient point, LDL-C documentation was at 84 percent, and 60 percent of our patients were at goal. To estimate the effects of that achievement among the 2,368 additional patients newly at goal, we turned to results of the Scandinavian Simvastatin Survival Study (Pedersen 1996) as the basis for our calculations. This study enrolled middle-aged men and women at high risk of a cardiovascular event (the subjects had angina or previous myocardial infarction (MI), and LDL-C levels ranging from 215 to 312 mg/dL). We estimated that in our practice, which numbered about 40 physicians at the time, getting 60 percent of patients to their LDL-C goal resulted in 78 fewer deaths, 158 fewer heart attacks, 38 fewer strokes, 532 fewer hospitalizations, 135 fewer bypass surgeries, and \$1.7 million in hospitalization costs avoided.

When medications are recalled, our electronic database facilitates the rapid notification of our patients. For example, when cerivastatin (Baycol) was recalled, within 12 hours of learning about the recall we had identified the 988 patients who were on the drug and had notified their primary care physicians. Similarly, when troglitazone (Rezulin) was withdrawn from the market, we called 200 patients within a period of 4 hours because we had the information in the EMRs, despite the fact that our physicians did not prescribe troglitazone themselves. When rofecoxib (Vioxx) was withdrawn, the EMRs showed that 1,800 of our patients were on that medication. Without the electronic database, it would have been extremely difficult to identify and contact these patients in a timely fashion.

TABLE 3 Medicare Health Support pilot programs

Organization	Location
Aetna Health Management	Chicago
American Healthways	Washington, D.C. and Maryland
CIGNA HealthCare	Georgia
Health Dialog Services	Pennsylvania
Humana	Central Florida
Lifemasters Supported SelfCare	Oklahoma
McKesson Health Solutions,	Mississippi
Visiting Nurse Service of New York	NYC: Queens and Brooklyn
Home Care and United HealthCare Services Evercare	
XLHealth	Tennessee

SOURCE: CMS 2005

Performance measures

Our most recent initiative involves practicewide performance measures as we pursue improvement of our disease management programs (Table 4). Collecting information from the EMRs allows us to send quarterly report cards via email to each physician, showing physicians their individual level of performance and how it compares with that of the group.

For all patients, we track whether the blood pressure is less than 140/90 mm Hg and whether the patient smokes and, if so, whether that patient has received education about smoking cessation.

For heart failure patients, we can track whether the patient is receiving an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB), or both; whether a beta blocker is being used if the patient has left ventricular systolic dysfunction or an ejection fraction less than 40 percent; whether the ejection fraction has been recorded; and whether the New York Heart Association class is in the record.

For patients with coronary artery disease, we can track whether the patient is receiving antiplatelet therapy. If the patient has diabetes, left ventricular systolic dysfunction, or an ejection fraction less than 40 percent, we monitor utilization of an ACE inhibitor or an ARB, or both. If the patient has a prior MI, we record beta-blocker utilization. We also can monitor whether the LDL-C level has been recorded; whether the LDL-C level is greater than 100 mg/dL; greater than 100 mg/dL, despite lipid-lowering therapy; less than 100 mg/dL; or less than 70 mg/dL.

Lower LDL-C is better

Our interest in tracking patients who achieve LDL-C levels less than 70 mg/dL stems from recent research that led to an update of the national cholesterol guidelines; in that update, a goal of 70 mg/dL is recommended as an

TABLE 4 Medicare Health Support performance measures, January 2004 through March 2005

	Q1 2004	Q2 2004	Q3 2004	Q4 2004	Q1 2005
All patients					
Total visits	11,902	12,288	13,203	13,262	12,706
Coronary artery disease	55.2%	55.5%	54.1%	53.6%	50.9%
Heart failure	27.5%	27.5%	25.4%	25.0%	23.6%
Blood pressure <140/90 mm Hg	61.0%	64.3%	64.9%	62.8%	63.2%
Current smoker	7.4%	8.6%	8.2%	8.6%	9.8%
Advised to quit smoking (goal 90%)	14.5%	16.0%	33.2%	39.8%	52.3%
Height documented (goal 98%)	61.1%	67.4%	69.2%	68.9%	70.0%
Weight documented (goal 98%)	98.2%	97.7%	98.1%	97.2%	98.1%
Coronary artery disease patients					
Total patients	6,570	6,820	7,042	7,107	6,473
Antiplatelet therapy	91.6%	91.5%	92.2%	91.9%	93.1%
ACE inhibitor with DM and/or LVSD (goal 90%)	79.2%	81.0%	78.8%	80.9%	82.6%
Beta blocker if prior MI (goal 90%)	77.3%	77.1%	78.9%	79.9%	83.0%
LDL-C in last year (goal 90%)	77.4%	79.5%	78.4%	80.6%	80.2%
LDL-C <100 mg/dL (goal 85%)	70.0%	71.8%	74.7%	75.3%	76.2%
DM screen for non-DM patients (goal 95%)	61.8%	65.3%	64.2%	65.3%	84.4%
EF documented (goal 90%)	52.5%	54.6%	58.7%	62.0%	76.3%
Heart failure patients					
Total patients	3,128	3,222	3,304	3,310	2,999
ACE inhibitor (goal 90%)	86.3%	87.6%	85.3%	86.7%	86.4%
Beta blocker (goal 85%)	78.1%	77.9%	78.8%	82.8%	87.3%
EF documented (goal 90%)	60.2%	62.6%	65.3%	68.4%	80.9%

ACE=angiotensin-converting enzyme, DM=disease management, EF=ejection fraction, LVSD=left ventricular systolic dysfunction, MI=myocardial infarction.

SOURCE: O'TOOLE 2005

optional goal for patients at particularly high risk (Grundy 2004).

Issued in 2001, the third report of the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP-3) matches a patient's LDL-C goal to the patient's estimated 10-year risk of a major cardiovascular event. For patients at the highest risk, ATP-3 recommends that LDL-C be less than 100 mg/dL (which also is described as the optimal level for everyone). Patients in this group include those with CAD or conditions posing an equivalent risk, namely, diabetes, peripheral arterial disease, abdominal aortic aneurysm, symptomatic carotid artery disease, or multiple risk factors conferring a 10-year risk exceeding 20 percent.

For patients at the lowest risk (no more than one risk factor), the recommended LDL-C level is under 160 mg/dL. If the risk is moderate (two or more risk factors, and a 10-year risk less than 20 percent), the LDL-C goal is less than 130 mg/dL. Note that the LDL-C level of less than 100 mg/dL set by ATP-3 as the goal for high-risk patients represented not the point at which maximal benefit was believed to be possible, but was the level sup-

ported by clinical evidence available at the time and also was the practical limit possible with the available therapies (Grundy 2004).

Since 2001, when the ATP-3 guidelines were issued, evidence from clinical trials suggests that some patients benefit from reaching an LDL-C goal well below 100 mg/dL. These studies include the Heart Protection Study (HPS), PROVE-IT, and Treating to New Targets (TNT).

Heart Protection Study. HPS was a 5-year study in the United Kingdom that enrolled 20,536 adults at high risk of a cardiovascular event due to coronary heart disease, peripheral vascular disease, diabetes, or hypertension (HPS 2002). Patients were randomized to simvastatin 40 mg or placebo. Compared with the placebo group, patients treated with simvastatin showed a 13 percent reduction in all-cause mortality, a 24 percent reduction in major vascular events, a 27 percent reduction in major coronary events, a 25 percent reduction in stroke, and a 24 percent reduction in revascularization procedures. HPS was the first study to show risk reduction at LDL-C levels below 100 mg/dL. Risk reduction was seen at all levels of baseline LDL. Even among patients whose LDL-C

was less than 100 mg/dL at baseline, a 22 percent reduction in relative risk was observed.

PROVE-IT. In the Pravastatin or Atorvastatin Evaluation and Infection — Thrombolysis in Myocardial Infarction 22 study (PROVE-IT), 4,162 high-risk patients (those who had been hospitalized for an acute coronary syndrome within the preceding 10 days) were randomized to treatment with pravastatin 40 mg or atorvastatin 80 mg (Cannon 2004). The manufacturer of pravastatin sponsored the trial, with the intent to show that pravastatin was not inferior to atorvastatin, but that hope was not realized.

At baseline, median LDL-C levels were 106 mg/dL, but after follow-up of a mean 2 years, median LDL-C levels fell to 95 mg/dL and 62 mg/dL in the pravastatin and atorvastatin groups, respectively. The risk of reaching a composite endpoint (all-cause death, MI, unstable angina requiring hospitalization, revascularization, or stroke) was reduced by 16 percent in the atorvastatin group relative to the pravastatin group. The benefit was considerably greater among subjects whose baseline LDL-C was 125 mg/dL or higher (34 percent reduction) than it was in those whose baseline LDL-C was less than 125 mg/dL (7 percent reduction).

Treating to New Targets. TNT was the first randomized trial designed to demonstrate the benefits of lowering LDL-C to concentrations below 100 mg/dL in patients with stable CHD. In this study, patients with stable CHD and LDL-C levels between 130 and 250 mg/dL (mean, 152 mg/dL) first went through an 8-week run-in period with atorvastatin 10 mg, after which 10,003 patients whose LDL-C had been reduced to below 130 mg/dL (mean, 98 mg/dL) were randomized to atorvastatin 10 mg or atorvastatin 80 mg (LaRosa 2005).

During the study, the mean LDL-C levels attained in the atorvastatin 10 mg and 80 mg group were 101 mg/dL and 77 mg/dL, respectively. The primary outcome measure was occurrence of a major cardiovascular event (death from coronary heart disease, nonfatal MI, resuscitation after cardiac arrest, or fatal or nonfatal stroke). This endpoint was attained by 10.9 percent of the atorvastatin 10 mg group and 8.7 percent of the atorvastatin 80 mg group, a relative risk reduction of 22 percent. Although there was no difference in all-cause mortality between the two treatment groups, the incremental benefits observed with atorvastatin 80 mg included significant reductions in the risk of coronary events and stroke in a population currently perceived to be well controlled at levels around 100 mg/dL.

