

DISRUPTIVE INNOVATIONS IN HEALTHCARE: EXPANDING THE DISCOURSE ON QUALITY AND VALUE

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Between the health care that we have now and the health care that we could have lies not just a gap, but a chasm.¹

I am a healthcare provider.
I am a patient.
I am a patient advocate for my aging parents.
I am a parent of a sick child.
I am an employer purchasing health insurance for my employees.
I am a physician educator.
I am a consumer educator.
I am a researcher.
I am a consumer of goods and services that impact health.

I stand at the interface of competing professional and personal needs and contradictory social, cultural, and economic forces that form the epicenter of our healthcare crisis and debate. I stand with many questions and few answers.

I stand inviting all the stakeholders in our society who are touched by our healthcare system (namely every citizen who may touch or be touched by healthcare in a myriad of ways) to ask new and potentially disruptive questions. We must have the courage to ask the questions that can enliven the current collective conversation about the need for changes in that system and create empowerment, alignment, enrollment, and sustainable well-being for our children and our children's children. It is only through a larger inquiry using our collective intelligence that we can align our thinking and actions to create quality and value in healthcare.

If any single stakeholder wins in the ecosystem of healthcare, we all lose. Diversity and complexity are principles of thriving systems. These are the questions we must face directly and with honesty if we are to survive the healthcare crisis. These are the questions that must be grappled with and explored by each candidate for US President in the 2008 election.

As a society, we must grapple with the questions of whether healthcare is a basic right of citizenship, like suffrage or property ownership, or a privilege to be earned by extremes of wealth, poverty, or age.

RETHINKING COMPETING NEEDS: ALIGNING ECONOMIC INCENTIVES

How can we, as a society, align all the needs and interests of stakeholders within the expanded ecosystem of competing forces that comprise our "sick" healthcare system? If we follow the trail through the healthcare forest, it will be clear that an alignment of values, needs, and interests must occur if there is to be meaningful change. It will also be clear that no one component can be separated from any other and that if we create change in one area of the system, often negative forces will fill in the blank space.

Follow the trail of a simple soda and french fries, for example.

The government subsidizes farmers to grow corn and soy crops with \$30 billion a year,² which fuels the fast and junk food industries with high-fructose corn syrup and trans fatty acids, which are used to produce energy-dense, poor quality, disease-creating foods such as soda and french fries. At the same time, funds for local schools are limited, hampering their ability to provide students with quality food choices and physical education. The food industry steps in, encouraging children to subsist on nutrient-poor, energy-dense foods from vending machines for their breakfasts and lunches. The marketing for these products exceeds \$30 billion a year (more than \$13 billion of which is aimed at children), increasing demand. These are tax-deductible expenses to corporations, which are in effect further subsidies from our government. These children, then, become obese and diabetic in their 20s and require care for heart disease and amputations before they are 30, for which the government in part must pay.

In fact, approximately 60% of our current healthcare expenditures (nearly \$2 trillion, or about \$6000 per capita) are paid for and administered by our government through the Centers for Medicare and Medicaid Services (CMS) and tax subsidies for health benefits. Bureaucracy and administration consume nearly a third of US healthcare expenditures, whereas Canada's single-payer system has only 1% administrative overhead.³ This does not include indirect costs such as agricultural and food industry policies that promote disease and not health. The silver lining in this startling fact offers hope if government leaders can leverage that financial burden into wholesale disruptive innovations producing quality and value, rather than a patchwork quilt of modi-

fications aimed at reducing symptoms but not fixing our seriously diseased and broken system.

Marion Nestle, PhD, professor of Nutrition and Food Studies at New York University, emphasizes the lack of alignment of interests for health promotion and disease prevention for the main stakeholders in our society that influence health and disease: industry and government. As she notes in her best-seller, *Food Politics: How the Food Industry Influences Nutrition and Health*,

It is difficult to think of any major industry that might benefit if people ate less food; certainly not the agriculture, food product, grocery, restaurant, diet, or drug industries. All flourish when people eat more, and all employ armies of lobbyists to discourage governments from doing anything to inhibit overeating.²

She goes on to suggest that

Existing food policies could be tweaked to improve the environment of food choice through small taxes on junk foods and soft drinks (to raise funds for anti-obesity campaigns); restrictions on food marketing to children, especially in schools and on television; calorie labels on fast foods; and changes in farm subsidies to promote the consumption of fruits and vegetables. The politics of obesity demand that we revisit campaign contribution laws and advocate for a government agency—independent of industry—with clear responsibility for matters pertaining to food, nutrition, and health.²

Monica Sweeney, MD, the director of the Bedford Stuyvesant Family Health Center in Brooklyn, said in a personal communication with me that the single biggest risk factor for morbidity and mortality is not socio-economic status or ethnicity, but education. For every year of education, healthcare costs decrease and health improves.

