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FROM THE EDITOR

Medicine's Response to Lifestyle-Related Preventable Illness

As our understanding of the broad range of factors that affect health grows, our health care system must align with this knowledge—researching, teaching about, and striving to prevent the many chronic diseases to which lifestyle contributes. Enormous amounts of time, money, and energy are spent on largely preventable illnesses that stem at least in part from lifestyle choices, behaviors, and environmental influences; it is well understood, for example, that many pervasive chronic diseases are related to nutrition, physical activity, sleep, environmental exposures, and other lifestyle influences. Such conditions have a profound effect on health care finance, with 75 percent of medical costs in the U.S. spent on care of individuals with chronic illnesses and 25 cents of every health care dollar spent on the treatment of diseases or disabilities that result from potentially changeable behavior [1].

As former secretary of the U.S. Department of Health and Human Services Tommy G. Thompson said a decade ago, “So many of our health problems can be avoided through diet, exercise and making sure we take care of ourselves. By promoting healthy lifestyles, we can improve the quality of life for all Americans, and reduce health care costs dramatically” [2]. This issue of *Virtual Mentor* centers on efforts to do just that.

According to the lifestyle medicine consensus panel, lifestyle medicine is “the evidence-based practice of helping individuals and families adopt and sustain healthy behaviors that affect health and quality of life” [3] and encompasses nutrition, physical activity, stress reduction, rest, and social support systems. Wayne Dysinger, MD, MPH, gives a brief overview of the skills and knowledge needed to practice lifestyle medicine. This focus on prevention may feel like a change from the treatment-focused medical culture of our time, and, as Jed W. Fahey, MS, ScD, and Dr. Thomas W. Kensler, PhD, indicate in their piece on dietary phytochemicals and chemoprevention, there is indeed cutting-edge work being done in the field. But thinking and talking about the connection between the body, the surroundings, and the mind is part of a long medical tradition, which Micah R. Sadigh, PhD, reviews in his history of medicine piece.

Looking at the role that individual decisions in lifestyles and behaviors play in determining risk for and experience of disease raises thorny ethical dilemmas. As illustrated in the second case commentary by Mark T. Hughes, MD, MA, many factors shape each individual's health, including medical care, social circumstances, genetics, environmental circumstances, and lifestyle factors, of which behavioral

choices are only one—albeit a key—element. Dr. Hughes points out that physicians and other health care professionals can guide and coach the patient in making health-promoting decisions, while respecting the patient’s self-determination and stage of readiness to change. This powerful form of medicine is only effective when the patient embraces it, and therefore the physician must respect the patient’s autonomy and empower him to take responsibility for his health. In his commentary on the first case, David Katz, MD, MPH, explores what happens if a patient requests pharmacological intervention when lifestyle changes would be equally or more beneficial and have fewer side effects. Amireh Ghorob, MPH, Rachel Willard-Grace, MHD, and Thomas Bodenheimer, MD, explain how health coaching satisfies ethical principles by promoting a process of shared decision making and improving patients’ understanding of and participation in their health care plans.

Health coaching is not all we can do, however. In this issue’s op-ed, Neal D. Barnard, MD, takes us beyond the narrow, individual scope of one-on-one counseling, proposing a range of physician responsibilities related to promoting beneficial lifestyle, from counseling to public advocacy to attention to doctors’ own health. The third case commentary, by Lenard I. Lesser, MD, MSHS, and Sean C. Lucan, MD, MPH, brings to light the ways in which the provision of healthy food in hospital cafeterias can uphold an institution’s ethical obligations while sending a broader message about the importance of proper nutrition.

Anthony L. Schlaff, MD, MPH, looks at how health-related counseling came to be widely embraced, exploring its relationship to medicine and public health in the United States. He explains that, despite our society’s focus on interventions that assume individual responsibility, public health research over the past half century has shown that behavior can be most effectively changed not by education or counseling but by altering the conditions in which the behavior occurs.

Such efforts tend to target populations rather than individual patients, working to protect the public while imposing limitations or regulation on everyone and utilizing scarce medical resources for prevention of disease for which not everyone is at risk. Andrew W. Brown, PhD, and David B. Allison, PhD, challenge the fairness of such programs, exploring the unintended adverse consequences of health policies that aim to reduce obesity and strategies that may minimize unintended ethical and other impacts.

Valarie Blake reviews recent policy efforts to bring about behavior change, including the contested New York City ban on sodas over 16 ounces. Andrew A. Strasser, PhD, and Lynn T. Kozlowski, PhD, look at the graphic cigarette warning labels required under the Family Smoking Prevention and Tobacco Control Act as an example of health policy and regulation that has shown to be effective yet faces intense legal and ethical scrutiny. Kristina H. Lewis, MD, MPH, SM, considers the use of such methods to improve individuals’ diets and nutritional choices. As she points out, such policy brings up complicated ethical considerations, since the effectiveness of these measures—the degree to which they benefit the public’s

health—often corresponds to the extent to which they intrude on personal rights and liberties.