Conclusion

The experience of a Midwestern cardiology group shows that the principles of disease management can be applied to a local population, and that electronic medical records can help physicians pay more heed to those

performance measures that are thought likely to result in improved outcomes for patients with heart failure or coronary artery disease. One performance measure in particular that may be extremely important for high-risk patients is the percentage who achieve an LDL-C level below 70 mg/dL.

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DISCUSSION

QUESTION: Would you address disease reversal?

VINCENT J. BUFALINO, MD: Nissen's work¹ showed that plaque regression on intravascular ultrasound was significant when LDL was lowered aggressively with

¹ Nissen SE, Tuzcu EM, Schoenhagen P, et al.; REVERSAL Investigators. Effect of intensive compared with moderate lipid-lowering therapy on progression of coronary atherosclerosis: a randomized controlled trial. *JAMA*. 2004;291:1071–1080.

atorvastatin 80 mg, compared to moderate lipid-lowering with pravastatin 40 mg. A study of interest in this area is Brown's work², a 3-year trial of patients with nonobstructive disease, where they did a catheterization, used rigorous therapy, and brought patient LDLs to the 80 to 90 mg/dL range, and then repeated their angiograms at 3 years. The investigators showed that 50 percent of patients had no change in disease, and 30 percent had plaque reduction. We've since had more data demonstrating that in the majority of cardiovascular patients, we can either maintain or improve the level of disease by taking their LDLs down. So, where we are philosophically is that we need statins in the drinking water, with the exception of the few patients with intolerance. Very few patients in our practice are not on a statin.

QUESTION: How low do you have to bring the LDL to stop progression in a high-risk patient with coronary artery disease, and how low do you have to go to start reversal?

BUFALINO: The clinical trials tell us that 70 mg/dL probably will be a new target. If the rate of coronary events is better at 70 or less, it's likely that it's because we're stabilizing plaque. Anecdotally, we're seeing fewer acute infarctions, possibly because many of these patients are on aspirin and a statin, and they're getting plaque stabilization and less plaque rupture. Most of those acute events are obviously plaque rupture; 60 or 70 percent of the people have an acute event with less than 60 or 70 percent obstruction. The problem is finding those with 30 and 40 percent obstructed lesions who climb a mountain or take a bike ride and then collapse. My bias is that ultra-fast CT will help with that, and also with looking at regression.

QUESTION: What about the person with no risk factors but elevated LDLs?

BUFALINO: There is a small subgroup of people, wherein the only risk factor is hyperlipidemia, and they have a Framingham risk of less than 10 percent. The guidelines say to bring LDL to 130, but 100 probably is where that is headed.

QUESTION: What about the next level?

BUFALINO: Somebody with a 10 to 20 percent risk certainly should get to under 100.

QUESTION: From a cost perspective, there is movement toward generics. What's your opinion on this?

BUFALINO: Generic lovastatin works, but it's probably not strong enough for most patients, especially when targeting levels of 70 mg/dL. Atorvastatin and rosuvastatin are used more often, because they're stronger. The first generation of statins was good, but looking at the number of patients I had on pravastatin and lo-

vastatin 5 years ago compared to today, it was 60 or 70 percent then and just 10 or 20 percent now, because they're not working.

QUESTION: How did you decide on which electronic record and on which vendor to use?

BUFALINO: We were seeking a new billing system. An electrophysiologist on our staff volunteered to spend 3 or 4 months evaluating various systems for electronic tracking. In California, he found a simple patient billing system containing an electronic record. We began working with the manufacturer to tweak our office system, which was basically a generic one. Ours is a blended system. Our dictation goes to central transcription for insertion in the EMR. So, I just dictate the three sentences, and that becomes the electronic note.

QUESTION: Do you get a break from your malpractice carrier for electronic records?

BUFALINO: We have presented this to the local plans, and our contracted rates are better because we've been able to show them the data. We've been able to show them that we're not just another five-physician practice on the corner. This is a way to prove we're better, so we continue to push this on our carrier.

QUESTION: What part of the electronic record improves quality of care? We've considered electronic notes, intelligent decision-making aids like clinical reminders, and physician order entry to prevent errors.

BUFALINO: I don't think we would use decision-making support. We are taking the pens out of doctors' hands and we dictate the progress notes daily. The nurse can read the notes, which in itself is a significant improvement.

This system allows us to measure, so we can provide feedback. Doctors inherently want to do a good job, and if you give them the data to demonstrate how they are doing, that's valuable. We're providing feedback at the hospital level, in terms of core measures. We're getting measurement by doctor and by case. So, perhaps, when a patient returns, or when the next patient comes in, the physician will make the necessary change.

Physician order entry works well at a university center where there are residents in training programs, but clicking through countless screens to input orders is too much. Yet we have many protocols for which we have standing orders; if you can just input those order sets, it is much easier.

Also, we depend on advanced practice nurses in the office and the hospital, who can input the data, allowing me to move onto the next patient. But for me, to do this all by myself, I'm still not ready to jump in with the Leapfrogs — because I don't buy it, frankly.

² Brown BG, Zhao XQ, Chait A, et al. Simvastatin and niacin, antioxidant vitamins, or the combination for the prevention of coronary disease. *N Engl J Med.* 2001;345:1583–1592.

Better Outcomes Through Health And Productivity Management

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In 2005, the United States is projected to spend nearly \$2 trillion for health care, which averages to more than \$6,400 per person (Heffler 2005). Through employer-provided health benefits, employers pay for more than a third of these costs, and the premiums for employer-provided health benefits have increased by double digits in each of the past 4 years. From the employers' perspective, the salient question focuses on why they should continue to provide such benefits rather than turning health insurance over to some national system. The reason it makes sense for employers to continue to have direct involvement in promoting their employees' health is that workers' health affects their productivity, which in turn affects the organization's performance and competitiveness. This article reviews the evidence we have published recently to support employers' continued engagement in managing employee health and productivity.

Today's new employee is a knowledge worker, not a

manufacturing worker, and productivity is at an all-time high, holding steady after years of impressive increases. The contemporary business environment is characterized by outsourcing, downsizing, layoffs, and reductions in force; mergers, acquisitions, and consolidations; global competition; pressure for innovation, adaptation, and reengineering; increased reliance on technology; and information overload. In such an environment, greater productivity can be achieved by improving technology; inducing workers to work longer, even though Americans now work more hours per week and more weeks per year than workers in other industrialized countries; ensuring that workers show up for work; making sure that workers are mentally at work; and increasing their motivation to achieve optimal performance.

But the drive for greater productivity produces a certain amount of fallout: increased job demands, a sense of detachment and depersonalization, increased health care usage, increased absenteeism, low job morale, increased disability rates, increased on-the-job accidents, an imbalance between work and life, and high levels of stress. The increased risks to health and productivity manifest in the medical, psychological, behavioral, and organizational dimensions (Table 1).

Typically, organizations attempt to handle these problems one at a time through different departments — the employee assistance program, occupational medicine, health promotion, worker's compensation, disability, and environmental health and safety. Each department approaches



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TABLE 1 Increased health and productivity risks

Dimension	Risk
Medical	Chest/back pain, heart disease, gastrointestinal disorders, headaches, dizziness, weakness, repetitive-motion injuries
Psychological	Anxiety, aggression, irritability, apathy, boredom, depression, loneliness, fatigue, moodiness, insomnia
Behavioral	Accidents, drug/alcohol abuse, eating disorders, smoking, tardiness, "exaggerated" diseases
Organizational	Absence, work relations, turnover, morale, job satisfaction, productivity

SOURCE: GOETZEL 2004A

these problems in parallel, instead of synergistically.

Several studies have demonstrated that organizational malaise is an important predictor of worker's compensation claims, disability, and absence. For example, a study at Boeing showed that the best predictor of how long an employee would be out on a worker's compensation claim for a back disorder was the employee's opinion of his supervisor (Bigos 1992); the lower the opinion, the longer the employee was out.

The list of problems afflicting employees has attracted a host of vendors, with so-called money saving solutions, such as managing disease, managing disability and absence, managing health and demand, managing stress, strengthening the employee-assistance programs, reengineering, reorganizing, creating incentives, and cutting pharmacy benefits. Nevertheless, the jury is still out with respect to the capacity that most of these interventions have to save money in the corporate setting. Focusing on their narrow area of responsibility, a department manager may, for example, bear down on high-cost drugs without ever noticing the effect of that action on absence, disability rates, and turnover.

Employees and supervisors have difficulty navigating the maze of benefit programs and organizing them synergistically. Yet, integrating the programs is a straightforward process, comprising four steps: diagnosing the problem, developing strategic and tactical plans, delivering the intervention, and measuring and reporting results.

Phase 1: diagnosing the problem

The idea of diagnosing the problem prior to intervening certainly will make sense to clinicians, but in this in-

stance the areas of focus extend beyond the medical to matters such as disability, absenteeism, and the newer notion of presenteeism. The diagnostic tools include medical claims analyses, a review of absence and disability records, and analysis of health risk appraisal (HRA) and presenteeism survey data.

To gather normative data about health and productivity management (HPM), we conducted a series of benchmarking studies in conjunction with the American Productivity and Quality Center and the Institute for Health and Productivity Management, pooling data from 43 organizations representing 1 million employees (Goetzel 2001). These data applied to health insurance, worker's compensation, absenteeism, short-term disability, long-term disability, demographics, and related topics. HPM program expenditures were aggregated in five categories: group health, turnover, unscheduled absence, nonoccupational disability, and worker's compensation. The median annual spending per employee in these categories amounted to \$9,992 in 1998 dollars, but less than half this amount was medical (Figure 1). Nevertheless, our data showed that organizations had an enormous opportunity to reduce these program expenditures by coming in line with "best practice" performance levels, which we defined as the 25th percentile for program expenditures in each area. Adopting best practices would result in annual savings of \$2,562 per employee, a reduction of 26 percent.

