Leading Innovations in Prevention and Cure

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In this article...

Discover the key concepts necessary to lead dramatic improvement in the care of chronic conditions, and read about one organization's success at controlling medical costs.

Medical organizations could and should be contributing to improving the health and sustainability of individuals, families, businesses, communities and governments. Their failure is reflected in the continual rise of health care costs along with the incidence of chronic diseases and the suffering and poor quality of life they beget. The situation is driving large nonmedical organizations to institute policies or programs to reduce their medical costs.

A common dilemma for leaders of medical organizations who wish to achieve breakthrough improvement is two-fold: how to proceed and where to obtain the necessary money. Money can be recovered by focusing on the treatment of chronic conditions that account for up to 75 percent of medical costs.[1]

Success, however, requires a shift away from tertiary prevention (i.e., controlling complications with the use of drugs and procedures). Initially, the strategy involves a shift to secondary prevention (i.e., reversing and curing the conditions), and ultimately to primary prevention (i.e., preventing the condition from occurring). Success would be a marked reduction in the incidence of chronic disease and reduced costs.

To achieve dramatic results medical organizations will need to be led by effective teams. Their effectiveness will require best practices drawn from three areas:

- Clinical science
- Finance
- Innovation in complex systems

Clinical science

Leaders need to create environments that ensure that health care professionals have the skills and resources to identify and apply the best clinical science in caring for patients. This is challenging for three reasons. First, the number of biomedical and clinical articles published annually has risen from 200,000 in 1970 to more than 750,000 in 2010.[2]

Second, health care professionals focus on tertiary prevention and know very little about primary and secondary prevention, and are especially lacking in nutrition.

Finally, relevant information and skills needed for interpretation of clinical studies and quality improvement are not widely known and applied by health care professionals.

Finance

If money is to be recovered and health care costs reduced, it is important to use an effective finance model. This model needs to be based on an underlying principle of ecological economics that shifts the emphasis from growth to development.[3] To support development, some of the profits of the innovation must be returned either directly or indirectly to the innovating clinical team as gain sharing. Figure 1 shows the conventional finance model as presented by Robert Kauer, MD.[4]

The boxes represent accounting values, and the arrows represent the key financial questions and flow of money in an organization. Question 4 is, "Of the profit, how much is going to dividend and how much is going to capital/innovation?" I have added gain sharing from profits as of the model.

Innovation in complex systems

Medical organizations and clinical teams are complex systems. They contain elements (i.e., both physical and nonphysical), interconnections (i.e., can be physical or information flows) and purpose (i.e., inferred from behavior and outcomes, not statements or rhetoric).

It is time for medical organizations to join Whole Foods Market in reducing the prevalence and incidence of chronic conditions, improving the health of their patients and employees, and reducing costs.

Complex systems are unpredictable, self-organizing and nonlinear. They create their own behavior, making them difficult to understand and control. However they can be redesigned and improved.[6] The redesign process is best focused at the smallest functional unit in medical organizations, the clinical team. [7]

Innovation in complex systems is more effective if the appropriate interventions are employed. Donella Meadow's list of "Places to Intervene in a System" (Table 1, left column)[8] is very useful when planning for breakthrough innovation. These levers of change range from the least (i.e., numbers) to the most effective (i.e., beliefs).

Successful innovation will align and properly use these levers (i.e., examples in medical organizations, right column). Two cautions: First, not everything that matters can be measured, and second it is necessary to monitor for unanticipated consequences. To avoid such consequences it is necessary to track results across all important areas.

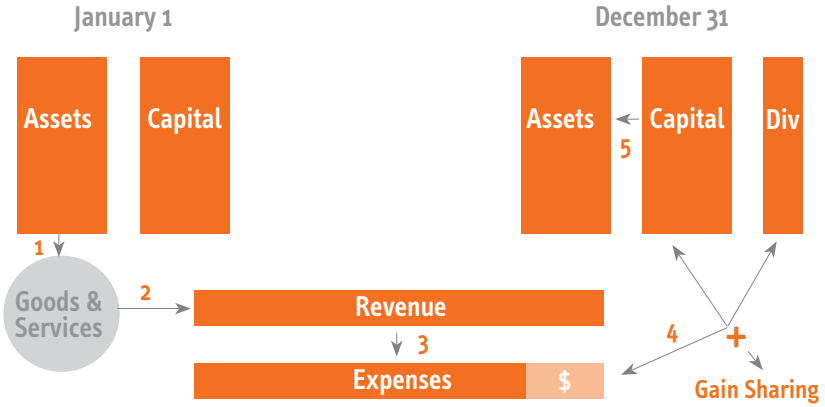
Without thorough evaluation an intervention may optimize one-outcome while creating poor results in other areas. For example, access can be optimized while quality of care and/or staff satisfaction is compromised.