Death and comorbidity from infectious disease are decreasing, only to be replaced by the greater toll on our health of chronic diseases, many of which are lifestyle-related. Our health care system must evolve in ways that address individual choice, acknowledge the impact of various lifestyle behaviors on health, and strive to prevent chronic disease rather than solely react to it.

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ETHICS CASE

Lifestyle is Medicine

Commentary by David L. Katz, MD, MPH

Dr. McDaniel is a cardiologist who is preparing to see a new patient, Mrs. Huber. As she looks through Mrs. Huber's paperwork prior to her visit, she sees that the patient is 42 years old and has a family history of diabetes, hypercholesterolemia, and heart disease. Her pre-visit blood work reveals mildly elevated LDL cholesterol and borderline low HDL cholesterol.

Dr. McDaniel sits down to speak with Mrs. Huber. She introduces herself and begins to review Mrs. Huber's medical history. While Mrs. Huber says that she currently has none of the symptoms that would suggest cardiac problems to Dr. McDaniel, no past hospitalizations or surgeries, and no history of personal medical issues, she is very concerned about her family history of cardiac disease. She keeps stating her worry that she will die of a heart attack like her father did when he was 67 years old.

Dr. McDaniel acknowledges her concerns, completes a physical exam, and discusses the laboratory findings. "While we did find mildly elevated cholesterol values on your blood work, Mrs. Huber, I am reassured by your personal medical history, lack of current or past health problems, and normal physical exam. I find that many of my patients are able to successfully improve their risk factors like elevated 'bad' cholesterol or low 'good' cholesterol by making some different choices in how they live their daily lives and incorporating healthy nutrition and physical activity. Often patients can improve their risk factors through such behavioral changes and avoid the development of further disease without having to take drugs."

Mrs. Huber appears anxious and expresses some concerns to Dr. McDaniel that her health risks must be dealt with immediately. "Doctor, I don't think I can afford to try some fruit and vegetables for the next 6 months. I don't know if I can wait any longer when my arteries are clogging up as we speak! Isn't there something you can give me to take care of this now so I don't have to keep worrying so much about dying of a heart attack?"

Dr. McDaniel appreciates Mrs. Huber's concerns and understands her anxiety, but she has seen that, in many cases, lifestyle interventions including dietary changes are very effective for improving patients' cholesterol levels and other cardiac risk factors. She also believes that teaching Mrs. Huber about dietary changes would have fewer potential adverse side effects than a medication at this time, and that, unlike a pill, educating her about nutrition and lifestyle behaviors will have benefits

on many aspects of her life, building skills she can use to make positive behavioral choices for a long time to come.

Commentary

This case presents us with the ostensible dilemma of a doctor and patient divided over what constitutes appropriate “medicine.” Before confronting the challenge to “ethical” and constructive practice implicit in this case, let’s acknowledge the rather important gaps in the story. There is much Dr. McDaniel does not know about her new patient; in fact, she knows very little. She doesn’t know why Mrs. Huber is acutely preoccupied with her father’s death from cardiovascular disease. It might have been recent, both because of the timing of the encounter and because the 25-year gap in age between Mrs. Huber now and her father at the time of his death would be plausible.

So, first, Dr. McDaniel must find out whether Mrs. Huber is seeing her in the immediate or nearly immediate aftermath of her father’s death. Is she in an acute stage of grief? Are the natural tendencies of mourning affecting her perceptions and priorities? Does she need, and if so has she received, suitable mental health counseling?

A sanguine interpretation of Mrs. Huber’s concern is that it constitutes a “teachable moment” [1], that is, a period of receptivity to behavior change often precipitated by a change of circumstance. All too often, that circumstance is adverse, such as a personal medical crisis or the death of a friend or relative. It can, however, be a much happier one, such as pregnancy. Perhaps in the aftermath of her father’s death, Mrs. Huber is inspired—by fear, presumably—to change her ways and thus avoid the fate implied by her family history.

But there are reasons in this case to be a bit less hopeful. Mrs. Huber’s father died prematurely at 67, but that is still a far cry—indeed, the span of a generation—from her current age of 42. She has neither symptoms nor a very overt set of cardiac risk factors. Why, then, is the patient here now? Why is she seeing a cardiologist rather than a generalist? Why is her acute worry seemingly so discordant with the 25-year gap between her age and her father’s age at death? Are there other reasons for the patient’s sense of urgency and, if so, what are they, and how should they be addressed? If Mrs. Huber is not in a state of acute grief, the acuity of her worry suggests the possibility of an anxiety disorder. This, too, must be explored before issues of cardiac risk management may be reasonably confronted.

