A Wellness-Based Healthcare System for Chronic Diseases: Prevention, Intervention, and Innovation
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**A Wellness-Based Healthcare System for Chronic Diseases: Prevention, Intervention, and Innovation**

*Made possible by funding from [Funding Source]*
A profound paradigm shift toward wellness-based healthcare for chronic disease has been brewing for years and is now emerging with rapid force. The progress of this wellness movement hinges on the 3 interconnected forces of prevention, intervention, and innovation.

On October 29, 2009, American Health & Drug Benefits held its Second Annual Summit on stakeholder integration in Washington, DC, to explore the undercurrents and dynamics of anticipated system changes. The meeting (which is the basis for this special supplement) was structured to address the shift to wellness-based healthcare for chronic diseases and how this will affect the various stakeholders. Key questions posted were: How will wellness-based healthcare be financed? What forces are driving and impeding it? What impact will it have on innovation? And what immediate and long-term actions can be taken to implement it?

The objectives in convening the summit were to explore wellness-based healthcare within the clinical, business, and policy arenas; identify a consensus for implementing this paradigm shift; and recommend steps required to implement system changes.

The presentations captured in this supplement extend beyond the confines of benefit design to address the role of key stakeholders—payers, patients, providers, purchasers, manufacturers, and policymakers—in the pursuit of wellness-based healthcare. The presumption that any one stakeholder has all the important answers neither solves problems nor encourages innovation.

This wellness-based initiative dovetails fittingly with the guiding principles of American Health & Drug Benefits—the balancing of cost, quality, and access by integrating the clinical, business, and policy aspects of our healthcare system.

The Complex Nature of Policymaking

Our healthcare system is by nature complex and is becoming more complex over time. Generating solutions involves a number of players. When these players take on multiple roles and multiple interests, conflicts arise.

The current legislative attempts at healthcare reform represent how complex and conflicting the various interests and the power roles of the government are. Understanding the nuances of each stakeholder is crucial in determining what steps must be taken in the healthcare system to promote wellness and prevention, sustain innovation, and ensure appropriate care delivery, particularly for people with chronic diseases.
The various roles of government include payer, purchaser, regulator, protector, and advocate. These multiple roles require juggling numerous, and sometimes conflicting, interests. As a payer, the government processes claims and contracts with providers. As a purchaser, the government ultimately contracts with health plans, attempting to leverage its buying power to improve the value of the services delivered.

Both the federal government and state governments have regulatory roles that include inspection and safety oversight. The US Food and Drug Administration, a powerful governmental regulator, can also exercise influence on payer and purchaser policies. The government’s multiple roles also result in the conflicts and delicate balances inherent in implementing its policies, some of which are currently under consideration on Capitol Hill.

In its role as protector, the government must balance doing enough to protect the public, without doing too much or overreacting. The government’s role as protector can ultimately influence what it may have to do on the regulatory side. An example of this is the impaired capacity of the United States to develop some vaccines, because of policies emanating from the government’s role as financier and purchaser. Subsequent proprietorship and low price-setting by the government diminished the incentive to develop vaccines and generate innovations in immunization.

In addition, in its advocate role, the government provides programs and services for the public, including the underserved, and must weigh the financial burden of these programs, such as Medicare and Medicaid, on taxpayers.

**Payers and Employers: Business Considerations**

This supplement provides a podium to stakeholders not often included in this type of forum—employers and payers, who offer their business perspectives about the most effective strategies for driving change. Employers and payers share similarities with the government with respect to balancing conflicting roles and delivering value in healthcare.

There are a number of economic inconsistencies in today’s healthcare market. Although most people agree that the current system needs to change, what is going to change, and the details accompanying that change, particularly as we move toward a culture of prevention and wellness, remain to be determined.

Preventing downstream expenses as a result of instituting prevention and wellness programs is becoming increasingly important to employers and to unions. We are beginning to see earlier and more aggressive interventions, as well as a growing advocacy for consumer involvement in their own health. Engaging employees, consumers, or union members earlier in incorporating healthy lifestyles and activities plays a key role in averting or reducing complications, and has a potential role in slowing or preventing the progression of chronic diseases.

Finally, the future of innovation is uncertain. How will changes in policy, coverage, and benefit design influence innovative approaches to prevention and wellness initiatives and shape future intervention models?

From the employer’s perspective, the economic benefit associated with healthy employees is key. Along the healthcare continuum, at the one end, health- and wellness-based programs that focus on nutrition and exercise provide an opportunity to curtail costs. At the other end, disease management programs that are designed to manage patients with chronic diseases aggressively are generally very expensive and resource-intensive. One of the challenges employers face is dealing with the largest sector—the gap in between these 2 approaches—by reducing the risks between wellness and major disease events/complications.

Employers now have an opportunity to apply the principles of insurance to help manage risks, prevent the preventable, and change incidence rates, thereby ultimately affecting the costs associated with the health status of their employees.

Improving wellness and fostering prevention in the workplace, although not a new concept, has taken on renewed urgency in the current wellness-based environment. Intervening early, before a disease progresses, and creating a culture of health at work are among the many exciting opportunities employers are continuing to explore.

**Overcoming Obstacles in the Prevention of Chronic Diseases**

Through the voices of many experts representing key stakeholders, this publication describes the chief obstacles to wellness-based healthcare and innovation, discusses the potential ripple effects—positive and negative—of anticipated changes, and presents recommendations for effective approaches to implementing wellness-based healthcare that balances the needs and interests of multiple stakeholders, including payers, patients, and providers. This supplement highlights potential system-wide changes that could result in improvements in our national health status, reduce overall costs, and usher in a sustainable, value-based healthcare system.
At the start of the last century, healthcare was financed in a much different manner than it is today. During the past 100 years, several financial “crises” have occurred that have led to significant recalibrations of this system. Although one can debate the relative value of these adjustments—and whether they were true long-term solutions as opposed to short-term reactions—they demonstrate concrete changes to the healthcare delivery system.

Presently, as the number of uninsured Americans remains at the level of 40 million to 50 million (approximately 15% of the population), questions are being asked about what can be done to improve access. At the same time, employers are concerned about the costs they incur in providing health benefits and the impact that those costs have on their ability to compete in a global marketplace. At a minimum, understanding our past may allow us to better resolve current or future difficulties. Furthermore, understanding the relative momentum or inertia of certain initiatives in our present system may allow us to predict how the system could move in the future.

In the Beginning: The Era of Cash and Generosity

In the early days of the 20th century, healthcare was a “cash business.” Physicians providing patient care would bill and collect from the patient. If a patient was unable to pay, the services would be provided pro bono, or a mutually agreeable payment strategy (eg, bartering, payment plan) would be established. For hospitals, the process was similar; however, much of the hospital care was funded through philanthropy. Many examples of these privately funded facilities remain today, including Geisinger Medical Center in Danville, PA, and the Johns Hopkins University School of Medicine, which was initiated with funding from several families in the Baltimore, MD, area.

Medical interventions available during that time were simple and few, and the financial system in place worked well enough to support the delivery of services. The rise of the hospital system was a huge step forward in providing effective care. The practice of surgery, greatly advanced and developed on battlefields, moved into a relatively germ-free hospital environment, reflecting the new consensus regarding the need to prevent infection in the surgical process. Paralleling these surgical improvements were advances in anesthesiology that enabled these procedures to be performed with greatly reduced trauma to the patient. These were qual-

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ity advances that society welcomed. Patients, employees, communities, and families would all benefit when patients recovered from serious illnesses and injuries and returned to productive lifestyles.

The indemnity insurance era was born. Although this model evolved as a solution to a funding crisis, its impact was much broader, and its effects are still evident today.

The response to the crisis, the creation of catastrophic or indemnity health insurance, was simultaneously innovative and disruptive. Described as “prepaid” healthcare or “voluntary taxation” to fund healthcare, an insurer would estimate the probability that a member would require hospitalization and the cost of those services, then divide these costs over the patient’s anticipated life expectancy. The fees were collected and invested, and the insurer bore the risks for payment of services, as long as premiums were paid in full. The patient would be protected from the sudden costs of a serious illness. Hospitals had a reliable payment stream that was slightly more palatable than collecting from ill patients or from their families.

There was a great deal of rhetoric at the time regarding the impact of these “third parties” on the long-standing physician–patient relationship. But this was not a decision to keep the old model or to accept a new model: the old model was not viable, and change was inevitable. The healthcare system could no longer rely on its traditional streams of revenue—change was necessary for the survival of the system. The indemnity insurance era was born.

Although this model evolved as a solution to a funding crisis, its impact was much broader, and its effects are still evident today. Because the model focused on providing funding for hospital care, the hospital became the crystal around which the American system grew, and graduate and postgraduate medical education grew around hospitals. Medical schools remained close ly married to hospitals until only the past decade, when curricula began to incorporate more ambulatory experiences. The catastrophic illness (ie, hospital care) became the focus of our care model. To this day, few residency training programs exist outside of this traditional model. Even “primary care” residents, who will spend most of their postgraduate careers outside of the hospital, spend most of their training hours in the hospital. The payment model—created to fund hospital care—led to the evolution of an American system of healthcare that focused on catastrophic disease. This system is perpetuated through the overall “view” of healthcare that developed in the shadow of this financial model.

An interesting twist occurred in the 1940s. World War II had significantly constricted the domestic work force. With industry supplying the war machine, there came an increased demand for labor. How better to attract mothers on the home front into the labor force than to provide health insurance for their families? Employers embraced the indemnity model of coverage as a benefit to be offered in lieu of salary increases, which were frozen by government fiat throughout the war. Insurance evolved from a private investment to an employer benefit, moving one step further from a personal responsibility to an “entitlement.”

The American patient began to lose the personal financial connection to healthcare expenditures, transforming the American healthcare economy into a most peculiar system, unresponsive to the basic economic principles and market forces that govern most other sectors. This would have important consequences as Americans lunged forward into a period when science would unlock seemingly endless opportunities to heal. As scientific knowledge grew, so did the inherent costs of providing new treatments and medications. The result was a decrease in mortality, and complications associated with illness, leading to longer life expectancy and longer courses of costly therapies.

Although the indemnity insurance model prevailed as the predominant mode of finance through the 1970s, this model was far from perfect. In the early days, when few treatments were available, life insurance was probably a better investment than health insurance. As technology advanced and survival increased, healthcare costs rose, as did indemnity insurance premiums. The old, the poor, and those with significant disease states were often “ uninsurable,” because the expected costs led to premiums that were unaffordable, or their illness prevented them from...
being able to work to afford the premiums or to access the employee benefits.

The Second Crisis, Access, Ushers in the Third Era: Government Programs
In the 1960s, a new crisis unfolded, namely, access to healthcare. The poor, the disabled, and the elderly were still excluded from private or corporate-funded indemnity programs. Costs were rising, and it became clear that in this model access to “insurance” was required for “access to care.” In the mid-1960s, this crisis led to the deployment of 2 social programs—which had been decades in the making—Medicare and Medicaid.

Medicare was developed as a federally funded and administered benefit for older Americans and those with chronic disabling illnesses. The program was created not as an insurance product but as an entitlement. The difference is significant. Insurance products must estimate current and future liabilities and maintain cash reserves sufficient to cover those liabilities. As an entitlement, Medicare did not establish such reserves to cover liabilities; rather, current-year costs were funded by taxes in subsequent years. At the time of the program’s development, this may not have been a concern, as the early stage of the baby-boom population was hitting employment age.

Today, however, the baby boomers are moving in the opposite direction, out of the work force and into the age-group where healthcare costs will be funded by Medicare. With continued increases in the number of beneficiaries and in the costs of care, concern over the ability to continue to fund this entitlement in its current form is well founded.

Medicaid was deployed as a program with partial federal funding but with administration by each state. The goal was to provide coverage to those who could not afford indemnity coverage. States developed a variety of programs to manage these populations, by managing access to coverage and services and even privatizing the benefit. However, burgeoning costs, complicated by regulations prohibiting many strategies employed by commercial insurers to manage medical costs, have created a tremendous strain on most state budgets.

Over the short-term, Medicare and Medicaid undoubtedly eased the burden of access created by the cost limitations of the indemnity insurance model, but other holes were developing. With a new understanding of preventive strategies—vaccinations, screening for early signs of disease, and new ambulatory technologies—consumers were interested in products that would fund these “outpatient” costs in addition to the inpatient coverage historically provided by indemnity plans. Similar demands were being made on the government-run Medicare and Medicaid plans. Healthcare was changing, and so were the payment mechanisms needed to adequately fund the new system.

Pharmaceuticals were being developed at a record pace, and access to drugs to control or treat disease, in the hopes of preventing the need for expensive hospitalizations, became a consumer expectation, as well as a possible tactic to control overall healthcare costs. New technologies continued to convert acutely fatal conditions to chronic disease states. With the benefit of survival came the cost of long-term therapy. As costs climbed, so did the actuarially based premiums. With higher premiums, a greater percentage of the population was unable to afford indemnity coverage, and the costs to employers required to provide healthcare benefits to employees became intolerable, limiting successful competition in an increasingly global market. Suddenly, healthcare costs became a “corporate tax,” not shared by other members of the global marketplace, who did not have the responsibility to fund healthcare benefits. As healthcare costs rose despite gains in survival and quality of life, a new crisis erupted: how to fund this model.

The Third Crisis, Cost, Ushers in the Fourth Era: Managed Care
Perhaps no term is as overused, ill-defined, or emotive as the term “managed care.” Some view this era as the enlightened era of healthcare delivery, others regard it as the true dark ages. Successful managed care products are those that meet or exceed the needs of their customers, who are anything but homogeneous in their expectations. Patients want insurance plans that cover inpatient and outpatient services, preventive
services, well visits, and prescriptions. All of these demands would reasonably be expected to increase the scope of services, and therefore, their prices. In direct contrast, payers (eg, government and employers) want a less-expensive alternative to indemnity plans, especially those required to provide coverage for their employees by government regulations. At first glance, this seems like an impossible task.

But the major philosophical change that occurred during the fourth era was the key: the belief that careful assessment of risk, combined with efficient utilization, could provide “more for less.” Indemnity plans focused on predicting the likelihood that the insured would become ill, and collected those costs over the insured's lifetime. This money could be invested with interest, and the premium and investment proceeds would cover the company's management expenses, medical costs and provide a dividend for shareholders if the product was for profit. The focus was on “predicting risk” and calculating premiums. In this new era, to successfully provide more for less, insurers would need to reduce risk, modify risk, and reduce the costs of services through contracting changes and developing efficiencies within the system.

This new philosophy placed a premium on preventive services and the role of the primary care physician (PCP) as the captain of the ship. Disease management programs bloomed, in hopes of changing financial and quality outcomes; however, attempts to develop regionally restricted networks with focused pricing collided with patients’ demands for free or unlimited choice. Plans and PCPs became “gatekeepers,” attempting to direct care and reduce inefficiencies. Health maintenance organization (HMO) plans prospered, and employers and other payers relished the low-cost options that drove most indemnity plans to adapt or become extinct.

Government payment structures changed as well, most notably with movement to a prospective payment scale for Medicare hospital payments and the resource-based relative value scale for Medicare physician payments. Burdens of paperwork and barriers to overcome in precertification and the proof for medical necessity led to a higher overhead. Pharmacy benefits quickly became hard to negotiate, as each plan, or each rider within a plan, defined its own formulary and benefits structure. PCPs controlled referrals, power bases shifted in systems, and everyone in the process was undergoing tremendous change. When patients refused to accept limited choice in more restricted HMO networks, preferred provider organizations (PPOs) and point-of-service plans further expanded the HMO market, often allowing greater choice, although with added expense to the consumer.

In some states, Medicaid patients were enrolled in private HMO/PPO plans. Medicare Choice programs attempted to entice patients to try the new system, often with more benefits than traditional plans (preventive services and pharmacy coverage) in exchange for accepting more restricted networks. More recently, the traditional Medicare program developed a pharmacy benefit under Part D. Managed care did at least temporarily manage cost increases. Preventive services, quality programs, disease management programs, and patient safety have all improved more rapidly than in past decades. But were the demands successfully met?

Employers’ costs of health insurance continue to climb and remain a barrier to effective competition in global markets. Revenues for providers are not rising to meet the additional costs of liability coverage, workforce shortages, and unfunded regulatory mandates. Providers are required to be at once lean and efficient, and yet prepared for surges of patients in disasters and pandemics. Access to health insurance and healthcare services remains an issue. State and federal programs focusing on quality reporting, the snowballing concept of pay-for-performance, patient safety reporting, information technology, and more rigorous accreditation tax already constricted resources, removing them from direct patient care, often without proven benefit.

The major philosophical change that occurred during the fourth era was the key: the belief that careful assessment of risk, combined with efficient utilization, could provide “more for less.” Indemnity plans focused on predicting the likelihood that the insured would become ill.

**The Era of Healthcare Reform and the Role of Wellness and Prevention**

Which solutions will be deployed to deal with these challenges, and how will the next era be defined? High costs continue to motivate employers to seek more affordable alternatives. Consumer-directed health plans, higher copays, and higher deductibles have transferred at least some of the financial risk back to the patient. A new focus on wellness and prevention may yet offer part of the answer to cost-escalation.

**Role of Wellness**

What is the role of wellness in the new reform era? Initial considerations should determine what a wellness model looks like and identify the chief barriers to
A wellness model requires a solid plan that identifies specific diseases on which our solutions should focus and outlines the direction for our national policy and strategy.

According to the Centers for Disease Control and Prevention, the top 10 leading causes of death in the United States include heart disease; cancer; stroke; chronic lower respiratory diseases; accidents; diabetes; Alzheimer’s disease; influenza and pneumonia; kidney disease; and septicemia. This may or may not be the list of diseases on which we should focus. At some time we will all die and will be assigned a cause of death. It is possible that these are the “right” causes. One could argue that the focus should be placed on the most costly diseases, those that cause the highest rate of absenteeism from work, or those that influence quality of life and productivity at midcareer. It is essential to determine which diseases we wish to impact, because some will respond to a wellness/prevention model better than others.

Tobacco use is a major risk factor that is shared among 6 of these top 10 causes of death. Hypertension is a risk factor common to 4 of these leading killers, yet 28% of Americans with hypertension are unaware of their condition, 39% are not receiving therapy, and 65% do not have their blood pressure adequately controlled.

Drug and alcohol abuse are risk factors for 6 of the top 10 diseases, including heart disease, cancer, stroke, chronic lower-respiratory diseases, accidents, and kidney disease. Diabetes, a major cause of death, is also a risk factor for 7 other top 10 diseases. Obesity is a risk factor for 6 of these diseases. All these risk factors cited lend themselves to more of a wellness-oriented approach rather than a catastrophic illness approach.

Despite massive investments in healthcare, the United States has a lower healthy life expectancy than many other major countries (Table 1). Wellness models focused on a continuum of health tend to include several dimensions: emotional, intellectual, social, environmental, and spiritual factors.

Emotional aspects include self-esteem, self-confidence, trust, love, and self-expression. Intellectual factors include the ability to learn, to grow, and to participate in decision-making, which is important to healthcare. Social aspects entail the ability to have satisfying interpersonal relationships, to respect differences, and to adapt to social situations in daily behavior as you interact with others. Environmental factors relate to an appreciation for the external environment and the individual’s role in preserving and improving conditions. Physical factors include body size, shape, sensory acuity, susceptibility to disease and disorders, body function, recuperative ability, striving for positive lifestyle behaviors, and personal responsibility for one’s own health and healthcare. In addition, the spiritual aspect of wellness involves a person’s search for meaning and purpose in life, personal belief systems, alignment of living with values, and a sense of inner peace.

**New wellness models demand solid strategies for 3 key areas: prevention, intervention, and innovation.**

This comprehensive vision of wellness is ambitious, and healthcare cannot realistically address the entire list. However, healthcare must take ownership for the physical and emotional dimensions of wellness. In addition, our system should play a role in understanding and enabling other wellness dimensions and operate in such a way to allow these other needs to be addressed.

**Wellness Strategies**

New wellness models demand solid strategies for 3 key areas: prevention, intervention, and innovation.

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**Table 1 Years of Healthy Life: World Health Organization**

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<td>72.6</td>
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</table>

The key to success is providing the right care at the right time. Diet, exercise, and regular physician visits are essential, as are early identification and treatment of chronic diseases.

A staggering 33.8% of Americans are obese, and 68% are overweight or obese. Forty-two percent of patients report being advised by a doctor that they should lose weight, and two thirds of obese patients report that they were trying to lose weight. Those with lower levels of education are almost twice as likely to be obese and to develop diabetes. It is vital that we understand and address the major barriers to wellness that may exist in these populations.

Barriers to wellness may include the fact that healthier foods cost more and are less convenient to some groups. Prepared foods tend to be less healthy and are both available and convenient. Fresh produce is not always available, and corn syrup and sweeteners are ubiquitous. Many people would prefer the quick “fix” of taking a pill rather than working to make difficult changes in their diet, behavior, and lifestyle. There is more confusion than clarity these days about whether we should count fats, calories, or carbohydrates. Wellness will require a focused, evidence-based strategy in addition to clear tactical guidance regarding best practices that are able to successfully improve outcomes.

**Conclusion**

The healthcare system that was created to deal with past crises must now be altered dramatically to enable future success. Steps for moving forward include determining which diseases present a clear and present danger, thereby warranting strategic focus; identifying risk factors common to those diseases that can be addressed, and understanding how wellness-based initiatives may successfully affect those risk factors. Understanding and resolving the barriers to wellness and addressing not only the physical and emotional needs of patients but also the intellectual, social, environmental, and spiritual dimensions will require changing the way we view health as a country. Our current system may not be capable of evolving to meet these needs; instead, a wholesale change in our philosophy and delivery systems may be required.

**References**


**Suggested Readings**


Epidemiology and Impact of Chronic Diseases: The Promise of Prevention

Nirav R. Shah, MD, MPH

Of the nearly 2.5 million deaths in the United States in 2006, more than 70% were the result of conditions categorized as chronic diseases. Many of these deaths, attributable to heart disease, stroke, cancer, and diabetes, can be prevented or delayed by preventive measures and risk factor modification: control of blood pressure, quitting cigarette smoking, increasing physical activity or modifying diet. Using appropriate metrics (eg, determining quality-adjusted life-years, evaluating the clinical preventable burden, or establishing the cost-effectiveness of services), one can best identify and prioritize the preventive actions that will have the greatest impact on health and costs. [AHDB. 2010;3(2 suppl 6):S89-S92.]

In 2006, almost 2.5 million people died in the United States. Although this may seem small relative to a population of more than 300 million people, many of these deaths could have been prevented, or at least significantly delayed. More than two thirds (1.7 million) of these deaths were the result of chronic diseases, which are mostly noncommunicable illnesses that are prolonged in duration, rarely cured, and often preventable.

The profile of diseases contributing most heavily to illness, disability, and death among Americans changed dramatically during the past century. In the early 1900s, acute and infectious diseases were the primary killers, and in much of the third world that remains the case even today. Chronic diseases, such as cardiovascular disease, stroke, cancer, and diabetes, are currently the most prevalent, costly, and eminently preventable conditions that are affecting the US population and healthcare system.

