

PERSONALIZING CARE: A HEALTH CARE FUTURE THAT WORKS

Prologue Series



WHAT IS PAST
IS PROLOGUE

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Prologue Series

I have come to understand that public service is a generational relay. Many of the most profound problems are not ours to solve in finality, but rather to incrementally improve during our temporary stewardship.

Three foundation goals thus form the basis for my public service: to leave things better than I found them; to plant seeds for the next generation; and to conclude my work knowing I have given my all.

For nearly sixteen years, my life has evolved in four year terms. I was elected three times as Governor of Utah. Some of what I consider our accomplishments were initiated in my first term, but fully matured in my third. Likewise, some seeds planted in my third term are only now beginning to flower.

Living in four year cycles has taught me the importance of choosing priorities and impressed the need for urgency. Time passes quickly.

I am currently in my fifth year as a member of President George W. Bush's Cabinet. I served first as the Administrator of the Environmental Protection Agency and now as Secretary of Health and Human Services. The constitutional constraints on the President's service imposed limits on what initiatives I might see to completion. However, I view it as my obligation to lead with a longer horizon in mind.

Over time, I have developed a set of tools useful in keeping a long-term vision in mind while managing the day-to-day problems. One such tool is establishing a 5,000 Day Vision, with a 500 Day Plan.

The 5,000 Day Vision is our aspiration for various long-term outcomes. The 500 day plan is more granular, listing what needs to be done now to bring about the larger vision. Both are recalibrated periodically.

As my stewardship comes to a close, it is time to plant seeds for the next generation. I intend to write and deliver a series of formal speeches to convey some of the 5,000 Day Vision and share what I see on our approaching horizon.

I call these speeches *The Prologue Series*. There is a statue behind the National Archives that I look at nearly every day as I drive between HHS and the White House. The statue, the work of Robert Aitken, is called "The Future." It depicts a woman looking up to the horizon from a book as if to ponder what she has just read. At the base of the statue are the words from Shakespeare's *The Tempest* "What is past is prologue."

I have titled this speech in *The Prologue Series*: "Personalizing Care: A Health Care Future That Works."

Michael O. Leavitt
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Speech given on November 14, 2008
in Boston, Massachusetts

There is an honorable tradition that goes back hundreds of years. I'm talking about the tradition where someone has a good idea, or maybe several good ideas, which he shares with the world ... and then loses his job.

The person I have in mind today is Ernest Amory Codman. Dr. Codman was a Harvard man: Harvard class of 1891, Harvard Medical School class of 1895, and then the Harvard faculty. Dr. Codman was headed for a successful surgical practice based at Massachusetts General Hospital.

But he was driven by an eccentric interest. He wanted to learn what happened to patients after they left Mass General. He wanted to learn from them what had worked, and what hadn't. He especially wanted to learn what might be fixed or improved at the hospital. And even more eccentrically, he wanted to publish the results—and actually let the public use the results to make judgments about their medical care

He presented these proposals to the Harvard faculty in 1914. He was relieved of his hospital privileges in 1915.

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We still lack a coherent system for measuring outcomes, for measuring quality, and hence for measuring value in health care.

We need to learn how to measure quality and value in health care. And we need to base our health care decisions, including payment decisions, on quality and value factors.

Dr. Codman was a man of many ideas. He was a leading founder of the American College of Surgeons. He helped create the predecessor to today's Joint Commission, for accrediting health care organizations. He helped bring together the first bone marrow registry. All-in-all, he probably should have felt lucky that he wasn't fired more often.

Ninety-seven years later, we still lack a coherent system for measuring outcomes, for measuring quality, and hence for measuring value in health care. We have a health care sector that, like Mass General in 1915, may be excellent and a leader in many ways. Yet, without the ability to measure and reward value, our health care sector cannot separate the wonders from the waste. Indeed this flaw threatens to bankrupt our health care sector today.