In another study, we turned to our MarketScan database, which included data on 4.1 million lives covered by more than 60 large companies with fairly rich benefit programs (Goetzel 2000). In this population, the 10

FIGURE 1 Establishing the "cost burden" of poor health

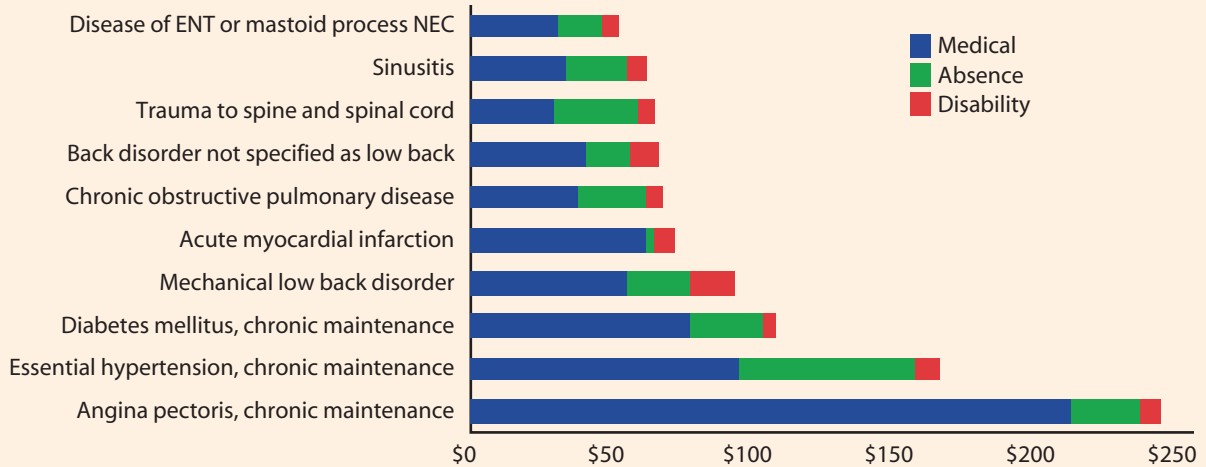
Median health and productivity management (HPM) costs per eligible employee (1998 \$)
Medstat/IHPM/APQC Benchmarking Study



SOURCE: GOETZEL 2001

FIGURE 2 Top 10 physical health conditions

Medical, drug, absence, STD expenditures (1999 annual \$ per eligible), by component



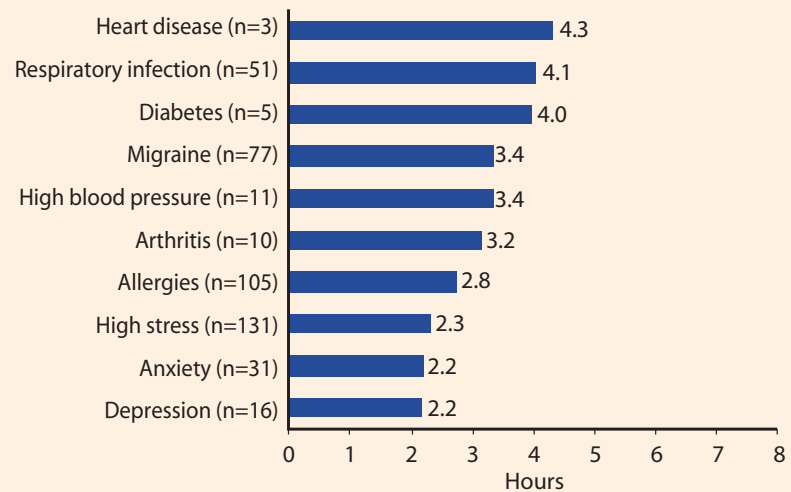
ENT=ear, nose, and throat, NEC=not elsewhere classified, STD=short-term disability.
SOURCE: GOETZEL 2003A

physical health conditions with the highest costs were coronary artery disease; gastrointestinal disorders; hypertension; vaginal deliveries; osteoarthritis; back disorders; ear, nose, and throat disorders; diabetes; cerebrovascular disease; and gall bladder disease.

In another study, we compiled a different top 10 list of physical health conditions by incorporating prescription drug, absence, and short-term disability data in addition to medical data (Figure 2) for 375,000 employees covered by six large firms (Goetzel 2003a). The 10 most costly mental health conditions in this population were bipolar disorder (chronic maintenance treatment); depression; bipolar depressive episode; neurotic, personality, and nonpsychotic disorders; alcoholism; anxiety disorders; schizophrenia (acute phase), severe bipolar manic episodes; nonspecific neurotic, personality, and nonpsychotic disorders; and psychoses. Among these mental disorders, absence and disability losses accounted for 45 percent of the total expenditures related to health and productivity, whereas absence and disability represented 29 percent of health and productivity expenses related to the physical disorders.

FIGURE 3 Presenteeism estimates: example from Work Productivity Short Inventory (WPSI)

Average number of unproductive hours in typical 8-hour workday*



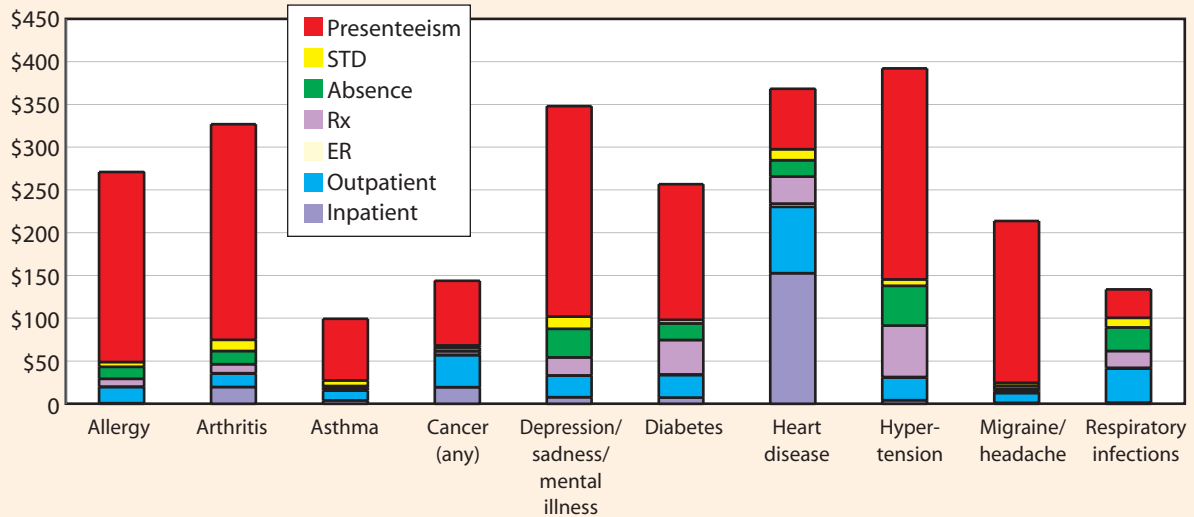
*On days when affected by the condition.
SOURCE: GOETZEL 2003B

The concept of *presenteeism* offers another perspective for viewing health and productivity management. Presenteeism relates to the employee who shows up for work but is characterized by the inability to focus on the task at hand, to concentrate, and to complete tasks on time. The most popular of the different measures developed in recent years to assess presenteeism is the Work Limita-

FIGURE 4 The big picture: overall burden of illness by condition

Using average impairment and prevalence rates for presenteeism (\$23.15/hour wage estimate)

Annual costs



ER=emergency room, Rx=prescriptions, STD=short-term disability.

SOURCE: GOETZEL 2004B

tion Questionnaire (Lerner 2001), but other instruments are available, including our own Work Productivity Short Inventory (Goetzel 2003b). The various instruments have different foci and applications.

To illustrate how a presenteeism instrument might be used, we administered the Work Productivity Short Inventory in a population of 563 employees working for the same organization. Employees were asked if they had certain health conditions and, if so, whether these conditions affected their work productivity, and the extent to which they affected productivity. The employees were asked whether the condition resulted in their absence from work or whether they came to work despite it, and, if so, what the magnitude of their performance decrement was (Figure 3).

Depending on an employee's wages, dollar values can be assigned to their responses about on-the-job productivity and added to the cost of absenteeism, which makes it possible for the employer to rank its losses attributable to both absenteeism and presenteeism. If these data are connected with medical and disability data, a hierarchy can be established for the full array of cost burdens associated with certain health conditions. In one of our studies (Goetzel 2004b), presenteeism costs exceeded medical costs for most of the conditions evaluated (Figure 4).

Logic suggests that if the health and well-being of employees improves, then the quality of their lives improves, health care utilization is reduced, disability is controlled,

and productivity improves. Yet, proving the value of disease prevention and health promotion remains a difficult proposition. Abundant evidence — more than 10,000 epidemiologic studies — exists to support the first proposition in the chain of logic (Table 2, page 32), but published evidence for subsequent links diminishes.

The leading causes of death in the United States are heart disease and cancer, accounting for more than half of all deaths (Mokdad 2004). The causes of these diseases quite often are modifiable risk factors — tobacco, alcohol, diet, hypertension, hypercholesterolemia, lack of exercise, obesity, and diabetes. In one study, we analyzed a database that contained medical claims data, eligibility data, and health risk data (behavioral and biometric) for 46,000 employees who were at six large organizations (Goetzel 1998a). In this study, the modifiable risk factors represented about 25 percent of total health care expenditures. Controlling for demographics and confounding factors, we tried to determine the independent effects of 11 modifiable risk factors on cost. Somewhat surprisingly, two psychosocial risk factors, depression and stress, were the most costly on an individual basis (Figure 5, page 33). Costs for an employee reporting depression, for example, were 70 percent more than for an employee who was not depressed. When these data are applied to the employee population, however, multiplying the prevalence rates by cost, the rankings shift somewhat (Figure 6, page 33). Thus, risk factors must be addressed at the individual level as well as across the population.