According to the Centers for Disease Control and Prevention, in 2005, 133 million Americans, almost half of all Americans, had 1 or more chronic conditions; and one fourth of these persons had significant limitations on their daily activities. It is estimated that >75% of healthcare costs result from managing chronic health conditions. In 2005, the leading causes of death in the United States were:

- Number 1—cardiovascular disease: 631,000 deaths
- Number 2—cancer: 560,000 deaths
- Number 3—stroke: 144,000 deaths
- Number 6—diabetes: 75,000 deaths.

Each condition has modifiable risk factors, and control of these risk factors can markedly reduce or delay the incidence of these events.

Risk Factors

Hypertension

A prime example of the link between certain health conditions and chronic diseases is hypertension and its impact on heart disease and stroke. According to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7), for every 10-mm Hg diastolic or 20-mm Hg systolic increase in blood pressure (BP) above normal, the risk of death from ischemic heart disease or stroke is doubled. By controlling BP to normal levels, the risk of death from these 2 conditions could be drastically reduced. But, as recently as 2003, only 70% of patients with hypertension were even aware that they had high BP; only 59% were being treated for hypertension, and only 34% had their BP adequately controlled.

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Smoking

Another factor affecting the prevalence of heart disease and stroke is cigarette smoking. Although the number of Americans who smoke is markedly less than a generation ago, about 1 of 5 Americans still smoke. A large number of smokers are teenagers or young adults—an age when they are more susceptible to such addictions—providing a longer time for the deleterious effects of smoking to occur. Many studies have shown that a significant amount of damage resulting from smoking is reversible if people stop smoking, even if they already have heart disease.

Lifestyle

More than one third of all adults fail to meet minimum recommendations for aerobic physical activity. Only 1 of 4 adults and 1 of 5 high school students follow a diet containing ≥5 servings of fruits and vegetables daily. Moreover, about 1 of 6 Americans aged ≥18 years engage in binge drinking, defined as >5 drinks for men or >4 drinks for woman during a single occasion in the past 30 days.5

Findings from a meta-analysis of studies investigating the potential effects of lifestyle and dietary changes on mortality showed that smoking cessation before age 50 reduces the mortality risk in people with coronary artery disease (CAD) by 35%, and in healthy people by 50%.6 This analysis also showed marked decreases in heart disease mortality from increased physical activity, moderation of alcohol intake, and improved dietary habits.6

Although some forms of cancer have a strong genetic link and cannot be prevented, many others are associated with environmental factors and lifestyle choices, which provide the opportunity for preventive measures. For example, melanoma is strongly associated with excessive exposure of the skin to sunlight. Smoking is recognized as the primary cause of lung cancer (as well as other chronic respiratory diseases). Cancers of the colon, breast (postmenopausal), endometrium, kidney, and esophagus are associated with obesity.7 Although cancer screening only prevents cancer for certain malignancies, it most often allows for detection of a malignancy in an earlier stage, which makes it more amenable to potential cure.

Diabetes

In 2006, the prevalence of diabetes in adults was 12.9%, with about 40% of diabetics undiagnosed.8 The prevalence of prediabetes (defined as impaired fasting glucose or impaired glucose tolerance) was nearly 30%, so in total more than 40% of the US population has either diabetes or prediabetes.9 The risk of death among people with diabetes is twice that of people of similar age without diabetes.9 About 7% of adolescents age 12 to 19 years old have impaired fasting glucose,9 which is especially prevalent in obese children. In a study of obese children, 25% of those between the ages of 4 and 10 years, and 21% of adolescents (11-18 years) had impaired glucose tolerance.10 These children are our future diabetics, unless something is done to reverse the obesity epidemic. If current trends continue, 1 of 3 Americans will develop diabetes sometime in their lifetime, and those with diabetes will lose, on average, 10 to 15 years of life. Diabetes is the leading cause of blindness, kidney failure, and nontraumatic lower-extremity amputations.

Obesity

Obesity has essentially become an epidemic (Figure 1). Using body mass index (BMI) as a reference point, normal weight range is defined as a BMI between 22 kg/m² and 25 kg/m²; overweight, a BMI between 25 kg/m² and 30 kg/m²; and obese, a BMI >30 kg/m². According to studies by the Behavioral Risk Factors Surveillance System, in 1988 not one of the states that reported data had an obesity prevalence >15%.11 In 2008, only 1 state had a rate <20%, 6 states had rates >30%, and the majority of the other states had rates of obesity >25%.11 According to the JNC-7, a 60% decline occurred in

![Figure 1 Percent of Obese (BMI ≥30 kg/m²) US Adults, 2008](source: Centers for Disease Control and Prevention. Behavioral Risk Factors Surveillance System. www.sustainabletable.org/2009/06/us-obesity-map/).
age-adjusted mortality rates for stroke in the United States between 1970 and 2000, with a corresponding 56% decline for CAD during the same period. This decreasing rate has leveled off, mostly because of the dramatic increase in obesity (Table). An obese person (BMI >30 kg/m²) is at more than double the risk for developing each of the chronic diseases, with an 18-fold increase for diabetes.

The effect of obesity on osteoarthritis (OA) is a major concern. OA is among the leading causes of disability in the United States. An estimated 46 million American adults, approximately 1 of 5, report doctor-diagnosed arthritis, and this number will increase as the population ages and gains weight. According to the Agency for Healthcare Research and Quality’s Healthcare Cost and Utilization Project, there were 553,022 hospital discharges with OA in 2002, with an average hospital stay of 4.1 days at an average cost of $27,300. This represents a total cost of more than $15 billion. The risk of OA is 47% in overweight and 61% in obese persons. It is estimated that by 2030, as many as one third of adults will have limited activity due to OA.

Costs

In 2007, the costs of chronic diseases represented almost 75% of the nation’s >$2 trillion expenditures in total medical care. Heart disease and stroke alone accounted for about $448 billion (Figure 2). Using appropriate metrics, one can best identify and prioritize the preventive actions that would have the greatest impact on health and costs. The “clinically preventable burden” is such a measure of the total potential health benefits if a service is offered to everyone who is eligible. Using the clinically preventable burden and taking into account cost-effectiveness, the services that should be prioritized include immunizing children, tobacco-use screening, and discussing aspirin use with high-risk adults. Alcohol use screening and counseling, colorectal cancer screening in adults older than age 50 years, and hypertension screening and treatment in adults are also highly ranked services. Relative to services such as dietary counseling of adults and cholesterol screening of high-risk women older than 45 years, higher-ranked services provide considerably more value than such lower-ranked preventive services, and should be prioritized by healthcare decision makers.

Challenges

The number of Americans older than 65 years will double between 2000 and 2030, which will present significant challenges to an already-overburdened healthcare system. For example, in 2005, there were more than 1 million adults aged >65 years in nursing homes in the United States, with more than half of them aged >85 years. These numbers are going to grow as we treat the patients who already have a disease and keep them alive longer. Conditions that will accompany the increasing aging population, leading to increased nursing home care, include cardiovascular diseases, mental and cognitive disorders, disorders of endocrine system, and joint disorders.

Who is going to treat all these patients? Mostly physicians, and more physicians are being trained. It is estimated that the total number of physicians will increase by 13.4% to 866,000 by 2020. However, there is a current and projected shortage of primary care physicians. Although the number of primary care physicians is projected to increase by 18% to 345,000 by 2020, this will not be nearly enough to handle the swelling number of patients, especially older patients who require a much higher level of medical care. It has been estimated that there will be a shortfall of 150,000 physicians by 2030. Of course, there may be major

<table>
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<th>BMI, kg/m²</th>
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BMI indicates body mass index.


Figure 2 Annual US Medical Cost for Chronic Diseases

Changes in providing healthcare as a result of possible healthcare reforms. The influence of these changes cannot be projected at this time.

Treatment and advances in treatment are beneficial, but prevention, both primary and secondary, is the best way to prevent or delay disease and potentially control healthcare cost.

Conclusions
Despite these projected future problems in managing healthcare, a comprehensive preventive approach offers significant hope for the future, saving lives and reducing needless suffering and costs. Treatment and advances in treatment are beneficial, but prevention, both primary and secondary, is the best way to prevent or delay disease and potentially control healthcare cost.

This requires a real interaction among all the stakeholders in healthcare, including patients, who have the most important role in preventive medicine. Researchers tend to talk about patients, but not necessarily with them, and that is one of the big needs in terms of identifying patient preferences for care and incorporating their voice in keeping them healthy. Other stakeholders include clinicians, health insurance companies, care delivery leaders, employers, consumers, and the government. Challenges exist, but they can be addressed by focusing on the tasks ahead and using available data to determine where the biggest gaps are, who is suffering disproportionately from chronic conditions, and what the most effective actions are, such as smoking cessation. Quantifying the potential impact of our activities will provide the means to prioritize these activities, whether by determining quality-adjusted life-years, evaluating the clinical preventable burden, or establishing the cost-effectiveness of services.

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Bending the Curve, Changing Provider Organization: Implications for Wellness-Based Healthcare

Lawton Robert Burns, PhD, MBA

Healthcare reform plays an increasing role in the lives of Americans. Attempts to improve delivery and reduce costs involve considerable controversy. Two main approaches in the current healthcare debate are “bending the (cost) curve” and “changing provider organization.” These approaches are intertwined. Costs for hospitals, physicians, and retail pharmaceuticals represent 62.5% of all healthcare expenditures. Because value is quality divided by cost, reducing the cost of healthcare will increase its value. This article presents recommendations for changing the healthcare delivery system and considers whether these can help in finding savings to reduce the cost of care. These options include reducing geographic variations, medical home, bundled payments, and accountable care organizations. The author explores the role of these models in managing chronic illness. [AHDB. 2010;3(2 suppl 6):S93-S97.]

Healthcare reform has become one of the most widely discussed topics in the country in recent months as both houses of Congress have attempted to arrive at a reform package that is acceptable to all parties involved, without bankrupting the country. Although nearly all Americans agree that reform is needed, the extent and type of reform necessary remain controversial.

Two major points of focus in healthcare reform are referred to as “bending the curve” and “changing provider organization.” The implication of these approaches on wellness and prevention in healthcare is the focus of this discussion.

Principles for Healthcare Reform

As a starting point, consider 2 sets of principles as enunciated by different sets of stakeholders in the healthcare debate. The first is from a report by the Commonwealth Fund, whose president is Karen Davis, PhD, former head of the Health Care Financing Administration, now the Centers for Medicare & Medicaid Services (CMS). Published in October 2009, this report summarizes 8 principles of healthcare reform aimed at protecting families’ financial health by providing access to health insurance and making that coverage affordable. These 8 principles are:

1. Protect families’ financial health
2. Make health coverage affordable
3. Aim for universality
4. Provide portability of coverage
5. Guarantee choice
6. Invest in wellness and prevention
7. Improve patient safety and quality of care

Principles 6 and 7 directly address the issue under consideration in this supplement.

Another influential group affiliated with the Brookings Institution, headed by John Bertko, FSA, MAAA, Consultant, and Mark B. McClellan, MD, PhD, Director, Engelberg Center for Health Care Reform, presented 4 steps for improving healthcare:

1. Build foundation for cost-containment and value-based care
2. Reform provider payment to create accountability for lower-cost and higher-quality care

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3. Improve health insurance markets
4. Support better individual patient choices.

The fourth principle falls into the wellness and prevention category. Therefore, at least in terms of principles that are being enunciated, wellness and prevention have a seat at the table.

**Bending the Curve**

To understand the concept of “bending the curve,” it is a good idea to look at what curve needs to be bent. In a testimony entitled “Financing Comprehensive Health Care Reform” given before the Committee on Finance, United States Senate, on May 12, 2009, Stuart H. Altman, PhD, Sol C. Chaikin Professor of National Health Policy at the Heller School for Social Policy and Management at Brandeis University, presented a slide (Figure 1) that shows the per capita growth in health expenditures during the past 43 years. A regression line drawn through the curve shows that healthcare expenses have been increasing almost linearly by 2% year after year (net of inflation) for more than 40 years. Bending the curve means trying to get that straight line to bend downward. But, there are 43 years of history to work against, during which time many different initiatives have attempted to bend that curve; the long-term success of those initiatives is apparent from Figure 1 (ie, none).

So one major problem is the straight line growth in healthcare costs. A second problem is the lack of demonstration of the value obtained for all those monies spent. Economists debate this left and right. Some say they get more than 100% return for every dollar spent. Others refer to how many billions of dollars are wasted on healthcare every year. Both sides of the argument get published but nobody knows what the value of the money spent really is.

If value is defined by quality divided by cost, and if the actual value cannot be determined, then reducing the denominator (ie, the cost) ensures that value will be increased, essentially bending the trend downward.

Many initiatives are being discussed and are part of impending legislation to try to bend the curve. Changes to Medicare Advantage are in nearly all the healthcare proposals. Other proposals include:

- Achieving lower drug costs in public programs through organized bargaining by the federal government with the pharmaceutical companies
- Bundling inpatient payments to hospitals and physicians
- Bundling payments to hospitals to include postacute care
- Coordinating care for the chronically ill
- Reducing hospital readmissions
- Incorporating electronic medical records
- Basing hospital reimbursement on performance (ie, pay-for-performance)
- Using value-based purchasing and utilizing patient-centered medical homes.

Other initiatives include the use of health information technology and comparative effectiveness research and incorporation of changes in payment for primary care and reimbursement for home healthcare.

Addressing variations in spending, reducing spending in high-cost areas, and promoting wellness and prevention are also among the proposed initiatives.

To increase value and bend the curve downward in healthcare spending, the obvious place to look is where the most money is spent. CMS releases the latest national health expenditures each year. Based on the 2007 data—the latest data released—31.1% of all money spent goes to hospitals and 21.3% goes to physicians. The third largest amount, 10.1%, goes to retail pharmaceuticals. The total of these 3 largest expenses represents 62.5% of all healthcare expenditures. This is where emphasis is placed when trying to bend the trend.
What causes healthcare to be of high or low value? At present, this is an unknown. Figure 2 depicts an approach from John Bertko at the Brookings Institution. On the left side are all the inputs to healthcare, the procedures or the drugs. Health technology assessment represents what is the right thing to use for a given patient, which patient gets the procedure or the drug, and who does the procedure. Beneath this is a huge black box that includes how providers are organized, and how they are paid. What goes in that black box and what is the optimal organization of providers that can lead to high quality and low cost is the goal of health services researchers.

Current concepts that may be considered to represent the content of the black box are areas involved in the present debate and include the following recommendations for changing the healthcare delivery system:

- Reducing geographic variations
- Medical home
- Bundled payments
- Accountable care organizations (ACOs).

The questions to consider are whether these may be the source of savings to reduce healthcare costs, and what these have to do with promoting wellness and prevention.

Reducing Geographic Variations

Reducing geographic variations is an outgrowth of the Dartmouth Atlas developed at the Dartmouth Medical School. The Dartmouth Atlas documents variations in spending on Medicare patients in hospital referral regions (Figure 3). The darker shaded areas in Figure 3 represent the higher-cost hospital referral regions in the country. There are also geographic variations in procedure rates. The question is—can that variation be reduced? Can the more expensive or profligate areas start to practice like the less expensive and profligate areas?

A recent report by the Kaiser Foundation suggests that this is probably the single area with the biggest potential to reduce healthcare spending. If providers could be made to reduce their variability across regions in the way they treat patients and in how they reduce cost, Medicare spending could be reduced by up to 30%. The problem is that no one knows how to do that. Some 30 years’ worth of good empirical research summarized by the Cochran Collaborative reveals uncertainty about how to change provider behavior. The single most important black box in this conundrum is how to get doctors to practice a different type of medicine from what they have been trained for.

At a July 2009 meeting entitled, “How Do They Do That? Low-Cost, High-Quality Health Care in America,” teams from 10 US regions that practice high-quality, low-cost healthcare gathered to discuss the local, regional, and national factors that form the basis for delivering high-value healthcare in their communities. At almost the exact time, President Obama picked up on the subject. A news report in June 2009 stated that President Obama referred to the Cleveland Clinic, as well as the Mayo Clinic in Minnesota, as examples of hospitals providing “the highest quality care at costs well below the national norm. We need to learn from their successes and replicate those best practices across our country.” The White House staff said that when Obama described the Cleveland Clinic as well and the Mayo Clinic as low cost and high quality, he was referring to statistics in the Dartmouth Atlas.

![Figure 2](image1.jpg)

Figure 2: What Causes Healthcare to Be High or Low Value?

![Figure 3](image2.jpg)

Figure 3: Per Capita Medicare Expenditures, by Hospital Referral Region, 2003

A group called How Do They Do That has now become sort of a national standard to get providers to practice according to the standards set at the Mayo Clinic and the Cleveland Clinic. What are the local, regional, and national factors that form the basis for delivering high-value healthcare? For example, in Sayre, Pennsylvania, a huge multispecialty clinic, the Guthrie Clinic, is now a part of a health system. In other regions there are large, multispecialty medical groups that practice with, and sometimes are salaried practitioners of, large hospital systems, and are referred to as the very integrated delivery systems. These are other areas of the country where providers have collaborated with the public sector and with the local government.

Patient-Centered Medical Homes

Patient-centered medical homes represent a method to reorganize primary care to promote coordinated care delivery. One of the principles that help define a patient-centered medical home is having a personal physician in a physician-directed medical practice who provides patient-centered care. This medical care is integrated and coordinated across providers, enhancing quality and safety. Open scheduling, expanded hours, and payment reform complete the picture.

Medicare beneficiaries present a major problem for the patient-centered medical home. More than half of all Medicare beneficiaries are treated by physicians who are either solo providers or in a group of 2. These doctors will not be able to become a patient-centered medical home, because they do not have the financial resources or the organizational capability to hire additional staff to coordinate care for all their patients. Much has to be accomplished in reorganizing primary care practices before they could begin to act as patient-centered medical homes. Another problem with a patient-centered medical home is its attempt to treat every possible patient. The real opportunity is to use this approach to treat the chronically ill patient rather than every patient in a physician’s practice.

Bundled Payments

The third suggested solution is bundled payments, which can be done in 3 ways. The payment to a hospital under the Medicare diagnosis-related group system can be bundled for the admission and for any readmission of the same patient. Medicare Part A and Part B can also be bundled, by lumping together the hospital payment with the doctor payment for a given episode of care. This payment approach was used in the 1990s for coronary artery bypass graft surgery. The demonstration worked but was politically killed by interest groups in the industry. It is now making a promising comeback.

CMS is launching an acute care episode demonstration featuring global payments within Medicare. A major problem is getting doctors and hospitals to cooperate and collaborate enough to split one lump sum of money.

Accountable Care Organizations

The ACO is an umbrella concept that includes bundled payments and the medical home. It involves taking all the doctors and the hospitals in a geographic area who are treating the same group of patients and giving them a capitated fee for those patients. With this one lump sum of money, they are now responsible for all the care for those patients. This is a global cap for all the hospitals and doctors in an area, and they have to figure out how to treat those patients under that budget cap. The 3 basic components of an ACO
are local accountability for cost, quality, and capacity; shared savings; and performance measurement.

Provider organizations able to handle this concept include Geisinger Health System, Kaiser Permanente, and the Mayo Clinic. But in most parts of the country, this type of fully integrated organization with salaried physicians does not exist. Most organizations have a private medical staff in a local voluntary hospital. These organizations would have to become virtual ACOs and work together even though they have no common ownership or common asset base.

**Review of 4 Initiatives to Reorganize Providers**

After a review of 4 of the initiatives that are being discussed seriously in terms of reforming the way providers are organized and operate, it is necessary to consider any issues facing these models. At 4 major issues should be considered.

The first issue is whether most providers can emulate the Mayo Clinic or the Cleveland Clinic. The answer is no. These organizations have been in existence for 100 years or more. It is naive to think that hospitals and doctors can start from scratch and emulate these organizations in the next 10 to 20 years. Of the more than 20,000 physician group practices in the United States, only 1% has 100 or more doctors. Currently there just are not enough building blocks to put together ACOs throughout the rest of the country. The system is probably 4 or 5 generations away from the rest of the country. The system is probably 4 or 5 generations away from the rest of the country.

The second question is what is the evidence base for these provider systems and models, bundled payments, the medical home, and the ACO. Indeed there is no evidence base. A 2009 Kaiser Foundation Report found that the evidence base was lacking. This does not mean that the reform proposals are bad, but there is a lack of evidence for these proposals.

A third concern refers to the time frame for expecting positive results from these new provider models. It may take at least 10 years, and probably more. There will be no short-term changes or bending of the curve based on these proposals anywhere in the near future.

The final question is what any of these provider systems and models have to do with chronic illness management. The answer is nothing. They do not address the problem at all. They are focused on hospital-based, physician office–based acute care, such as orthopedic surgery or cardiac surgery. But, they are not targeted at the proposals being discussed.

**Conclusion**

In health policy circles today, an “iron triangle of healthcare” exists, with the 3 angles of the triangle representing the 3 goals that our healthcare system aspires to achieve—reducing the rate of increase in cost of healthcare, improving access to healthcare, and improving the quality of healthcare.

In this context, bending the curve focuses on reducing the rate of increase in the cost of healthcare, the first angle, while the healthcare reform proposals under consideration focus on improving people’s access to care through access to health insurance, the second angle. The final angle, the quality angle, is the one addressed more through the wellness and prevention services than the other 2 angles. It seems that there are 3 distinct voices talking about 3 different policy goals. People are talking past one another without a coordinated effort to tackle these things at a time, let alone 3 at a time. Much improvement is needed in collaboration, coordination, and decision-making about the ultimate goals, methods, and evidence required to strengthen each supporting angle of the healthcare triangle to appropriately target the prevention and wellness angle.

**References**


Wellness-Based Healthcare: Economic Incentives and Benefit Design

Gene Reeder, RPh, PhD

This article explores some of the recent approaches to health insurance benefit design that are aimed at reducing medical costs through preventing disease rather than treating the disease after its onset. The traditional 7 basic principles of insurance are discussed in the context of healthcare utilization. Health insurers typically use certain methods to manage utilization and cost, which can be affected by preventive efforts. Instituting preventive care can help to modify the clinical, economic, and humanistic impact of chronic diseases. Alignment of economic incentives with health behaviors may induce the demand for preventive care, based on current examples of wellness-based health plans that have been shown to be effective. Results of a recent survey of payers illustrates their use of wellness-based benefits and their perception of the effectiveness of different approaches to achieve the desired results of benefits offered. [AHDB. 2010;3(2 suppl 6):S98-S103.]

Traditional healthcare insurance is generally focused on whether the insurance covers expenses associated with a medical condition. These expenses may include hospital costs, doctor visits, laboratory tests, diagnostic examinations, medications, and screening examinations, although screening remains controversial. Short of rationing care, these expenses are difficult to contain, let alone reduce. Newer approaches to healthcare seek to reduce costs by actually preventing disease, or at least minimizing or delaying its development and progression. Because chronic conditions are the major causes of mortality and morbidity and consume the vast majority of medical expenditures, chronic diseases are the primary target of these prevention and cost-reduction efforts.

Impact of Chronic Diseases

Chronic diseases—particularly cardiovascular disease, cancer, and diabetes—are among the most prevalent, costly, and preventable of all health problems. Morbidity and disability from chronic diseases, such as diabetes or arthritis, result in extended pain and suffering, impaired physical and social functioning, and decreased quality of life. Chronic, disabling conditions cause major limitations in activity for more than 1 of every 10 Americans. In 2005, 133 million people—almost half of all Americans—were living with at least 1 chronic condition.1

The 7 Principles of Insurance

Providing access to health insurance for all Americans through convenient and simple mechanisms is a primary goal. However, it is important to frame the discussion of health insurance in terms of the 7 basic principles of insurance2:

1. A large number of homogeneous exposure units
2. Definite loss
3. Accidental loss
4. Large loss
5. Affordable premium
6. Calculable loss
7. Limited risk of catastrophically large losses.