Chronic conditions: Type 2 diabetes

Diabetes costs about $174 billion annually[9] and affects an increasingly larger percentage of people in the United States. The

Fig. 1

Flow vs. Boxes



Gain-shared money should be used for "satisfiers" (i.e., training, improved service, work environment) and not "dissatisfiers" (i.e., salary, bonuses).[5] The amount of money needs to be significant enough to obtain buy-in by members of the innovating clinical team and to support further development and profit.

Table 1

Numbers	Standards
Materials stocks and flows	Organizational structure
Regulating negative feedback loops	Prevention
Driving positive feedback loops	Growth
Information flows	Access to information
Rules of the system	Incentives, constraints
The power of self-organization	Innovation
The goals of the system	Profit, health of populations
The mindset, belief or paradigm	Cure of chronic disease

lifetime risk for people born in 2000 is estimated to be 33 percent for males and 38 percent for females.[10]

It accounts for 44 percent of new cases of kidney failure, 60 percent of nontraumatic lower-leg amputations, raises the risk of heart attack and stroke two to four times, and is the leading cause of blindness between age 20 and 74.

The current biomedical studies show that fats in the diet down-regulate genes controlling mitochondria[11] and increase insulin resistance.[12] Further, a low-fat plant-based diet leads to reduced intracellular fat and decreased insulin resistance.[13]

All cells in the body metabolize glucose (i.e., the bodies preferred fuel), whereas fructose, by contrast, is predominantly metabolized in the liver producing fatty acids, cholesterol and uric acid. [14] Complex carbohydrates that are composed of long chains of glucose molecules, then, are not the cause of Type 2 diabetes.[15]

Understanding the science helps explain the clinical studies that support the use of a low-fat plant-based diet as superior to the American Diabetic Association diet that emphasizes reducing carbohydrates.[16, 17] Coupling the best clinical science with successful approaches from the quality improvement literature is important.

Larry Staker, MD, at Intermountain Healthcare demonstrated that by changing the patient's display of daily fasting blood glucose data from tables to a specification chart, patients improved HgbA1C values on average by 0.5 percent.[18] His specifications were chosen with a goal to "control" the patient's diabetes.

Given the more recent studies, and consistent with Meadow's levers of change, we can shift the patients' goal from "controlling" to "curing" Type 2 diabetes. The goal of curing diabetes (i.e., the normalization of glucose and the absence of medication) changes the approach from tertiary prevention to secondary prevention. To support this goal providers must be aware of the literature and accept the paradigm that it is possible to cure Type 2 diabetes.

In my clinical practice many patients with Type 2 diabetes cured their diabetes. Unfortunately the electronic health record in my clinic was incapable of registering this success (e.g., no diagnosis of s/p Type 2 diabetes). As such, an important feedback loop was absent.

And I was faced with a dilemma. I could continue to label cured patients as diabetic, which would partially but not entirely capture the success of the treatment program, but not accurately reflect the patient's status. Or, I could remove the diagnosis altogether, accurately reflecting their status, but leaving the organization's "global percent control" lower than it should be.

One of the characteristics of change in complex systems is the production of unanticipated consequences. These clinical and nonclinical results can be either good or bad.

For instance, patients reversing and curing their Type 2 diabetes also lose weight, improve their blood pressure and lipids, and even reverse complications (e.g., diabetic neuropathy[19] and microalbuminuria).[20] These results need to be tracked to give feedback to the patient to reinforce their and their health care provider's behavior. They are also important to demonstrate savings to the organization. These include short-term savings due to less medication, testing and visits, as well as long-term savings involving specialty consultations and treatments (e.g., dialysis, diabetic retinopathy and amputation).

Obesity

Obesity is a costly chronic condition affecting 35.7 percent of adults and 17 percent of youth. [21] Medical costs are estimated at $147 billion per year in 2008 dollars. [22] Since the overweight condition is easy to self diagnose, patients are targets for direct marketing. In addition to medical costs, consumers pay substantial amounts for diet aids and services.