The politics of food, agriculture, environment, and education cannot be divorced from the traditional healthcare stakeholders—patients, providers, insurers, employers, payers, and government. Hope exists only in creating solutions that address the roots of the problem within the whole ecosystem of our society and envision an environment where all stakeholders thrive.

ENLARGING THE DISCOURSE

How can we change the language of our discourse from symptomatic treatments or patchwork repairs of the crumbling architecture of our healthcare model to whole-systems thinking that can lead to a sustainable healthcare ecosystem? We speak of containing costs; shifting costs between payers, employers, and patients; reducing errors; implementing software solutions; and improving efficiency. What if these strategies only temporarily relieve the pressure on the system, ignoring the real issues, which are how do we adopt a major shift in our scientific approach to

disease from reductionism to systems biology and how do we change the existing structures and methods with which that care is delivered?

How can we identify and implement disruptive innovations that create the dramatic shift we need in both the content (the nature of the science we apply) and the delivery of healthcare (the systems and processes through which we care for each other)?

How can we enlarge our view of the myriad of influences on health that should be brought into a discourse for change? Just as we ask, “What is the real cost to society of cigarette smoking?” might not we ask, “What are the real long-term costs of a nation of overfed and undernourished citizens with unfettered access to goods and services that have been clearly shown to create disease and increase costs? How do we address our citizens’ limited access to health-promoting foods, activities, products, and services?”

What is the true cost in lost dollars, productivity, health, and well-being of a large serving of trans fat–soaked french fries or a 48-oz soda consumed 3 times a week for a decade or more? What is the cost of cities and communities designed around cars rather than human beings? What is the impact on our bodies of decreased fitness and progressive muscle loss that results from our car- and computer-addicted population and that is linked to every known degenerative disease?

There is no magic pill to cure our diseased healthcare ecosystem. There are opportunities, challenges, and obstacles that must be overcome to move from our ordinary thinking about change toward extraordinary thinking, out of which a new, thriving sustainable ecosystem of healthcare can emerge and function.

The conflicts within our system must be transformed into alliances based on 2 very simple principles: quality and value.

Though it might seem self-evident that our healthcare system uses measures of quality and value to determine what kind of care is delivered, these are unfortunately far from the top of the list of guiding principles.⁴ Value can be assessed as the unit of benefit based on the success of outcomes divided by the cost. Quality in healthcare is a subjective soft measurement and can be defined more in terms of quality of life, optimal functioning, vibrant well-being, productivity, and thriving.

Quality also can be thought of in more concrete, simple terms. We use it as a measure every day for the choices we make in the purchase of goods and services. However, it is mostly absent from the healthcare debate. If you took your car in to have a flat tire repaired and it came back with the tire only half full of air, you might find that it caused other problems, such as tire misalignment and increased tire wear for the other 3 tires, or worse, that it caused imbalances that led the other tires to blow out or doubled the car’s gas consumption. Then you would seriously question the value of the repair. The outcome for the cost did not create value. This example is replicated over and over in healthcare.

Despite the rallying cry for evidence-based medicine, many of the practices in medicine are handed down through lore and apprenticeship. And randomized controlled trials, as the gold-

standard methodology of valuation, fall short in assessing real people with multiple chronic complex conditions.

In fact, is it perplexing that our healthcare practices are measured in isolation and not as part of an ecosystem of sustainable healthcare outcomes. It is odd that healthcare is the only sector of our society in which we can repeatedly pay high prices for goods and services that don't provide value.

Using the yardstick of value=outcome/costs, we fall far short.

THOUGHTS ON CROSSING THE QUALITY CHASM AND CREATING A NEW HEALTHCARE SYSTEM

Do you see what you believe or do you believe what you see?

—Sidney Baker, MD

This story has been told in great detail in the Institute of Medicine Report *Crossing the Quality Chasm: A New Health System for the 21st Century*.¹ This report was a landmark honest evaluation of the failings of our current healthcare system produced by a cross-section of 20 stakeholders in the healthcare arena. Anyone who is involved directly or peripherally in healthcare should read the executive summary, if not the whole report.

The report provides a working blueprint for moving forward. It highlights 6 aims for improvement. Care should be safe, effective, patient-centered, timely, efficient, and equitable. It defines 10 rules for the redesign and whole-scale reinvention of healthcare, including basing care on healing relationships and customizing care according to patient needs. The patient should be the source of control, and knowledge of health information should be shared and should flow freely within the system. Medical and healthcare decisions should be evidence-based (and, I believe, based on layered levels and quality of evidence based on mechanisms, causality, and systems analysis—not simply randomized controlled trials). The healthcare system should be safe and transparent. Anticipated needs, decreased waste, and cooperation among clinicians and healthcare teams are foundational principles.