These principles have been taken from the classic book *Principles of Insurance.* Historically, these 7 principles have been used without significant variation since Lloyds of London began providing marine insurance in the late 1600s. The first principle says that there must be a large number of homogeneous exposure

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units, meaning very large classes of people with a similar risk of peril.

According to the second principle, a definite loss will result from an event that takes place at a known time, in a known place, and from a known cause. One of the early forms of individual insurance coverage was for life insurance, because death is definite and can be predicted with some certainty based on current age, sex, and health status.

The third principle is that the loss must be accidental. The event that causes the loss must be fortuitous and not under the control of the beneficiary of the insurance.

Fourth, the loss must be substantial. Trivial losses should not be insured because the administrative costs of dealing with small losses would exceed the value of the loss itself.

Fifth, premiums should be affordable. If the likelihood of the peril is so great and the potential loss is so large that the premium becomes unreasonable, people will not buy the insurance and will take the risk, unless they are required to buy it or be penalized. Mandatory health insurance is being considered in the various healthcare reform bills currently before Congress.

The sixth principle purports that loss can be calculated, or at least reasonably estimated, based on 2 key pieces of information: the probability of the loss and the cost involved if the loss occurs. From a pharmacist’s mindset, the question may be whether prescription drugs are an insurable benefit. The current healthcare reform trend appears to be moving away from insurance and the idea of an insurable event; that is, do they meet the 7 criteria for an insurable peril? Probably not, because prescription drugs typically represent a large volume of small claims that are often used at the discretion of the insured patient.

Today, much of what is discussed under the domain of health insurance is more closely aligned to group purchasing than to insurance.

Utilization and Cost Management Methods

Payers and employers deal with the issue of managing utilization and cost every day. Among the tools available to insurers, 4 management options are often used:

- Policy limits
- Policy exclusions
- Patient cost-sharing
- Risk ratings.

Policy limits are used frequently. Decisions must also be made about whether and what the annual or lifetime dollar limits will be. Currently, most insurers place $1 million to $2 million caps on lifetime benefits. To prevent large losses, limits are frequently placed on the quantities of prescription drugs or on other types of services in addition to annual or lifetime dollar limits.

Policy exclusions are the subject of ongoing debate. Frequently excluded are preexisting conditions, investigational treatments, and custodial care. Not paying for these exclusions can significantly reduce healthcare expenditures. Although the most “cost-effective” strat-
The change to wellness-based healthcare represents a true paradigm shift. The current treatment model focuses on the “supply side” of the equation, endeavoring to control unit cost and utilization. In contrast, the wellness model focuses on the “demand side,” by attempting to induce behaviors that promote and maintain health.

Cost-sharing by the insured is also a popular strategy to reduce marginal utilization and control cost. As a simple price effect, cost-sharing relies on the basic economic law of supply and demand: in general, as the price of a product or service increases, people’s demand for that product or service will diminish. Preventive services and perhaps other healthcare services can present an interesting economic dilemma: people may not be willing to pay for preventive care (ie, their demand for preventive care is zero when the care is provided at no charge). This raises the question of whether individuals should be “paid” or incentivized to consume services they would not otherwise purchase. For example, should smokers be paid to quit smoking so the health benefits of not smoking accrue to the individual and society? The economy of wellness and prevention can be complex, because many preventive healthcare components have a “negative price”—to get people to consume them, we have to pay them. That is, we may have to pay or subsidize particular individuals to get them to behave in a certain way.

**Impact of Preventive Care on Health Outcomes**

Clinical outcomes are relatively easy to determine. Mortality, morbidity, and degree of morbidity are generally quite apparent. Economic outcomes such as utilization and direct costs are likewise not difficult to determine. Although indirect medical costs require more extrapolation, they are generally straightforward.

But the outcomes that perhaps matter most to patients are the humanistic or patient-reported outcomes. These outcomes address the values of health-related quality of life and productivity from the patient’s perspective. Whether someone does not come to work (absenteeism) can be measured rather easily; however, measuring the value of productivity when people are working at only 50% of capacity (presenteeism) because they are sick, depressed, or suffering from day-after-the-night-before effects is much more difficult.

The change to wellness-based healthcare represents a true paradigm shift. The current treatment model focuses on the “supply side” of the equation, endeavoring to control unit cost and the utilization of hospitals, physicians, pharmacies, and pharmaceuticals. In contrast, the wellness model focuses on the “demand side,” by attempting to induce behaviors that promote and maintain health, with employers and health plans providing the incentives, tools, and the necessary resources to members. Of course, the supply has to be there to make this happen. The major challenge is how to get individuals, as well as providers and payers, to get involved in maintaining health. How do we create the incentive system or the benefit design that will integrate this approach and encourage beneficial wellness behaviors? Many benefit designs already include incentives and tools to help people better manage their own health. The question is why this is not working better.

**Risk Factors Influencing Medical Expenditures**

Although medical expenditures resulting directly from a given medical condition are fairly obvious, factoring in the impact of the risk factor for that medical condition into medical costs is not so obvious. By comparing medical costs for a cohort of patients who are at high risk for a specific medical condition with the medical costs for a comparable cohort of patients who are at low risk for that condition, we can estimate this difference. This provides some insight for the potential benefits of reducing the risk of the condition through wellness and preventive care (Figure 1).

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**Figure 1 Impact of High- vs Low-Risk Factors on Medical Expenditures**

![Graph showing the impact of high vs low-risk factors on medical expenditures.](#)

In all the conditions listed in Figure 1, expenditures are greater in the high-risk group, especially in the group with depressive disorders. The cohort with a high risk of depression has almost 70% greater medical expenditures than the cohort with a lower risk of depression. If it were possible to prevent depression or to intervene when people are tending toward depression, these incremental costs could be mitigated. Instead, today we typically end up treating full-blown clinical depression, but we are not so aggressive in preventing depression in people who are at risk.

Wellness-Based Healthcare

The model for wellness-based healthcare involves 4 basic elements. The first is provider incentives, which are generally part of the basic benefit design. These incentives include aligning payments for providing or prescribing preventive and wellness services, as well as incorporating at-risk assessments for their patients.

The second element addresses the roles of employers and payers, including workplace initiatives and incentives, to encourage wellness activities and behaviors. Offering affordable plans that include wellness benefits represents a major role for payers and employers.

Third is the role of government. The current proposed healthcare reform bills are considering both workplace incentives for wellness as well as required coverage for preventive services. The key question is, “How much incentive and what type of preventive services will be included?”

The fourth element is concerned with the type of incentives (positive or negative) that may be used to motivate individuals to engage in healthy behaviors. The positive, or “carrot,” approach rewards a particular behavior, such as regular exercise, by offering a reduced membership fee to a nearby exercise facility. The negative, or “stick,” approach penalizes an individual for failing to participate in healthy behaviors or for engaging in unhealthy behaviors, such as smoking. For example, many insurance companies now require their insured to sign affidavits that they do not currently smoke or use tobacco products, nor have they done so in the previous 2 years; otherwise, the members must pay a higher monthly premium to account for their increased risk of medical use. Both carrot and stick approaches are designed to encourage people to engage in behaviors that improve health and reduce or avoid risks.

Moral Hazards and Adverse Selection

Two major challenges for any insurance benefit design, including those with a wellness option, are moral hazard and adverse selection.

Moral hazard has to do with the insured person behaving differently from how they would behave if they were fully exposed to the risk. As seen with car accidents that are the driver’s fault, if the consequences of the person’s action do not rest fully on their shoulders, their propensity to do or repeat that action increases.

Adverse selection involves the tendency of people to purchase insurance against perils they are likely to incur; that is, people’s demand for insurance is highly correlated with their likelihood of experiencing the peril. For example, suppose an orthopedic surgeon tells a person that she requires a total hip arthroplasty. That person then calls her insurance company to determine if it covers the surgery. If not, the person will likely find a company that does cover the procedure and change insurance companies during the new or open enrollment period.

Two major challenges for any insurance benefit design, including those with a wellness option, are moral hazard and adverse selection.

When people are allowed to self-select in this way, those with the illness or condition will likely do so. Although this is labeled as the “moral hazard” in insurance, there is nothing inherently immoral about it. Much of the discussion about coverage for the uninsured or underinsured involves the issue of self-selection and its consequences for utilization and cost. Some people will either not purchase insurance or will choose a lower premium policy with higher out-of-pocket costs because they are not likely to experience certain events. For example, younger, healthier individuals may not purchase medical insurance, because they perceive a very low probability of a becoming ill.

Transitioning to Wellness-Based Insurance

Figure 2 shows the evolution of insurance products
from an indemnity model in which the insured pays 80% of the medical costs, and that is all that is covered (so-called major medical plan), down the cascade to where indemnity-based insurance began to exert some management controls. Today, we are in the managed markets arena and moving toward a wellness-based arena. In moving past managed indemnity, we have shifted from the insurance model into more of a group-purchasing model.

In 2009, the Kaiser Foundation conducted a survey of employer-sponsored health benefits and wellness-based benefits, comparing large firms with ≥200 employees with smaller companies (Figure 3). Although the prevalence of wellness benefits varies by the size of the employer, the majority of all employers surveyed offered at least 1 wellness-based program. A wellness program may be very limited, perhaps offering only a single coupon for a health club visit or a nutrition consultation, or more generous, providing an array of wellness programs. More generous wellness benefits tend to be offered by some of the larger employers in the United States. Several examples of wellness-based benefits offered by large employers are presented below.

IBM offers the Healthy Living Rebate program, which was started in 2004. It focuses on exercise, healthy eating, weight loss, smoking cessation, and health risk appraisal. In 2007, the program was expanded to include the Children’s Health Rebate program. Both programs reward employees for being healthy and for incorporating good nutrition and physical activity into their lives. Employees can get cash rebates of $150 for up to 2 activities each year, with an additional 2 rebates for the children’s program. Rebates are paid after completion of the required activity by the employee.

Walmart, one of the largest employers in the United States, offers a variety of wellness programs, including plans that allow access to additional preventive care coverage before meeting the annual deductible cost. The plans cover mammograms, colonoscopies, flu vaccinations, and other interventions demonstrated to be cost-effective, preventive strategies. Through purchasing agreements with associated organizations, Walmart also offers associates discounts on a number of wellness services, including fitness programs, weight-loss programs, personalized diet plans, and hearing aids. Wellness programs offered include nutrition for children and adults, as well as smoking cessation.

Pitney Bowes has been recognized for its healthcare...
benefit program, and this is also the case for its wellness programs. The Fit ‘n’ Fun activity, a 6-week family health and fitness program started in 2007, guides employees and their families on a variety of fitness and healthy-cooking activities. In 2008, enrollment nearly doubled (from 188 to 336 families), and 59% of families said they were exercising regularly by the end of the program, a 17% increase from a pre-enrollment survey.

Pitney Bowes also offers the Learn and Earn program, designed to educate and motivate healthy living. Another wellness program offers short courses on weight management and stress management and rewards participants with cash and other prizes. Other programs include discounts for Weight Watchers, local gyms, and tobacco-cessation programs.

This response suggests that “sticks” are more effective than “carrots” in incentivizing behaviors, and represents a marked inconsistency between what medical and pharmacy directors believe works, and what they are allowed to do in their insurance markets.

Wellness-Based Benefit Design in Managed Care

A survey of 60 medical and pharmacy directors participating in the Managed Care Network (www.mcn-web.com) was conducted by Xcenda in October 2009 to identify wellness-based benefit design programs offered by their plans. In response to the first question in the survey, “Does your health plan offer a wellness-based benefit design?” (described as a wellness program that included actual incentives for wellness activities), 19 participants said yes, 40 said no, and 1 was not sure. When those who answered no or not sure were asked if their plans were considering offering wellness benefits, only 15% said yes, 51% said no, and 34% were unsure.

In the 19 plans that offered wellness benefits, the most frequently offered wellness-based benefit was a smoking-cessation program, followed by a weight-loss program and activities to reduce blood pressure or cholesterol, and other benefits that address conditions with preventable components.

When these 19 responders were asked what incentives in their plans were designed to align behavior with wellness, about 60% had monetary incentives similar to those of IBM, and >60% had lower premiums for healthy behaviors. Therefore, nonsmokers had a lower premium than smokers—an example of a positive, or “carrot,” incentive.

However, when all 60 participants responded to the statement that “charging higher premiums for individuals who engage in unhealthy behaviors is more effective than rewarding individuals to pursue healthy behaviors,” 47% agreed or strongly agreed with the statement. This response suggests that “sticks” are more effective than “carrots” in incentivizing behaviors, and represents a marked inconsistency between what medical and pharmacy directors believe works, and what they are allowed to do in their insurance markets.

Conclusion

Plans involved in designing wellness/preventive health benefits are engaged in a real-life tug of war. The tug is between individuals pursuing very real, and what may be called hedonistic lifestyles, and the potential benefits of increased life expectancy and decreased physical limitations. The rope in the middle represents the benefit plans and the various carrot and stick incentives that may be employed to change behaviors. The success of any health reform program will depend in part on which side wins that war.

References

Significant changes to Medicare, Medicaid, and private insurance coverage are under consideration in the healthcare reform bills. These include an array of reforms intended to promote prevention and wellness. The reforms raise the prospect for genuine improvements to prevent disease and improve care for chronic conditions. However, some proposed changes may result in unintended consequences, harming efforts to increase access to preventive services. Major proposals are discussed, barriers to wellness-based health policy are explained, and specific recommendations to advance wellness are offered. [AHDB. 2010;3(2 suppl 6):S104-S108.]

In recent years and continuing along its current path, the government has assumed a growing, complex, and conflicting role in healthcare. For better or worse, the government is increasingly serving several, often conflicting, roles—protector, advocate, financier, payer, purchaser, and regulator. In addition to each of these roles presenting its own challenges and obstacles, the juxtaposition of multiple roles creates layers of complexities that affect wellness-based healthcare policy. This article discusses wellness policies currently under consideration in the healthcare reform bills, addresses the barriers to promoting wellness and prevention innovations, and provides policy recommendations for moving forward.

Wellness Policies under Consideration for Medicare

Among the provisions being discussed on Capitol Hill related to wellness and prevention, several policy changes are anticipated for the federal Medicare program. Perhaps the most positive change is the planned elimination of copayments and other cost-sharing for preventive services. This, however, raises the question of what qualifies as a preventive service.

Today, Medicare relies on the US Preventive Services Task Force (USPSTF) to advise on which preventive services Medicare, particularly Medicare Part B, should cover. The USPSTF consists of a group of physicians who advise the Agency on Healthcare Research and Quality, part of the federal Department of Health and Human Services. The USPSTF traditionally reviews clinical evidence and cost-effectiveness. It then assigns a rating for a particular service (ie, A indicates that a treatment or service is supported by compelling evidence, B indicates less-compelling evidence, and so on). If the USPSTF recommends a service, Medicare may cover it without going to Congress for approval. If a service is not recommended by the USPSTF, Medicare coverage is unlikely.

Patient advocacy groups—notably the American Diabetes Association and the American Heart Association—have expressed concern that the process used by the USPSTF is significantly limiting patient access to preventive care, particularly screenings. While ample scientific evidence of the clinical and economic merits of a given preventive screening or treatment may exist, tests and services not strongly supported by randomized controlled trials will most likely not pass the high evidentiary standards required by the USPSTF. Randomized controlled clinical trials are a “gold standard” for evidence but are by no means the only source of reliable and valid evidence of a service’s effectiveness. By insisting on such a high bar for evidence, there is a risk that the USPSTF will become
both the floor and the ceiling with respect to decisions about preventive services in benefit packages for Medicare, Medicaid, and the public sector.

As the pendulum for coverage decision-making continues to swing from anecdotal and perceived merits to an evidence-based approach, questions about what constitutes the appropriate level and type of evidence for preventive services must be addressed. Controlled clinical trials for prevention claims involve studying large populations over an extended period of time, requiring large research budgets. Ignoring “good enough” evidence while waiting for “perfect” evidence raises serious ethical and practical issues as opportunities to save lives and reduce disease are irretrievably lost.

If the government, in its role as regulator, changes policy to expand coverage of preventive services and prohibit patient cost-sharing for preventive care, the question remains what constitutes prevention. For most of Medicare’s history, an act of Congress was required to cover a new screening test or preventive service. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) gave the Centers for Medicare & Medicaid Services (CMS) the authority to consider USPSTF recommendations in Medicare coverage determinations.

Today, as result of the Medicare Modernization Act of 2003, it was determined that decision coverage would be delegated to an existent advisory body, the USPSTF, whose recommendations could automatically be covered by CMS. It certainly makes sense to have a go-to task force of clinical advisors and to allow CMS to add preventive services to the Medicare benefit package without need of legislation or lengthy rule-making. However, if the USPSTF becomes the only go-to entity and only uses an exceptionally high standard for basing its recommendations, many valuable preventive services may not be covered. Because private payers often follow Medicare’s lead in coverage policy, the influence of the USPSTF is magnified.

Another concept being proposed for Medicare is an educational campaign to improve provider education and patient awareness of covered preventive services. An annual wellness visit, with a comprehensive health risk assessment is also being proposed for all Medicare beneficiaries. The Welcome to Medicare comprehensive physical program offered to new Medicare beneficiaries garnered a disappointing 2.8% uptake rate. Incentives for Medicare beneficiaries to participate in healthy lifestyle programs have also been proposed.

**Wellness Policies under Consideration for Medicaid**

A number of key considerations for Medicaid and the Children’s Health Insurance Program (CHIP) are in the current healthcare reform bills. A significant expansion of healthcare coverage is planned, via a roughly 25% expansion of Medicaid enrollment (about 15 million additional enrollees nationwide) and new, taxpayer-subsidized health plans. This expansion represents a major opportunity to reach the underserved population, particularly moderate-income families and chronically ill Americans previously unable to buy affordable health insurance. In addition, state Medicaid programs would be incented or mandated to cover preventive services endorsed by the USPSTF. Congress also envisions incentives to reward chronically ill Medicaid beneficiaries to participate in healthy lifestyle programs.

**If the government, in its role as regulator, changes policy to expand coverage of preventive services and prohibit patient cost-sharing for preventive care, the question remains what constitutes prevention.**

Another proposal is to make it much easier for state Medicaid programs to cover (without federal waivers) integrated home- and community-based care for frail seniors and beneficiaries with severe disabilities. Of particular interest to policymakers are dual-eligible persons, the more than 7 million beneficiaries who are enrolled in Medicare and Medicaid. Dual-eligible people are responsible for more than 40% of a typical Medicaid program’s expenditures.

**Innovation Center**

The Senate proposes to create an innovation center within CMS to test, evaluate, and expand different payment structures and methodologies. Although an innovation center could generate more bureaucracy, it is expected to bring positive reforms primarily to Medicare, as well as Medicaid and CHIP.

Designed to provide an infrastructure and an epicenter for payment and delivery system reform, this new center will evaluate innovations that improve care coordination and care delivery for beneficiaries with chronic illnesses, as well as those with dual Medicare-Medicaid eligibility. The goal is to foster patient-centered care and improve quality of care in Medicare, Medicaid, and CHIP. The innovation center will assess innovations that slow the rate of cost growth.

The new innovation center will address some of the resources that are desperately needed, including new ideas, new models, and a structure to test demonstra-
Innovations of new ideas and models. The innovation center will likely be focused on preventing the progression of a chronic illness rather than preventing the onset of such an illness. Inclusion of innovations that prevent the onset of disease, such as preventing prediabetes from progressing to diabetes, or preventing slightly elevated blood pressure from progressing to hypertension and heart disease, would be a welcomed strategy.

Other Potential Policies for Private Health Insurance

Among other policies under consideration is requiring the new, taxpayer-subsidized health plans to cover all USPSTF-recommended preventive services and to prohibit private insurers from charging copayments for USPSTF-endorsed services. Congress is also expected to create a multibillion-dollar initiative of grant programs to support prevention and wellness initiatives at the state and local level. These will largely focus on reducing the incidence of chronic conditions, such as diabetes and obesity. The healthcare reform legislation also calls for an elaborate national strategy for quality improvement, with interagency coordination, measures development, and quality reporting.

Also under consideration is the revision of federal labor laws to allow employers to provide wellness programs that are currently not allowed because of nondiscrimination requirements. Some consumer advocate and patient advocate groups are concerned that relaxing these laws may open the door to discrimination by employers against people with certain conditions or those whose outcomes do not improve as a result of wellness program participation. As an alternative, some argue that more emphasis should be placed on incentives for participating in wellness programs rather than on tracking or designating the health status of employees.

Policy Obstacles to Wellness

Most of the prevention-related proposals contained in the healthcare reform legislation are welcome improvements. However, our policy process continues to place major roadblocks in the way of a genuine wellness-based healthcare system. The top 10 obstacles to wellness-based health programs are:

1. Evidence base and level of evidence. We continue to need more evidence with regard to prevention, but we also have to start using the evidence we have to convince policymakers and benefit designers to include the appropriate benefits. When it comes to prevention, we cannot afford to let the perfect be the enemy of the good, or analysis the enemy of action.

2. Federal budget scoring and fiscal estimates. The current process used by the Congressional Budget Office (CBO) to score the costs and savings of legislation tends to underestimate the long-range savings from prevention. Federal budgeting is largely an accounting exercise idiosyncratic to Congress and the fiscal structure of federal programs. The estimating capacity, methodologies, and data sources used are limited. Advances in epidemiologic analysis may improve the CBO’s ability to score savings from prevention.

3. Attribution of costs and benefits across time and players. A classic example of the attribution of the costs or how the costs play out occurs between Medicare and Medicaid. About 7 million people are currently dual-eligible beneficiaries, accounting for a collective annual cost of more than $300 billion in healthcare services.

   States and the federal government should share cost-savings resulting from initiatives that improve outcomes while reducing hospital and nursing facility admissions.

4. Short-term thinking, short-term gain. Our national tendency to think in terms of short-term tradeoffs...
has consequences. Saving money today by cutting prices, raising taxes, or restricting access to care may ultimately result in deferring these costs to the future and severely inhibiting innovation.

5. **Long lag time in providers applying best practices.** Even after the grueling process of acquiring appropriate evidence, coverage support, and established recommendations for a particular service or treatment, it can still take as many as 15 to 20 years for a majority of physicians to practice in a way consistent with best practices.

6. **Misaligned incentives for providers.** Provider payments must be aligned with expectations for quality and safety, including prevention and patient wellness. Performance should be based on quality, not quantity. Traditional fee-for-service reimbursement is riddled with problems and misaligned incentives and must be replaced with fee-for-value systems that empower providers and patients while incentivizing performance improvement. Examples include global payment and episode- or condition-based bundled payments with quality measures and incentives.

7. **Opaque performance of providers.** We cannot fix what we cannot see. Transparency is essential for a high-performance healthcare system. Decision makers—physicians, hospitals, other caregivers, patients, and payers—must have access to comprehensive information on the clinical and economic performance of providers and systems of care.

8. **Disjointed, provider-centered delivery system.** Our current delivery system is based on a highly disconnected, uncoordinated mass of providers. In addition, care delivery is too often provider-centered and not patient-centric. We must move toward a genuinely connected, coordinated, and empowered patient-centered approach to care.