TABLE 2 Chain of logic to support workplace health promotion

Proposition	Evidence (examples)
1. A large proportion of diseases and disorders is preventable. Modifiable health risk factors are precursors to a large number of diseases and disorders and to premature death.	Healthy People 2000, Healthy People 2010, Amler 1987, Breslow 1993, McGinnis 1993, Mokdad 2004
2. Many modifiable health risks are associated with increased health care costs within a relatively short window of time.	Milliman & Robertson 1987, Yen 1992, Goetzel 1998a, Anderson 2000, Bertera 1991, Pronk 1999
3. Modifiable health risks can be improved through workplace-sponsored health promotion and disease prevention programs.	Wilson 1996, Heaney 1997, Pelletier 1999
4. Improvements in the health risk profile of a population can lead to reductions in health care costs.	Edington 2001, Goetzel 1999
5. Worksite health promotion and disease prevention programs save companies money in health care expenditures and produce a positive return on investment.	Bank of America (Fries 1993), California Public Employees' Retirement System (Fries 1994), Chevron (Goetzel 1998b), Citibank (Ozminkowski 1999, 2000), Johnson & Johnson (Ozminkowski 2002), Procter and Gamble (Goetzel 1998c)

Done correctly, the risk profile of a population can be changed. In a literature review, we examined 47 studies, conducted over a 20-year period, of worksite health promotion programs (Heaney 1997). We concluded that programs vary tremendously in comprehensiveness, intensity, and duration. The greatest positive effect was produced by programs providing individualized risk-reduction counseling within the context of a comprehensive program sustained by a health-promoting culture.

Phase 2: developing strategic and tactical plans

An econometric forecasting model that we constructed for the Dow Chemical Co. illustrates how baseline diagnostic information can be used to change risk in an employee population, thus making a business case for health promotion. The outcomes (dependent variables) in the model were the health risk profile of the Dow population, using the same eight modifiable risk factors previously mentioned; the projected annual medical expenditures for the decade following 2001; and the program's return on investment (ROI). The independent variables were the employee demographics (current and projected over the 10-year period) and the ability of the program to affect the employee health risk profile under four scenarios. The first scenario posited no program, in which case demographics would drive the risk profile. The second scenario assumed the program would keep risks constant (at 2001 levels). The third and fourth

scenarios assumed risk would be lowered by 1 percent and 10 percent, respectively, over 10 years. This population comprised 25,828 employees with a mean age of 43. The employees were 75 percent male and 82 percent white.

The model showed that, to break even after 10 years, the program would have to reduce risk by 0.17 percent per year. The response by senior management at Dow to this finding was to introduce a company health strategy with prevention as a key pillar, and to consider employees as key assets whose health and human capital should be maintained via ongoing investment, not as simple line items on an expense report. As one executive put it, "Let's take care of employees at least as well as we take care of other assets."

We have done similar studies for other corporations. For Motorola, we showed the break-even point would be achieved if the program reduced employees' risk by 0.67 to 1.15 percent per year, depending on the company's investment (Ozminkowski 2004). For the Union Pacific Railroad, the program would break even if it reduced employees' risk by 0.49 percent per year (Leutzinger 2000).

Phase 3: delivering the interventions

Health promotion and disease prevention programs encompass primary, secondary, and tertiary prevention programs; immunizations; screenings; behavioral health intervention; and self-care, consumerism, and demand management. Interventions that can occur in the work-

place environment include ergonomics, job design, safety, medical surveillance, and job accommodation.

For these to succeed, the corporate culture may need to be transformed into one that supports positive health habits. For example, such a culture might encourage workers to use part of their normal scheduled work time to exercise, and it would encourage the use of stairs instead of elevators. A supportive culture also would provide healthy food choices in vending machines and cafeterias.

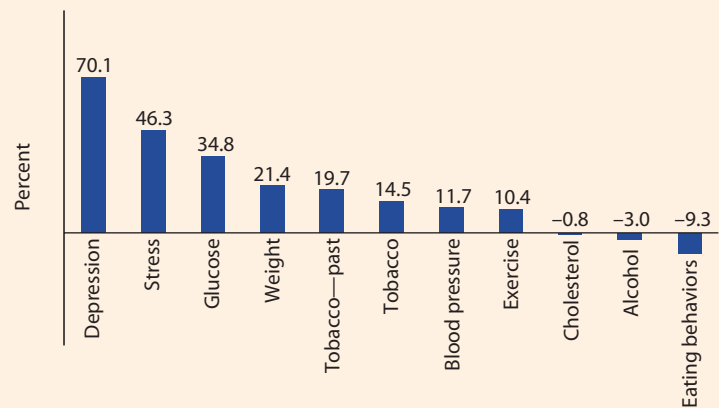
Phase 4: measuring and reporting results

Results can be obtained through descriptive studies, but organizations often want econometric analyses that show their ROI — what they received in exchange for the interventions they put in place. Documenting ROI necessitates the measurement of intermediary points. These are ensuring that the employees in the target population are aware of their health, participate in the programs, increase their knowledge, improve their attitudes, change their behavior, reduce their risks, and ultimately reduce utilization. If all these activities reach certain levels of success, a positive financial effect on ROI will be realized.

For example, in 1994, Citibank instituted a \$1.9 million health management program that saved between \$4.53 and \$4.73 for every dollar that was invested (Ozminkowski 1999). In this program, participants were assigned to high- or low-risk intervention categories on the basis of a health-risk appraisal administered to the population. The 3,000 high-risk employees, who constituted 20 percent of the participants, received fairly frequent and fairly intensive interventions in the form of tailored communications from physicians, all delivered through the mail, Internet, or telephone. These high-risk modules focused on arthritis, back pain, smoking, diabetes, obesity, high blood pressure, heart conditions and other chronic conditions, and combinations of risky behavior. After 2 years, the improvements in 11 risk categories were relatively small (Figure 7, page 34), with the exception of improvements in exercise habits, seatbelt usage, and stress levels (Ozminkowski 2000). Nevertheless, this study shows that changing the risk profile of a population even in small ways can reduce health management costs.

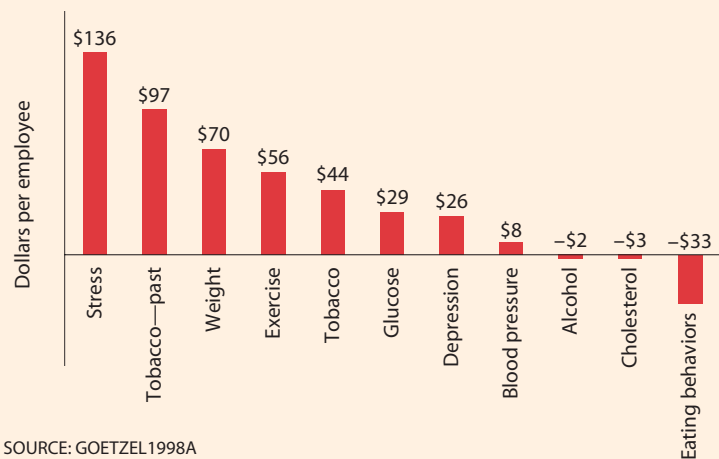
FIGURE 5 Incremental effect of controlling modifiable risk factors on medical expenditures

% difference in medical expenditures: high-risk vs. lower-risk employees



SOURCE: GOETZEL 1998A

FIGURE 6 Annual per capita cost of high-risk status



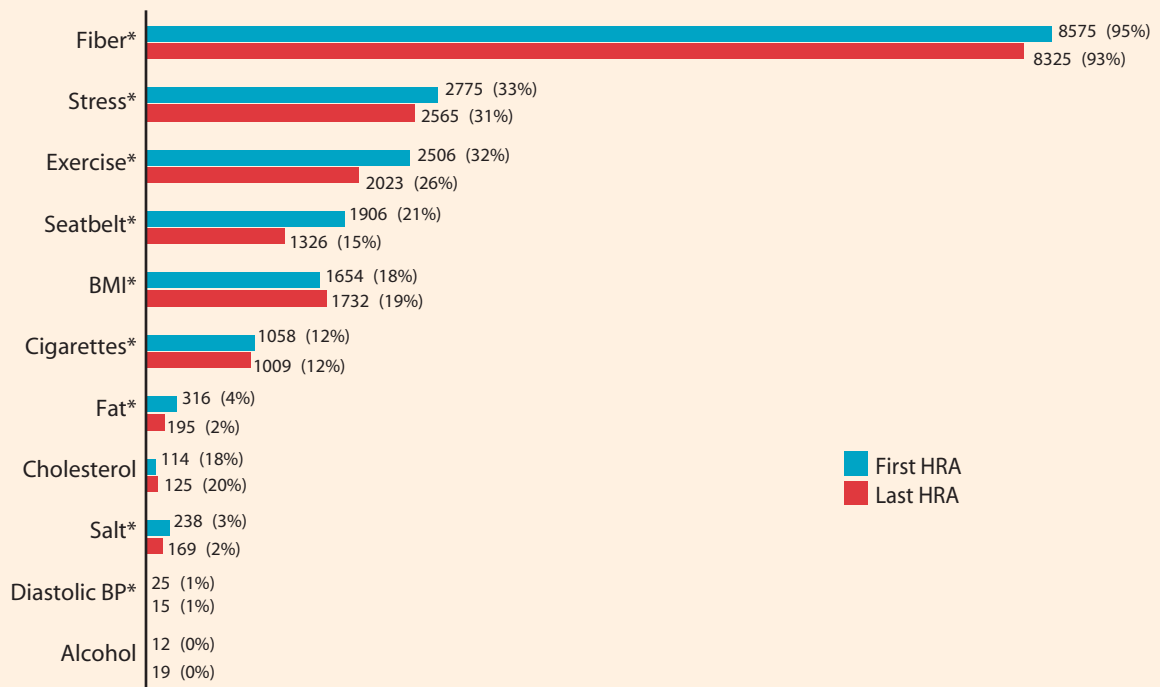
SOURCE: GOETZEL 1998A

In 1995, Johnson & Johnson changed the focus of its health management programs. A key change was offering participants a \$500 reduction in their annual medical premiums. Ninety-two percent of the population participated. If a health profile showed an employee was at high risk, that employee was required to participate in a follow-up program or else forfeit the \$500 reduction. In the high-risk group, after 2.75 years, risks were reduced in seven risk categories (high cholesterol, low fiber intake, poor exercise habits, cigarette smoking, hypertension, seat belt usage, and drinking and driving) but increased in four related categories (body weight, dietary fat consumption, risk for diabetes, and cigar use) (Goetzel 2002).