As with Type 2 diabetes, it is important to use correct measures and set appropriate goals. Medical organizations use the Body Mass Index (BMI) to diagnose patients as overweight, obese or extremely obese. Unfortunately the BMI has been shown to fail to accurately diagnose up to 50 percent of adult obesity. [23] In 1972, Ancel Keys who popularized what was originally the Quetelet Index[24] said the measure

should be used for populations and not individuals. [25] Given the limitations of the BMI measure, it is best to use an individual's weight to measure their progress and reserve BMI to track progress of populations.

With the high prevalence of obesity and its association with up to 18 comorbidities (e.g., diabetes, many cancers, arterial disease, osteoarthritis, asthma, gall bladder disease),[26] medical organizations have implemented secondary prevention programs. They often use focused approaches such as eliminating sugar and increasing exercise, or diets centering on calorie restriction or high- protein intake. These approaches are not supported in well-controlled studies. [27]

Further, high-protein diets are by design high in cholesterol, saturated fat and dietary acids, and low in dietary fiber and carbohydrates leading to chronic conditions (e.g., arterial disease, renal insufficiency).[28] These poorly designed secondary prevention programs that require multiple visits and manufactured products are examples of waste.

Worse, many organizations and health care professionals are pursuing tertiary prevention with the active promotion of drugs or procedures such as gastric by-pass surgery. The number of these procedures has escalated from 14,000 in 1998[29] to 170,000 in 2005. The cost ranges from $17,000 to $26,000/case.[30] Studies are being done to expand the market (i.e., treat lower BMI's) and include recommendations for other conditions such as Type 2 diabetes. Although surgical treatment of obesity yields impressive short-term success, there are no long-term studies to show true costs, harms and benefits.

The science supports the prescription of diets that have low calorie density and that are eaten "ad libitum"(i.e. eat when hungry) as the most successful approach. [31] We need to shift our treatment belief from reducing calories to reducing the calorie density (i.e. calories/gram or calories/pound) [32] of the foods we eat. This requires the elimination of animal products, refined oils and most processed carbohydrates.

The shift from the standard American diet to a low fat, plant-based diet is further supported by epidemiological studies that show that the BMI is lowest in those populations consuming the latter. [33]

As with Type 2 diabetes it is important to set the proper goals (i.e., curing obesity, eliminating weight loss surgery), track improvement across other clinical areas (e.g., cholesterol, fasting blood sugar, blood pressure) and record financial outcomes (e.g., cost savings).

Arterial disease

Arterial disease covers a wide range of conditions amenable to primary and secondary prevention including coronary artery disease, hypertension,[34,35,36] stroke, [37] aortic disease,[38] carotid disease,[39] peripheral vascular disease, back pain,[40] narrowed discs[41] and sexual dysfunction in both males[42] and females.[43] The treatment of coronary artery disease in the United States in 2006 consisted of 1.3 million angioplasties and 448,000 bypass surgeries at a cost of more than $100 billion. Additionally, there were 27,000 deaths attributed to these procedures.

The primary and secondary prevention of arterial disease represents a significant opportunity for savings, improved care, and reduced morbidity and mortality. This high incidence and cost of arterial disease represents a significant opportunity for medical organizations to employ effective secondary prevention programs to avoid subsequent events.

Autopsy studies done on soldiers in Vietnam[44] and Korea[45] demonstrated that coronary artery disease is present early in life. The Pathobiological Determinants of Atherosclerosis in Youth study[46] showed that arterial disease is present by age 19 and has progressed to a significant degree by age 39. This high incidence, coupled with the silent nature of its progression, also makes arterial disease an ideal target for primary prevention programs.

Initially biomedical literature focused on cholesterol and the blockages within the arteries.[47] Early on we also began to understand the significance of diet. [48] It was puzzling that acute coronary events were not related to degree of stenosis and, in fact, generally occurred in arteries with less than 50 percent blockage.[49]

The discovery of the nitrous oxide system by Robert Furchgott and others helped us understand the underlying mechanisms. [50] We are now better able to understand the success reported by Dean Ornish[51] and Caldwell Esselstyn.[52] They demonstrated improved symptoms, reversal of blockages and a marked reduction in subsequent events over years. A more recent study[53] demonstrated the improvement of symptoms within weeks. Exercise is helpful as well. This makes a strong case for shifting our focus from procedures that target discrete blockages to care that stabilizes the underlying disease.