The answers to these questions have relevance to the concept of ethics, which is all about distinguishing right from wrong. How much emphasis to place on lifestyle in medicine is a matter of judgment, alternatives, preferences, opportunities, and aptitudes and is rarely likely to be right or wrong. In contrast, it would be wrong to ignore or neglect a grief response and equally wrong to overlook depression or anxiety lingering after such a response normally abates. The notion of culturally sensitive care is well established, but ultimately clinical care is about an individual

and the required sensitivity is at the n-of-1 level. Our care is ethical when it conforms to the specific needs of a given patient at a given time—and, arguably, unethical when it does otherwise.

Now to the conflict between Mrs. Huber and Dr. McDaniel: Mrs. Huber wants “medicine” to modify her cardiac risk factors, while Dr. McDaniel—apparently, and encouragingly, at odds with the prevailing tendencies in modern medicine—prefers an application of therapeutic lifestyle changes. Is there a right answer?

There are, at least, salient considerations to inform a right answer. Perhaps foremost among them is the fact that, to the extent possible in clinical practice, the patient is the boss. That is what the notion of “patient-centered” [2] care is all about. And, of course, it simply stands to reason. Health care is for the health of the patient. It’s about the patient, always. This is uniformly true in medicine—but even more so in the realm of lifestyle as medicine [3]. We practitioners have substantial control over the prescriptions we dole out and nearly complete control over the procedures we conduct. But lifestyle plays out between office visits, not during them. It intersects with our purview, but does not reside within it. We can advise a change in lifestyle practices; only the patient can implement it. The patient is, *ipso facto*, the boss; the arrangement is not negotiable.

But that does not invite us, as clinicians, to get bossed around. We are obligated by our professional vows to provide the information on which a patient’s good decisions can be based. We are committed to best and most substantiated practices. We are duty-bound to decline requests for futile action. And we are obligated, first, to “do no harm” [4]. This was never quite an accurate assertion, in the Hippocratic Oath or elsewhere, but we are, indeed, obligated to avoid actions more likely to confer harm than benefit. That, then, becomes our second salient consideration: our need to encourage the “treatment” we consider right.

This leads in turn to the third key element of the right answer in this case: what is the proper treatment?

Honestly, we don’t quite know. We are told Mrs. Huber has a mild dyslipidemia. The pattern—a slight elevation of LDL and low HDL—makes for a very incomplete picture. What are her triglycerides? The low HDL in a premenopausal woman (at 42, Mrs. Huber is almost certainly premenopausal barring oophorectomy, and no prior surgery was uncovered during her medical history taking) is most likely to occur in the context of insulin resistance [5]. If Mrs. Huber is insulin-resistant, we would expect elevated triglycerides. We might also expect other signs of insulin resistance, including central adiposity (an elevated waist circumference), and at least a borderline elevation of her blood pressure. But the physical exam was “normal.” Perhaps Mrs. Huber’s weight, BMI, and waist circumference are truly in the optimal range [6], or perhaps Dr. McDaniel neglected these measures. Such neglect is, alas, still more the norm than the exception.

Thus, Mrs. Huber either has some semblance of insulin resistance, or a mild type IIa dyslipidemia. In either case, first-line therapy is, unequivocally, lifestyle change [7].

The power of lifestyle as medicine, Mrs. Huber's seemingly dismissive attitude toward it notwithstanding, is, in fact, unmatched. The evidence is decisive that a lifestyle intervention can cause regression of atherosclerotic plaque [8]. The evidence is decisive that lifestyle intervention can slash the risk of myocardial infarction in even high-risk patients [9, 10]. The evidence is incontrovertible that lifestyle as medicine outperforms pharmacotherapy in the prevention of diabetes in high-risk adults [11].

An aggregation of evidence over a span of decades [12, 13] has established as a bedrock fact of modern epidemiology that tobacco, poor diet, and lack of physical activity constitute the leading causes of chronic disease, including cardiovascular disease, and premature death. Conversely, salutary use of feet, fork, and fingers represent the potential to slash the risk of all chronic disease by 80 percent [14-16]. A complementary and aggregating body of evidence attests to the epigenetic potency of lifestyle interventions [17], demonstrating the capacity to alter gene expression with diet, physical activity, tobacco avoidance, stress management, social connections, and adequate sleep [18].

The final nail in the coffin of Mrs. Huber's dismissal of lifestyle as medicine pertains to temporality. This patient is operating under the misapprehension that pharmacotherapy works fast and lifestyle only slowly. However, numerous studies show that salutary or adverse effects on the vasculature play out acutely in the post-prandial period. Any given meal, or cigarette smoked or avoided, can influence cardiovascular risk all but immediately [19-21].

As an aside, I note that, in my experience, Mrs. Huber's attitude is unusual. Far more often, I see the converse: patients are reluctant to take medications. They've heard the ads on TV and know all about that long list of intimidating side effects. They have no symptoms from their dyslipidemia and wonder why there is any need for medication at all. More often than not, patients are hoping we will consider lifestyle ahead of drugs.