9. **Limited patient education.** Patients need the appropriate information to become more accountable for their own health and wellness.

10. **Limited, uncertain incentives for innovation, coupled with poor understanding of innovation among policymakers.** There is a basic lack of understanding and respect for what it takes to innovate and test new technologies, therapies, and delivery systems. There is also little appreciation for the clinical and economic benefits of medical innovation or how to sustain innovation with appropriate policies and incentives.

**Strategic Framework to Advancing Wellness through Health Policy**

Where and how do we begin to address these policy obstacles to wellness? The most important step is for policymakers and other stakeholders to adopt a clear strategic framework in how to help transform federal and state health programs to support prevention and wellness. The **Figure** outlines a basic strategic framework, with 5 key considerations, to align policies to promote wellness:

![Strategic Framework for Wellness-Based Health Policy](image)

**The most important step is for policymakers and other stakeholders to adopt a clear strategic framework in how to help transform federal and state health programs to support prevention and wellness.**

1. **Expectations.** Ultimately, performance expectations—for providers, health plans, or health programs—must be clear and defensible. It is essential that we identify exactly what we expect from prevention and wellness. In turn, these expectations must be reflected in coverage and reimbursement decisions.

2. **Measurements.** We have to determine how we plan to measure whether the programs, agencies, health plans, or providers meet established expectations for prevention and wellness.

3. **Disclosures.** Whether and how expectations will be publicly disclosed is an important decision. Full disclosure requires ensuring that decision makers at all levels have the information they need to make effective decisions and track their own levels of performance at key intervals.

4. **Rewards.** We must decide whether to reward performance, and if so, how. Positive, well-crafted incentives, financial or nonfinancial, are critical for providers, beneficiaries, health plans, and others.
5. Support. Finally, a solid structure must be in place to support ongoing communication, collaboration among stakeholders, sharing of best practices and lessons learned, provision of education and technical assistance, and refinements to expectations, measures, and rewards.

Specific Policy Recommendations
The specific policy recommendations for wellness-based healthcare policy are self-explanatory (Table). The foremost essential step is building the fiscal case for prevention and wellness, with new methods of scoring federal budget savings. Strengthening the fiscal framework will require developing new methods for explaining the true budgetary impact of the current system of scoring prevention and wellness programs. Long-term transparency of performance and new, value-based payment methods, are also necessary.

Conclusion
The major obstacles to wellness-based policy will continue until and unless they are directly addressed. Effective health policy demands well-defined, clearly communicated expectations; appropriate measurement parameters; and disclosures to decision makers at all levels. Prevention should be evidence-based, but the quest for ideal evidence should not become a barrier to care. Payment methods must be aligned with quality and other expectations for performance. Although wellness programs can be fostered by employers, it will be important to guard against the unintended consequences of discrimination. Policy recommendations include removing barriers, reducing lag times, providing and aligning incentives, and improving coordination between public and private programs, particularly in relation to Medicare and Medicaid. In addition, care delivery models must be genuinely team-based and patient-centered.

Disclosure Statement
Mr Piper is a consultant to Genzyme and to Novo Nordisk.

References
FDA Policies and Wellness-Based Healthcare: Approving and Paying for Prevention

Scott Gottlieb, MD

The US Food and Drug Administration maintains an exceptionally high regulatory standard when it comes to granting claims that a product can prevent or reduce the risk of disease. The result is that the path for approval of drugs aimed at the primary and secondary prevention of disease is difficult, lengthy, and costly. Even when a preventive treatment or screening test receives the agency’s approval, Medicare may not reimburse patients for the products. The Centers for Medicare & Medicaid Services has been reluctant to open up new areas of reimbursement, especially when it comes to molecular diagnostics aimed at identifying the potential for developing disease. Yet these diagnostic tests are an essential part of clinical strategies aimed at risk reduction. The protracted regulatory approval processes for prevention and risk reduction claims, along with the unclear pathway for gaining reimbursement for these products, are slowing the development and incorporation of prevention-based treatments in our medical armamentarium. [AHDB. 2010;3(2 suppl 6):S109-S111.]

There are many barriers to getting a product approved by the US Food and Drug Administration (FDA) for the purpose of preventing disease. Because the agency often requires a demonstration of clinical benefit—and increased survival—for treatments aimed at preventing disease, it often means very large and long clinical trials to gain regulatory approval. This is especially true regarding a treatment aimed at primary prevention, where the absolute risk for a clinical event may be small. For example, a safe and effective drug that reduces the risk for heart attack in a largely healthy population may provide a great deal of public health benefit. But demonstrating that the drug can provide a survival advantage in this group of patients may require a very large and long clinical trial, because only a few people in that clinical trial population are likely to have heart attacks in any given year, and even fewer will die as a result of the event.

This is a main reason why more of the medicines available in our pharmacopeia target the symptoms of disease or are disease-modifying treatments rather than preventive therapies, even though the latter represent perhaps more significant public health opportunity. Treatments aimed at disease prevention are those that may (or may not) provide any symptomatic improvement, but they can slow the biological onset of a disease. The most significant benefit can come from strategies that enable doctors to identify patients who may be at risk for developing an illness, and then prescribe safe and effective drugs that can help prevent the onset of the disease in the first place (Table).

Approving Prevention Claims: FDA

Primary prevention generally involves the prevention of a disease before it occurs. Secondary prevention, by comparison, refers to measures that prevent recurrence of a disease or development of a more severe disease after symptoms are already manifested. One such example involves drugs that are aimed at the prevention of cancer. A drug that is targeted for the primary prevention of cancer would work by reducing the likelihood that a person would develop cancer in the first place. Such therapies are sometimes referred to as “chemoprevention.”

Dr Gottlieb, a Practicing Physician and Resident Fellow at the American Enterprise Institute, was former Deputy Commissioner of the FDA from 2005 to 2007. He is a partner in a firm that invests in healthcare companies.
The general consensus is that progress at developing strategies aimed at preventing disease has been slow and frustrating.

The FDA’s approval process for a product aimed at primary prevention of cancer can be made more efficient by enrolling carefully selected enriched populations of patients, for example, those who express biomarkers or premalignant findings that put them at risk for cancer. Because such patients would presumably be at greater risk for developing a primary malignancy, they could be followed for shorter periods of time to see a clinical benefit: in the case of cancer, this would be a reduced risk for a first malignancy. However, it remains unclear whether the FDA would allow the demonstration of a benefit in such an “enriched” population to be generalized to a population that does not have the same risks. For more information see “Prevention of Disease—Primary Prevention, Secondary Prevention, Tertiary Prevention, Prevention Research and Goals.”

There are examples where the FDA allowed benefits seen in an enriched population to be generalized to a broader group of patients. One such example is the use of angiotensin-converting enzyme (ACE) inhibitors for the prevention of cardiovascular morbidity and mortality. Enrolled patients with class IV heart failure demonstrated a benefit in mortality with the introduction of an ACE inhibitor. The FDA approval was subsequently generalized to include patients with class II and class III heart failure—a less-sick population—based on the presumption that the physiologic effects (and clinical benefits) should also be recognized in these classes of heart failure. In this particular case, unmasking a similar benefit in a clinical trial of the healthier population would have required enrolling thousands of patients and following them for many more years since they experienced fewer clinical events in a given year.

This example of ACE inhibitors, however, stands as a regulatory exception. The agency usually requires drug sponsors to demonstrate benefits in the population of patients that they intend to treat. It is rare that the FDA allows benefits seen in one population of patients to be surmised to exist in a group of patients with less-severe disease. This limits the ability to study preventive treatments in enriched populations of patients.

All of this does not mean that there has not been some progress at developing drugs for the primary and secondary prevention of disease, especially in the field of cancer. For example, the 7-year follow-up data from the Breast Cancer Prevention Trial provide evidence that tamoxifen reduces the incidence of invasive breast tumors by more than 40%; recent studies using aromatase inhibitors and raloxifene are also promising. And the Prostate Cancer Prevention Trial showed that finasteride reduced prostate cancer incidence by 25%.

There are also some notable examples of drugs aimed at primary and secondary prevention in the field of cardiology, including aspirin for the prevention of heart attacks or cholesterol-lowering statins for the prevention of cardiovascular disease. Moreover, in a guidance document the FDA released in 2008 to advise sponsors on the development of strategies for therapies aimed at diabetes, the FDA included for the first time a section focused explicitly on drugs for the prevention, as well as for the treatment, of that disease.

But the general consensus is that progress at developing strategies aimed at preventing disease has been slow and frustrating. Regulatory obstacles have played a role in that lack of progress.

The FDA takes a similarly conservative posture when it comes to prevention claims on food products, especially regarding qualified health claims that eating certain foods can provide health benefits. In some cases, the FDA has gone as far as to require prospective, randomized trials to allow sponsors to make qualified health claims for food products. Yet conducting randomized tri-
als based on food intake is often not feasible, because it is difficult to rigorously control peoples' diets. The practical challenges that underpin these stringent regulatory standards should be considered, if we are going to embrace strategies that make development of dietary information more feasible.

From a regulatory standpoint, the FDA also needs to pay close consideration to the potential risk, relative to the prospective reward. Eating a certain food because of the potential for public health benefit carries a lesser risk than other health decisions and should therefore be held to a different standard of evidence than the standard applied to regulated medical products.

What is the FDA’s philosophy regarding the regulation of prevention claims, and its concerns? The FDA’s general philosophy is that any prevention or risk-reduction claim on drug products must meet a very high standard, because of the unknown risks for people who expose themselves to active ingredients for prolonged periods of time, sometimes over many years. In other words, even if a drug may provide a small reduction in the risk of a serious disease, when taken for years or even decades, that drug may also cause small increases in the risk for other medical problems.

With respect to food products, the agency has set a high standard for allowing qualified health claims on foods, because of concerns that these claims can lead to confusion among consumers. The FDA worries that people may be inclined to overeat certain foods based on incomplete evidence of benefit, or that people may pursue less effective dietary strategies in lieu of more effective medical products if the 2 options—the food and the drugs—carry similar claims (eg, eating Cheerios to lower cholesterol rather than taking a statin drug).

Paying for Prevention: CMS

Even when product developers successfully navigate the regulatory process, getting government agencies to pay for their products is not a sure thing. This is especially true for diagnostic tests aimed at identifying peoples’ risks for disease. The Centers for Medicare & Medicaid Services (CMS) has generally been reluctant to embrace reimbursement for these tests, especially for molecular diagnostics. Yet these tests are an essential part of identifying patients at risk for a disease and allow doctors to develop strategies aimed at the prevention of that disease onset.

Currently, CMS has no pathway for the reimbursement of diagnostics. There are many examples whereby CMS did not reimburse clinically important diagnostic tests that had been approved by the FDA. One recent example is a genetic test for identifying patients at risk for developing an overdose to the blood thinner warfarin.

The FDA needs to provide more disease-specific guidance on how sponsors can design reasonably sized trials to test drugs aimed at primary and secondary disease prevention.

Conclusion

Provision of preventive services is included in all the current healthcare reform bills. However, existing regulatory and reimbursement obstacles slow the development of medical technology that can aid in the prevention of disease. In particular, Medicare needs to develop a more comprehensive and better-informed strategy for evaluating and reimbursing diagnostic tests that can reliably help patients and doctors identify their risk for disease. The FDA needs to provide more disease-specific guidance on how sponsors can design reasonably sized trials to test drugs aimed at primary and secondary disease prevention. These strategies can leverage biomarkers that help sponsors enrich clinical trials for patients who may be at increased risk for developing a disease or one of its complications. The FDA’s incorporation of explicit consideration of treatments aimed at preventing diabetes in one of its recent guidance documents (for diabetes therapeutics) is an encouraging recognition by the agency of the unique obstacles, and opportunities, that characterize strategies aimed at preventing disease.

References
The Diabetes Ten City Challenge: Value-Based Benefit Design for Wellness-Based Care

Toni Fera, BPharm, PharmD

The Diabetes Ten City Challenge represents a successful new approach to value-based benefit design models that had been implemented in the past. This implementation of a community-based pharmacist patient self-management program was built on the premise that achieving value-driven outcomes for chronic diseases must include removing the barriers to wellness-based care and aligning incentives, as well as moving patients from inertia to action to sustain behavioral changes. A program that included enhanced access to care, patient support and education, and value-based financial incentives, such as waived or reduced copayments for medications was shown to be effective for driving improvements in healthcare outcomes in diabetic patients. By focusing on medication adherence, improving health measures, and engaging patients to participate proactively in managing their own health, the program demonstrated its ability to impact not only process measures and outcome measures, but financial outcomes as well. [AHDB. 2010;3(2 suppl 6):S112-S116.]

The Diabetes Ten City Challenge, the implementation of a diabetes self-management program in 10 cities/locations across the United States, represents a novel, effective approach to value-based benefit design. Patients began enrolling in January 2006, and outcomes were measured through December 31, 2007, with interim clinical and final reports published in 2008 and 2009, respectively.1,2 The success of the Diabetes Ten City Challenge program exemplifies the relevance of wellness and prevention within the larger healthcare marketplace and the current regulatory environment.

Access to Care: Removing Barriers and Aligning Incentives

The initial approach to the Diabetes Ten City Challenge was based on the value formula that achieving value-driven outcomes for chronic diseases must include removal of barriers to wellness-based care and alignment of incentives. Although some health plans assume at times that removing barriers is the same concept as aligning incentives, this is not the case. Even when barriers to care are removed, unless people are driven to make good decisions and take advantage of relevant offerings, change has not occurred. The key is to move people from inertia to action, and then have them sustain the action over time—this sustained action constitutes change.

The barriers to healthcare access may include financial, educational, behavioral, physical, and social factors. Clearing these barriers paves the way for aligning incentives. The process of aligning incentives requires these key steps:

- Determining the cost burden for achieving a value-driven outcome
- Supporting people to self-manage their health and make appropriate health-related decisions
- Coaching people to reinforce their care plan, and help them continue to make good decisions.

Against the backdrop of this formula for achieving value-driven outcomes, the following crucial questions formed the framework for brainstorming sessions on the Diabetes Ten City Challenge project (which may

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be applied to any chronic disease program being considered for implementation):

• To whom do we want to offer the program?
• What are the key drivers of successful care outcomes in that population?
• What barriers are there to engaging patients in those drivers?
• What incentives can we align with appropriate care delivery?

Value Proposition for Chronic Care: Diabetes

Among the chronic illnesses, diabetes was the logical starting point, based on well-established data showing that expected outcomes can be improved when diabetes is properly controlled. Every 1% drop in hemoglobin (Hb) A1c has the potential to reduce the risk of microvascular complications (ie, eye, kidney, and nervous system diseases) by 40%. Correspondingly, for every 10 mm Hg reduction in systolic blood pressure (BP), the risk for any complication related to diabetes—including death, microvascular complications, and myocardial infarction—is reduced by 12%. Improved control of low-density lipoprotein (LDL) cholesterol can reduce cardiovascular complications by 20% to 50%.

Diabetes also represents a profound burden for employers (Figure 1). In the 18- to 35-years age-group, costs associated with the diabetic population are more than double the costs for people without diabetes, and diabetes-associated costs continue to grow exponentially over time. Consequently, patients with diabetes are certain to use more resources over time, which translates to more complications, less productivity, and reduced quality of life. Consideration should be given to offering wellness/prevention programs to the younger age-groups of patients with diabetes in addition to those in the higher age-group, who may be at highest risk. Inclusion of lower-risk patients presents an opportunity for employers to affect long-term change and prevent or delay the progression of diabetes-associated complications.

When establishing a value-based benefit design for a chronic disease, it is important to identify drivers that are known to positively impact the course of the disease. One of the primary ways to manage diabetes and prevent complications is through the effective use of medications. Medications have inherent value in terms of outcomes in patients with diabetes not only for glucose control, but also for risk reduction related to BP and lipid control. Of note, medication nonadherence in diabetic patients has been shown to increase the rate of hospitalization and mortality. Despite scientific evidence supporting the important role of medications in controlling diabetes, however, medication adherence remains a significant problem.

Diabetes Ten City Challenge Model

Once the new model for value-based benefit design was developed, it was implemented across the country through the Diabetes Ten City Challenge. This program (sponsored by the American Pharmacists Association Foundation and supported by funding from GlaxoSmithKline) involved 10 different sites and multiple self-insured employers. The 10 locations were Honolulu, HI; Los Angeles, CA; Colorado Springs, CO; Milwaukee, WI; Chicago, IL; Northwest Georgia; Tampa, FL; Pittsburgh, PA; Cumberland, MD; and Charleston, SC.

Every 1% drop in hemoglobin A1c has the potential to reduce the risk of microvascular complications by 40%. When establishing a value-based benefit design for a chronic disease, it is important to identify drivers that are known to positively impact the course of the disease.

The Asheville Project, a model that was implemented 12 years ago, provided a basic framework for the diabetes program. The aim was not to test the replication of the Asheville Project, but to test its scalability and application in multiple regions across the country. Because the Diabetes Ten City Challenge was a well-
ness-based self-management program, it was determined that it had to be a comprehensive care approach, rather than focused on just one aspect of the disease.

Reducing or waiving copayments for medications, a requirement for Diabetes Ten City Challenge employer participants, is considered to be one of the most effective incentives implemented, because it aligns care toward effective medication use and removes barriers to adherence.

A “value continuum” illustrates how the model applies to each of the key barrier areas (Table 1). For each of the key barrier areas, a corresponding incentive lever, incentive applied, and intended outcome is suggested. Of utmost priority was the incentive to reduce the cost to receive preventive measures. Reducing or waiving copayments for medications, a requirement for Diabetes Ten City Challenge employer participants, is considered to be one of the most effective incentives implemented, because it aligns care toward effective medication use and removes barriers to adherence.

As a result of working closely with the self-insured employers, some chose to offer added incentives, such as to waive copayments for prevention measures and required laboratory monitoring. For example, copayments for physician visits or certain required laboratory tests were waived (eg, HbA1c and LDL testing).

Overall, the aim of the program was to alleviate the barriers and thereby increase adherence, improve health measures, and empower patients to become more accountable for their own health.

Based on the premise that access to care was the driving force for the diabetes model, the players with key roles in this program included physicians, pharmacists, employers, and patients. Physicians served as the primary care coordinators who set the care plan and were provided with regular patient updates.

As one of the most accessible resources in the community, pharmacists played a valuable role. Because they were trained in medication adherence, drug-related problems, and helping people to manage their medications, pharmacists served as coaches in the diabetes model.

The model also included employers as payers and patients as participants. Some participating employers offered space at the work location, providing a convenient way for employees to be seen onsite by a physician. Because the program was a self-management program, patients were also required to be actively engaged.

How the Model Works

The Diabetes Ten City Challenge provided special training for pharmacists. These pharmacists, from local or regional pharmacy networks, met with patients to provide them with self-management coaching designed to ensure that people have the knowledge and skills to take care of their disease, and that they recognize the importance of consistent, ongoing diligence.

Pharmacists who participate in the program have specific responsibilities, including orienting the patient to the program, reviewing the patient’s history and existing care plan, assessing clinical indicators (ie, body mass index, waist circumference, HbA1c, LDL, and BP). They also ensure that blood tests are being performed at key intervals and assess lifestyle factors, such as diet, exercise, nutrition, and smoking. In addition, they coach patients with a focus on medication adherence, document the care provided, communicate with other care providers, and make necessary referrals.

When restructuring incentives for the key stakeholders, the incentives must be aligned with the value. Incentives for the Diabetes Ten City Challenge included:

- Waived or reduced copayments for diabetes medications and supplies (required), and lipid-lowering drugs (optional)
- Waived copayments for well care support, including primary care physician visits, some laboratory tests (HbA1c, LDL), and diabetes education classes (optional)
• Regularly scheduled coaching session with a community-based pharmacist (required)
• Individualized self-management education and assessments (required).

**Diabetes Ten City Challenge: Value-Based Outcomes**

Interim clinical results for 914 patients who participated in the Diabetes Ten City Challenge and had a minimum of 3 months of care showed a significant decrease in average HbA1c levels, from 7.6 to 7.2.1 The mean (±SD) duration of enrollment was 10.2 ± 3.7 months. Results also showed a substantial increase in the percent of patients who had an improvement in wellness indicators, such as flu shots, foot/eye examinations, and lipid profiles.

In addition, the patients were asked for their level of satisfaction with their overall diabetes care at the beginning of the program compared with 6 to 9 months into the program. Responses showed a dramatic shift to a score of 10 (very satisfied) with their diabetes care, indicating that the program influenced patients’ perceptions as well.1

Financial outcomes for the Diabetes Ten City Challenge were similar to those shown in the pilot studies.2 Although there was an increase in actual total costs (medical and prescription spending) from baseline year compared with year 1 actual costs, there was a decrease in overall cost compared with projected costs (ie, had there been no intervention; Figure 2). Most interesting is the decrease in medical costs, and the slight increase in the pharmacy costs, overall.3 It is speculated that actual medication costs likely increased as a result of an upturn in adherence, based on people having their prescriptions filled because of the waived copay. In addition, some patients may have begun taking a preventive medication they were not previously taking, such as an angiotensin-converting enzyme inhibitor.

Clinical outcomes, based on the group with medical claims and prescription claims for 573 participants of the Diabetes Ten City Challenge, were compared with the HEDIS (Healthcare Effectiveness Data and Information Set) 2007 indicators for the National Council for Quality Assurance commercial accredited plans.2 The Diabetes Ten City Challenge showed striking results, with outcomes exceeding HEDIS indicators on every value that was measured for diabetes (Table 2).2

**Program Sustainability**

The Diabetes Ten City Challenge looked at a large group of patients in diverse locations across the country over a 12-month period. Additional study is required to determine if the improvements are sustainable over time. A small group of patients from 2 employers in an earlier pilot study who were followed for 3 years, saw continued decrease in overall costs for their diabetes patients compared with projections.1 In addition, 1 employer tracked 33 participants and saw a decrease in emergency department visits and hospitalizations over time. Physician office visits increased during the first year of the program, then stabilized over time. Trends from this practice-based research indicate that appropriate utilization of resources was indeed translating to improved clinical outcomes over time.

**The Diabetes Ten City Challenge showed striking results, with outcomes exceeding HEDIS indicators on every value that was measured for diabetes.**

**Practical Implications**

Today, as the program has evolved over time, an increasing number of employers have begun offering onsite flu shots and eye examinations, and this practice is likely to become even more prevalent in the future. Employers are also addressing how to increase employee enrollment, including exploring the use of opt-out programs versus opt-in programs or other financial incentives for those who participate in prevention and wellness programs, such as reduced insurance premiums. In addition to financial incentives, some employers are working to identify patient champions: motivated employees who can encourage their peers to enroll.

Lifestyle incentives, including weight-loss programs, nutrition counseling, fitness centers, and smoking-ces-
sation programs are also beginning to be offered by some employers, but the potential to effect change and the demonstration of the effectiveness of these incentives warrant further study.

The key for employers is to ask what and how much more they can be doing to modify behaviors and effect improved outcomes.