The report calls for a “Healthcare Quality Innovation Fund” of \$1 billion to facilitate the healthcare system redesign and recommends that the Agency for Healthcare Research and Quality (AHRQ) identify 15 or more common conditions for which to create improved systems-based care processes and then work with stakeholders in healthcare to advance the implementation of these processes.

The redesign of the healthcare environment demands additional changes to the current structures and processes, including applying evidence to healthcare delivery, using information technology, and aligning payment policy with quality improvement (not necessarily pay-for-performance, but payment and distribution of funds to optimize healthcare outcomes using a wide array of tools, services, and methods).

That is a broad overview of this pivotal report. The report truly focuses on 2 main issues—the *type of medicine* we practice and the *way we practice it*—the content and the delivery of healthcare.

The first issue tackled in detail is our limited capacity and

dismal failure to translate and incorporate rapid advances in medical thinking and science into clinical practice that would lead to improved quality and value, in contrast to the current well-documented rampant overuse of ineffective treatments and underuse of proven therapies or misuse of existing practices.

What was not addressed directly but is hinted at obliquely in this analysis is the need to reinvent healthcare based on emerging principles of systems biology, functional medicine, health promotion, and prevention. A landmark paper by Martha Herbert, MD, a Harvard Neurology and Autism researcher,⁵ provides a template for using systems theory and thinking to reinvent our approach to complex chronic disease. Far from a brain disorder, autism is now recognized to be a multi-causal, genetically heterogeneous systemic “body disorder” that affects the brain and is characterized by altered immunology, brain inflammation, gut disturbances, and unique profiles and collections of genetic polymorphisms affecting nutritional status and the capacity for detoxification.

Widespread training in and adoption of this type of thinking that cuts across established medical silos and scientific domains are imperative if we are to solve the puzzle of complex chronic illness, which accounts for the greatest burden of suffering, morbidity, and mortality—and for 78% of our healthcare expenditures.⁵

Medical thinking and care that is organized into separate scientific or clinical silos (known as specialties) become less useful as the common causes, mechanisms, and networks of dysfunction that create clinical disorders and diseases are revealed. Methods of research and standards of evidence-based medicine must be reexamined for their limitations, not held up as the gold standard for medical decision-making.

How many clinicians use one drug or intervention to treat single disorders in the setting of complex chronically ill patients? Very few, I suggest. Disease occurs in clusters because of common interlocking mechanisms, not in isolation, as we are trained to believe. Research and treatment methods are designed for single disease entities, which ignore the complex biological web of functional disturbances that give rise to the named clinical condition. This type of care presumes clinical medicine is a pure science, which it is not. Perhaps novel decision architectures using systems thinking, pattern analysis, and ecosystem therapeutic solutions (team approaches; care as education; lifestyle, nutrition, and exercise instruction; relaxation and cognitive tools; and integrative care models) more closely approximate real patients' needs.

In defending his concept of biochemical individuality, Dr Roger Williams said, “Nutrition [and medicine] is for real people. Statistical humans are of little interest. People are unique. We must treat real people with respect to their biochemical uniqueness.”⁷

Research funding and agendas need to be shaped by measuring quality, value, and impact, not by selecting the most profitable intervention. They must emerge from objective inquiry about the best possible health outcomes from all potential interventions. We are enamored with the latest medication or proce-

ture, which is adopted without demonstration of a clear advantage over past medication or procedures or without direct comparison to known lifestyle therapy benefits but at dramatically increased costs. Funding choices are focused on reductionist interventions, not whole-systems approaches, despite their clear demonstrated benefits.

Dean Ornish, MD, et al did not study a singular intervention for cardiovascular disease prevention or treatment, but a whole-systems approach designed to enhance and promote health based on the best available current scientific principles and accepted measured outcomes, such as heart disease progression and the need for angioplasty, cardiac bypass, or transplant.⁸ We reflexively quickly adopt new medications or classes of medications, such as Avandia, Vioxx, or hormone replacement therapies despite limited efficacy or direct comparison to integrated lifestyle and functional therapies. Placebo should not be the control in studies of chronic illness; rather, a whole systems lifestyle intervention of improved diet, exercise, stress management, and cognitive tools for health promotion should be used. In every such study, a whole-systems approach (even in limited application) exceeds the power of pharmacological interventions.⁹

Clearly, the translation of innovations in science must find pathways for rapid dissemination and integration into practice. As a society, we don't have to suffer countless preventable deaths or wait 264 years for implementation, as happened with Captain Lancaster's discovery in 1601 that scurvy could be prevented with lemon juice until the British Navy adopted a universal preventive policy on scurvy.¹⁰

Equally as clearly, research agendas and funding must match the evolution of medical and biological sciences and its growth from reductionist analytic endeavor to a necessary synthesis and integration of emerging unifying and common biological laws and principles.

