

QUALITY IN HEALTHCARE: ASKING THE RIGHT QUESTIONS

THE NEXT TEN YEARS: THE ROLE OF CAM IN THE “QUALITY CURE”

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The *Nei Ching*, or *The Yellow Emperor’s Classic of Internal Medicine*, was the first medical text I read, more than 25 years ago. The Yellow Emperor reminded us that “The ancient sages did not treat those who were already ill; they instructed those who were not ill.” The traditional Chinese physician was responsible for maintaining health. He did not wait until symptoms arose and the levels of care and cost increased. In fact, traditional Chinese physicians were paid only if the patient remained well. The quality of care was not measured by the success of treatment, but by the effectiveness of disease prevention and health promotion.

More than a generation ago, the optimistic sensibilities, the searching and questioning of the pioneers of complementary and alternative medicine (CAM)—though no such appellation existed then—reflected a longing to return humanism to medicine. It arose in a climate of rapid technological innovations and alienation of patients from their physicians. “Real” doctors scorned alternative medicine. It was not part of the national healthcare dialogue; it was on the fringe of society and separate from science. Alternative medicine was often practiced in secret to avoid discipline from one’s medical board. The landscape has shifted dramatically, as outlined in David Eisenberg’s reflections on the *Institute of Medicine (IOM) Report on Complementary and Alternative Medicine in the United States*, which appear on pages 10-15 of this issue. The IOM report is a set of recommendations and guidelines commissioned by the National Institutes of Health to provide guidance and direction for research, education, practice, and policy in healthcare. The report boldly challenges the view that CAM is “alternative” by recommending that the “the same rules apply for testing the effectiveness and safety of any therapy regardless of its origin, whether the therapies are viewed as complementary and alternative or conventional medicine.”¹ The discourse has shifted from finding what works in CAM to finding what works in medicine and healing as a whole. In other words, the goal is to find the most effective and cost-effective approach to prevention, health promotion, and the treatment of illness, regardless of the modality’s origins.

The national healthcare dialogue has omitted discussions

about the nature and quality of care. Much has been written, however, about our current healthcare crisis: the high cost of healthcare; the \$1.5 trillion (ie, 15% of the nation’s gross national product) spent on healthcare; the lack of universal healthcare access and the resulting 45 million uninsured Americans; the insurance morass and their control of healthcare spending; the disenchantment and disempowerment of physicians; the frustration of patients and healthcare consumers; the lack of incentives for practitioners or insurers to foster prevention and health promotion; and the startling lack of measures for healthcare quality and outcomes.

This lack of focus on quality must be central to the current debate on healthcare. The past 10 years—and a decade of exploration before that—and the work of many individuals and pioneering organizations in CAM have been devoted to creating recognition, acceptance, validity, and funding for CAM. The field has gone from ridicule to recognition to respect in a very short time, and the IOM report places CAM at the very center of the debate on our current healthcare crisis and the issue of quality of care. The ancient Chinese physician was paid for quality, not quantity, of care, creating an incentive for disease prevention and health promotion. The incentives are reversed in the current healthcare environment, where providers are paid by the piece, regardless of quality or outcome. There is no evaluation, or serious consideration in the research world, of quality. In no other area of our economy is quality or evaluation of the “product” removed from the equation.

We speak of evidence-based medicine, not quality-based medicine. Although evidence is important, it is not enough, particularly when the evidence is limited mostly to what is funded by private interests or grounded in the pharmacologic treatment of disease. The fundamental flaw in our approach to the discussion about evidence-based medicine versus quality-based medicine is the lack of focus on prevention and wellness and the lack of funding and research on comparative approaches to chronic healthcare problems.

When a fabled New England farmer was asked, “How is your wife?” he answered in a way that all research institutions and policy makers should respond when evaluating any proposed treatment: “Compared to what?” We compare conventional treatments to placebo in the gold-standard randomized, controlled trial (RCT). But should we evaluate alternative modalities using the same methodology in studying a particular herb, a

single vitamin, or therapeutic touch? My answer is no.

There are two fundamental problems with using RCTs to study alternative modalities. The first is that CAM modalities are often part of a system, a philosophical approach that is centered on facilitating and promoting balance and health in the body, rather than ameliorating a particular symptom. In an RCT, therefore, the CAM modality is examined out of context, and consequently, the results often do not indicate the most effective treatments. Second, CAM and its varied philosophies and methods are not measured against conventional treatments. If we compare CAM only to placebo and not to conventional approaches, we may miss the opportunity to rewrite the textbook of medicine.

The fundamental theme in nearly all CAM disciplines and lifestyle medicine, including nutrition, exercise, and stress management, is the restoration of balance in each individual. Conventional interventions are focused primarily on blocking, interfering with, or exciting a biochemical or physical manifestation of disease. CAM approaches typically focus on restoring normal function and balance, and thus indirectly treat symptoms. This is CAM's real contribution to the healthcare debate. The restoration of balance is synonymous with disease prevention and health promotion. The concept has its origins in the humors of Hippocrates, the *qi*, the five elements and *yin/yang* of traditional Chinese medicine, the *prana* and *doshas* of Aryurveda, the law of similars of homeopathy, and the notions of air, bile, and phlegm in Tibetan medicine. These traditions provide guidance on lifestyle behaviors, diet, exercise, and spiritual practices, supported by adjunctive therapies of pills, potions, touching, and needling.