During the first 4 years of the program, the company saved an average of \$225 per employee per year

FIGURE 7 Citibank study: Participants at high risk at first and last health risk assessments (HRA), by risk category

N=9,234 employees tracked for an average of 2 years



Percentages represent the proportion of total participants for whom data are available, by category.
*Statistically significant at the $P < .05$ level (McNemar Chi-square).

BP=blood pressure, BMI=body mass index, HRA=health risk appraisal.

SOURCE: OZMINKOWSKI 2000

(Ozminkowski 2002). These savings came from a reduction in inpatient days (\$119 per employee), fewer mental health visits (\$71), and fewer outpatient visits (\$45), compared with baseline.

In a review of nine studies of corporate health promotion programs, we found that the ROI ranged from \$1.40 to \$4.90 per dollar invested (Goetzel 1999). In one of these programs, at Procter and Gamble, no significant cost differences were found between participants and nonparticipants during the first 2 years, but health care costs in year 3 were 29 percent lower among the participants, and their lifestyle-related costs were 36 percent lower (Goetzel 1998c).

Performing applied research in corporate settings is extremely difficult, because their outcomes may be affected by issues such as study design, randomization, self-selection bias, attrition, poor instrumentation, and “wish bias” (the possibility that the investigators may influence the outcomes because they hope to obtain certain outcomes). For these reasons, health promotion studies

vary in their scientific rigor. One reviewer recently sorted 72 published studies into five categories according to their degree of rigor (Aldana 2001). Among the 32 evaluation studies, 28 showed a positive financial impact by health promotion programs. None of the four studies that failed to show a positive impact used a randomized design.

Good studies of the economic impact of disease management are few in number. We recently reviewed 44 published studies that provided enough information to comment on ROI (Goetzel, in press). Varying in interventions and quality, these studies dealt with management of diabetes, asthma, heart failure, depression, and multiple conditions. We found that ROI varied by condition. Disease management programs for heart failure, asthma, and multiple conditions show promise, but disease management programs for diabetes and depression may cost more than they save, at least in the short run. Many studies were only 1 or 2 years long, and they did not account for productivity outcomes like absenteeism and presen-

teism. Effects on productivity have not been well evaluated for disease management programs.

Conclusion

Interventions introduced in the 1980s to contain health care costs fall into four categories: cost shifting, benefit plan redesign, negotiated discounts, and utilization management. Throughout the 1980s and into the early 1990s, these strategies were extremely effective in curtailing health care costs. From an employer's perspective, it is relatively easy to reduce costs in a variety of ways, but the question remains: what value is received for the dollars spent?

The difference today is that more attention is being directed at quality of care and health outcomes. There is growing recognition among employers that health and productivity are related and that some economic advantage accrues from providing good-quality health care. A growing body of literature suggests that well designed evidence-based health and productivity management programs can improve workers' health, lower their risk for disease, save businesses money by reducing health-related losses and limiting absence and disability, improve worker morale and worker relations, improve productivity, and improve the financial performance of the organizations instituting these programs.

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DISCUSSION

QUESTION: Dr. Bufalino talked about significant improvements he has made with electronic medical records and virtual lipid clinics, and one of your slides showed that 4 of the top 5 drivers of productivity losses were cardiovascular. If you could marry Dr. Bufalino's data with your research, could he claim productivity credits for his outcome improvements and market those to employers to get them to invest in electronic medical records?

RON Z. GOETZEL, PHD: There is a lot more research going on now that is focused on productivity outcomes. Some of this research relies on applying instruments, such as the WLQ [Work Limitations Questionnaire], which has only eight items. But if you add those instruments to your clinical trials or other studies, you can look at the productivity effects of different interventions and assign them a dollar value.

Now, whether linking it back to an electronic medical record helps you to achieve those clinical outcomes is a different question. My hypothesis would be that the answer is yes, because if you do that, you will remind people of their need to take certain drugs and come in for certain procedures, and get a certain type of care. Then your medical and productivity outcomes will improve.

QUESTION: I'm a little skeptical about disease manage-

ment programs and their ROI. Also, now that this has come under scrutiny, it looks like they are using presenteeism to prove ROI. I would like to hear more about what Al Lewis from the Disease Management Association of America calls the coalition of the willing — the people who participate in disease management programs being the ones who would have done better anyway.

GOETZEL: Mention was made earlier of the chronic care improvement program, which is a completely different model. In fact, the disease management evaluations that we conduct look at populations, so essentially you are handed a group of patients. There are certain inclusion criteria used to identify the heart failure patients, the asthma patients, and that is the population you have to deal with — not just the people who volunteer, but everyone. At that point your job is to recruit and engage those people, and you will be measured by the capacity to affect the population, whether or not they volunteer for the program. That is the right approach, in terms of disease management evaluations and health management evaluations. The focus of this research is on population effects, not just the individuals who participate in the disease management programs.

In a corporate setting, we try to manage the internal validity problem. We try to determine the characteristics that would lead someone to participate in the program. Then we create propensity scores, which we use to match a person in the treatment group with a person in the control group. After we have done the matching and followed the subjects over time, we apply multiple regression methods to control for selection bias. New techniques permit control for self-selection bias. That said, the problem remains that this is not a randomized clinical trial, and many people in the research community still will not accept these findings as being truth. Yet, this is what can be done in large populations. From the perspective of benefits directors, if you can get a large segment of the population to go from one level of risk and cost to a different level, they will be happy.

QUESTION: When you measure presenteeism, not all employees come in at the same level. There are good employees and bad employees. How do you measure presenteeism, based on what their baseline would have been? And, let's say, it wouldn't have been very good.

GOETZEL: You collect baseline data, so people with poor presenteeism scores are followed longitudinally to see if the program has an effect on their productivity. Some people will be at 100 percent and some at 60 percent, and then you can look at improvements or decrements in their scores.

QUESTION: Would you please share your perspective on member incentives relative to participation in care

management and wellness programs?

GOETZEL: Incentives are important to get people into the tent, because unless you give them something, most won't show up. You have to give them a reason to pay attention to you. You may wish to provide a gift or, as Johnson & Johnson has done, a \$500 incentive for program participation. I don't believe in using incentives to induce people to change behavior or biometric values, but incentives can be used to engage people in the program. Then, it's up to the program to get individuals to change their behavior.

QUESTION: What about integrating care management with wellness programs and disability programs?

GOETZEL: The ability to integrate these programs is what we're advocating, in terms of organizations getting all the key players together. It starts with a senior manager of the company, saying: I want the medical director, the benefits director, and the EAP [employee assistance program], to all come together and say we want to develop a uniform strategy. That way, you're not doing something that is countervailing what I'm doing. Often, that is true in terms of policies and programs, where people will shift employees to another person's responsibility so that they don't have to deal with those employees. An integrated approach, in and of itself, will save money.

QUESTION: What is unique about the congestive heart failure and asthma DM programs that you found in your studies that made them somewhat better than the others? Is there something we can adopt from them to manage other DM programs?

GOETZEL: They probably apply best practices more than some other programs, but they may just reflect the nature of the diseases. My sense is that it is easier to achieve short-term gains, in terms of health improvements and cost savings, in those categories. If you do the right things with CHF and asthma, within a year you can obtain noticeable results, as opposed to diabetes or depression, which may take much longer.

QUESTION: Many studies show that CHF disease management programs reduce hospitalizations. As I under-

stand it, the review focused on costs other than productivity costs, presumably mostly medical costs. Inpatient costs still dominate, and that is where CHF and asthma disease management programs work, because you keep people out of the hospital. It's kind of a reprise of what managed care was doing 10 years ago.

GOETZEL: Right, that is the most expensive category, so if you can reduce the rates of hospitalizations by X percent, that will have a huge impact on cost.

QUESTION: Just to push this a little bit more, the savings in diabetes DM programs are from cardiovascular costs, so it depends on what you are looking at.

GOETZEL: Yes, that is an important point, that when these studies are published, they do not always look at overall costs. They sometimes focus on specific categories, rather than the big picture. Al Lewis and others argue that if you are going to measure costs you really have to look at comprehensive costs instead of just focusing on a specific category of illness.

QUESTION: Given that the benefits of the health and wellness and productivity programs — presenteeism, absence reduction, and so on — tend to accrue more to the employer, not the health plan, what have you observed about how employers and health plans are working this out, in terms of who pays for the programs and who benefits from them?