Innovations in medicine (and in general) are slow to be adopted, especially if they are as complex as systems biology and medicine.¹¹ Even in the context of reductionist medicine, the spread of innovations is dangerously slow. Only 1 in 5 elderly patients with myocardial infarction received current accepted standards of care to prevent recurrence.¹² The fact that 45% of patients do not receive recommended care measured with 439 indicators of quality of care for 30 different health conditions and prevention should be cause for alarm and a critical analysis of the reasons for this failure.¹³ The failure lies both in the realm of the content of medical care—what we practice—and the delivery of care—how we practice.

We don't look critically at how resources are applied to improved outcomes. How can we spend 40% more per capita than any other nation on healthcare and yet rank 27th in infant mortality and 27th in life expectancy, and have consumers of that care who are less satisfied than citizens of other developed nations are with the care they receive?¹¹

Not directly addressed in the IOM report is the larger economic and social ecosystem problems that impact health—the web of businesses and interests that in one way or another con-

tribute to our poor quality of health or to the increasing cost of healthcare. This basic intrinsic misalignment of economic incentives needs thoughtful, creative, and potentially disruptive but innovative solutions that will create value for all stakeholders. Those who profit from the promotion of disease or the care of people with disease are not aligned in creating change and they comprise up to a third of our economy. This includes the health administration bureaucracy, the pharmaceutical industry, the insurance industry, the food industry, the agriculture industry, and the media, which benefit from advertising dollars from big food and pharma.

Also not identified in the report are natural allies for change—namely large corporations that can't compete in a worldwide economy because of the burden of healthcare costs for employers. We must question the intelligence of a system where Starbucks pays more for health insurance than coffee beans.¹⁴ Employers have a natural alignment in promoting health and preventing disease, and their intelligence and motivation for change should be harnessed.

CHANGING HOW WE DELIVER HEALTHCARE

The next critical issue addressed in the Institute of Medicine report is not the content of care, but the delivery system itself—in other words, all of the systems, processes, organizations, and methods involved in delivering care and reimbursement or payment structures for that care. How might our delivery system be reinvented with a fresh view of the needs of patients and providers, putting aside our habitual practices and ways of collecting and interpreting clinical information as well as educating, training, and assembling a personalized plan of care in any one individual?

The old Normal Rockwell model of the country doctor based on the 6- to 15-minute office visit consisting of getting the patient's symptom- or condition-focused history, examining the patient, and dispensing a prescription does not meet the needs of complex chronic illness or facilitate the interpretation of complex data based on systems medicine. It also does not offer a pathway for patients to become partners in their health through information sharing, education, and supported changes in lifestyle and medical treatment recommendations.

This has been a subject of great interest to me as I have moved through various roles in my life, from provider as family doctor and emergency room doctor to practitioner of systems and functional medicine, to chronically ill patient, to advocate for sick parents and children, to business owner and payer for employee healthcare, to professional and consumer educator and interpreter and synthesizer of health information, to researcher, to practice manager, to electronic health record purchaser and user. I find myself practically and literally at the interface of all the changes in medicine over the last half century.

The main question we face today is this: how can we find a way to reinvent healthcare practices to accommodate the changes in science, the advance of information technology, and the shift toward patient-directed and patient-centered healthcare? How do we match the changing content of science to a reengineered

healthcare delivery system at all levels within the system?

This inquiry is essential to our collective survival and renewal in a desperately outdated, flawed, expensive, and misaligned healthcare system.

These questions and concerns form only the starting point for conversation and debate. Might we take as the guiding principle the need to change from ordinary to extraordinary thinking? Might we examine how our current thinking leads to actions and results that may not reflect our common unspoken goal—to create a sustainable healthcare system and society so our children and their children can thrive for generations to come?



—Mark Hyman, MD
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LETTER TO THE EDITOR

INTRAVENOUS NUTRIENT THERAPY

In your May/June issue, Dr Massey reported that 7 patients with fibromyalgia improved after intravenous administration of a combination of magnesium, calcium, B vitamins, and vitamin C; however, none of his patients became pain-free.¹

In my experience with approximately 30 fibromyalgia patients given a similar treatment, some (perhaps 25%) became pain-free. Most of my patients received more magnesium chloride hexahydrate (800 mg vs 400 mg) and calcium gluconate (200 mg [2 mL of a 10% solution] vs 40 mg) in their infusion than did those treated by Dr Massey. In addition, the usual infusion rate for my patients was 5-15 minutes, depending on their tolerance. In contrast, Dr Massey's patients received the infusion over 20-30 minutes. While there are risks associated with too-rapid infusion of magnesium and other nutrients,² the higher peak serum nutrient concentrations that occur with more rapid administration may result in enhanced cellular nutrient uptake and a greater therapeutic effect in some cases.

Sincerely,
Alan R. Gaby, MD
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