Though it is still a matter of public debate, there is ample evidence that lifestyle therapies equal or exceed the benefits of conventional therapies. Nutrition, exercise, and stress management no longer can be considered alternative medicine. They are essential medicine, and often the most effective and cost-effective therapies to treat chronic disease, which has replaced infectious and acute illnesses as the leading cause of death in the world, both in developed and developing countries.² In 2002, the leading chronic diseases, including heart disease (17 million deaths), cancer (seven million deaths), chronic lung diseases (four million deaths), and diabetes (one million deaths) caused a total of 29 million deaths worldwide. These ailments are almost entirely attributable to clear lifestyle risk factors, including poor diet, sedentary lifestyle, and tobacco and alcohol use. The misconception that these diseases affect primarily developed and affluent societies has led to a misappropriation of resources and fails to address the exponential growth of chronic lifestyle- and diet-related disease. The major global health policy makers and agencies do not allocate appropriate resources to prevention of chronic disease either because they have yet to recognize the problem or because perceived or real economic concerns govern their actions. Heads of state, health ministries, the World Health Organization, academic and research institutions, non-governmental organizations, private donors, the World Bank, and the United Nations allocate only a fraction of their resources to chronic disease prevention despite a rich evidence base for the roles of lifestyle and diet in the prevention of major chronic diseases.

In his book, *Your Money or Your Life: Strong Medicine for America's Healthcare System*, David Culter, dean of social sciences at Harvard College and former member of the Clinton healthcare reform team, challenged the conventional wisdom that the answer to our healthcare crisis lies in reducing healthcare costs by rationing care, limiting access, and reducing payments to physicians and care providers. The solution is on the other side of the ledger—improving quality and effectiveness of care, which will lead to reduced costs and better outcomes. Though the concept is correct, he misses the opportunity to focus on where the greatest gains in quality of care can be made—from the world of CAM and lifestyle medicine, the patient-centered model of self-care, consumer education, and societal support for behaviors and habits that promote health. That requires change outside the healthcare economy, primarily in the food, advertising, and transportation industries, as well as in community design.

Culter's argument falls short in his cost analysis of increased technological spending and quality. He asserts that higher spending, on cardiac care, in angioplasties and cardiac bypass, for example, resulted in an additional \$30,000 of medical costs per three years of increased life expectancy for the average 45-year-old. A bargain, he believes. But when we ask the question, "How cost effective are our expenditures on end-of-life or late-stage interventions on cardiac disease?" the response should be the same as the New England farmer's: "Compared to what?" How do bypass and angioplasty compare to an integrative lifestyle, and a nutritional and complementary approach? This question has not been studied adequately. The limited data we have comparing conventional treatments to CAM therapies demonstrate dramatic, effective, and, I would suggest, lower cost for better quality.

In fact, our higher spending overall does not result in better quality. We spend more of our gross national product than any other nation on healthcare, but rank 12th out of 13 industrialized nations in 16 major healthcare quality indicators.³ Our own healthcare system has been ranked anywhere from the third to the first leading cause of death, as a result of such problems as drug reactions, medical errors, nosocomial infections, etc. Studies of higher-intensity practice patterns, with higher costs because of more physicians and more procedures performed, found them to be associated with a lower quality of care and worse outcomes than more conservative practice patterns.⁴ Our well-trained, well-intentioned physicians do not measure up when evaluated against quality-of-care standards for chronic health conditions, failing to deliver recommended care 54.9% of the time.⁵ Clinical research is not translated into clinical practice, leaving a large gap in healthcare quality (eg, 40% of patients do not receive aspirin after a myocardial infarction).⁶ This is, in part, related to the economic disincentives for providers, payers, or corporations to practice, pay for, or invest in disease prevention and health promotion. This is compounded by the regrettable lack of basic nutrition and lifestyle training in our medical institutions. Thus, the argument that more care equals better care, that improving quality by increasing access to more technology and pharmacology, as Culter suggests, does not hold up to scrutiny when com-

pared to the best available options to deal with chronic healthcare problems. When compared to doing nothing, the argument can be made for high-cost, technological interventions. When compared to changing our medical care system from one that focuses on treating end-stage disease to one that focuses on preventing disease and promoting optimal health through nutrition, lifestyle, stress management, and adjunctive complementary therapies, the conversation shifts dramatically. The IOM report is the fulcrum upon which the healthcare debate should shift, and in which the solutions to the healthcare crisis can be found.

Diet, Lifestyle, and Chronic Disease: A Model for CAM Research in Quality of Care

A brief examination of the nutritional literature and a direct comparison to other efforts to prevent or treat chronic disease, such as pharmacologic approaches, highlight the powerful, cost-effective, and critical role nutrition plays in causation, prevention, and treatment of chronic disease. This can be seen as a harbinger of other research initiatives in other disciplines of CAM that require novel research strategies and can bring the issue of quality of life and outcomes into sharper focus.