Working with employers, health plans, pharmacists, physicians, and patients over the past 5 years on the Diabetes Ten City Challenge and other programs has yielded some important takeaway lessons:

- Incentives matter greatly, and if properly placed, they can drive high-value care
- Communication among providers is critical. Improvement is needed in getting information to and from physicians and other providers who work closely with patients on self-management programs
- Access must be convenient. If people are not able to get to the service easily, even a waived copayment will not matter to them
- A culture of wellness drives higher enrollment rates. When the workplace philosophy and culture are highly participatory, people tend to sign up
- Health behavior change takes time, understanding, and patient empowerment. Understanding a patient requires a face-to-face interaction
- Financial outcomes data are difficult to obtain and analyze. Acquiring actionable information is a challenge. Moreover, because data sets sometimes use different terminology, information is open to different and potentially conflicting interpretations
- Portable programs are desirable. In general, prevention and wellness programs work better when plan offerings can be delivered consistently over the long term, and complement existing health plan design. Self-insured employers tend to prefer plans with portability to avert the unintended domino effect of one minor change requiring a series of other changes.

Conclusion

The Diabetes Ten City Challenge demonstrates that an effective self-management program for a chronic disease has the potential to impact not only process measures and outcome measures, but financial outcomes as well. It is important for incentives to be aligned with value-driven outcomes. Establishing a comprehensive value-based benefit, such as described in the Diabetes Ten City Challenge, may be effective in improving outcomes for patients with chronic diseases and reducing the development of costly and disabling complications. Implementing creative value-based incentives, such as waived or reduced copayments for medications, waived or reduced copayments for well care, and lifestyle change support programs, offer promising results, particularly when combined with patient coaching to reinforce the physician’s care plan and self-management education. The key to improving short-term and long-term outcomes is to motivate people to action and empower them with the tools to sustain behavioral changes over an extended period of time.

Disclosure Statement

Dr Fera has received honorarium from Novartis Pharmaceuticals.

References
7. Unpublished data on file at HealthMapRx, LLC.
The Role of Wellness for Large Corporations: Trends and Models

Wayne M. Lednar, MD, PhD

The cost of healthcare insurance is a key factor in determining the bottom line for a company. Most large companies are self-insurers, and methods to achieve lower costs include reduction in the expense of purchased medical treatment and improving workforce effectiveness through wellness activities. Reducing costs has become more difficult during the recent global economic downturn. It is important to attempt to view healthcare wellness as a business element and determine measures of performance. Corporations should play a role in encouraging employees to participate in and stay active in disease prevention activities, and companies should shift from promoting intervention to being innovative, embracing the “good health is good business” motto, and implementing necessary change in the workplace and company policy. This article discusses the concept of health wellness from the perspective of a company’s primary objective, to make a profit and succeed in business. [AHDB. 2010;3(2 suppl 6):S117-S119.]

Employers have a legitimate and important role to play in wellness and prevention, and not just because they are the source of a large amount of the funds that make it possible to pay for both medical treatment and preventive services. Employers are accountable for a number of actions as part of the prevention and wellness agenda.

It is helpful to start with the objectives of the company/employer. Corporations are owned by the share owners, who entrust their money with the expectation of getting a return on their investment. To put it directly, the goal of a corporation is to make a profit. In considering a healthcare system focused on prevention and wellness, it is useful to think in terms of how employers and businesses look at prevention, and how wellness can be reconciled with their respective goals.

“What’s in it for Me?”

There is an underlying question in these considerations that can be summarized as, “What’s in it for me?” Although this concept is self-centered in nature, this question must be answered for businesses that are providing the funds for employees who are looking to get involved in their own wellness. If there is nothing in this approach that is clearly and sustainably for employees—for example, overweight people who need to reduce their health risks—all the health benefit designs, incentives, and health-related posters on the walls are not going to get the company or its employees to where they need to be.

Part of the reality for businesses is that healthcare becomes a human resource purchasing action, with the usually expected goal of spending less money this year than the previous year on health benefits. Human resources, often without any kind of medical expertise, is responsible for making purchasing decisions, frequently without much knowledge about health conditions or aspects that affect care delivery, cost, and clinical quality.

With respect to wellness and prevention, workforce effectiveness plays a significant role in the company’s profitability. A contributor to profitability is system efficiency and effective use of human capital. As a result, any discussion about wellness and prevention has to be described in terms that businesses use to measure and monitor business performance as much as possible.
A company's business culture has a powerful effect on wellness and prevention. The company’s culture is a foundation to operate the business to deliver the enterprise goals. The importance of a workplace culture, and the way it affects employees and their health, cannot be underestimated. Employees spend a lot of waking hours in the workplace. How does that affect the culture of wellness and the decisions on behavior? It is the company's responsibility to create a culture of wellness, to be involved in the wellness process, and to understand the importance and value of a healthy worksite culture. This is one area where real innovation is needed.

Employers can and should think differently about linking wellness and prevention to business performance.

It is the company’s responsibility to create a culture of wellness, to be involved in the wellness process, and to understand the importance and value of a healthy worksite culture.

Impact of the Global Economic Downturn

It is useful to look at today's economy by focusing on the global economy during the fourth quarter of 2008 and the first quarter of 2009. The global economic meltdown began about the end of the third quarter of 2008. What that meant for businesses, particularly in the fourth quarter of 2008 and first quarter of 2009 is that business activity around the world began to contract to extraordinarily low levels. Declines in customer demand of 30% to 50% were not uncommon. Thus, revenues declined abruptly and severely. Revenues represent the money companies take in to pay their bills, including the employers’ portion of healthcare benefits.

Many companies started taking actions to respond to the global economic slowdown and the recession and reduced the size of their workforces. Some people lost their jobs and their health benefits, and others had reduced hours. Economists say that the recovery is beginning, that “green sprouts” of improved business activity are appearing. When companies report their quarterly earnings, this is interpreted as a good sign about the financial performance of companies. Many companies’ financial condition remains weakened, and those involved in health benefit purchasing negotiations should remain cognizant of the employers’ current realities.

Wellness and Prevention

It is important to get back to how health and wellness may help business performance. Keep in mind that business performance is measured by different factors, such as the change in market share or the amount of annual revenues derived from products introduced in the previous 5 years. Companies have to be innovative and have a pipeline of new products and technologies that will give the business a future. These business measures, as well as the impact of health on business performance, can provide an important connection.

What is the best way to approach a prevention activity in business? It is helpful to discuss prevention and wellness with business leaders in terms of the difference these approaches make to their business rather than talking about wellness as a “holistic” or autonomous health concept. The following examples illustrate this point:

- A global multinational corporation has many people who are traveling all over the world. The company does not want its employees to get sick or get hurt when they travel, thereby becoming ineffective; the company wants them to succeed. Therefore, travel medicine is an important clinical prevention activity. Many large companies make arrangements throughout the world, setting up networks for the purpose of responding to medical emergencies, should they occur, and medical evacuations, should they be necessary.
- Another example is the worksite vaccination program for seasonal influenza, which has become widely available. The success and understanding of these programs are going to be very helpful nationally, particularly in light of the current pandemic flu threat. The level of comfort and experience that has been accomplished in the workplace around influenza immunization will likely pave the way for effective response to potential flu outbreaks in the future. The impact of clinical prevention on business continuity is increasingly recognized by business leaders.
- Reducing work pressure is another area that may help support wellness and prevention. “Work pressure,” a term used more in Europe than in the United States, tends to resonate better with employees than “work-related stress.” Employees must be able to operate in the workplace in a way that eliminates unnecessary work pressure, which can lead to medical problems later.

Nonmedical Prevention

Nonmedical elements, such as ergonomics and human factors, also play a key role for employers. Examples may include a computer workstation design, or other work systems, or human considerations. All the benefits of training and providing appropriate equipment can be negated by a work system that operates in a way that overwhelms the capability of workers.
in the system. More attention must be made to the system and not just to the individual space. Leading employers are applying considerable efforts in this area, because it improves business performance.

Many jobs require a certain amount of musculoskeletal fitness. Many young people coming into the workplace, particularly those in the 18- to 25-year-old age-group, are going into a job that demands a certain amount of manual physical activity. These young people, just out of high school or college, may be very inactive physically, with little or no upper-extremity strength, aerobic capacity, or flexibility. In some places, the first step after hiring is an up-conditioning program so that the newly hired people can come into the workplace able to do the job safely and effectively. It is quite common for people to be so physically out of shape that they are potentially vulnerable to injury unless they are up-conditioned.

**Incentives for Wellness Programs**

The standard wellness factors often are covered benefits. Many employees are taking statins or antihypertensives regularly. However, it is important to remember that although employees may have been prescribed antihypertensives, many times their blood pressure is not adequately controlled. Although many people have been diagnosed with diabetes, their glycosylated hemoglobin levels may not be where they should be.

Clearly, medication adherence is necessary for employees with a given diagnosis, but more important, it is essential for the problem to be recognized. To make real progress on prevention and wellness, employees must become engaged, and opportunities for work policies that support health must be fully exploited.

Much of this innovation involves less medical and more behavioral choices. Typical health education is not going to achieve the desired goals of wellness for employees. Social marketing expertise is needed to help change perceptions, engage people such that they will want to do something, and motivate them to sustain a path of wellness and prevention with regard to their own health. Appealing to people by informing them they can prevent diabetes or myocardial infarction may simply not be a sufficient motivating factor. Other incentives are often needed.

What may make a wellness program attractive and sustainable is the “I want to go on vacation to the Caribbean, and I want to look good in a bathing suit” approach. Vanity works. Rewards work. This approach may provide more incentive for people to push back from that third piece of pepperoni pizza than a courteous comment of nonenthusiastic commitment in the course of a clinical encounter.

**Employer’s Role**

We need to remember that employers make some very important decisions that can affect what everyone wants to achieve. These decisions concern the structure of health benefits. Many large employers are self-insured. Health plans then are administer based on those employer decisions, and the right kind of insight in the benefit design is needed so that it can be administered to reach enough people.

To make real progress on prevention and wellness, employees must become engaged, and opportunities for work policies that support health must be fully exploited.

It is necessary to do a better job of auditing performance where clinical prevention is involved and where data are available. This is being done in care processes reflected in HEDIS (Healthcare Effectiveness Data and Information Set) measures, such as the first prenatal visit during the first trimester of pregnancy. However, considerably more data visibility is necessary regarding participation in colonoscopy screening and cervical cancer screening, as well as other programs that employers are currently paying for (eg, pneumococcal pneumonia immunization).

**Conclusion**

To keep employers actively involved in healthcare, there has to be some tangible benefit for them, and that benefit is a clear connection between employees’ health and business performance. Employers need to move away from thinking that “we offer what everybody else offers, because we want to be market competitive” and shift gears to the philosophy of “good health is good business.”
Employers and a Culture of Health

Alberto M. Colombi, MD, MPH

Good health is good business: it fosters health-related productivity and prevents sickness care costs. Today, it is essential for employers to integrate sustainable interventions that create a positive culture of health in the workplace. Achieving health-related value demands that employers partner with their employees to act on a number of dimensions simultaneously, including healthcare costs, affordability, quality, and the ability to remain innovative and competitive in employee health management as well. Population health management requires examining the total value of health and using the appropriate decision-analysis tools. One of the most effective investments for employers is to keep healthy people healthy. Population health management can be more effective than individual disease management. Employers should consider effective approaches for generating a culture of health, including innovative ways for managing the process of chronic disease rather than managing the disease itself. Such a model, and its empirical practices, are presented in this article, which also discusses how measuring quality in terms of prevention can improve adherence to guidelines and medications, thereby leading to reducing risks and improving outcomes. [AHDB. 2009;3(2 suppl 6):S120-S125.]

Employers want sustainable healthcare, and they want to remain competitive worldwide. In addition to having a healthy, productive, and engaged workforce, they also want to reduce the cost of sick care and increase the value of health. After all, good health is good business. Furthermore, employers seek to enhance health-related performance and invest in valuable health strategies, knowing that it is more productive to invest in health promotion and prevention than in defect management and catastrophic care.

Capturing the Value of Health

To capture health value, employers must address a number of key areas simultaneously, including behavior, prevention, plan design, care efficiency, and work performance (Table).¹

In the plan design category, costs are shared between employers and employees. Instead of taking the size of the “cost pie” as a given, however, a novel approach would be to shrink the size of the burden by using behavioral modification to achieve some degree of health risk reduction. This could be further enhanced by rolling the burden upstream and reducing its size through early intervention in the disease process where costs are proportionally lower, using early detection and preventive services.

Inefficiencies and waste in the care delivery system can be addressed by rescuing some resources through quality applied to the care delivery system. Finally, health value can be further enhanced and care costs further alleviated by enhancing the health-related work performance component, which is of particular interest for populations at work. In fact, although the direct costs of care represent a major concern for employers, lost productivity as a result of suboptimal health, whether in the form of lost days or subpar performance, is also an important component of overall health value.

The dichotomy between plan design and health promotion needs to be put into context. Benefit design through cost-sharing—that is, by placing an increased financial responsibility for copayments and other costs on the employee—is certainly a rapid way to reduce costs, but it is also a mechanism that is easily saturated,

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leaving the administrator with very few additional options. Intervening through lifestyle changes and health promotions is a slower approach: it would increase health and prevent disease as a way to curb costs. Such an indirect way would take more time than cost-sharing, but would be more strategic and sustainable. Currently, most successful employers work simultaneously on these approaches.

**Key Business Concepts**

To capture the value of a wellness and prevention initiative, the total value of health must be considered, including direct costs, indirect costs, and productivity. The full economic picture involves analyzing the total burden of a specific population on health, such as occupational factors, nonoccupational factors, personal health factors, and productivity loss. These components are combined to calculate the total burden of disease and the total value of health when the disease is prevented.

Rather than focusing primarily on the final end point, it is important to assess modifiable components, such as health risk assessment participation, risk reduction scores, screening participation, and any other elements of the process that may influence the final result. Understanding the different streams that comprise the total value of health and the steps that influence the cascade is vital when making a final determination of cost outcomes.

From a business perspective, healthcare costs are associated with population health risks and age. The higher the risk profile of a population, the greater the costs incurred. And the older the population, the greater the burden of the health risk. In his book *Zero Trends: Health as a Serious Economic Strategy*, Edington provides insightful points about health management strategy.

For instance, certain characteristics are present in the 12-month period before and after a sudden clinical event, such as a heart attack. Options for improving outcomes would include working on sickness management to reduce errors, and coordinating services at the time of the cardiac event. In addition, after a cardiac event, a disease management program that encourages people to stay on protocol could help avert relapse or disease progression.

The full economic picture involves analyzing the total burden of a specific population on health, such as occupational factors, nonoccupational factors, personal health factors, and productivity loss.

According to Edington's experimental work, the most productive investment is exercised before the fact, that is, when the implementation of wellness management provides the best return. People who have a sudden event are already on a fast lane toward a catastrophic event, whereas people who do not have an event are on a safer lane. Therefore, the key is to move...

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**Table** The 5 Areas for Health Value Capture

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<thead>
<tr>
<th>Content</th>
<th>Measure</th>
<th>Aim</th>
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<tr>
<td>1. Behaviors</td>
<td>HRA participation rate</td>
<td><strong>Shrink</strong></td>
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<tr>
<td>• Participation</td>
<td>Risk reduction</td>
<td><strong>Prevent</strong></td>
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<td>• Incentives</td>
<td>Preventive screening rates</td>
<td><strong>Shift upstream</strong></td>
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<tr>
<td>• Motivation</td>
<td>Avoidable admissions</td>
<td><strong>Share</strong></td>
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<td>• Skills</td>
<td>Disease management</td>
<td><strong>Clear waste</strong></td>
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<td>• HRA expand</td>
<td>Healthcare cost and utilization (PMPM)</td>
<td><strong>The other face of the moon</strong></td>
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HRA indicates health reimbursement arrangement; PMPM, per member per month; STD, short-term disability.
people who are in the fast, high-risk lane to a safer lane. Even better, the key is to keep those who are on safe behavior from getting worse or lapsing into higher risk. This raises the provocative question of how much time and energy should be devoted to identifying people who do not have the potential to become well. Although this question is worth pondering, the fundamental economic strategy rests on prevention, in working to keep healthy people healthy.

**Approaches That Don’t Work**

Lessons based on trial and error during the past 10 years have provided insight into which specific approaches work or do not work. The following strategies do not work:

- “Paying less” and “doing less,” or otherwise denying care by rationing expenses or services produces considerable backlash
- Although taking responsibility for our own health is critical, blaming individuals for their at-risk behavior is not an effective behavior-changing approach
- Tagging and chasing high-risk people has turned out to be much less effective than was originally purported
- Negative reinforcement and punishment: some bribe-and-coerce techniques may backfire, because many people are quick to perceive an obvious “carrot and stick” approach as being contrived, and therefore reject it.

Positive psychological reinforcement is much stronger than negative reinforcement and punishment. Rewards that represent positive recognition have the potential to work. Similarly, economic incentives are more effective if oriented toward positive rather than negative reinforcement. Remember, however, that incentives are primarily an accelerator of change and not a substitute for establishing processes for real change. An incentive can make change happen faster, but it does not replace the need for systemic or cultural change and its management.

**Potential Strategies That Work**

Two effective approaches include (1) doing better rather than paying less/doing less, and (2) integrating health into the work culture or system. This requires the capacity of simultaneously addressing several components, such as:

- Leadership
- Programs
- Processes
- People involvement
- Rewarding and measuring change.

Fostering improvement requires that the process and systems that lead to defects are changed. The quality movement of the past 2 decades has shown that managing quality is not accomplished by identifying defects and fixing them but rather by identifying the process that generates the defects and the critical points in the process that could be modified to prevent their emergence.

This is a key concept. Chronic disease can be perceived as a process in and of itself in the sense that it is the result of several steps, multiple factors, and several processes. Consequently, by analyzing the process that leads to a chronic disease outcome, identifying and charting the critical elements in that process, and influencing the elements that could be modified, we could prevent the final outcome and, ultimately, the breakthrough of a chronic disease.

Providing health promotion at PPG is integrated into value delivery, as well as into our business culture. Our “lifestyle partnership” vision statement is—“Our products and operations will be ecologically sustainable and benefit society.”

**Creating a Culture of Health at PPG**

Providing health promotion at PPG is integrated into value delivery, as well as into our business culture. Our “lifestyle partnership” vision statement is—“Our products and operations will be ecologically sustainable and benefit society.” In terms of governance, wellness is inscribed within the value delivery proposition of the “environmental health and safety” deliverables for the company. Our lifestyle partnership mission is to identi-
fy modifiable risk factors, initiatives, and measures that can improve the health and well-being of our employees, retirees, and their families.

**The 10 Keys to Healthy Living and Aging**

Corporate leadership, however, is just the beginning of the story. Operational leadership and employee mobilization are the next necessary ingredients. To that effect we opted, in partnership with the University of Pittsburgh, to develop a priority system that revolves around the “10 keys to healthy living and aging,” which were established by the Center for Healthy Aging, a Centers for Disease Control and Prevention Research Center, and developed by the Graduate School of Public Health at the University of Pittsburgh:

1. Check blood pressure regularly
2. Stop smoking
3. Participate in cancer screening
4. Get immunized regularly
5. Regulate blood glucose
6. Lower LDL cholesterol
7. Be physically active
8. Prevent bone loss and muscle weakness
9. Maintain social contact
10. Combat depression.

These 10 keys allow operational focus in terms of programs inventory and progress measurement. We measure all programs that are being implemented and clearly communicate the measurements and outcomes to the worksite management and employees. Each of these steps can be measured at any given worksite to determine how well we implement programs in terms of these 10 priorities. Results can be analyzed alongside measurements for per capita net healthcare costs, health risk assessment participation, population health risk profile, and maturity of worksite wellness management.

Implementing health promotion, measuring implementation progress, and communicating such measures to those who ultimately can make things happen—that is, operational and employees leadership—help grow a culture of health.

For instance, because amputation is a common complication of poorly treated diabetes, one narrow way of thinking about quality is to find the best surgeon in town to perform a diabetes-associated amputation. Quality, however, should also capture what should be done to prevent that amputation. One intermediate step would be to focus a bit more upstream on adherence to treatment guidelines. Based on 2002 PPG data that compared the desired clinical treatment for diabetes as described by consensus guidelines with the actual treatment received in practice by our employees who had diabetes, we found that fewer than half of our employees received a retinal examination if they were already diagnosed with diabetes. Less than 30% had been given a kidney function test if they had diabetes, even if they ended up on dialysis—an unconscionable and unacceptable level of care.

Besides claiming better quality of care for our employees—because it has been demonstrated many times that poor treatment adherence increases hospitalizations as a result of complications of diabetes—we pushed our analysis further upstream and studied which factors would enable behavior or constitute a barrier toward improved adherence to treatment guidelines and use of prescribed medications.

As an example of such wellness intervention in a chronic disease process—by using the quality approach and creating a culture of health—we could refer to the type 2 diabetes prevention process. The premise of our approach is that since chronic disease (in this case, diabetes) is a defective outcome of a multifactorial, multistep process, it is essential to manage the process rather than the defect.

Therefore, we mapped the total burden of disease and the total value of health related to preventing diabetes, including its risk factors, its treatment according to guidelines, and its complications, but we shifted our quality thought process to focus on all aspects of the continuum, not just on its downstream components. We are not in the “business” of “manufacturing diabetes,” but the emergence of such chronic disease includes the interaction of several upstream and midstream steps in a long-term process that may respond to intervention and that can borrow from “process management” methods.
We found that increasing the cost-sharing for employees with higher copayments drove treatment adherence down. Driving treatment adherence down would increase further downstream utilization, because of relatively higher emergence of complications.

With respect to influencing chronic disease, the idea is to identify and to work on what is “in between,” that is, the factors that link wellness and outcomes and that possibly influence disease.

Finally, we looked further upstream in the process, by focusing on the cardiometabolic risk of a given population, including the prevalence of the population of overweight and obese people, the level of their physical activity, and their rates of hypertension, before the emergence of diabetes altogether—that is, to the possible source of “zero defects.”

**Influencing Chronic Disease**

With respect to influencing chronic disease, some people focus on outcomes and some focus on the wellness factor. The idea is to identify and to work on what is “in between,” that is, the factors that link wellness and outcomes and that possibly influence disease. This can be illustrated by using the analysis of the diabetes example and diabetes episodes of care per 1000 members at 29 PPG worksites (Figure 1).

We found that more than half of the variance in the occurrence of diabetes in 29 worksites was explained by the combination of 3 factors, each independently significant: the worksite proportion of people substantially obese (body mass index $\geq 35$ kg/m$^2$), a pejorative effect, and 2 mitigating factors—the proportion of...
those exercising and the worksite score for healthy-eating supportive environment.1

Although this equation does not show any new concept about the nature of which risks may be relevant, it does offer a quantitative prediction about how much disease occurrence can be influenced by risk modification.

Similarly, we found a strong correlation between the occurrence of hypertension and diabetes episodes of care in the same worksite populations.1 In a previous article, we illustrated the relationship of multiple risk factors to the number of episodes of hypertension treatment per 1000 members. In that case, 74% of the variance in the occurrence of hypertension-associated episodes of care per 1000 active members in 29 worksites was influenced by 3 factors—the proportion of people aged ≥50 years, and countervailing that, the proportion of people who were at low risk, and again, the intensity score by which we provide an environment supportive of healthy nutrition (Figure 2).

These 2 examples show the interaction of personal and environmental health factors.

This quality approach allows us to describe in 1 equation the risk profile and behavior of multiple working populations, and the organizational and cultural components of their environment.