We need to acknowledge that measuring quality and value in health care is not easy. Applying standards of care for practitioners has been fraught with difficulties. Diagnosis can be like St. Paul's expression, looking "through a glass darkly." Medicine has been a mixture of science and art. So if we lack coherent outcomes and value measurement, the reasons are many and complex.

Nonetheless, I do believe, Dr. Codman's day may finally be at hand. The fact is, we can't afford to keep ignoring his call for a coherent quality system. We need to learn how to measure quality and value in health care. And we need to base our health care decisions, including payment decisions, on quality and value factors.

I'd like to present an argument for this —

- The time is here for health care reform;
- Reform needs to address not only the driving issues of access-to-care and insurance, but

it must also address the issues of value and value-measurement in health care;

- One of our most important tasks in health care reform (and perhaps the most challenging) will be building systems that will enable us to measure and reward value; and
- The goal of “personalizing” health care should be recognized as an explicit objective in our drive toward better value in health care and better health for Americans.

Health Care Reform

We can’t afford the spending trend we’re on. More precisely, we can’t afford the billions of dollars of waste, which reflect our failure to deliver consistent and cost-effective quality care.

It isn’t just that we’re spending twice as much as other nations for health results that are no better. It’s the trend. If the current spending trends continue, then by 2017, our health care spending will be aggressively crowding out other investment and opportunity in the United States.

There is no room on the world leader board for a nation with our kind of exorbitant health spending. So the time for reform is here.

Roles of Value

Health care reform will be aimed at access to insurance and care. But to be successful, reform will need to include another element as well. It will need to include value.

Most reform proposals focus, quite rightly, on the human and the cost consequences of our health care sector. It is frightening to see spending at this level, without real control. And it is painful to consider

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that, even at these spending levels, we are failing to deliver health care in a rational and effective way for all Americans.

Our health care sector is a dysfunctional marketplace. We're all caught in it: providers, payers and consumers alike. It's a zero-sum game — I carve out my advantage at your expense, and neither of us is ultimately focused where we should be — on value. That's because our reimbursement system doesn't pay according to value for the patient. Instead, it pays on the basis of the volume of services that are delivered—pretty much regardless of outcome.

In a functioning marketplace value is continually improved. Stakeholders throughout the system pursue value—that is, they pursue a good quality product at a competitive price. But in health care the guiding compass of value is missing. We do not yet have a reliable system for measuring the quality and value of the care we deliver.

No matter what choices we make about how Americans get coverage, or even who pays, we won't achieve our goals of good health and good care at an effective price unless we build value into the health care sector.

How to Achieve Value

It's not enough just to want value. We need to start at the beginning by addressing our very capacity for measuring quality and value. In this way, health care really is different from other sectors. In health care, we need to build the systems to make value measurement and value reward possible. And we need to do it in a collaborative way.

During my term as Secretary, I have endeavored to start building a value-yielding system for health care:

one that includes all stakeholders, and one that can keep up with the advances and subtleties of medical care.

I have identified a framework for a value-driven health care system which we call the four cornerstones. We've begun putting those cornerstones in place. They constitute a national work plan of sorts, a means for organizing the independent work of millions into a common direction.

The first cornerstone is quality measurement.

We've made a good start at developing coherent, science-based standards for measuring quality in health care, and a formal mechanism to develop more. We have identified and inventoried existing quality care guidelines. We have established linkages between the many different organizations involved in quality measurement. And we have initiated a regionally-based system of organizations called Chartered Value Exchanges for reviewing and improving quality performance at the local level.

It is worth emphasizing that we've aimed at a national process for recognizing and harmonizing standards — and then a local and regional process for making use of those standards. To paraphrase the late senator Tip O'Neill: "All health care is local." Providers, payers, and consumers need to be able to sit down together at the local and regional level to understand and apply quality standards in their own area.

The second cornerstone is cost comparison.