GOETZEL: Forward-thinking employers are saying: "This is something we should be organizing and managing, because the treatment community is still in its silos and that will not change much." The medical doctors are not going to suddenly become absenteeism doctors and presenteeism doctors, but they need to be aware of those issues. What the employer can say is: "If you need to keep the patient in the hospital longer or provide rehabilitation services, I'll pay you more to do that if it will produce better health and productivity outcomes." You need to get into that dialog. So it's not about what is quickest and cheapest; it is instead about what will produce the best health and productivity result — not just on the medical dollar savings side, but also in terms of the broader picture.

Quality of Care: Where Do We Go from Here?

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There is widespread agreement that our health care delivery system must strive to improve the quality of care it delivers. Study after study has found shortfalls, and there have been calls from across the political spectrum for action (McGlynn 2003). Much of the burden for doing so will rest on medical managers, who must struggle day in and day out to implement quality-management programs. This article seeks to give medical managers the background to succeed in that endeavor, drawing mostly from research in which I have had the privilege to participate.

Defining quality of care

The most commonly cited definition of quality of care is one used by the Institute of Medicine: “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (Lohr 1990). Although inspirational, this definition lacks everyday utility. The application of the definition to real-world problems follows a four-step process that connects the underlying professional knowledge to changing provider behavior.

The process begins with the collection of efficacy data from randomized controlled trials, which define optimal clinical practice in carefully selected populations. The next step is to conduct effectiveness studies, which assess the extent to which the optimal practices can be applied to broader populations. The third step is quality assessment — an attempt to quantify the gaps between optimal and actual practices. The final step, quality improvement, is concerned with translating those gaps into quality improvement and better practice. This article focuses on the last two steps — quality assessment and quality improvement — but it should be

remembered that these two steps are dependent on the first two steps.

The classic conceptual framework for thinking about quality assessment has three components: structure, process, and outcomes (Donabedian 1980). *Structure* refers to characteristics of the community, the health care organization, providers, and the population — the stable features of the population and delivery systems

that affect access to care and provision of care. Because of the intervening processes, in many cases it is difficult to do studies that relate structure to outcome. One of the few established examples is the so-called volume-outcome relationship. This is the common-sense finding that facilities that perform a high volume of a particular procedure are better at it and thus have better outcomes than facilities with a low volume.

Process measures are more commonly used than structural measures, and they are much more intuitive. But like structural measures, it is important to remember that what

matters is not the process itself, but how strongly that process is related to an outcome. In quality assessment, process refers to an examination of technical and interpersonal excellence — what was done to the patient (e.g.: Did the patient receive a beta blocker?) and how well it was done (e.g.: How well did the physician explain the need for the drug?). Because of its subjectivity, interpersonal excellence is difficult to measure, and so it will not be addressed in this article.

In contrast, technical excellence can be more objectively assessed. Researchers have identified three categories of poor technical quality: too little care or underuse (i.e., the failure to provide an effective service when it could have produced a good outcome); too much care



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or overuse (i.e., providing care when its risks exceed the potential benefit); and the wrong care or misuse (e.g., giving the wrong dose of medication). Note that this definition of quality considers the balance between medical harm and medical benefit, and it specifically excludes financial costs.

It is important to realize that all three kinds of errors can coexist, not just in the same delivery system, but also in the same facility, the same physician, and even the same patient; finding one type of error does not preclude finding either or both of the other two. In many instances, medical harm is not as obvious as one might think. For example, several studies have suggested that the

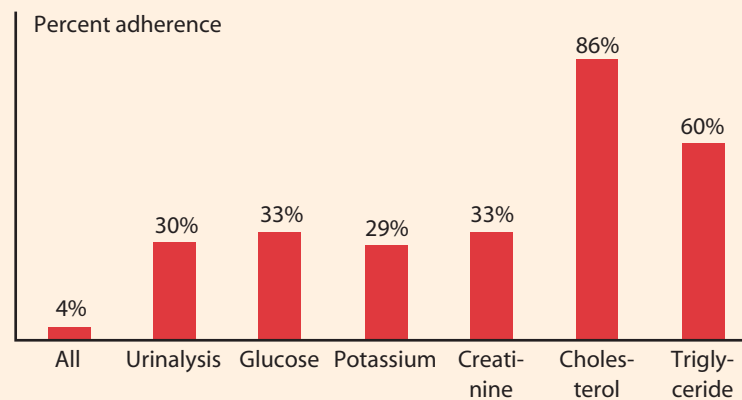
prostate-specific antigen (PSA) test is overused — not because the PSA itself causes much harm, but because a false-positive result leads to a biopsy, and the biopsy may generate morbidity and mortality.

As an illustration of underuse, we once examined 13 quality-of-care indicators in women with hypertension (Asch 2001). One indicator was the use of laboratory tests for patients who were newly diagnosed with hypertension. The optimal battery of tests for such patients includes a urinalysis and glucose, potassium, creatinine, cholesterol, and triglyceride assessments. In our study, most of these tests were performed in about a third of patients, and very few received comprehensive testing (Figure 1). Across all indicators, the average woman received less than two thirds of recommended care.

In another study of the overall health care experience of adults in 12 U.S. metropolitan areas (N=6,712), we compiled a list of 439 quality-of-care indicators for 30 acute and chronic conditions and preventive care (McGlynn 2003). On reviewing the participants' medical records (with their permission), we found that patients received only about 55 percent of recommended care, with the adherence to quality indicators varying, depending on the mechanism of care delivery (mode) for the processes in question (Table 1). (At least part of the apparently poor performance in counseling/education may stem from lack of documentation.)

Other studies have instead concentrated on assessing the quality of the decision to implement high-cost procedures. During the 1980s, Rand and the University of California–Los Angeles developed a method for evaluating process quality for such procedures, the appro-

FIGURE 1 Hypertension and new diagnosis laboratory tests



priateness methodology, which underlies much of quality measurement today. In the original form, project staff would review the literature about a particular procedure and draft a number of detailed clinical indicators of care. A nine-member panel of expert clinicians would rate the appropriateness of the component indicators for the procedure on a scale of 1 to 9. Care was considered appropriate if medical benefits outweighed medical (non-financial) costs. If the care was inappropriate, then the procedure was considered overuse in that case.

Rand conducted a series of studies in the 1980s showing that several extremely common and expensive procedures — coronary artery bypass grafts, cardiac catheterization and angioplasty, hysterectomy, endoscopy, carotid endarterectomy, abdominal aortic aneurysm, cataract surgery — were overused between one third and one half the time. Measuring appropriateness of high-cost procedures is undergoing somewhat of a resurgence as concern over costs has again become a salient issue. *Outcomes* are the results of the process, the biological, mental, or physical status of the patient —

TABLE 1 Adherence to quality indicators

Mode	Number of indicators	Percentage of recommended care received
Encounter	30	73
Medication	95	69
Immunization	8	66
Physical examination	67	63
Laboratory testing or radiography	131	62
Surgery	21	57
History	64	43
Counseling/education	23	18

SOURCE: MCGLYNN 2003

morbidity and mortality. Many would include patient satisfaction as a subcategory of outcomes quality, though some think of it as a separate and worthy endpoint in itself, apart from quality. The reason is that satisfaction is a difficult outcome to interpret, because it does not necessarily follow from the structure and technical process. Instead, it is much more closely related to interpersonal process, and sometimes it is most closely related to factors unrelated to medical care (e.g., ease of parking). So, like interpersonal process, we will leave satisfaction aside for now.

Why measure clinical outcomes? The first reason is that physicians and, more importantly, patients care about outcomes directly. Provided they get better, most patients do not care how that is accomplished. The second reason is that measuring outcomes encourages innovation in processes, while direct measurement of processes does not. Providers can make improvements in process that managers might not have thought of in advance.

Although outcomes are the quality measure on which everyone wants to focus, there are some problems with outcome measures that should discourage us from relying on them completely. A major problem is sample size. To compare mortality rates, extremely large samples are needed. For example, to determine whether there is a statistically significant difference between mortality rates of 12 percent and 16 percent among heart failure patients at two different hospitals, a population of 957 patients at each hospital would be required. Heart failure is a common cause of hospitalization, yet a great many hospitals would not admit that many heart failure patients in a year. For rarer outcomes, like birth defects, statistical comparisons become virtually impossible at the facility level. Severity of illness also needs to be taken into account. Although improving the quality of medical care can reduce mortality rates in patients hospitalized for heart failure, for example, the greater predictor of mortality in heart failure patients is how sick they are at admission. Without adjusting for the degree of illness, measuring outcomes in such a population becomes problematic, and we often lack the data needed to make adequate adjustments. A related problem with outcome measurement is the question of accountability. The treatment for which providers are being measured should have a big impact relative to other factors that are beyond their control. Often, however, the clinical outcomes of a disease process depend on factors that are beyond providers' control, like socioeconomic status.

Measuring quality of care

The oldest form of quality measurement is physician implicit review. Many health plans, hospitals, and medical groups use implicit review for privileging, for example. In its most structured form, it elicits physician judg-

ments on specific categories, using anchored rating scales. This approach has been a standard tool in many landmark quality-of-care studies, but it is more a "bronze" standard than a gold standard (in a field that lacks a gold standard).

Why is implicit review not used more often? First, it is expensive, necessitating highly trained physician reviewers. Second, it lacks reliability, especially in nonresearch settings, because it is difficult for physicians to agree on what good quality is. In the research setting, this is partially overcome by giving the implicit review some preset structure and through the use of statistical techniques to adjust for reliability problems. Finally, with implicit review, it is difficult to relate physician-implicit standards to quality improvement. That is, if a physician is told his rating for hypertension management is 6 on a scale of 1 to 10, the physician has been told he is doing something wrong but he does not know what he is doing wrong.

For these reasons, explicit measurement systems are often preferred for assessing quality, using preset defined criteria. Explicit systems fall into two groups, focused systems, which employ just a few measures, and global systems, which involve a great many measures. The Health Plan Employer and Data Information Set (HEDIS) and the External Peer Review Program (EPRP) within the Veterans Health Administration (VHA) are examples of focused systems. They are easily understood and represent actions that can be carried out. Nevertheless, focused systems have been criticized, because it is possible to game them — that is, to focus resources on the few measured items at the expense of other nonmeasured care that might be more important for patients.