In any given case, the power of lifestyle as medicine relates to the magnitude of plausible change. Does Mrs. Huber smoke? If she does, quitting would exert an immediate, and almost certainly greater, effect than any medication. Does she eat well or poorly? Does she exercise?

If our patient does not smoke, eats optimally, and exercises routinely, then her dyslipidemia exists in spite of the application of lifestyle as medicine. We can't fix what isn't broken! In this case, pharmacotherapy becomes a far more reasonable consideration. If she smokes, eats poorly, is sedentary, or any combination thereof, there is a compelling basis to direct our efforts there.

Where does all of this leave us? Assuming the patient's lifestyle is other than optimal, the best evidence-based guidelines argue for lifestyle change as first-line therapy of her mild dyslipidemia. We are thus duty-bound to make that case. If we are persuasive, but Mrs. Huber remains ambivalent, the appropriate response derives from motivational interviewing [22]. If Mrs. Huber is both convinced and ready for lifestyle change, our job is to help direct and support her initiative [23].

If despite our best efforts, Mrs. Huber remains emphatic about the use of pharmacotherapy—and assuming there is no mental health condition needing treatment first—her preference becomes a factor in our risk-benefit assessment. After all, in the absence of therapeutic alliance, our potential to facilitate lifestyle change over time disappears entirely. It might be that even temporary risk mitigation with relatively safe pharmacotherapy, such as a statin and perhaps aspirin in this case, would help establish that therapeutic alliance and provide us the traction we need to make the case for lifestyle as medicine longitudinally.

In this case, and often, lifestyle truly is the best and most potent medicine we have. But medicine can only be of utility if it actually goes down. The patient is, ultimately, the boss; the decision to swallow or spit resides with him or her. When our practice patterns are inattentive to this constant imperative, our best efforts devolve to dogma—and futility.

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ETHICS CASE

Meeting Patients Where They Are

Commentary by Mark T. Hughes, MD, MA

Mr. Kresser was on his way to see his primary care physician, Dr. Patterson, when his wife phoned to say that she had to work late and he needed to pick up the children from their afterschool activities. Mr. Kresser knew he could not leave his children at their activities but was concerned since he had been late for his last appointment with Dr. Patterson a month before when he was stuck at a job interview. The month before that, he cancelled his appointment because he was out of work and could not pay for the visit. Mr. Kresser also worried that Dr. Patterson would be upset with him because, with all the stress in his life, he had not stopped smoking, a behavior that Dr. Patterson had been telling him for years to stop. Even worse, he had not lost any of that extra weight Dr. Patterson was always on his case about. Mr. Kresser knew that his eating habits were not helping with his weight, but, frankly, his weight and smoking were not the aspects of his life that he was most worried about.

Mr. Kresser picked up his kids, dropped them at home, and then rushed to get to Dr. Patterson's office, arriving more than an hour and a half late. The receptionist told him to wait while she asked whether Dr. Patterson could see him. Dr. Patterson had had a busy day and was running behind his schedule also.

The receptionist told Dr. Patterson that Mr. Kresser had arrived for his appointment an hour and a half late and asked whether Dr. Patterson could see him. Dr. Patterson said "sure." He wanted to find out whether Mr. Kessler was making any progress on his weight control and smoking. As Dr. Patterson closed the exam room door, he said, "You just caught me. I was about to leave. What's going on?"

Mr. Kresser felt ashamed at his inability to make better choices for his health. He said, "I have been so busy, and I was on my way on time for my appointment, but I had to pick up the kids at the last minute." Dr. Patterson took a deep breath and said, "Well you made it. Now how are you doing on the changes to diet and smoking that we talked about?"

Mr. Kresser looked down at the floor. He believed that Dr. Patterson wanted the best for his health, but didn't think the doctor appreciated all that was going on in his life that was making it difficult for him to change his eating and smoking habits. He felt like he was doing the best he could with everything he had to worry about.

Commentary

It is interesting that the case is presented from the perspective of the patient, Mr. Kresser. The judgments attributed to his physician, Dr. Patterson, are speculations by the patient, and we do not know if they actually represent the mindset of his physician. Attitudes such as disappointment and anger cannot necessarily be assumed based on the interaction described. Whether these may have been expressed in previous encounters is not certain. If anything, the fact that Dr. Patterson agreed to see Mr. Kresser despite his being late for the appointment suggests that the physician is subordinating his own interests (e.g., going home or attending to other responsibilities after a busy clinic day) to the interests of his patient.

Before addressing the core issue of the case, namely behavioral counseling, it is worthwhile to comment on clinic scheduling as an issue of professionalism. In today's health care setting, physician appointments are largely doctor-centered. Some physicians have become more consumer-oriented by offering evening and weekend hours, but the majority of appointments occur during the day and are geared toward the availability of the physician, not the patient. Patients have to schedule appointments around (or in place of) other commitments, such as work, childcare, or household responsibilities. This is not patient-centered. Truly patient-centered scheduling might mean a return to home visits, rather than requiring the patient to come to the doctor's office.