As I have said many times: the way we pay for health care in today's system is simply irrational. When a patient goes to the doctor or the hospital for a treatment or a procedure, we should be able to determine a fair price for the end product, measure how it was accomplished, and pay in a way that

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enables cost comparison. And we should not be paying for every \$5 aspirin tablet along the way.

We've developed the first stages of a mechanism to create cost groupings, so that payment can be made for a total outcome, not singly for each component and procedure.

The third cornerstone is health information technology (health IT).

Modern information technology has transformed other sectors of our economy, to the benefit of the consumer. It can do the same in health care.

We recognize that health care is complex, and it's important to build our information systems carefully. But that very complexity makes health IT and health informatics all the more important for progress and affordability in medical care.

We have taken a giant step forward. During the last four years, we've established a well-accepted, consensus-driven process to develop standards for interoperable health IT.

The fourth cornerstone is incentives.

It's true when they say: "You can't manage what you can't measure." But once you can measure, then you can pay for what you want—on a competitive basis. And when we reach that point, I believe, we will have untangled the Gordian knot of health care. At that point, stakeholders will be enabled to pursue their own advantage by selecting products and services that enhance value.

Using these basic value measurements, insurers and payors in both the public and private sectors are beginning to reward low-cost, high-quality care. We are indeed beginning to learn together how to reliably measure quality and value, and then use that information to reimburse in a productive manner.

I see these as the elements of a workable system to support high value in health care. The base we've built will be helpful in achieving real, sustainable health care reform.

But there's one more step—and that's the concluding part of my argument.

Personalized Health Care

If we reduce waste in our system, we will make huge gains. It is commonly estimated that wasteful procedures and payments constitute as much as a third of our health care spending. To eliminate that waste, it is indeed essential that we first make better use of what we already know. And that is what the four cornerstones of value-driven health care aim to do.

But looking forward, we also have new opportunities, based on advances in science that we're only beginning to reap. The symbol for these new opportunities is the Human Genome Project, which is leading us to a new level of understanding of our human biology as well as the biologies of disease agents. In reality, the Genome Project is the surrogate for a host of new technologies that can improve our health and our medical care, and do so in cost-effective ways by increasingly "personalizing" care.

The concept of Personalized Health Care may be misunderstood by many people. It is not about designing one drug individually for you and another drug individually for me. But it is about recognizing that we're different—that my metabolism is not your metabolism, that my genome is not your genome, and that the quality of our health care can be improved by learning those variations and targeting the right care to each of us.

Personalized Health Care is an amazing process of discovery that is underway to sort out those variations

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between us and understand the mechanisms behind them. It's about the information tools that will help us put those discoveries to work in a cost-effective way.

Personalized Health Care cannot become merely a series of new tests and diagnostics to be billed for. It has to become part of a new economic equation that reduces cost and increases quality.

I believe Personalized Health Care improves value in health care for several reasons:

- It supports quality standards. Personalized Health Care is about understanding our individual variations so we can learn what works and for whom. That's virtually synonymous with ever more effective standards of care.
- It supports precision in care, and that can help avoid waste. For example, when we can get the correct diagnosis the first time, or prescribe the right drug for the right patient, that's better quality at a lower cost. We've developed powerful pharmaceuticals, yet most drugs prescribed in the United States today are effective in fewer than 60 percent of patients. One study found that prescribed drugs are ineffective or less effective for at least 70 percent of those who take ACE inhibitors and beta-blockers. Imagine the gains in quality, cost, and good health if we could prescribe the right drug on the first encounter.
- Personalized Health Care also holds the promise of prediction and disease preemption. If we can use new genetic knowledge to spot disease early and preempt it, or identify a predisposition to disease and help prevent it, that would represent quality at the highest level and the right price.

- In addition, Personalized Health Care is at the leading edge of health IT. To my mind, Personalized Health Care will actually be based 50 percent new biological discovery, and 50 percent on the informatics to understand and deliver these advances.

Personalized Health Care is the right organizing concept for progress in medical care. It is not a niche concern. It takes the newest and most promising scientific knowledge and directs it at the oldest and best intentions of medicine. It asks the right questions and applies the right tests as we seek a high-value health care system.