Providing an environment supportive of healthy nutrition is relevant in the hypertension and the diabetes prediction profilers, and hypertension seems to be a key precursor or covariate of diabetes occurrence. Interventions to offset highest healthcare costs associated with diabetes can predictably focus, therefore, not only on treatment adherence of hypertension and of diabetes, but foremost also on environmental and cultural factors, such as expanding the nutritional and exercise support environment, particularly in locations with low levels of support, or in older people, in a quantifiable and predictable manner.

Conclusions

Employers must take the appropriate steps to incorporate a culture of health into the workplace. One of the most effective investments for employers is to keep healthy people healthy. Because doing nothing is unsustainable, it is not an option. Rather than pouring resources into people whose conditions may not improve, employers should consider investing in people who may have a risk burden but do not yet have a disease. Population health management can be more effective than individual disease management. The total value of health must be examined, including all the different data streams, which involves using appropriate decision-analysis tools based on total population health, to determine what is most important and what is least relevant. Acquiring solid economic evidence for total population health management requires analyzing a large-enough population, or several populations, and several health factors simultaneously over an extended period of time—long enough to see the fruition of its positive impact.

Employers should consider new and different ways of thinking about how they analyze data, how experimentation is accomplished, how innovation is implemented, and how innovation effectiveness is measured. Measuring the effectiveness of a cultural, organizational, and wellness intervention may require moving away from the clinical trial model toward the use of “value trials.” Designing and establishing a golden standard for value trials, although challenging, is worthy of further study.

Finally, it is important to aim to curb the existing trend in health and wellness by ushering in sustainable systemic interventions that create a positive culture of health. Because chronic disease is a process, it is vital that we learn how to manage the disease process rather than focus merely on managing the disease itself.

References

Healthcare Reform: Impacts on Business

F. Randy Vogenberg, RPh, PhD

American companies, whether self-insured or with fully funded health insurance plans, are trying to maintain financial stability under the weight of ever-increasing healthcare benefit costs, while keeping an eye on Congress and its attempts to reform healthcare insurance and its delivery. Employers are looking for opportunities to help control costs, and wellness and prevention strategies are potential answers to some of the problems associated with healthcare costs. Some insurance principles give insight to the problem and provide guidance in addressing the issues of costs, with the goal of allowing companies to satisfy their employees and stockholders. [AHDB. 2010;3(2 suppl 6):S126-S129.]

The US healthcare system is potentially on the verge of undergoing dramatic changes. The House has passed a 1990-page healthcare reform bill, and the Senate has passed a 2074-page version. The Obama administration had generally remained in the background, waiting to see what actually comes out, but now is aggressively forging a compromise toward a bill that can be signed into law. When this kind of situation is finally placed in the lap of employers, what are they going to do? How will this affect the different healthcare marketplace stakeholders, namely, payers, especially the employer?

This question has become a very important issue for many businesses, particularly those that are self-insured, the large market-size corporations that are dealing in the international competitive marketplace and are really trying to find some relief. But, there is a mixed message here for employers. Do they really want to keep the status quo? Employers have to become more competitive, but they wonder who is going to run this change, who can do a better job at delivering healthcare, and they’re not convinced that the current debate is the correct solution.

Another issue is a potential conflict in cross-purposes across the stakeholders. What is good for one stakeholder may not be good for the other. The employer looking at this is saying, “I am just trying to make a buck and be profitable in doing it. Do I really want to get into this mess? I am not a healthcare company. I am just trying to buy something that is not going to create a problem for me.” All employers have been of late, however, are increasing problems. Even the Chamber of Commerce, with the smaller and medium-size fully insured companies, feels totally unempowered in this healthcare debate, and these companies are just trying to compete within the United States.

What can be done is to start looking at the business aspects of healthcare delivery and health insurance, and start aligning some of the incentives and opportunities for change, especially those that involve wellness and preventive strategies. Many companies, regardless of their size, are embracing this concept (Figure).

Role of Wellness and Preventive Care

The healthcare debate does not consider the question of change in terms of wellness and preventive care, or how it will potentially help bend down the cost curve that we keep hearing about. Another question is who is getting the value out of whatever is being done. If an employee uses a statin, for example, and there is a benefit after 20 years, who is getting the value? Is it the employee, the health plan, the pharmacy benefit manager (PBM), or the employer? And what exactly is that value?

The same problem exists with preventive healthcare and wellness. How can we develop a value equation that everybody can understand? How would we calculate the return on investment that was so prominent
about 6 or 7 years ago? That has essentially been passed by, and now people are looking in the direction of Pitney Bowes and its 10-year history in the design and management of employer-sponsored health benefits, with the objective of realizing much greater value from these benefit plans, for themselves and for their employees. Other companies are trying to follow its example of deriving corporate value from implementation of aligned healthcare strategies.

**Cost factors**

In many discussions about the key issues involving cost—both direct and indirect—it is usually agreed that occupational health-related costs are very important, but that indirect costs are more important than direct cost. At most companies, the indirect cost that can be attributed to some aspect of health becomes increasingly important, and that starts to increase the opportunity for the demonstration of a value proposition around wellness and preventive care. In looking at the organizational culture component, how do we begin to look at wellness and treatment, and potentially integrate them? How can we put these into action, and how do we sustain them? The marketplace is littered with many good examples, but these are very difficult to replicate. Even the Pitney Bowes example has never been replicated. To this day, actuaries and benefit consultants argue that these cases were “flukes,” and there is really no way to refute this argument.

That becomes another problem as we try to replicate and sustain what we are trying to put into play in the marketplace. When we think about the business of healthcare, and how employers look at healthcare, it all comes down to managing the risk and how to alter and affect the incidence of disease rates. It is not just the cost per person but rather how many persons—and that becomes the key variable that we have to look at.

**Insurance Principles**

A number of basic insurance principles have to be considered when looking at this problem. The number of principles varies, depending on the application, and who is applying them. In our case, there are 7 principles (Table).

**Principle 1: Financing High-Quality Care**

A principle that has been around for a while, if we are able to target our dollars, is that financing high-quality and appropriate care can boost the value of healthcare spending. That was part of the fiscal concept that many chief financial officers were trying to put into play when making decisions about their healthcare benefits.

One of the problems seen repeatedly is that while everybody knows what the real problems are, there are no real clear objectives. For example, what did we want to achieve with our healthcare benefit? There was no alignment to the company goals and objectives. To truly get to the value of healthcare, it is necessary to make sure that risk management and the financing of that risk are done in alignment with the profitability goal that the corporation is seeking. That is obviously the opposite of what the US government is trying to do. The government is not worried about making money or making a profit; it is just trying to enhance the societal goodwill.

**In looking at the organizational culture component, how do we begin to look at wellness and treatment, and potentially integrate them?**

**Principle 2: Moral Hazard**

Another concept that continues to be argued as to whether it is important, and whether it works, is moral hazard. A white paper produced by the Biologic Finance and Access Council defines moral hazard as “the phenomenon by which the mere presence of insurance is thought to promote inefficient, if not ‘immoral,’ behavior that results in unnecessary use of the health benefits.” For the purpose of this paper, it is defined as referring to one’s use of additional healthcare services, thanks to the presence of health insurance.

Associated with moral hazard is the development of managed care backlash. If one is using services because those are available, and then they are suddenly taken away, backlash occurs. In contrast, if we remove the caps from the access to care to make access unlimited, what happens? No one knows. This presents a problem,
because everyone is trying to increase access to care, as is seen in the healthcare reform debate.

Moral hazard benefits society when the results are better health and higher productivity, but how do we measure it, and is it possible to achieve societal agreement concerning that concept?

During the current economic recession, particularly in the second and third quarters of 2009, there was a precipitous drop in the filling of prescriptions, both new and refills. People encountered a societal rethinking about where and how they were going to spend their money, so they were choosing not to fill their drug prescriptions. People were also choosing not to have elective surgeries. Another dynamic was that with people who were employed and had health insurance, there was a big increase in utilization of benefits for procedures and elective activities, including dental care. This hurt the medical loss ratios at many health plans, because many people started using all of the services in fearing of getting laid off and losing their health insurance.

That increase in utilization is resulting in an increase in premiums, because health plans have to deal with their medical loss ratio and state insurance rules. This cause and effect continues and relates back to the moral hazard issue.

**Table Insurance Principles**

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.</td>
<td>Financing high-quality, appropriate care can boost the value of healthcare spending</td>
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<tr>
<td>2.</td>
<td>Moral hazard refers to one’s use of additional healthcare services thanks to the presence of health insurance. Managed care backlash and access to care Effect on moral hazard is uncertain</td>
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<tr>
<td>3.</td>
<td>Insurance is offered as an alternative to higher wages and is not contingent on employer generosity</td>
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<tr>
<td>4.</td>
<td>Cost-sharing reduced healthcare consumption regardless of whether it is wasteful or beneficial</td>
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<tr>
<td>5.</td>
<td>Insurance may enable consumption that benefits society, depending on what resources are consumed by whom</td>
</tr>
<tr>
<td>6.</td>
<td>Moral hazard benefits society when the results are better health and higher productivity; moral hazard can be efficient if insurance helps a person to achieve better health and productivity</td>
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<tr>
<td>7.</td>
<td>Employers that shift too many healthcare costs to workers may lose more money than they save</td>
</tr>
</tbody>
</table>

**Principle 3: Insurance as an Alternative to Greater Income**

Insurance is offered as an alternative to higher wages and is not contingent on employer generosity. Unlike the benevolence in the 1800s and early 1900s, when there was a company town, a company store, and a company physician, as the more structured offering of insurance has grown, companies have gotten away from the concept of generosity or pro bono benefits being offered by providers or by employers. Insurance has become an expected benefit both from the employers’ perspective and from the employees’ perspective in lieu of higher wages.

**Principle 4: Cost-Sharing Curbs Healthcare Utilization**

Among other things, cost-sharing was introduced to try and manage not only the cost but also the consumption of services that occurred as a result of the moral hazard. Cost-sharing was also an attempt to reduce healthcare utilization. But using this kind of a blunt stick to stop everything, whether it was wasteful, inappropriate, or actually beneficial, created other problems. And this was true in the employer sector, as well as in the public sector.

**Principle 5: Insurance Encourages Consumption**

Insurance can enable consumption that benefits society, depending on what resources are consumed and by whom. It is potentially possible to leverage moral hazard properly and use some of the principles of insurance in a good way. The difficulty is how this situation has emerged and evolved. How do we start turning it around and get a focus that covers the entire country, because of the many federal regulations and laws, whether one is a self-funded program under the Employee Retirement Income Security Act (ERISA) or a fully funded health plan or plan sponsor under state regulation. How to start doing this collectively becomes somewhat problematic.

**Principle 6: Moral Hazard Benefits Society**

Moral hazard benefits society when the results are better health and higher productivity, but how do we measure it, and is it possible to achieve societal agreement concerning that concept? It has been suggested that if our society could come to grips with death, it would solve a lot of the issues in the healthcare system. In the mid-1990s, the Oregon experiment was being conducted, both in Medicaid coverage and in end-of-life benefits. This was a hot issue in Medicaid at the time. The question was whether when there was only a finite amount of dollars, would it be possible to draw a
line after a medical procedure or several hundred products that would be covered in a pharmacy program, and can that line be held? The answer was no, it could not be done. There was no societal agreement, and even today when talking about the “death panels” in the legislation, it has nothing to do with death panels. It is a tough battle trying to figure out how far to go in controlling this health insurance program.

Moral hazard can be efficient if insurance helps a person to achieve better health and productivity. Appropriate care and involving the right people at the right time can contribute to the employers’ goal of improving the workforce effectiveness as well as achieve profitability for shareholders.

**Principle 7: Employers Can Lose Money with Cost-Shifting**

Employers who shift too many healthcare costs to workers may lose more money than they save. This strategy may work for a little while, but fundamentally it is not going to work over a long period of time. Stand-alone PBMs that are not fully integrated with health insurance plans become very problematic, because there is no real incentive for the PBM to do what’s in the best interest of the employer or for the health plan, for that matter. As patient costs increase to $3000 or $4000 a month in drug expenditures, significant amounts of money need to be addressed.

**Conclusions**

There are abundant challenges and many changes underway in the marketplace. Some of the proposed changes were recommended years ago and have resurfaced for the third or fourth time. The details of healthcare reform are still being framed, and a great deal of uncertainty exists in the marketplace. Clearly, people are looking for change within the employer/commercial insurance community, and they are looking to the government and the marketplace to provide some guidance so they could make better business decisions.

We are dealing with the political calendar and how things happen in Washington, how bills become law and get implemented to regulation, but we also have the calendar with respect to benefits and insurance. The calendars, however, do not coincide neatly, so whatever happens in “Washington” is not going to change anything in the employer community for 2010, because it is already fixed. By the time Congress gets through the legislative process, the healthcare reform may not even have an effect in 2011. It will probably be 2013 or 2014 before anything happens, so employers have 2 or 3 more years to try and figure out what things they may be able to influence once the final bill is framed, passed, and signed into law, and what they can do in the meantime to remain in compliance. Regulations are going to be particularly important, but how they will affect ERISA in the case of the large employer, and how they will affect the state requirements for health plans and other plan sponsors that are licensed under state regulation remain uncertain.

**Disclosure Statement**

Dr Vogenberg is on the Speaker’s Bureau of Boehringer Ingelheim, GlaxoSmithKline, Merck, Pfizer, and sanofi-aventis, and is a consultant to Cephalon, Johnson & Johnson, and Pfizer.

**References**

Pharmaceutical R&D Strategy and the Transition to Personalized Healthcare Planning

Michael F. Murphy, MD, PhD

The demand for personalized medical planning in pharmaceutical R&D is growing in step with the recent growth in genetic and phenotypic risk modeling and the advent of innovative biologic markers and tailored therapies. Of particular relevance is the interaction of genotype with environment, diet, and lifestyle on the patient’s risk of disease and response to treatment. New prospective evaluation models are required to support risk assessment, early detection, prevention, early intervention, and individualized health-promoting programs. Genetic and other disease-related and pharmacodynamic biomarkers represent key assessments in this modeling process and are also paving the way for adaptive clinical research programs that reduce development cost by discontinuing marginal drugs in earlier development stages. The future of drug R&D is promising, with prospects for innovative therapy, efficient development programs, and new therapeutics that will contribute to clinical care models characterized as much by value as by novelty. Therefore, some crucial questions affecting key healthcare stakeholders must be addressed. [AHDB. 2010;3(2 suppl 6):S130-S136.)

A traditional model for a medical examination and decision-making includes capturing the patient’s chief complaint, the history of the illness, past medical history, family history, social history, a physical examination, standard low-cost diagnostic tests, and a subsequent assessment and treatment plan. However, advances in biological research and enabling technology provide options for an expanded algorithm, with a focus on health risk analysis and long-term health planning. This new prospective evaluation model retains the use of static metrics (e.g., family history) and routinely available clinical procedures and incorporates advance screening technology, such as gene-expression profiling or molecular imaging to yield a personalized health plan that entails:

- Capturing the patient’s health profile summary
- Characterizing the current (immediate) health status
- Creating a health risk analysis, including genetic, environmental, and lifestyle variables
- Offering tiered evaluation and treatment milestones (1-year vs 5-year outlooks).

Advanced modeling capabilities are designed to support risk assessment, early detection, prevention, early intervention/prevention, and an individualized health plan program, including an effective delivery system and reimbursement mechanism. A key component in this emerging algorithm is the incorporation of genomic information and other disease-related or therapy-specific biomarkers into personalized health planning. A review of the genesis of research in this area—potential benefits and limitations and their impact on clinical research methodology and commercialization—provides a fascinating insight into the evolution of

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discovery and development efforts within the pharmaceutical industry.

**Biomarkers in Historical Context**

As opposed to a clinical end point, a biological marker (ie, biomarker) can be characterized as an objectively measured characteristic reflecting normal biological functioning, pathologic processes, or a response to medication. Whether referred to as *intermediate outcomes*, *intermediate end points*, *leading indicators*, *surrogate end point biomarkers*, or *surrogate intermediate end points*, neither the concept nor its application are new.

The historical context for identification and clinical application of a variety of biomarkers is enlightening, characterized by a maturing sophistication of opportunities and identified limitations. For example, serologic investigations of the “blood of the insane” beginning in the 1850s and 1860s, suggested by 1912 that the Abderhalden’s defensive ferments reaction test could predict whether patients with dementia could be distinguished from healthy individuals and from those with other psychiatric disorders. Although the test was reproducible, easy to use, readily available, and had a strong scientific and biological rationale by the then-current evidentiary standards, it resulted in misinterpretations and misguided therapeutic interventions.

For example, in the early years of the 20th century, Dr Henry Cotton from a psychiatric institute in Trenton, NJ, interpreted a positive reaction using this “biomarker” to mean that an infection existing in the appendix, cervix, or teeth accounted for psychiatric manifestations in some patients. Dr Cotton conducted dental and other experimental surgery on approximately 2000 patients over a 20-year period following the logical implication of the results of this test. Despite the sophistication of modern science, an undercurrent of caution in the interpretation and utilization of potential biomarkers for patient identification and treatment selection still pervades clinical research today. With notable exceptions, the use of biomarkers for decision-making purposes is dominant in exploratory as opposed to definitive clinical investigation in which a biomarker can substitute for a clinical end point as a surrogate.

The notion that a substituted variable was easier to measure than a clinical end point was first published in 1963. It was thought that this substituted variable would be easier to observe while providing important prognostic information with greater precision. In 1973, the word *biomarker* was first used in reference to the search for extraterrestrial life, while the first use of the words *surrogate* and *outcome* appeared in 1976. The first publication using the term *biomarker* appeared in the context of prostate cancer in 1980, and the tradition of innovation in clinical trial methodology in oncology persists until today. At this stage, it became apparent that some biological variables could eventually substitute for an eventual clinical outcome, and the first report that coupled the concept of biomarker with surrogate appeared in 1983 (eg, as a substitute for a clinical end point), in the context of the use of radiographic data in rheumatoid arthritis.

With notable exceptions, the use of biomarkers for decision-making purposes is dominant in exploratory as opposed to definitive clinical investigation in which a biomarker can substitute for a clinical end point as a surrogate.

However, an evolving appreciation that a proposed surrogate may not capture in totality the combined risk-benefit assessment also was noted. In 1989, the Cardiac Arrhythmia Suppression Trial (CAST) suggested that using an established antiarrhythmic agent might reduce the risk of mortality post–myocardial infarction. The study, based on a compelling plausible biological rationale, was terminated early, when the active group showed a 2.5-fold higher rate of mortality compared with the control group. This high-profile “surrogate end point failure” represents a counterintuitive example in which an anticipated benefit was associated with patient harm, and implications from this study as well as others have cast a shadow over all attempts to use a biomarker as a proxy for a clinical outcome.

The decade of the 1990s represented a period of rapidly developing biological, biostatistical, clinical, and ethical/regulatory considerations in the use of biomarkers as surrogate end points, propelled by the need to identify active drugs for the treatment of patients with HIV/AIDS. By 1992, the US Food and Drug Administration (FDA) instituted the accelerated approvals for serious and life-threatening conditions, with specific caveats that a surrogate end point might reasonably be assumed to suggest benefit, pending completion of adequate, well-controlled studies that would establish the magnitude of clinical benefits to patients.

In 1995 (and 1999), Dr Robert Temple of the FDA provided what is now considered the classical definition for a surrogate as “a laboratory measurement or physical sign used as a substitute for a clinically meaningful endpoint that directly measures how a patient feels, functions, or so lives. Changes induced by thera-
py in a surrogate endpoint are expected to reflect changes in a clinically meaningful endpoint. A triad of supporting evidence subsequently was considered necessary: biological plausibility, success in clinical trials, and a risk–benefit calculation that supports public health intervention based on those data.

By 1996, the potential utility of biomarkers, and limitations as surrogates, became better understood. Citing examples in cardiovascular indications, oncology, HIV, and osteoporosis research, authors’ support for the use of biomarkers in early-phase development accelerated, while precautionary notes regarding the use of a biomarker as a surrogate emerged. Today, research involving genetic/phenotypic hypotheses and the assessment of disease-related and pharmacodynamic biomarkers is dominant in early- rather than in later-stage clinical investigations across many therapeutic indications.

In 2000, Buyse and colleagues demonstrated the validation of surrogates in meta-analyses of randomized controlled studies. In 2001, the National Institutes of Health, the FDA, and the pharmaceutical industry conducted 2 excellent workshops on methodology for biomarkers, and in 2004, the FDA released a critical path initiative, which provided additional impetus to biomarker development. By 2007, scientifically valid and appropriately measured schemata for biomarker-surrogate evaluation appeared, capturing all relevant considerations that could potentially impact program design.19

Impact of Biomarkers on Program Design

In broad terms, the term biomarker may include diverse parameters, such as biochemistry, electrophysiology, imaging, or neuropsychological testing, as well as epigenetic information. As Lassere indicates, biomarkers serving as surrogates may accrue through time, with one surrogate marker substituting for yet another surrogate marker substituting for still another surrogate marker, as research in the indication evolves (eg, coronary artery disease). Some of the most notable successful biomarker-to-surrogate transitions—those that facilitate modeling of clinical outcomes—include blood pressure changes, total lipids, CD4 cell counts, RNA viral load, tumor size, and coronary artery occlusion.

These biomarkers have led to drug approvals for HIV, cancer, diabetes, hypercholesterolemia, and hypertension, as well as generic agents. However, in the current research and development (R&D) environment, the impact of biomarkers on early-phase program design is much more notable. Based on the historical perspective, the interpretation of biomarker-related clinical data has progressively become more conservative even as their development has progressively increased, and the methodology supporting their identification has become more sophisticated.

Successful applications in early-phase research can now be used when:

• Dose-response relationships are unknown and an exploration of a large-dose range is required with maximal efficiency of sample size and trial duration
• There is a need to replace a distal clinical end point with a proximal one to accelerate the drug development process
• The short-term biological assessment is regarded as more easily or precisely measured than a clinical one for any given sample size
• The biological parameter of interest is minimally affected by other concomitant treatment, as it is closely coupled to the mechanism of action of the interventional compound (eg, the biomarker and primary target are closely related).

Correspondingly, key entry points for these data include target validation or pharmacokinetic/pharmacodynamic investigations; safety/efficacy testing or segmentation and stratification of patient populations before the drug is actually approved; and ultimately, personalized medicine programs, when the product comes to market. These data can assist in decisions regarding the discontinuation of marginal drugs early in development before they ascend to phase 3, in which more representative patients and physicians evaluate product attributes at considerably greater investment of resources and time.

Adaptive Trial Design

Today, many companies are interested as much in accelerating decisions regarding the discontinuation of a marginal compound as in accelerating the actual transi-
Adaptive trial designs also generate confusion, because of proliferation of multiple terms and meanings. Because people may have different interpretations of the same term, it is important to exercise caution and ensure that discussions are based on a consistent context. Terms that may be interpreted differently include flexible design, sequential design, self-designing experiments, multistage designs, response-driven designs, dynamic designs, and novel designs. Although many of these terms are not new, and the concept of a study that is modified as it is executed is not unique, the field has changed rapidly and application of this technology is a hallmark of current R&D efforts.

There are several common themes to describe programs in which biologic end points, not properly considered surrogates, weigh more heavily than clinical outcomes. Of note, the “sponsor’s risk versus society’s risk” perspective makes it easier to gain agreement for the use of adaptive trial methodology, including the use of biological versus clinical end points in early clinical research in which a “proof of concept” hypothesis, not product approval, is the prime objective. Agreement on adaptive methodology during late-phase, potentially pivotal investigations yielding results directly relevant to registration is less certain, although there are representative examples within the regulation of devices.