To thwart gaming, there have been several attempts to develop more global assessments of quality of care, using hundreds of measures instead of dozens. Rand's QA-Tools is an prominent example. A global tool usually reports aggregated scores rather than scores for specific indicators, though the information for specific indicators is available. Global systems could spark broad systematic change, but they have the disadvantage of not being directly related to quality improvement because the sample sizes make it difficult to provide individual indicator scores.

Choosing measures: practical considerations

Choosing the measures for a health plan or a medical group entails choosing the areas of interest, selecting the indicators, designing their specifications, and testing the measures. Choosing an area to measure depends on the importance that is attached to it and the terms in which it is thought about — mortality, morbidity, utilization, and cost. An employer might be more concerned about injuries, for example, because of their association with days lost from work, whereas a public health officer in-

terested in overall morbidity and mortality would concentrate on coronary artery disease and cancer.

When choosing measures, it also is important to focus on areas where there is potential for improvement. For example, the rate of beta-blocker treatment after a heart attack has risen by more than 30 percent since the introduction in 1996 of a HEDIS measure for this process. Now the rate is in the 80 to 90 percent range at some plans (NCQA 2004), leaving little room for added improvement.

Additional considerations are how the measure might be affected by characteristics of the enrolled population that are beyond the control of providers, and the actions providers or clinical laboratories can take to improve their performance. If actions cannot be identified, the measure is flawed.

Unlike defining quality, cost-effectiveness is an important factor when choosing among quality indicators, provided it is remembered that cost-effectiveness is not synonymous with cost savings. Sometimes spending money does result in saving money — a positive return on investment (e.g., saving \$14 for every \$1 spent on certain immunizations) — but, usually, that is not what happens. For the most part, health care money is spent to obtain quality (e.g., spending tens of thousands of dollars for cervical cancer screening to save 1 quality-adjusted life-year).

Designing measure specifications is complicated, comprising the following steps: defining the indicator very specifically, identifying the target population, defining the eligible population, determining the need for risk adjustment, identifying data sources, writing data collection instructions, and developing scoring rules. At Rand, it usually takes about 5 months to develop one indicator.

The best measures are extremely clinically specific, paralleling the way that doctors think about how to take care of patients. An example of a measure from QATools follows:

Men with a new diagnosis of prostate cancer, who have not had a serum PSA in the prior 3 months, should have serum PSA checked within 1 month after diagnosis or prior to any treatment, whichever comes first.

This indicator includes time frames and definitions of the indicated care. This kind of clinical detail often is missing in quality measures, sometimes because simplicity facilitates measurement. Nevertheless, the clinical detail in measures should reflect what physicians consider important in caring for patients.

Once developed, there are at least three ways to test a measure: reliability, validity, and interpretability. *Reliability* indicates the proportion of times that repeated use of the measure in the same population gives the same result. *Validity* is the extent to which the measure accurately represents the concept being assessed. *Interpretability* is

the ease with which the target audience can understand and use information generated by the measure. No matter how good the measure is, there must be a way to present it to the people who care about it in a way that they understand. At Rand, we have often adopted the policy of addressing the interpretability of a proposed measure at the outset of the measure-development process, so as not to waste time perfecting an uninterpretable measure. No matter what type of measures are chosen, they can be used for both internal and external purposes. Benchmarking one's own processes or outcomes allows for a future comparison relative to progress and change, whereas external benchmarking allows for comparisons against national standards.

Improving quality: What is the evidence?

There is a plethora of quality improvement techniques in use today, but we will touch on four of the most common. Four quality improvement techniques in common use today are the audit feedback, collaboratives, electronic medical records, and pay for performance. The audit feedback simply feeds quality information back to physicians, health plans, hospitals, and even the public in the hope that things will improve. The National Committee for Quality Assurance (NCQA) uses its HEDIS measures in this fashion, and New York State has done so with outcomes of coronary artery bypass grafting at the facility and physician level, resulting in reduced surgical complications.

Evidence that providers will improve when their performance is measured comes from the VHA's experience, among others, where audit feedback is used extensively. In one study, we compared the performance of VHA physicians with a national sample in performance measures targeted by the VHA, as well as measures related and unrelated to those targets (Asch 2004). In the VHA-targeted measures, the performance by VHA physicians was 24 percentage points higher than in the national sample (67 percent vs. 43 percent). A lesser improvement in performance — a halo effect, if you will, was seen in the measures related to the VHA targets and even in measures unrelated to the VHA targets. For the related measures, there was a 12-percentage point difference between the VHA and the national sample (70 percent vs. 58 percent), and for the unrelated conditions, there was a difference of 5 percentage points (55 percent vs. 50 percent). We speculate that the reason for the halo effect is that when providers are held accountable for giving influenza vaccinations, for example, they also are induced to think about other preventive care processes and perform them more often as well. A crucial element in any audit feedback program is that those measured (the providers) accept the legitimacy and validity of the measures themselves, and many previous programs have failed to garner such acceptance.

Collaboratives essentially are conferences at which the participants discuss their experiences in quality improvement and try to learn from each other. The Institute for Healthcare Improvement (IHI) «www.ihl.org» is probably the most famous proponent of collaboratives. Most have relied on historical or case study design for clinical endpoints, so there is potential for bias; but there is strong evidence that collaboratives improve provider satisfaction and organizational parameters. One Rand study in heart failure showed improvement in key processes, and another showed improvement in glycemic control in patients with diabetes (Asch 2005).

There is widespread belief that EMRs improve quality, but the evidence is weak. Individual components of an EMR have been tested, such as reminders and computerized physician-order entry (CPOE). These have been shown to improve the targeted indicators, but there have been no tests of the synergistic effects of the EMR. IT-intensive systems (e.g., Kaiser, VHA) tend to score better on explicit quality measures. Structured reviews of this topic are underway.

The evidence that paying providers more for better quality of care (a key element of pay-for-performance programs) is effective in improving quality of care is sparse, despite the proliferation of such programs. Small evaluations of increasing payments for specific services — for immunizations or smoking cessation counseling, for example — have been shown to decrease underuse. Larger evaluations are underway (Rosenthal 2004).

Future of quality assessment and quality improvement

Predicting the future of quality measurement and improvement is always risky, but some trends already are apparent. First, in addition to paying for process, more programs will pay physicians, medical groups, and health care facilities to improve their IT infrastructure and disease management. Even though a full EMR is not in our immediate future, integration of IT will occur in other areas. Some plans already have access to automated laboratory and pharmacy data, and in the future, plans' use of such data in quality improvement will accelerate. In addition, more sophisticated physician profiling is on the horizon. Unlike in the past decade, it will focus on quality of care instead of just cost and utilization. Finally, given the number of quality measures already in use, there will be a coalescence of measures around the National Quality Forum (NQF) «www.qualityforum.org» standards to avoid unnecessary duplication of effort.

Conclusion

Done properly, quality assessment and quality improvement programs can be used by medical managers to improve the quality of health care. Quality-of-care indicators should be used to assess provider performance

only if they point to specific actions that the providers can take to improve their performance. There is evidence that improving the quality of care in one area leads to broad improvements in other areas, even if they lack a direct connection with the area of interest.

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DISCUSSION

QUESTION: The avoidance of patients who may be problematic keeps arising in pay-for-performance programs. Has Rand done anything to assess such physician behavior, and what can be done to avoid it?

STEVEN M. ASCH, MD, MPH: At least two Rand studies are underway in pay for performance. One is taking place in Taiwan, where they have instituted a pay-for-performance initiative in the context of a national health insurance program. Another one is evaluating private insurance-based programs in California, which is being led by Cheryl Damberg. There is also an evaluation underway of the British program. I do think that if you use outcomes in pay for performance, you will run into the problem you mentioned, because there is no way to do a satisfactory risk adjustment. That is why many of us always have advocated a balance of process and outcomes measures in pay for performance. Nobody will solve the problems of accountability, risk adjustment, etc., for outcomes measures; therefore, what we need is balance.

QUESTION: What savings opportunities could health plans achieve if we could apply some of the Dart-

mouth data from Wennberg and Fisher on the supply side — the fact that physicians are overdelivering care where there is excess capacity in the market? Is there an opportunity for health plans to save if they challenge or reengineer some of this supply-side excess?

ASCH: Where you live certainly determines whether you get many major procedures. There are huge cost differences across various Medicare regions, probably due to the supply of physicians and other providers; that is Wennberg's original insight from 20 years ago. But, how to translate that information into appropriate care, not just reduced utilization? Because of overspending on these things, one could argue for the approach used in places with limited supply, such as Canada, which saves money by limiting the supply of CAT scans, CABGs, etc. Yet, if you compare the appropriateness of CABGs in Canada versus New York, the difference is minimal. So simply restricting the supply won't improve quality. It will decrease access, however, as it's supposed to, and it will decrease costs. You have to put quality into the equation to actually measure whether people are doing a better job, and then reward them for so doing.

QUESTION: I am a medical director for an MCO in Baltimore. In my experience as a practicing physician, I knew that my quality had improved when I was able to educate patients about their needs. Could you comment on quality from the perspective of educating the patient? Are we looking at any qualifiers to determine if we made a difference in that patient's life?

ASCH: You can parse variation in quality of care to the patient, physician, facility, and system level. The literature shows that most variation in quality is at the patient level. So, patients already are making a lot of the difference as to whether they get necessary care. The chronic care model, which is behind many collaborative techniques, emphasizes patient activation. If you activate patients with heart failure by getting them to weigh themselves every day, you keep them out of the hospital. As to how to know whether that's occurring in any plan or any medical group, it's a question I cannot answer fully. Surveys have been used to measure patient activation, but these measures can be difficult to put into quality assessment systems.