What will Personalized Health Care look like? How might a consumer judge how “personalized” his or her own health care really is? I suggest six tests:

Number 1 — Do I have an electronic health record? In particular, do I have an electronic health record that is interoperable, so it can be shared securely between data systems? From a practical standpoint, the interoperable electronic health record is the beginning and “sine qua non” of Personalized Health Care.

Number 2 — Does my physician provide me with a strategic plan for health maintenance, based on my own biology, family history, and other personal factors? And do I take the responsibility to understand it and act on it? A strategic plan like this may become much more sophisticated over time, but there’s no reason this kind of personalization shouldn’t be a standard feature of medicine today.

Number 3 — Do my doctors have access to decision support tools, and do they use them? Do I have access to such tools as well? This can range from simple

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health reminders to drug interaction alerts, all the way to a future that uses genomic profiles. Medicine is complex, and informatics tools can help physicians and patients alike.

Number 4 — Do I have the expectation that treatments will be recommended to me based on my own biology and preference, not just best guesses and population averages? Patients and doctors should come to expect and use more information to help them get the right diagnosis and the right drug. This bar needs to get higher.

Number 5 — Is my personal genomic information, or other personal molecular information, available for clinical use? Ideally, is it included in my electronic health record? This is the futuristic view of Personalized Health Care. It's not around the corner. In all candor, we don't really know which of many possible technologies or discoveries may work soonest or best. But personal molecular information, embedded in the EHR, is the classic picture of Personalized Health Care.

Number 6 — Do I have the opportunity, if I wish to do so, to make my clinical information available for research, and thereby contribute to new knowledge? This is the step that completes the cycle of Personalized Health Care. As consumers, we stand to benefit from new scientific knowledge. As patients, we can be in a position to contribute to new knowledge.

Last year, I went on to the community of Framingham, Massachusetts to thank the residents who have been part of the Framingham heart study over the past 60 years. Over 10,000 participants and three generations have participated in medical tests and interviews to help us better understand the causes of heart disease.

They were proud of the contribution they've been able to make, simply by sharing their personal clinical information, in a secure manner, for use in research.

In a Personalized Health Care culture, where we'll need large volumes of information to understand individual variation, I would hope that every one of us might have that opportunity. This is the picture of a "Learning Health Care System" for America.

How soon will we have Personalized Health Care? It will take time. But it will come faster if we understand the destination, and if we integrate this journey with our journey toward value in health care:

- ◆ We need widespread adoption of health IT and interoperable electronic health records.
- ◆ We need to put a new focus on medical evidence—how to turn data into actionable evidence more quickly, and how to keep building and adjusting the evidence base as science moves forward.
- ◆ We need to find ways to pay for services that prevent and preempt disease. Today, reimbursement is strongly tied to post-symptomatic treatments. But we hope Personalized Health Care will give us the ability to act sooner and preempt expensive treatments or prevent disease altogether. We need to learn how to quantify that value and pay for it.
- ◆ We also need to focus on the needs of consumers—starting with education and privacy protection. And we need to do a better job of bringing physicians into the process of change.

A Personalized Health Care culture is the picture of a "Learning Health Care System" for America.

We need to put a new focus on medical evidence.

Change is inevitable.

I want to offer what I've learned, and help those who come after me. Change is inevitable. It may seem alluring one day, and frightening the next. But it is a condition of life.

We need to do a better job of bringing physicians into the process of change.

Change in health care is coming. It will look threatening to some. But it is truly an opportunity to be seized.

America possesses strong health care resources. We have created the base for a new kind of Personalized Health Care. Change can make us stronger. There are three ways to deal with change: Fight it and die. Accept it and survive. Or lead it, and prosper.

In a global market there are three ways to approach change. You can fight it and fail; you can accept it and survive, or you can lead it and prosper.

We are the United States of America; let us lead.

What is past is prologue...