Characteristics of development programs that incorporate adaptive trial methodology are many, but may include making decisions regarding sample size or patient characteristics based on a pharmacodynamic biomarker, or the creation of a common data set by integrating dose finding or other data across phase 2 and phase 3 trials, potentially significantly shortening overall development time. Innovative clinical research within this context also raises the specter of additional ethical considerations, in that allocation to treatment in an adaptive trial design depends on accumulated information that attempts to optimize the next treatment assignment during the trial, as opposed to influencing treatment after the trial. Therefore, in contrast to a traditional design, the last patient in an adaptive trial design may be treated quite differently from the first patient randomized, engendering concerns regarding physician equipoise. A genetic or other biomarker that has been demonstrated to predict response thus raises issues about ethics, pragmatics, and the timing and method of sharing data within the realm of clinical research.

**Biomarkers can affect product labeling, but they may not influence reimbursement.**

**Impact of Biomarkers on Drug Labeling**

Biomarkers can affect product labeling, but they may not influence reimbursement. The warfarin dose-finding study is a good example of a genetic-based marker that directly influenced patient care. In addition to having a sound scientific and clinical rationale, this study asked appropriate questions about whether genetic information–guided therapy improved efficiency and safety and reduced cost. The focus was on efficiency rather than on effect or efficacy: An effect represents the biologic readout; efficacy represents outcomes in optimal patients treated by optimal physicians against selected clinical targets. Efficiency encompasses the concept of value. Results demonstrated that treatment with warfarin was both safe and cost-effective, with a combination of genetic and clinical information accounting for approximately 79% of the variability in clinical outcome. The cost for testing was $250 per gene, and the cost per patient savings by the
Equally important in the process is the resolution of outstanding issues regarding the disclosure of information as part of the physician–patient decision process. A hypothetical scenario positing 100% accuracy in test results was informative in the area of Alzheimer’s disease (AD), for example. In this survey, adult children with a living parent diagnosed with AD and a matched comparison group of individuals with no parental history of AD were surveyed regarding the potential impact of genetic testing on the risk of subsequent illness.

Positive and neutral responses included:

- It would be helpful to learn about personal risk
- It would be helpful to learn about my children’s risk
- It would help determine my treatment, plan for the future, or satisfy my family’s concerns.

Responses that were concerning or negative included:

- Fear about my reaction or my family’s reaction
- It would be too expensive and may not be reimbursed
- Treatment options are not good, regardless of genetic predisposition
- Results may be inaccurate and cause undue anxiety
- Results could affect my insurance
- Results could affect my employability.

Although considerable national interest exists in the presymptomatic testing for genetic diseases (eg, breast and other cancers, cystic fibrosis), research on the impact of such information for a number of other chronic illnesses—in which genetic information is not wholly deterministic—is less well defined. Because the implications of test results garner controversy and concern, they must be considered and addressed as a component of a pharmaceutical development process that attempts to incorporate patient traits (including genetic predisposition) into a treatment algorithm.

4 Key Issues/Stakeholders

When identifying who will develop certain illnesses and determining the best interventions for these illnesses in a personalized medicine directive, it is important to consider what questions should be addressed with respect to genotypic/phenotypic risk-modeling tools and related biologic data. Four key issues and stakeholders are vital components of decision-making, using genetic and phenotypic tools, and have been cogently reviewed by Garrison and colleagues; they are illustrative of the multifaceted prism through which R&D development efforts must be viewed (Figure 2).

Pharmaceutical R&D

In pharmaceutical R&D, smaller, faster, cheaper clinical trials in the early phase of drug discovery may require considerable allocation of time and resources into basic biology before targeted drug development.
Exceptions are identified in situations in which the marker is so intrinsically coupled with the compound’s mechanism of action that the two are actually the same (eg, Herceptin). Another potential application is the rescue of a failed study by evaluating one of its subgroups based on genetic information, particularly if a randomization variable at baseline provides the basis for a prespecified, statistical contrast (eg, the subgroup is defined as part of the randomization process rather than as a post hoc/ad hoc exploratory analysis). It may also be possible to capture relevant safety information via a high-risk subgroup, using a specific test in a safety prevention strategy in concert with a postmarketing risk-map program designed to limit exposure to selected patient populations.

From a pharmaceutical R&D point of view, the use of biologic and genetic readouts early in development and the incorporation of these assessments into a research program are directly relevant to their inclusion into the decision process of personalized medicine after approval.

**Regulatory Guidance**

Currently, approximately 20 product labels carry some regulatory guidance regarding the utility of genetic markers, although testing as an antecedent to initiation of therapy is not explicitly required. Key unresolved questions include the status of regulations regarding laboratory testing, potential standards for stand-alone genetic testing, and whether the FDA would restrict biomarkers based on a defined population in cases involving recognized, clinically important adverse events. The impact and potential regulatory implications of direct-to-consumer advertising for genetically based assessments also is unknown. Specifically, although the cost of identifying a genetic trait conferring disease susceptibility could prove nominal, the information package necessary to interpret the data in the context of other patient characteristics is in its infancy, and the implication of a misapplication of information may generate additional public health concerns.

**Physicians and Care Providers**

One of the major questions to be answered is who will recommend these tests—specialists, genetic counselors, pharmacists, or others—and who will interpret the results. Also in question is whether consent would be required, and if so, for which tests. Currently, no consent as such is required for routine laboratory assessments (eg, hemoglobin), but a fairly elaborate consent process is used for genetic information that has a high predictive value for illnesses that are potentially fatal or severely disabling. Indeed, life-altering information may require a formal engagement by counselors, and the nature of the proposed evaluation may mandate written as opposed to verbal consenting procedures.

It will be important to know if changes in liability will occur for physicians or other healthcare providers accessing this technology, and if the information changes the dynamic of interactions with patients during the process of selecting specific patient management options. In the absence of considerable scientific acumen, for example, the ability for some caregivers to adequately engage in a risk assessment/mitigation strategy based upon genetic information might be limited, effectively restricting application of new methodology to only centers of excellence. As in all laboratory-based assessments, codification of procedures used in collecting, storing, de-identifying, and using the data in various analyses are required to ensure sample integrity and patient privacy.

The future of personalized medicine is dependent on resolution of a number of outstanding scientific, clinical, regulatory, and ethical questions, many of which are amenable to innovative research methodology.

**Economics**

How will the economics of genetic and biologic information affect a product’s reimbursement pattern and product lifecycle? Decisions include whether the cost of testing would be reimbursed, and if a designated amount of reimbursement would be “calibrated” based on the implied value of the test. Specifically, the value of genetic and biologic information in the treatment decision process is a key consideration that will provide clues as to how this innovation will be rewarded. Measures that explain proportionately little regarding the variability in patient outcomes may not be reimbursed in contrast to very predictive tests that are strongly coupled to clinically important outcomes.

**The Future of Personalized Medicine**

The future of personalized medicine is dependent on resolution of a number of outstanding scientific, clinical, regulatory, and ethical questions, many of which are amenable to innovative research methodology. The pharmaceutical industry faces questions about efficiency: how to make the R&D process quicker, better, and smarter with adaptive trial designs and earlier readouts with therapeutic interventions that compete on “overall value” rather than exclusively pharmacologic nov-
Physicians and healthcare providers have a stake in ecologically valid outcomes that drive costs, economics, and reimbursement decisions. Establishing multistakeholder perspectives during the discovery and development process is one step toward facilitating that outcome.

Disclosure Statement

Dr Murphy is Chief Medical Scientific Officer for Worldwide Clinical Trials, a contract research organization. Services encompass activities within early- and late-phase clinical research related to design, execution, and analysis of clinical studies. Current relationships extend across approximately 70 organizations. No activities involve the endorsement and promotion of marketed products or products under investigation.

References

The Role of Health Plans in Prevention and Wellness

Gary M. Owens, MD

Wellness and wellness education must become priorities in health plans, the workplace, the community, and in schools. Our focus on prevention and wellness should proactively address the underlying risk factors for chronic diseases. Because people have a major impact on their own health outcomes and subsequently on healthcare spending, engaging them in managing their health and health risks should be the cornerstone of healthcare reform. Achieving sweeping changes in health-oriented behavior will require driving the cultural, societal, and behavioral changes necessary to improve outcomes and reduce spiraling costs. Beyond financing more care for more people, healthcare reform must support research that will help us understand the cultural and societal issues that foster a healthier population, concerted efforts to raise health literacy, and better education on the role of diet and exercise in maintaining good health. We must find ways to encourage a broadly accepted cultural shift toward personal accountability for our own health. Although controversial, financial incentives may help encourage healthy behavior. [AHDB. 2010;3(2 suppl 6):S137-S140.]

Chronic disease is an area of growing concern for health plans. One of the key questions facing health plans is whether we can successfully shift from a reactive stance to a proactive stance in managing chronic diseases. The disease states of major concern include asthma; chronic obstructive pulmonary disease and other pulmonary conditions; hypertension, stroke, and coronary heart disease; diabetes and related disorders; cancer; and depression and mental health disorders. The objective of this article is to address why health plans are focusing on wellness initiatives and explore ideas for making individuals more accountable for their own wellness.

The Increasing Incidence of Chronic Diseases in the United States

Obesity and Diabetes Epidemics

The changing demographics of chronic diseases in the United States are alarming. Obesity trends (measured by body mass index [BMI]) have climbed steadily during the past 20 years.1 In 1990, the highest prevalence rate for obesity (ie, BMI ≥30 kg/m²) in any state was 14%.

In 1990, the distribution of obesity in the United States was not so alarming, according to the following prevalence rates1:

- 4 states, unknown
- 9 states, <10%
- 37 states, 10%-14%.

But by 2008, the obesity picture across the country looked quite different, revealing alarming prevalence rates1:

- 1 state, <20% (Colorado)
- 49 states, ≥25%; of these, 6 states ≥30% (Alabama, Mississippi, Oklahoma, South Carolina, Tennessee, West Virginia).

In addition, the number of adults (aged ≥20 years) who have been diagnosed with diabetes has increased dramatically in recent years. By 2008, nearly 24 million people in the United States have been diagnosed with diabetes, representing an increase of >3 million diabetic patients since 2006.2

The US map that depicts the prevalence of diabetes in the United States (Figure) closely resembles the areas of concentration of obesity prevalence.3,4 This

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picture is also similar to the concentration of heart attacks, based on a recent national survey. Furthermore, the concentration of people who do not participate in any physical activities over long periods of time coincides with the geographic areas where obesity, diabetes, and heart attack are prevalent.

These repetitive geographic patterns strongly suggest that chronic illness is a major societal and cultural issue that will require corresponding societal and cultural shifts. Obesity, diabetes, heart disease, and inadequate levels of physical activity are interrelated parts of the chronic disease overview in the United States.

Basic interventions to improve health could result in reduced costs of $217 billion annually by 2023 and $1.1 trillion in potential cumulative reduced costs by 2023.

The Link to Inactivity Persists

Despite all that we know about the benefits of physical activity, the incidence of chronic diseases continues to rise, and inactivity persists as a major liability to improving our national health status. In fact, recommendations and supporting data on the benefits of physical activity have been available since 1999 in the US Surgeon General report on physical activity and health. According to this report, regular physical activity is associated with lower mortality rates overall, decreased risk of mortality associated with cardiovascular disease, decreased risk of colon cancer, and lower risk of developing non–insulin-dependent diabetes mellitus.

Physical activity also helps maintain muscle strength, joint structure, and joint function, and weight-bearing exercise is essential for normal skeletal development during childhood and adolescence. In addition, physical activity can relieve symptoms of depression and anxiety, and improve mood and health-related quality of life.

No drug or treatment in the world can approach the health benefits conferred by physical activity. Yet, although physical activity is not difficult and does not require a special place or expensive equipment, most people simply do not get enough exercise on a routine basis.

Modest Changes Reap a Substantial Impact

The economic input of chronic diseases is staggering. Even modest changes in lifestyle can have a massive impact on chronic disease outcomes. According to a Milken Institute study, basic interventions to improve health could result in reduced costs of $217 billion annually by 2023 and $1.1 trillion in potential cumulative reduced costs by 2023. The cost of chronic diseases and avoidable treatment costs and output losses for each of the major chronic diseases, based on these 2023 projection, are shown in the Table. The proposed interventions for improving health include weight control combined with improved nutrition, exercise, further reductions in smoking, aggressive early disease detection, a faster adoption of improved thera-

### Table: The Growing Impact of Chronic Disease: Avoidable Costs, 2023 Projections

<table>
<thead>
<tr>
<th>Disease</th>
<th>Direct cost, $ billions</th>
<th>Indirect impact, $ billions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>37</td>
<td>373</td>
</tr>
<tr>
<td>Heart disease</td>
<td>76</td>
<td>137</td>
</tr>
<tr>
<td>Hypertension</td>
<td>23</td>
<td>172</td>
</tr>
<tr>
<td>Mental disorders</td>
<td>28</td>
<td>88</td>
</tr>
<tr>
<td>Diabetes</td>
<td>17</td>
<td>73</td>
</tr>
<tr>
<td>Pulmonary conditions</td>
<td>26</td>
<td>47</td>
</tr>
<tr>
<td>Stroke</td>
<td>10</td>
<td>14</td>
</tr>
</tbody>
</table>

Total avoidable cost, $217.6 billion + total indirect, $905.1 billion = total, $1.1 trillion.

pies, and less-invasive treatments. It is estimated that as much as 50% to 70% of all healthcare costs are driven by personal behavior, as well as social and cultural factors that are not well addressed by the current system. In the past, health plans were confronted with daunting questions, such as how to save money, or how to find better treatments, or what type of technology do we need to apply. Much was accomplished in these areas; for example, several approaches have attempted to reduce the burden and cost of illness.

Cost-oriented strategies included utilization management, technology evaluation and management, comparative effectiveness, higher cost-sharing, and cost-shifting to health plan members. Quality-oriented strategies included pay for performance, comparative effectiveness, disease management, case management, and wellness initiatives. In some cases, these approaches conflicted (ie, quality-oriented strategies related to patient behavior, such as medication compliance and preventive programs) and actually increased costs initially.

Today, our major issue is how to organize and finance the healthcare system to achieve high value and personal accountability. The goal is to create a healthcare system that is focused on prevention and wellness, a system that is not based on reacting to disease but rather on addressing the underlying causes and risk factors for chronic diseases.

One of the challenges we face is that consumers do not always respond as predicted by economists. For some consumers, avoiding financial loss may actually be more desirable than achieving financial gain. For example, in downward trending financial markets, many investors move funds to “safer investments” rather than sustain losses, even though history shows that virtually all market losses are made up and over the long haul gains are achieved by investors who do not flee the market. Moreover, social and cultural norms are a major factor in health-related behaviors, and consumers may not respond to health risk in entirely predictable ways.

A recently published study on adherence to disease-modifying therapy for multiple sclerosis (MS) underscores the complexities inherent in patient behavior. This multicenter, observational study used 3 waves of online surveys of patients with MS. Patients were recruited by healthcare providers at 17 neurology clinics. A total of 798 patients responded to the baseline survey, and 708 responded to all 3 surveys. The rates of nonadherence, as defined by missing ≥1 injections, remained relatively stable across all 3 surveys. The most common reasons cited by patients for missing injections was (1) forgetting to administer the medication (58%); (2) not feeling like administering the medication; and (3) stopping injections (if injectable). These findings highlight some of the barriers to optimal adherence and the implication for the effective treatment of MS.

Setting the Stage for Wellness and Prevention

The Institute of Medicine has established guiding principles for equipping patients with the appropriate resources for making informed decisions. According to these guidelines, “Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over decisions that affect them. The healthcare system should be able to accommodate differences in patients’ preferences and encourage shared decision-making. In addition, the healthcare system should make available to patients and their families information that allows them to make informed decisions when selecting a health plan, hospital, or clinical practice, or when choosing among alternative treatments. This should include information describing the system’s performance on safety, evidence-based practice, and patient satisfaction.”

Social and cultural norms are a major factor in health-related behaviors, and consumers may not respond to health risk in entirely predictable ways.

Individual states have already begun setting the stage by emphasizing wellness and disease prevention. Michigan recently enacted legislation intended to “promote the availability of health behavior wellness, maintenance, and improvement programs” in private insurance. This program allows group health plans and insurance carriers to give premium rebates of up to 10% if workers or members participate in group wellness programs. Vermont allows insurers to offer “healthy lifestyles” discounts of up to 15% of premium for compliance with a health promotion program. Rhode Island is promoting healthy lifestyles in private insurance through its wellness health benefit plan. In California, there is a proposed health reform proposal featuring incentive and reward programs, including a premium reduction for engaging in healthy activities.

A Modest Proposal

Patients have a major impact on their own outcomes and subsequently on healthcare spending. Approaches implemented by health plans, such as providing information, coaching, and case managers, have met with
only modest success. We have reached a crossroad whereby personal health accountability must become the cultural norm. The time has come to create financial incentives, both positive and negative, to encourage healthy behavior.

Access to healthcare is now being considered a fundamental right; however, it is a right that comes with personal responsibility and accountability. Engaging consumers in managing their health and health risks should be the cornerstone of any healthcare reform, and it should be supported by the required financing.

To achieve sweeping changes in health-oriented behavior, we need a better understanding of the social and cultural norms, including research on these norms, concerted efforts to raise health literacy, and better education on the role of diet and exercise in maintaining good health. Schools, community centers, and employers are good starting points for these initiatives. Financial incentives, both positive and negative, must be built into the current system to encourage participation.

Access to healthcare is now being considered a fundamental right; however, it is a right that comes with personal responsibility and accountability.

Initially, incentives may include reduced out-of-pocket (OOP) contributions for people who actively participate in designated wellness initiatives, or a form of healthcare credit that is applied to people who achieve prespecified wellness goals. If needed, additional incentives may include increased OOP contributions from individuals who have not engaged in preventive and wellness activity. Another more controversial approach might include raising rates for people with high-risk behaviors, such as smoking, obesity, or documented noncompliance. This strategy could help make people more accountable for their personal health.

Conclusion

Although we cannot prevent all illness or eliminate human suffering and death, we can find ways to eliminate the burden of unnecessary illness, including excess costs. Our focus must be on driving the cultural, social, and behavioral changes that are essential to reducing our spiraling healthcare costs. We must all become personally accountable for achieving and maintaining healthy lifestyles and for engaging in recommended screening for chronic diseases. And we need to find ways to encourage a broadly accepted culture of accountability.

We have to start somewhere to propel this cultural shift. By thinking big and starting small, wellness and wellness education must become a priority in health plans. Wellness must also become a priority at work, much like the integration of on-the-job safety. Wellness education must also become a priority in schools. Healthcare reform must look beyond merely financing more care for all of us; it must also support research that provides a better understanding of the cultural and social issues that will foster a healthier population.

Disclosure Statement

Dr. Owens is a consultant to AstraZeneca, Eli Lilly, Genentech, Novartis, and Schering Plough.

References

The role of pharmacy is real and inherent in traditional healthcare, because of the efficacy of the vast array of pharmaceutical products in treating, managing, and occasionally curing many medical conditions. Less obvious is the role that pharmacy plays in the wellness concept of healthcare. From this perspective, one thing that stands out is activity to increase the adherence and persistence of patients taking their medication because it is good for their health. The question is— is it really too little, too late?

An interesting analogy is the case in which somehow sand was getting into an oil pipeline crossing a desert, and hence into the oil. Quality improvement of the pipeline initially consisted of putting a filter at the end of the pipeline to get the sand out of the oil. Eventually someone realized that if the location of the sand leak could be determined and the hole sealed, the filter would not be required, and money could be saved. Similarly, if we can engage patients at the front end of the wellness process, it will be less of a problem later to get them to become more adherent to therapy, resulting in better outcomes as measured by improved health and reduced disease progression.

**The Scope of Lack of Adherence**

According to a survey conducted by the US Chamber of Congress, more than 50% of all prescriptions written annually are taken incorrectly by patients. Many patients who have had asthma for a number of years still do not know how to use an inhaler correctly, because it is assumed in the system that they know how to use an inhaler. After all, they have been using them for many years. In addition, it is estimated that up to 50% of all prescriptions fail to produce the desired results. Obviously, much improvement is needed in matching the right drug to the right patient. Some of the fault lies in the fact that patients are not openly engaging with their physician. About 10% of all hospitalizations and 23% of nursing home admissions have been attributed to patients’ inability to manage or follow drug therapy, resulting in decreased quality of life and increased costs.

**WHO: The 5 Dimensions that Affect Adherence**

In its 2003 publication Adherence to Long-Term Therapies: Evidence for Action, the World Health Organization (WHO) developed the concept of the 5 dimensions that affect adherence. These dimensions are:

1. Social and economic factors

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Copays are increasing, and the higher the copay, the lower the response from the patients. Raising copays too high becomes a barrier to access for drugs.

Healthcare team and system factors. Inadequate or poor member services or reimbursement issues are all too common. Copays are increasing, and the higher the copay, the lower the response from the patients. Raising copays too high becomes a barrier to access for drugs, because patients are unwilling or unable to pay the copay. In some situations, if providers are overworked, they may be restricted to short patient consultations and little or no follow-up. Many providers simply do not have enough time to spend with patients.

Massachusetts has universal healthcare, with only about 2.6% of the population uninsured, but the average wait time for a primary care provider averages 44 days, and the average wait time for a specialist is 19 to 44 days. There are nearly a half million newly enrolled insured patients in Massachusetts who are trying to find primary care providers to help them get the services they need. This is a major problem and promises to be just as big a problem at the national level if all the currently uninsured people enter the healthcare system.

Condition-related factors. Symptoms associated with a given medical condition play a role in adherence, depending on the type and severity of the symptom. The level of disability associated with the symptoms, the rate of disease progression, and the presence of comorbidities (especially in the elderly) obviously can have a significant impact on medication adherence. In addition, substance abuse is a prevalent issue and is relevant to adherence.

Therapy-related factors. Probably the most important factors affecting compliance are related to the therapy itself. It is not one drug solving all the problems anymore. Patients are often expected to manage very complex regimens composed of 3, 4, or 5 different medications used to treat a disease or a combination of diseases. These drugs are taken at different schedules and with different methods of administration.

Patients using inhalers for asthma, for example, may confuse the beta agonist with the steroid, and vice versa, using the steroid as their rescue medication instead of their beta agonist. This is further aggravated when adverse events or treatment failures occur, resulting in changes in medication. It is not surprising that many patients fail to maintain their drug regimens.

Patient-related factors. Patients frequently lack knowledge of their disease and may have an altered perception of the impact of their disease. Denial often enters the picture, as does the social stigma that some patients still attach to certain diseases, occasionally leading to depression. Patients often fail to perceive any benefit from treatment (it is not always that obvious). Sometimes they just forget to take their medication. It is difficult for people to get engaged if they cannot remember to take their medication.

Barriers to Adherence

Poor provider–patient communication is a major barrier to medication adherence. The issue is not that providers are unwilling to communicate with their patients. They just do not have the time to sit down and have lengthy consultations. The advent of the Minute Clinic may provide an opportunity to get patients better engaged concerning these matters. For basic healthcare-related issues, patients can go into these or similar retail clinics and receive the information they need. These clinics may solve some of the basic, less-complicated health problems that develop, because patients cannot get in to see a primary care physician to discuss health problems.