QUESTION: Are there other programs that are more focused on process change for providers, and how they have fared with quality improvement? By process change, I mean, giving providers tools to get to the next level, not just giving them monetary incentives.

ASCH: My take on this is that to change provider behavior, you have to realize two things. One, like all human behavior, it's socially constructed. The way providers change their behavior is not by reading books, or by getting paid more, but by talking to others in the same situation and determining how they solved the prob-

lem. You have to engage providers' social networks in garnering change, and produce clinical champions for change. The second point is that systems produce change more than individuals. When you look at how Toyota changed its manufacturing processes, you see that it's not one group's or one person's job to improve quality. I had the opportunity once to ask an automobile manufacturer's quality supervisor what they spend on quality every year. He looked at me as if I had asked the wrong question. He said: "That's all we spend money on; we don't spend money on anything else. What we do is produce a high-quality product."

So, for providers to have to take all this on their shoulders is not how things will improve. Instead, we have to think of it as a complicated system with lots of interlocking parts, from the clerks to the doctors to the computers. That is how you give providers the tools they need.

QUESTION: I would be interested in your observations about optimal approaches for measuring physician performance even after we have some consensus about what the measures are. What recommendations would you make?

ASCH: In one project, we were trying to improve quality of HIV care. Quality measures are relatively easy to find for HIV, because of a proliferation of quality guidelines and measurement sets. Nonetheless, when we started our quality improvement effort in HIV, we first convened all providers who were to be measured and asked what they thought the right way to be measured would be. We gave them existing measures, which they debated for a day and a half before coming out with a measurement set that was very close to the one that we originally gave them. The major difference was that they owned them — they thought the measures were theirs. As a result, they were much more interested in how they were doing on those measures than they would have been if we had never done that process. When we omitted this step in another project for another condition, participating physicians complained that the measures did not get at true quality. As you might expect, this was an obstacle to focusing on quality improvement. So, when you think about how to change adult behavior, and consider how people incorporate normative changes, you find that it is the result of group processes. It's a result of talking to other people about how they approach a problem, and seeing if it applies to you. A rare person opens a book, thinks about it, and makes changes without talking to anyone. Such processes will help physicians to accept that they are going to be measured and to participate in the process. If we physicians don't participate in the construction of the measures by which we will be judged, there will be no shortage of other people willing to fill that gap.

CONTINUING EDUCATION POST-TEST

HOW CAN MEDICAL DIRECTORS HAVE THE GREATEST IMPACT ON QUALITY IMPROVEMENT?

Please tear out the combined answer sheet/evaluation form on page 45. On the answer sheet, place an X through the box of the letter corresponding with the correct response for each question. There is only one correct answer to each question.

- In a review of worksite health promotion programs, Goetzel and colleagues concluded that the greatest positive effect was produced by programs that provided:**
 - A wide range of healthy snack foods and beverages in vending machines.
 - Financial incentives.
 - Financial penalties.
 - Individualized risk-reduction counseling within the context of a comprehensive program sustained by a health-promoting culture.
- The greatest cause of mortality in bariatric surgery is a/an:**
 - Ischemic stroke.
 - Kidney failure.
 - Peritonitis stemming from a leak at junction of stomach and small intestine.
 - Pulmonary embolism.
- To date, the only prospective data about treatment of patients with HF-PSF have been provided by:**
 - CHARM-Added.
 - CHARM-Alternative.
 - CHARM-Preserved.
 - I-Preserve.
 - TOPCAT.
- Seventy percent of health care spending is accounted for by _____ percent of patients.**
 - 5.
 - 10.
 - 20.
 - 40.
- With respect to quality assessment, HEDIS is an example of:**
 - A focused explicit measurement system.
 - A global explicit measurement system.
 - Implicit institutional review.
 - Implicit physician review.
- Which of the following studies has not contributed to the belief that some patients will benefit from an LDL-C goal that is well below 100 mg/dL?**
 - HPS.
 - PROVE-IT.
 - TNT.
 - WOSCOPS.
- Which nonsurgical treatment for severe obesity has been shown to have long-term efficacy?**
 - High-protein diet.
 - Low carbohydrate diet.
 - Orlistat (Xenical).
 - Rimonabant (Accomplia).
 - None of the above.
- In Asch's view, quality-of-care indicators should be used to assess provider performance only if:**
 - Appropriate measures are in place to discipline underperforming providers.
 - The indicators are complemented by feedback from a statistically significant sample of patients.
 - The indicators can be tied to pay-for-performance incentives.
 - The indicators point to specific actions the providers can take to improve their performance.
- The Work Limitation Questionnaire is a tool for measuring:**
 - Absenteeism.
 - Disability.
 - Presenteeism.
 - All the above.
- The most effective therapy for achieving complete, long-term control of type 2 diabetes is:**
 - Bariatric surgery.
 - Glyburide.
 - Insulin.
 - Metformin.
 - Rosiglitazone.
- According to national guidelines, optimal treatment of HF-PSF employs which of the following?**
 - ACE inhibitors.
 - Calcium channel blockers.
 - AV pacemaker.
 - Ventricular pacemaker.
 - Optimal treatment of HF-PSF remains to be defined.
- The \$2 trillion that the United States spends annually for health care consumes what percentage of national gross domestic product?**
 - 5.
 - 10.
 - 15.
 - 20.
- Pseudotumor cerebri is caused by:**
 - Acute spinal trauma.
 - Cerebral hemorrhage.
 - Increased intra-abdominal pressure associated with central obesity.
 - Subarachnoid hemorrhage.
 - Type 2 diabetes.
- Which of the following drug classes is used in the treatment of HF-PSF but not in the treatment of systolic HF?**
 - ACE inhibitors.
 - ARBs.
 - Beta blockers.
 - Calcium channel blockers.
 - Spironolactone.
- The 14 percent of Medicare beneficiaries with heart failure account for what percentage of Medicare spending?**
 - 23.
 - 33.
 - 43.
 - 53.
- According to National Institutes of Health guidelines, obese patients with a comorbidity are eligible for bariatric surgery if their BMI is:**
 - >30.
 - >35.
 - >40.
 - >50.
- What percentage of U.S. health care expenditures is paid out of pocket by patients?**
 - 7.
 - 14.
 - 28.
 - 56.
- Gastric bypass (Roux-en-Y) is best described as a primarily malabsorptive procedure.**
 - True.
 - False.
- According to Goetzel, if an employer wishes to reduce the health care costs associated with modifiable risk factors, the risk factors must be addressed at the:**
 - Executive level.
 - Individual employee level.
 - Individual employee level and the population level.
 - Population level.
- The first widely used weight-reduction surgery was the:**
 - Adjustable gastric banding.
 - Nonadjustable gastric banding.
 - Gastric bypass (Roux-en-Y).
 - Jejunioleal bypass.
 - Vertical banded gastroplasty.

CONTINUING EDUCATION ANSWER SHEET/EVALUATION/CERTIFICATE REQUEST
HOW CAN MEDICAL DIRECTORS HAVE THE GREATEST IMPACT ON QUALITY IMPROVEMENT?

CE Credit for Physicians/Pharmacists

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I certify that I have completed this educational activity and post-test and claim (please check one):

- Physician credit hours
 Pharmacist contact hours

Signature: _____

PLEASE PRINT CLEARLY

First name, MI _____

Last name, degree _____

Title _____

Affiliation _____

Specialty _____

Mailing address _____

City _____ State _____ ZIP _____

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Physician — This activity is designated for a maximum of 4.0 category 1 credits toward the the AMA Physician's Recognition Award.

Pharmacist — This activity is approved for 4.0 contact hours (0.4 CEU).

ACPE Universal Program Number (UPN): 812-000-05-013-H01
 Release date: Oct. 15, 2005
 Expiration date: Oct. 15, 2006

To receive credit, complete the answer sheet/evaluation form and mail or fax the completed form to:

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Please allow up to 6 weeks for processing.

Credit will be awarded upon successful completion of assessment questions (70 percent or better) and completion of program evaluation. If a score of 70 percent or better is not achieved, no credit will be awarded and the registrant will be notified.

The cost of this activity is provided at no charge through an educational grant from AstraZeneca Pharmaceuticals LP.

0175CAZ

EXAMINATION: Place an X through the box of the letter that represents the best answer to each question on page 44. There is only ONE correct answer per question. Place all answers on this form:

- | | | | | | |
|-----|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | A. | B. | C. | D. | E. |
| 1. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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| 3. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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| 5. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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| 19. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

PROGRAM EVALUATION

So that we may assess the value of this self-study program, we ask that you please fill out this evaluation form.

Have the activity's objectives been met?

- Determine techniques an MCO can use to improve quality of care Yes No
- Highlight recent research and advances in the prevention and treatment of cardiovascular disease and related conditions Yes No
- Describe current health issues that are affecting health plans' priorities and goals Yes No
- Identify issues that medical directors face with respect to challenges, perspectives, and best practices Yes No

5. Understand how bariatric surgery can address a wide range of comorbid conditions affecting morbidly obese patients Yes No

6. Gain insights into treatment for heart failure with preserved systolic function Yes No

Was this publication fair, balanced, and free of commercial bias? Yes No

If no, please explain: _____

Did this educational activity meet my needs, contribute to my personal effectiveness, and improve my ability to:

- Strongly Agree5*
Agree4
Neutral3
Disagree2
Strongly Disagree1

Treat/manage patients?
 5 4 3 2 1 N/A

Communicate with patients?
 5 4 3 2 1 N/A

Manage my medical practice?
 5 4 3 2 1 N/A

Other _____

5 4 3 2 1 N/A

Effectiveness of this method of presentation:

- Very*
Excellent good Good Fair Poor
 5 4 3 2 1

What other topics would you like to see addressed? _____

Comments: _____