Set appointment times in doctor's offices entail expectations and responsibilities for both physicians and patients. Physicians need to keep on schedule, so as not to inconvenience other patients scheduled later in the day. It is accepted, however, that extenuating circumstances can arise in which the complexity or acute nature of a particular patient's condition necessitates giving him more time than was allotted for his appointment. It is also an expectation in the system that patients will arrive on time for their appointments, so as not to inconvenience other patients or the doctor. But patients can also have extenuating circumstances, from delays in finding a parking spot to having concomitant duties like picking up children at daycare. When an expectation cannot be met, the responsible party should extend the courtesy of notifying the other person and determining how the situation can be resolved to mutual satisfaction.

Time is one of the most valuable (and scarce) resources in health care. Appointment times have been shortened in an effort to increase clinical productivity. Time management has become a crucial skill for health professionals. The patient's responsibilities for keeping appointments on time are generally not considered. In viewing the clinical encounter through the lens of beneficence, whatever is in the best interests of the patient should dictate the time allotted to the patient. Patients are not obliged to consider their impact on the doctor's schedule; they may accept it (or be resigned to it) as a reality of the system that the doctor's time is short, but this is in some respects buying into the doctor-centered view of clinical time.

It would be a vastly different world if patients could schedule visits for a length of time that correlated to their conditions or symptoms or they thought they needed. Billing mechanisms would have to change, doctors would have to be more receptive to the patient's goals, and more clinicians would most likely be needed to fill the need. But this is a "pie in the sky" dream; we have to work within the system as it currently exists. If a patient's agenda requires more time than the scheduled time permits, then the physician and patient need to negotiate how to best manage the time they have.

Negotiation is the key strategy to achieving lifestyle changes for patients. Physicians need to meet patients where they are, not where they want them to be. Each can have agreed-upon goals such as improved health, prevention of disease, and reducing or eliminating unhealthy behaviors, but how to get there has to be negotiated. The physician has to balance respect for autonomy (allowing patients to make choices, even if some of their decisions are bad or counterproductive to achieving health and healing) with beneficence (working toward the patient's best interests). Acting in the extremes of either principle can have undesired consequences. Simply letting the patient persist in unhealthy behaviors in deference to self-determination can lead to poor health outcomes. Going too much in the opposite direction and pushing the patient toward doctor-centered goals can result in paternalism. The middle ground is for the physician to be a guide or a coach.

Using the analogy of the patient being on a journey, the physician's role is that of a tour guide, providing direction on the trip but leaving the itinerary up to the patient. Advice can be given, and facts can be presented to educate the patient about guideposts along the way, but the physician follows the lead of the patient. The journey may involve detours, pit stops, and backtracking, but the guide is there to lead the patient to the final destination.

As an alternative analogy, the physician is a coach who is there to inspire and motivate the patient. The challenge comes in knowing when to push the patient, when to comfort and console, and when to cheer. A good coach or team manager may have his or her own style of managing, but also needs to adapt to the needs of the players over the course of a game or season. For the physician, this entails knowing the patient well enough to know what strategy will work in which instance.

Part of knowing the patient is determining what stage of change the patient is in. The physician's approach to the patient will differ depending on the stage of change [1, 2]. In order to have any success in lifestyle modification, the patient has to be ready to make the change. Pushing the patient to change when he is not ready sets him up for failure—leading to the sort of guilt, shame, and disappointment that Mr. Kressler feels. Fostering these negative emotions in the patient makes future attempts that much more difficult and ultimately is not compassionate. The physician's task is to understand the patient and diagnose his readiness to change. If there is too much going on in the patient's life (as seems to be the case for Mr. Kresser), the present might not be the time to advocate for significant lifestyle modification.

As the guide or coach, the physician should help the patient achieve the stage of change that is needed next in the process [2]. If the patient is in precontemplation, then the physician should help with consciousness-raising by providing information about health benefits of changing a behavior or helping the patient to reevaluate his or her circumstances to identify the barriers to change. When the patient is in the contemplation stage, the goal is to help him or her move toward making a change. The physician should facilitate the patient's process of thinking about options for change and barriers that may be encountered.

Once the patient is in the preparation stage of change, the physician should establish the patient's commitment to change and assist the patient in picking realistic goals that he or she feels confident about achieving. When the patient is in the action phase, the physician should praise him or her for accomplishments and work through obstacles to success. Empowering the patient's autonomous decisions and agency is important in this stage and in the maintenance phase. The patient has to discover for himself or herself what works in a given situation. With open-ended questions, the physician can help the patient with this self-directed learning to continue the lifestyle changes and potentially build on them. If the patient relapses, the physician has to help him or her identify what stage he or she is in currently and start the process over again. Rather than focusing on the failure, past successes should be praised and the patient's willingness to change should be reassessed. If one of the goals of the healing relationship is to make the patient feel better, then keeping a positive focus is crucial, especially in the relapse phase.