The best science currently supports the prescription of a low-fat plant-based diet with Vitamin B12 supplementation.[54] Exercise should also be prescribed.[55] The prescription should include judicious use of medications. All demonstrated successful interventions (i.e. diet, exercise, medication) should be incorporated into a well-designed shared decision model for patients.[56,57] Success in secondary prevention would be measured by decreased procedures (i.e., angioplasty, bypass surgeries) and decreasing recurrences and time to recurrence for coronary events. Primary prevention would be reflected in a decreased incidence of myocardial infarctions and strokes.

Health care professionals focus on tertiary prevention and know very little about primary and secondary prevention.

Steps to take

The first step is for health care leaders to design an innovative process based on the aforementioned concepts. Initially, a single functional primary care team should be selected to target Type 2 diabetes.

In my clinical experience the results with Type 2 diabetes are quickly apparent, as are short-term savings (e.g., visits, medications) and member satisfaction. There are also significant long-term savings (e.g., avoidance of referrals, treatment of eye, renal and arterial complications).

Further, the experience gained with successfully reversing and curing diabetes is easily translated to other chronic conditions often seen in primary care such as obesity and arterial disease, especially hypertension.

By starting with one clinical team, health care leaders can develop the financial and clinical models essential to demonstrate success and provide gain sharing with the alpha site. The accounting and finances will be challenging since the adoption of a science-based program for diabetes will also result in improvement in and/or avoidance of many chronic conditions (e.g., arterial disease, obesity, autoimmune disorders, certain cancers, osteoporosis). [58]

After demonstrating success the process will more easily spread to beta sites in the same clinical specialty. A properly designed and implemented program will generate enough savings for gain sharing and funding additional projects in other primary care specialties. The process can be extended to specialty departments to create a culture that is skilled in the primary and secondary prevention of chronic disease.

The next step would be considering adding a system that delivers on primary prevention. One highly successful well-documented program was the Multiphasic Testing Program developed by Morris Collen, MD, with Kaiser Permanente Medical Program in Oakland.

This two-visit program was available to all adult members every four years before age 50 and every two years after. [59] Whole Foods Market is demonstrating what is possible by implementing innovative programs targeting both primary and secondary prevention.

Success at Whole Foods Market

Whole Foods Market (WFM) is self-insured for medical costs. Between fiscal years 2005 and 2006 it experienced a 15.7 percent increase in medical costs as a percent of sales. In 2006 it added a health savings account to its benefit package. The increases for the next three years were 15.7 percent, 10.7 percent, and 13.3 percent.

In 2009 it introduced two policies that accelerated the reduction of medical costs as a percent of sales and improved the health of team members. The first is a voluntary biometric testing program for employees. All Whole Foods employees receive a 20 percent discount on purchases.

The biometric program consists of testing for weight, height (for BMI), blood pressure, and fasting cholesterol and glucose. Depending on the results, employees can be placed in the bronze, silver, gold or platinum health category, receiving discounts of 22.5 percent, 25 percent, 27.5 percent and 30 percent, respectively.

As of September 2011, 8,294 team members representing 12.9 percent of its almost 65,000 members had taken advantage of this policy. This represented almost $2 million in additional savings for those members.

The second policy is to pay the transportation and attendance costs for team members in poor health to attend one of four residential eight-day immersion programs. WFM invests more than $4,000/member to attend one of these programs. WFM requires interested team members to use their own leave and apply for consideration.

I have personally provided medical care to WFM team members at the McDougall Whole Foods program in Santa Rosa, CA. The immersion programs are modeled after the successful 10-day program by John McDougall, MD, and generate similar results. [60] The results in improved quality of life and decreased use of medication are remarkable.

Conversations with attendees attest to other benefits such as improved employee morale and decreased use of sick leave.

All three policies contributed to no increase in medical costs from 2009 to 2010 and a 10.4 percent decrease from 2010 to 2011, resulting in savings of $10 million to $20 million dollars. [61]

It is time for medical organizations to join Whole Foods Market in reducing the prevalence and incidence of chronic conditions, improving the health of their patients and employees, and reducing costs.

Health care leaders need to build work environments that support the development of sustainable high-performing clinical teams that deliver world-class service.[62] Clinical teams properly supported can duplicate and build on the success of pioneering physicians such as McDougall.

Coupling clinical success in the exam room with supportive systems of care can help begin to reverse our bleak health care situation. I look forward to the first medical organization that is able to achieve a 50 percent reduction in the prevalence of an important chronic condition and lower health care costs. I believe it is achievable in the near future.

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