An emerging body of literature provides a firm foundation for practice and public policy in nutritional and lifestyle interventions for chronic disease.⁷ A single nutrient, food, or lifestyle habit, when studied as an isolated intervention, though helpful, may not show significant effect, but when assessed collectively, the power of lifestyle over pharmacologic approaches for primary and secondary prevention is clear. Adherence to healthful lifestyle practices, including a Mediterranean diet, moderate physical activity, non-smoking status, and moderate alcohol consumption in an elderly population was associated with a nearly 70% reduction in all-cause and cause-specific mortality.⁸ Other observational studies showed similar data,⁹ including an 83% reduction in coronary artery disease,¹⁰ 91% reduction in diabetes in women,^{11,13} and a 71% reduction in colon cancer in men.¹⁴ Though more difficult in design and execution, a few randomized trials have confirmed the effectiveness of diet and lifestyle in disease prevention. The Lyon Diet Heart Study,¹⁵ showed a 79% reduction in heart disease in patients with established heart disease after they followed a Mediterranean diet (ie, whole grains, vegetables, fruits, nuts and olive oil, fish) for a few years. The PREMIER researchers used an intervention of increased activity, weight loss, and dietary approaches to stop hypertension (DASH), which reduced blood pressure over six months.¹⁶ In a secondary prevention trial, an integrated lifestyle approach of a plant-based diet, exercise, smoking cessation, and stress reduction demonstrated a 50% reduction in cardiac events.¹⁷

Long-term assessment of outcomes in dietary trials (and in many other fields of CAM) is difficult, particularly in areas such as the effects of trans fat intake, carbohydrate quantity and quality, and alcohol consumption on chronic disease burden. Yet randomized trials of a healthful lifestyle can be used to assess shorter-term effects on clinical outcomes, biochemical markers of risk, or intermediate end-points. Where these are not possible, a careful analysis of basic science research, along with available

clinical and epidemiological research, should be used to help form a picture of the overall role of diet on disease. A randomized study of adults on a Mediterranean diet (ie, the treatment group) versus a “cardiac healthy” diet containing less than 30% fat illustrated the importance of intermediate markers of disease. Even after controlling for weight loss and physical activity, the authors found that inflammatory markers, insulin resistance, and endothelial function improved in the treatment group.¹⁸

The evidence that a healthful diet, including whole grains, legumes, nuts, vegetables, fruits, olive oil, fish, and perhaps moderate alcohol intake, is associated with a decrease in chronic disease burden and all-cause mortality is overwhelming. The harmful effects of trans and certain saturated fats, refined carbohydrates, and other food additives or toxins are well documented in the medical literature. An examination and integration with clinical data of the basic mechanisms involved in disease causation and health promotion can provide a new framework for understanding the role of diet in chronic disease. The effects of diet on health can be seen by looking at its effects on gene expression, cell signaling and informational systems, and bioenergetics. In turn, these basic nutritional concepts—nutrigenomics, cell signaling, and bioenergetics—exert their influence on health and disease through their effects on all of the basic physiologic and functional processes, the nature and roles of which are being clarified daily through research. These concepts can be seen as a transitional framework for understanding biology that will continue to undergo refinement and revision. For now, the model of nutrition and lifestyle therapies can serve to focus our assessment of healthcare quality and provide a context and method for implementing new data into the practice of medicine.

How can CAM take the center of the debate on quality in our healthcare crisis? As David Eisenberg reminds us, consumers spend more than \$40 billion on CAM and visit more complementary care providers than conventional primary care physicians. What motivates them? What do they seek? Why do they sometimes turn away from conventional medicine, but more often turn to CAM for their healthcare? Perhaps the primary motivation is a desire for empowerment, education about the tools of self-care, restoration of balance in their lives and in their health, partnership with their practitioners, and something more than the amelioration of symptoms. They seek what is embedded in the ancient traditions of healing, and remarkably, what is reflected in the themes emerging from modern bio-science that take us back to those ancient notions of balance and function. Nutrition is the field of CAM that most easily crosses the divide between conventional and complementary and integrative medicine, and the effectiveness, low cost, and improved outcomes of good nutrition as a treatment approach are clear. Hopefully, then, the next 10 years will see a focus on not just the mechanisms of complementary and integrative therapies, but also on measuring their role in improving overall healthcare quality and reducing healthcare costs. Hopefully, the discourse begun by the IOM report will spur policy makers to refocus federal efforts and funding on quality, disease prevention, and health promotion and will help us find the right medicine, regardless of its origin.

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that will serve to pass the sacred lineages of the ancients from the East to the West.

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CME Test answers

Self-Assessment Answers

- (B) Polyunsaturated fatty acid
- (B) Flaxseed oil, canola oil, and walnuts
- (D) Both A and B
- (B) False
- (D) Both B and C
- (A) Most observational studies, particularly those in US populations, have seen significant protective associations between ALA intake and CHD risk.
- (C) Randomized trials have demonstrated that a healthy dietary pattern that includes ALA significantly reduces the risk of a recurrent CHD event (secondary prevention).
- (D) All of the above.

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