Returning to the case, Mr. Kresser has not achieved the goals established during his previous visits with Dr. Patterson. We do not know how those goals were established. Generally with lifestyle changes, it is best to create specific, measurable goals (e.g., picking a smoking quit date or reducing the number of cigarettes per day; keeping a food diary or eating fewer sweets 3 days a week). From the gist of the case, it does not sound as if there was any specificity in the plan other than trying to achieve the healthier lifestyle goals. If this is the case, it could set the patient up for failure, especially when there are major obstacles in his life, such as unemployment and other stressors. Perhaps now is not the right time for the patient to be making major lifestyle changes (i.e., he is in the contemplation stage). If the patient was in the preparation stage at the last appointment, was Dr. Patterson aware of these concerns at the time? Did they discuss strategies to overcome these challenges? Did they simplify behavior modification goals in light of these potential barriers? We learn from the case that Mr. Kresser feels that the doctor does not appreciate all that is going on in his life, but we do not know if these issues have been overtly discussed at previous encounters.

Thus, a different approach by Dr. Patterson in the encounter described may have been more helpful. It is a natural inclination on the part of the physician to "cut to the chase" when the appointment and clinic are already running late. Hence, it is understandable that Dr. Patterson asked, "Now how are you doing on the changes to diet and smoking that we talked about?" But a more appropriate response to the

patient's first statement would have been to be more open-ended, such as repeating his initial question of "What's been going on?" Or Dr. Patterson could have responded, "You've been busy? What's been going on in your life?" or "What's been happening since the last time we met?" Keeping the question general allows the patient to direct the flow of the conversation (and makes it more patient-centered). It also enables the physician to understand the patient's context, so as to be better able to counsel him about lifestyle changes.

Discussing the patient's stressors may be more than enough to cover at this visit. But if there were a need to discuss lifestyle changes attempted since the last visit, then keeping the focus on positive results (what things the patient was successful with or how long the patient was able to institute some changes) would be preferable. A judgmental tone could engender more shame for the patient, whereas praising the patient, even for small changes, may make him more motivated to get additional positive reinforcement in the future.

Behavior change is one of the most difficult tasks for anyone to accomplish. The person has to feel that the change is important. He has to be committed to the change and feel confident that he can accomplish it. Success has its own rewards and can lead to reinforcement of the behavior and an incremental increase in goal-setting. Having an ally in the fight, a trainer in the corner, or a guide on the journey can aid a person in achieving his goals. The physician who is able to be all of those for his patient is likely to achieve better results.

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ETHICS CASE

The Ethics of Hospital Cafeteria Food

Commentary by Lenard I. Lesser, MD, MSHS, and Sean C. Lucan, MD, MPH, MS

Dr. Ashby, Dr. Bennett, and Dr. Morgan all serve on their hospital board, which met to discuss a proposed new policy to revamp the cafeteria and inpatient dietary offerings. The board members expressed many opinions about this issue, and the physicians debated the issue hotly.

Standing to address the board, Dr. Ashby said, half jokingly, “Esteemed colleagues, I believe that it is simply unethical to be serving patients’ families and visitors and our staff members the unhealthy food that is currently being sold in this institution. It is our responsibility as a health-promoting organization to foster all aspects of health. The hospital is a role model for our visitors and staff, and we must set high-quality standards when it comes to our nutritional offerings.”

Next to the podium was Dr. Bennett. “While I agree with Dr. Ashby that we want to promote health,” states Dr. Bennett, “When it comes down to it, it’s every person’s responsibility to make his or her own food choices. Our main responsibility as the hospital’s representatives is not to change individual behavior but to serve the low-income population in our community—and to do that we must ensure the fiscal future of our institution. Our current food vendor is the only option that makes that possible. In order to uphold both our fiscal responsibility and our duty to educate the public about health issues, we could post the ingredients, calories, and nutritional content such as the amount of fat, cholesterol, and sodium in the cafeteria offerings and then leave it up to the visitors and staff to make their own choices.”

Dr. Morgan piped up, “While I think that Dr. Ashby and Dr. Bennett both bring up valid points and have some solutions that we might want to consider, we should not forget that, as a large hospital, decisions we make about the food served in our cafeteria affect not only the health of the patients, their visitors, and employees, but also the broader community, society, and the environment.”

Commentary

A Hospital’s Mission to Promote Health and Healthy Eating

Before considering ethics related to a hospital’s cafeteria offerings, it may be useful to consider a hospital’s mission more broadly. Hospitals have traditionally engaged in treating acute illnesses and had financial incentives to keep beds full. Now they also manage chronic conditions and have financial incentives to keep patients well. Hospitals today have incentives to prevent readmissions and, more generally, to promote community wellness and public health. As large employers, hospitals are

invested in keeping their workers healthy, and, as teaching institutions, they are invested in passing on lessons of wellness to their students and clinicians in training.