Often the patient’s interaction with the healthcare system is at fault. Missed appointments, poor access to medications, and formulary limitations all contribute to the problem.

Another area involves physicians’ interactions with the healthcare system, in which poor knowledge of drug costs, insurance coverage, and formulary designs
often come into play. In addition, a low level of job satisfaction is becoming increasingly common.6

Predictors of Adherence

Hundreds of studies have been published on adherence and the problems associated with it. Some of these studies are fascinating. One study of transplant patients who were using an immunosuppressant drug found adherence rates of 2% to 68%.7 It would appear that after a transplant, the patient would be motivated to take that drug, so why did the patients in the study fail to take it? They had legitimate reasons, such as side effects and cost issues, but we would hope that in this situation, medication adherence would be much higher.

The Asheville Project

From a pharmacy level, activity typically flows through the retail pharmacy, but the retail pharmacies in the general community are not carrying out many active wellness programs and services. They sell various products associated with health and wellness, such as vitamins and devices, but the demand of the outpatient pharmacy practice conflicts with the time needed to address health and wellness. There are, however, some engagement success stories.

The Asheville Project was started in Asheville, North Carolina, in 1996. Its purpose was to provide education and personal oversight for employees with chronic health problems, including diabetes, asthma, hypertension, and high cholesterol.8 The program was implemented through intensive education in conjunction with the Mission-St. Joseph’s Diabetes and Health Education Center. Patients were teamed with community pharmacists who made sure the patients were using their medications correctly.8

Based on the results of this initiative, in the diabetes program, employees, retirees, and dependents with diabetes soon began experiencing improved hemoglobin (Hb) A1c levels, lower total healthcare costs, fewer sick days, and increased satisfaction with their pharmacist’s services. Over a 5-year interval, average HbA1c levels decreased from 7.6% at baseline to 6.7%. Over the same time period, total direct medical costs decreased as well, from more than $7000 per patient per year (PPPY) to less than $5000 PPPY. While the costs for both diabetic and nondiabetic prescriptions increased, the cost of medical claims decreased significantly, from more than $6000 PPPY to less than $2000 PPPY (Figure 1).4

Harvard Pilgrim Health Plan Wellness Programs

What does the road to wellness look like? To some extent, it starts with basic clinical programs that aim to educate patients, promote self-management, and assist in the clinician–patient interaction. How do we get the clinician to engage the patient in self-care? What programs and services can we provide, disease-specific or more general in scope, such as nutrition or exercise?

Harvard Pilgrim Health Care has developed quality clinical programs with these issues in mind. These programs are designed to educate patients and assist with informed decision-making, promote self-management, assist in the clinician–patient decision-making process, and provide actionable information to clinicians.

Harvard Pilgrim has a population-based approach that focuses on key diseases—chronic obstructive pulmonary disease, asthma, and diabetes—as well as medication safety, including medication reconciliation. These programs provide patient and provider education, using a variety of media, including telephone, written, and online resources.

Harvard Pilgrim also uses interactive voice recognition technology to call thousands of members with personalized health reminders, offer written materials to members who request it, and explore barriers that may prevent members from getting important screening tests. Feedback from our members has been very enthusiastic, reaching between 60% and 80% of our

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**Figure 1** Direct Medical Costs Over Time

target population. We have used this technology to remind parents about recommended immunizations for their children, influenza vaccination, and to encourage healthy lifestyle and medication adherence.

Preventive Care

As part of the Harvard Pilgrim wellness approach, considerable effort is directed toward preventive care. Targeting diseases such as breast cancer, colorectal cancer, cervical cancer, and chlamydia infections, where screening can identify the disease earlier, allows patients to be treated early and avoid long-term progression and complications.

As part of the Harvard Pilgrim wellness approach, considerable effort is directed toward preventive care. Targeting diseases where screening can identify the disease earlier allows patients to be treated early and avoid long-term progression.

Other preventive care programs include reminders about childhood and adolescent immunizations, as well as flu and pneumonia immunizations.

Medication Safety

Many patients today are prescribed multiple medications when discharged from the hospital. The safety of a patient using many medications is imperative. To this end, Harvard Pilgrim has established a medication reconciliation program, with a goal of reducing the risk of adverse medical outcomes or medication errors. The program focuses on reconciling pre- and posthospitalization medication regimens for individual patients at the time of discharge from an inpatient facility. An algorithm is used by care management to identify members for outreach based on discharge diagnosis, number of medications, and the employer account.

These patients are then assigned to a nurse case manager, who works with the case management department. The nurse conducts a medication assessment, and if the member is taking 5 or more medications and does not meet any of the exclusion criteria (eg, obesity, cancer, end-stage renal disease, transplant), the patient care plan summary is sent to a clinical pharmacist for review.

The clinical pharmacist conducts a review and sends back information to the case manager regarding interactions, duplications, and side effects for select patients. The pharmacist provides feedback through case notes to the case manager, who then can consult with the patient concerning their specific disease(s) and medications.

Defining Wellness

The traditional physician approach to wellness is reactive, and typically includes smoking cessation, weight loss, cholesterol management, tests and procedures, and specific health-related programs that are aimed at improving the current health of the patient. In contrast, a health plan view tends to focus more on stress reduction, meditation, organic foods, nutrition, and related approaches.

In discussions about wellness between these 2 entities, it is important to make sure they are talking about the same thing and not coming from completely different perspectives. Integrating these 2 concepts would yield a complete wellness approach.

Harvard Pilgrim’s approach to wellness reflects the belief that supporting a healthy lifestyle is the simplest and most cost-effective way to protect and maintain health. Wellness integrates physical, emotional, and spiritual vitality; creates balance among relationships, family, work, and community; and supports a sense of stability and harmony. Each person’s wellness story is unique and evolving, changing over the course of a lifetime.

Harvard Pilgrim’s Worksite Programs

Harvard Pilgrim’s worksite programs help participants achieve behavioral change to reduce the risks and costs associated with cardiovascular disease and other serious chronic conditions. These programs use face-to-face encounters and biometric measures to help
participants develop and achieve realistic health goals and risk reduction. Workplace counseling by clinicians, regular check-ins to track progress, and financial incentives combine to motivate employees to participate and to achieve goals.

Harvard Pilgrim has several worksite programs that can be customized to meet an employer’s needs. These include:

- Health screenings
- Biometric tracking
- Interactive workshops
- Health risk assessments
- Cooking demonstrations
- Mindfulness training
- One-on-one health consultations
- Incentive programs.

Many employers have onsite clinics with a physician or a nurse practitioner on location. This provides an opportunity for the health and wellness programs to integrate with a clinic onsite at the workplace. Often, the clinic is staffed only 2 days a week by a provider and is vacant 3 days a week. On the days that it is vacant, a plan staff member can use the clinic to schedule cholesterol screening, nutrition counseling, blood glucose monitoring, or other functions, providing an opportunity to interact with patients and generate considerable interest in health and wellness programs.

During the 3 years between 2006 and 2008, more than 2000 on-site employee wellness screening programs were held, and more than 500 programs have been held during the first half of 2009 (Figure 2).

In addition to being well received by the employees, these programs were relatively cost-effective. The screening programs represented an easy and relatively inexpensive way to get a good return: employees thinking more frequently about their health. When employees feel better and are happier on the job, the result is lower absenteeism and higher productivity.

Engaging Constituents

There are many ways to engage all the constituents in the wellness process. For patients, there are value-based benefit designs and consumer-directed health plans. When patients have more risk in the process, they have to make decisions, which provides an opportunity for them to feel that they are in control of their health. By using a designated internal member website, patients can compare costs for a particular service and make an informed decision to choose the least costly alternative if they happen to be in a consumer-directed plan with a large deductible.

For physicians, one method is pay-for-performance or pay-for-outcomes. To optimize payments, a physician must be closely involved to achieve optimal outcomes, which are often reflected in higher Health Employer Data and Information Set (HEDIS) scores. These higher HEDIS scores are important to health plans because of their role in the accreditation process and the standards of excellence.

Conclusion

Overall, there are a number of effective touchpoints, whereby the different players in the process can improve overall engagement in wellness. Health plans and employers that offer wellness programs can benefit from their members or employers getting involved in their own wellness, which in turn helps them to become more adherent to treatment, improve their health, and potentially reduce costs.

References

Medical research in the United States is highly diverse, well funded, and largely conducted by independent investigators, with a very strong trend over the past decade toward multisite and increasingly complex multidisciplinary teams. Although funded projects span from basic science endeavors to more pragmatic health services research, the practice of research largely occurs independent of strategic and routine interaction with the healthcare delivery process and systems. Recent changes at the National Institutes of Health, the Agency for Healthcare Research and Quality, and other funding agencies are expected to motivate more research that directly translates into real healthcare (ie, improving patient outcomes at a lower cost). However, even with these changes, the research enterprise lacks a quality that is inherent to traditional research and development models common to most businesses. At the Geisinger Health System, research is viewed as a core strategic asset, essential to system-level efforts to create value in healthcare through collaborative endeavors among research centers, clinical researchers, and system leaders. This approach represents a fundamental shift away from the traditional approach to medical research practiced in the United States in the past 60 years toward a model that is traditional to businesses that view research as a core competitive asset. Geisinger has focused its research endeavors on a limited number of domains deemed most relevant to transforming healthcare, including genomics, comparative effectiveness, predictive modeling, behavior change, and the science of healthcare delivery. If the focus is on improving care efficiency, patient outcomes, and the business of delivering care, the solution must fit the practice setting.

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Funding sources are also diverse, including the government, industry, foundations, and private sources, among others. The National Institutes of Health (NIH) is the major source of funding for medical research, but historically, the NIH tended to favor preclinical basic science research and clinical trials. While funding for research has increased substantially over the past decade, growth has reached a plateau along with caps to budgets, cuts in awarded budgets, and a shift from investigator-initiated awards to institutional-directed initiatives.

In parallel with changes in the funding climate, there is a growing trend toward implicit and explicit changes in expectations for medical research. The demand is increasing for research that directly translates into practice. However, the notion of translational research lacks a fundamental quality inherent to research and development common to most successful business enterprises. Namely, research is a core strategic asset for sustainable business endeavors that is used to create value in new products and services. In healthcare, the notion of value has parallels to other business sectors: research is used to develop new means of delivering the same patient outcome today at a lower cost tomorrow. The research enterprise at Geisinger Health System is rapidly evolving toward this traditional model.

Geisinger is a comprehensive health system located in central Pennsylvania that includes independent

The Geisinger Model: Research Is a Core Asset

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In the United States, medical research is a truly diverse and well-funded enterprise that includes, among other domains, basic science research, clinical trials, and outcomes or health services research.
businesses in managed care, ambulatory clinical practices, and hospitals and other facilities. Beginning in 1995, Geisinger began to install an electronic health record (EHR) system in its ambulatory practices (Figure 1) and has accrued a substantial longitudinal data repository on approximately 2.4 million patients. Research has grown substantially in the past 7 years, with the launching of the Center for Health Research (CHR) in 2003. The goal of the center has been to foster a research and development model and a role for research that was strategic in nature. In part, this approach to research required that the views of competing stakeholders (ie, patient, clinical practice, hospitals, and insurer) be considered in research endeavors with the intention of creating value in areas where interests could be aligned.

To some degree, CHR has sought to leverage system-level infrastructure to facilitate and accelerate research, assets that include health information technology, a stable regional population (ie, low out migration rate), system-level laboratory resources, and others. In addition, CHR has established strong ties with health system leaders involved in managing the clinical practice, managed care organizations, hospitals, and other operational units in information technology, finance, and innovation.

**Our research strategy is oriented to create assets and support systems that will make innovation easier, simplify the logistics associated with research, and expand capabilities for conducting research throughout the system.**

Our research strategy is oriented to create assets and support systems that will make innovation easier, simplify the logistics associated with research, and expand capabilities for conducting research throughout the system. The strategy is designed around research cores that leverage system level resources, build programs around those cores, and link the cores to system-level
innovation, keeping in mind that research itself is not an end point, and that it is necessary to focus on innovation, business value, and thoughtful metrics. The 5 core research cores, which are discussed in detail below, are genomics, comparative effectiveness, behavior change, predictive modeling, and the science of healthcare delivery.

The prominence of CER has increased because of the need for relevant evidence—meaningful to policymakers, patients, payers, and providers alike.

By focusing on research questions that are relevant to creating value, the research enterprise itself establishes a value proposition that is implicitly sustainable. In academic settings, the goal of research is often to create a solution relevant to a defined outcome, but the solution is not usually easily translated to practice and is not intended to create value. Academic research findings are often unsustainable beyond the duration of the grant. At Geisinger, researchers begin with a consideration of how an idea for a potential solution may create value in practice and then begin with a practical solution that approximates how it may actually be used in practice, knowing that after the study is done, continued effort will have to be invested to iterate the solution from a prototype to a fully functional product or service that creates value within the system and that may eventually offer value in other settings.

**Research Core Assets**

**Genomics**

Geisinger is building a system-level biobanking repository, the Geisinger MyCode Project, which is a system set up to store biologic information based on blood samples collected from patients. A 2-year pilot program involving volunteer clinic patients is currently underway. Primary care and specialty care patient populations are included, with patients giving consent in the clinic after check-in. At present, samples from nearly 24,000 patients have been collected, representing an opt-in rate of more than 90%.

Sample collection is automated when the patient has blood work ordered. Extraction and labeling are done on the plasma and serum samples, which are then stored centrally. Each time a patient returns for any routine blood work, additional vials may be drawn and stored, creating a longitudinal dataset for a large population that includes EHR (phenotypic) data to complement the genotypic (plasma and serum) data. Because of the high degree of organization and high patient volume, the process is very efficient. The program is growing, with a capacity to collect more than 200,000 samples annually.

Another application of the MyCode Project is development of novel biomarkers. Biomarkers for any medical condition are difficult to determine and even more difficult to validate. Good biomarker studies are lengthy and very expensive to conduct. A well-designed blood biobanking model may have the potential to sidestep some of these difficulties and significantly speed up the process. For example, Geisinger is currently using the congestive heart failure (CHF) predictive model (described below) in an effort to create new biomarkers. Patients who present for routine clinical care and are at high risk for developing CHF are identified. When blood tests are done, their blood is stored for later use. A few years later, a researcher can identify new-onset CHF from the previously enriched, high-risk population, and test stored blood for specific biomarkers to see which, if any, are predictive. This is a very efficient way to find new markers in high-risk patients within 2 to 3 years, at a cost of less than $2 million compared with 5 to 7 years and more than $10 million required for traditional biomarker development studies.

**Comparative Effectiveness**

According to the Congressional Budget Office (CBO), comparative effectiveness research (CER) is “a rigorous evaluation of the impact of different options that are available for treating a given medical condition, for a particular set of patients.” The prominence of CER has increased because of the need for relevant evidence—meaningful to policymakers, patients, payers, and providers alike. Such evidence, with costs taken into consideration, can best be created using real-world data as opposed to the “ideal” and often artificial conditions of randomized controlled trials. As an example, considerable data from clinical trials exist on the effectiveness of angiotensin-converting enzyme (ACE) inhibitors for controlling hypertension. Angiotensin receptor blockers (ARBs), which have a mechanism of action similar to ACE inhibitors, are assumed to be as good or better for most patients. But long-term trials of ARBs have never been conducted, and patients such as the elderly or those with multiple comorbidities have not been studied.

Are the newer, more expensive ARBs truly better than the mostly generic, proved ACE inhibitors? Using data from Geisinger's EHR, it is possible to directly compare many long-term users of ACE inhibitors with users of ARBs and address these knowledge gaps—which would take years for a comparable clinical trial to answer. In addition, networks of EHR data, such as
the HMO Research Network can examine trends across the country and over time in ways that no single system could accomplish alone. Networks such as these have garnered substantial interest and attention from the NIH and the CBO; look for more observational studies from such groups in the coming years.

Predictive Modeling

When a clinician diagnoses a patient with CHF, it is usually too late. The patient has generally had subclinical disease for years before detection (Figure 2), and little can be done to alter the natural history of this debilitating condition after the index/diagnosis date. Patients with CHF have a higher 5-year mortality rate than those with most types of cancer.

Often, earlier signs of CHF have been present, but they may not have been recognized. For example, if a patient has been “looking sick” over the past few visits and CHF is not diagnosed, blood tests, an x-ray, or another test may pick up silent disease. If enough signals can be detected and analyzed in real time (beyond the ability and time constraints of most physicians), early diagnosis and aggressive intervention become options.

In a pilot study at Geisinger, only 11 variables were needed from the EHR to identify patients at high risk for developing CHF in the subsequent 12 to 18 months, and these variables can be gleaned from data collected for clinical purposes. These variables include factors that are not observable or that are observable but are not understood by the clinician as leading to CHF, for example, subtle increases in visit frequency. Predictive models using EHR data in real time can provide similar benefits for numerous conditions, such as prediabetes and chronic kidney disease.

Behavior Change

Another core asset is designed around the goal of giving the patient a voice and integrating it into a program of behavior change. Although capturing patient preferences for care is frequently discussed, it is rarely done in routine practice for most conditions. Part of the problem is presenting choices in a meaningful context to the patient, capturing preferences without placing undue burden on the provider, and doing so without increasing the time of the visit. Paper-based or scanned questionnaires have not worked. Touch screen kiosks in the waiting room, however, are a solution that works well. Just as patients are sent to a laboratory for blood, they can be asked to complete questionnaires at such kiosks, and have the data imported directly to their EHRs to drive intelligent clinical decision support. This allows patients to participate in their own healthcare, by providing them with decision aids and giving them choices that normal clinic workflows would not allow.

As an example, a patient's 10-year risk of having a heart attack can be determined using the Framingham score with data derived from the EHR system. This score and underlying risk factor data—elevated blood pressure (BP) in this example—can be displayed for the patient at a kiosk in the waiting room, with a touchscreen interactive program (Figure 3). The patient's information is then shown on the screen, revealing a 12.2% risk of having a heart attack over the next 10 years, and the patient is shown how specific choices for lowering BP can best lower the patient's 10-year risk to 4.7%. Interventions may include taking medications; making lifestyle changes, such as increasing exercise or making dietary changes; seeking counseling; or doing nothing at all. Selecting different choices changes the risk in real time, and this interactive format, based on the patient's actual clinical data, allows the patient to clearly see the impact of each possible intervention on the risk of having a heart attack.

The underlying logic supporting this program is derived from widely accepted guidelines, albeit tailored to specific patients. In their paper-based version, guidelines are rarely used. The new model described above makes effective use of patient-reported data with real-
time assessment of those data. It provides very nuanced and complete expert advice in actionable and brief messages that fit the workflow and can be accessed as needed by physicians. Behavior change is hard to do but is much more possible if a patient’s preferences are integrated into a program of care and reinforced by the physician.

The Science of Healthcare Delivery

Traditional health services research is often conducted in isolation. The primary focus is on testing an idea, controlling all external factors, with the result that the test solution tends to be artificial, and success is measured by the influence of the idea on outcomes, not on its relevance to the practice setting. At the end of the study, the scientist publishes an article and moves on to the next great idea. Realistic testing of the idea in a practice setting is a distinct hypothesis and requires a different type of study. If the focus is on improving care efficiency, patient outcomes, and the business of delivering care, the solution will fit the practice setting. In this approach, success is measured by how well the solution influences outcomes and is adopted in the clinical setting, as well as the business sensibility, sustainability, and portability of the solution. This developing research core sits at the intersection of decision science, informatics, operations research, and financial management and represents a new research paradigm—a new “R&D” model applied to healthcare.

Conclusion
Endeavors aimed at leveraging information to create knowledge may include repurposing already-collected biosamples, capturing otherwise unrecognizable signals in EHR data, or engaging patients creatively with increased involvement in their care. It also involves looking at all the data from EHR, claims, patients, and other sources as a whole and combining them to arrive at real-time answers. This research and development philosophy, in use at Geisinger, shows how research has the power to transform practice.

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References
Where Goes Wellness in the Scheme of Things? Acting on Prevention, Intervention, and Innovation

Robert E. Henry, Editor-in-Chief, American Health & Drug Benefits

There are 2 temptations I urge the reader of this publication to resist. The first is simply to “move on” after reading what can be perceived as a dazzling group of interesting, disparate presentations—to go about one’s way without attempting to apply the knowledge to one’s daily practice of healthcare resource management. The second is to use a “cafeteria approach” to these variegated articles, “This one applies to me, the others are ‘soft’ topics more suited to…I really don’t know who needs those items.”

The truth is, this summit was conceived to demonstrate the holistic unity of multiple facets of healthcare skills, disciplines, stakeholder considerations, and overall operational concepts that together comprise this emerging thing: a new healthcare system requiring practical administration that is based on the best understanding of the governing principles of what we now call a wellness-based health system. Omit any phase of it, fail to integrate all the presentations into the whole picture, and we miss the picture in its entirety, playing only to old, preconceived notions of the healthcare “system,” which is just what healthcare has not been doing very well.

Wellness is a goal that had to elude the abilities of healthcare providers up until recently, because evidentiary knowledge was too weak to provide reliable evidence on how to achieve it. From our understanding of pathophysiology to the impact of drug utilization on the clinical and economic sequellae, evidence-based medicine and health information technology, on which much of it is based, were inadequate to allow providers, payers, and patients to do much more about their health than take a good guess. This is changing with the arrival of remarkable new research findings on the 3 aspects of wellness: prevention, intervention, and innovation. These are inseparable, as are the presentations in this supplement—the composite wisdom of brilliant healthcare experts in their respective fields, who came together for one special day to share their wisdom and their data, their questions and their concerns.

I urge you to reflect on their findings, question them at every corner, and seek to implement their core pursuit in your professional activities: the proactive mastery of sickness via a wellness-based health system of prevention, intervention, and innovation. This is the polar opposite of a reactive system of healthcare that waits until something has gone wrong with the patient for so long. No clearer path to waste of precious healthcare resources could be devised, but no verifiable alternative was available until recently.

New technologies are evidentiary methods permitting us to learn the governing dynamics that enable the leap from reactive to proactive healthcare. Preventive medicine and healthy living will take the burden off excessive, misplaced drug and diagnostics utilization, making possible the allocation of resources to quality medications (intervention), which in turn provides funding for the necessary advances in treatment (innovation) to prevail over the impending healthcare challenges posed by the ominous aging of the baby boomers. We will need strong innovation, not an anemic harvest of incrementally modified drugs when the time comes to keep the boomers out of nursing homes. This does not have the ring of an empty theory but a cultural change, where all members of society finally take health seriously, because it is now codified clearly enough—from what we eat at the country fair to patient adherence to treatment regimens; from physician adherence to guidelines to payers balancing cost, quality, and access in benefit design, rewarding innovation and making possible the next generation of breakthrough drugs. In short, acting in terms of wellness amounts to traveling with a compass, making up remedies suited not to 1 stakeholder but to the common good.

A holistic, evidence-based, patient-centered, value-based approach to health and healthcare are in order. This wellness summit has thrown down the gauntlet for payers, purchasers, drug makers, and policymakers to take the steps needed to move to wellness. We welcome your questions, feedback, and results as you move to apply the principles and findings of this outstanding faculty, comprised from the 4 corners of healthcare, and acting as a team, each essential in the leap to this new healthcare paradigm.