Prevention is a principal focus of most hospitals' work. Given that many leading causes of preventable illness and premature death in the U.S.—obesity, diabetes, heart disease, cancer—are diet-related, it is logical that hospitals have a stake in providing health-promoting food. Doing so helps a hospital fulfill its mission to prevent disease and promote wellness and health, both by sending a message about proper nutrition and by nourishing patients, students, volunteers, staff, visitors, and others.

Financial Considerations and Mission

In order to fulfill its mission, a hospital has to remain fiscally solvent. As Dr. Bennett notes, a chief concern is to ensure the fiscal future of the institution. Whether a hospital is for-profit or not-for-profit, its fiscal future depends on an overall balance of revenue over costs, and ideally each of the services it provides should be “in the black.” Cafeteria service is no exception.

However, if a hospital cafeteria achieves profitability by selling items that promote poor eating habits and poor health, there is a conflict between that business practice and the hospital's broader mission. Certainly, a hospital might generate valuable revenue by selling any number of products that are bad for one's health (e.g., cigarettes). But selling such products would contradict the health-driven mission, and any revenue generated would not be a defensible offset. Offsets from selling foods that clearly damage human health would, likewise, be indefensible. We agree with Dr. Ashby that serving definitively unhealthy food items to patients, visitors, and staff is simply unethical.

Individual Choice and Paternalism

Dr. Bennett might argue that it is not the hospital's responsibility to change individual behavior. We disagree. Promoting health and preventing disease in an era of chronic disease *is* part of a hospital's mission, and that mission can only be achieved through behavior change. Insalubrious behaviors are principal causes of chronic disease, and poor diet is (perhaps only after tobacco use) chief among them [1, 2]. Just as doctors (derived from the Latin *docere*, “to teach”) are responsible for teaching individual patients about good eating practices, so are the hospital systems for which they work responsible for promoting dietary change in broader communities. To do otherwise would undermine their doctors' efforts.

We agree with Dr. Ashby that a hospital is a role-model for both visitors and staff that must set high-quality standards when it comes to nutritional offerings. Food service is particularly outward-facing; it is an extension and a symbol of the hospital's relationship to the broader community and the foods provided should be consistent with dietary advice of clinicians. Patients are likely to interpret what hospitals serve as “healthy.” For instance, one study showed that families visiting a

hospital with a McDonald's in it were twice as likely as those visiting a hospital without a McDonald's to think McDonald's was healthy [3].

Without regard to the foods hospitals serve, Dr. Bennett argues that individuals are responsible for the choices that impact their health. We agree that individual responsibility is important. But many food choices bypass conscious deliberation; they are strongly influenced by the environment in which choices are made [4]. Thus, we believe it is a hospital's ethical responsibility to make the health-promoting choice the easy choice. Hospitals have no obligation to provide definitively unhealthful foods, and there is an ethical problem with doing so. Individuals unable to satisfy their food preferences in hospital cafeterias can choose to eat elsewhere, or bring food from home, or order in. But hospital cafeterias should work to discourage the eating of unhealthful food. Hospital cafeterias should capitalize on their inherent convenience and promote their healthful options over unhealthful options available elsewhere (for the good of the institution's bottom line and the health of patients, visitors, students, volunteers, and staff).

Local and Global Responsibility

Surrounding communities might benefit, too, as cafeteria policies may reach the broader world with messages about what does and does not promote health [4, 5]. For instance, hospitals could recognize local restaurants that offer and promote nutritious food [5]. This could transform the food offered in proximity to a major medical center. Hospital policy can also send a message to the community. With smoking, it was hospitals that started the movement to ban smoking in public spaces [5]. In the food arena, Montefiore Medical Center in New York recently banned sugar-sweetened beverages in cafeterias on all of its campuses [6], sending a very clear message to New York City and the nation as whole that such beverages are not healthy.

Beyond spreading messages of good nutrition, as duly noted by Dr. Morgan, a hospital should ensure that its offerings are beneficial not only for those it serves directly, but for our planet and its inhabitants as a whole.

Doing what is ethical in a global sense—with concern for people, animals, and the planet—may also help an organization best serve its local mission [7]. For a hospital cafeteria, for example, choosing dairy products produced without antibiotics for growth promotion is better for the animals *and* may reduce the problem of emerging infections with multidrug-resistant bacteria for local hospital patients [8]. Choosing food grown regionally may support local farmers and economies, improving the standard of living and health for local patient communities [9]. Ensuring beef comes from cows pastured on vegetation as opposed to those fed unnatural mixes of corn, antibiotics, and offal serves animal and environmental welfare and may improve the nutritional quality and safety of the food for cafeteria consumers [10]. Still, even responsibly raised beef might contribute more to greenhouse gas emissions than other sources of protein like poultry and fish (which in turn contribute more to greenhouse gases than lentils, nuts, beans or grains) [11]. Thus, menu selection can

have an impact on human, animal, and environmental health, and ideally a hospital would do what is ethical for all.

Idealism vs. Pragmatism

From a practical standpoint, an inherent sticking point with the arguments above is that the concepts of “healthy” and “unhealthy” foods are not absolute but relative, contextual, debatable, and ever-evolving. Even within the nutrition community, there is disagreement as to how to categorize various foods [12]. Are 100 percent fruit juices healthy [13, 14]? Are fruits [15]? Eggs [16]? Red meat [10]? What about food constituents like sodium [17]? Cholesterol [16]? Does “organic” make a difference, or the way foods are produced more generally [10]?

In an ideal world, a hospital would focus on providing health-promoting foods. From a practical standpoint it is not clear that “health-promoting” is possible to define precisely, let alone possible for hospitals to provide exclusively. Perhaps focusing on whole, minimally processed foods, produced using ecologically friendly means is a start; foods that nourish individuals, communities, and ecosystems. Admittedly, agreement about what foods those are might vary.

It may be easier to define what foods are unhealthful and have hospital cafeterias focus on not offering those [5]. For instance, there is probably broad agreement that highly processed foods are not health-promoting. Candies and sodas, chips and fries, refined grains, and cured and preserved meats provide some examples. Yet even these foods may not pose as great a risk to one’s health as a product like a cigarette does. If they did (and the evidence is emerging in this regard), it would clearly be unethical for hospital cafeterias to sell these foods or to contract with fast-food chains that have such foods as their core offerings.

Current Reality and Where to Go From Here

Unfortunately, foods widely believed to be unhealthful are currently abundant in hospitals, and a substantial number of hospitals have fast-food chains operating their cafeterias [18]. A recent study in California’s children’s hospitals rated hospital cafeterias on a “healthiness” scale from 0 to 37, where 0 was least healthy and 37 was the healthiest possible; the average score was 19 [19]. The California study did not consider societal or environmental impacts of food. As discussed above, these impacts may be appropriate to include in an overall “healthiness” rating scale.

Such a scale, applied to individual foods, might be one way for hospitals to move forward. That is, until there is broad consensus about what foods are definitively health-promoting or not, hospitals will inevitably have to provide a mix of both “healthier” and somewhat “less-healthy” foods and attempt to distinguish between them. A rating scale could help serve this purpose and allow hospitals to promote the consumption of “healthier” over “less healthy” foods. Such a rating scale is a variation of Dr. Bennett’s suggestion for labeling (i.e., to “post the ingredients, calories, and nutritional content”), which would be another option. Other options include selective signage (e.g., promoting “healthier” items only) [20], price

adjustments (charging more for “less-healthy” items, less for “healthier” items) [21], portion modifications (making “less-healthy” items available only in small amounts) [5], and changes in product placement (e.g., positioning “less-healthy” items further from the point of purchase [22]). For instance, at the UCLA hospital cafeteria, simply putting fruit next to the cash register and cookies further away led to an increase in fruit purchases and a decrease in cookie purchases (unpublished data).

Whether cookies make the list of “less-healthy” foods a hospital is willing to provide based on consideration of its mission will be a matter of debate. Regardless, all of the above strategies make use of what economists have termed *asymmetric paternalism* [23], nudging individuals towards healthier behavior without limiting freedom of choice. Such strategies can allow hospitals to maintain ethical integrity as they attempt to navigate the gray areas between choice and responsibility.

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MEDICAL EDUCATION

Lifestyle Medicine Competencies for Primary Care Physicians

Wayne S. Dysinger, MD, MPH

In June 2012, the American Medical Association adopted a resolution that called for all physicians to “acquire and apply the 15 clinical competencies of lifestyle medicine, and offer evidence-based lifestyle medicine interventions as the first and primary mode of preventing and, when appropriate, treating chronic disease within clinical medicine” [1]. What is evidence-based lifestyle medicine? What are the 15 lifestyle medicine clinical competencies? And how does every physician acquire these?

Defining Lifestyle Medicine

Lifestyle medicine is the application of simple, natural healing approaches to chronic disease care and prevention. The Lifestyle Medicine Competency Development Panel defines it more fully: “Lifestyle medicine is the evidence-based practice of helping individuals and families adopt and sustain healthy behaviors that affect health and quality of life” [2]. Lifestyle medicine pioneer Dean Ornish has stated that lifestyle medicine has four major components: nutrition, physical activity, stress reduction and rest, and social support systems [2].

Although we are hearing a great deal about the lifestyle medicine concept recently, it is neither new nor alternative. In fact it is not a dramatic shift from what has been known since ancient time. The Hippocratic physicians of the fourth and third centuries BCE believed that food was medicine and vice versa. More recently national organizations such as the American Heart Association and the American Diabetes Association, using consensus panels to create practice guidelines, have consistently recommended that disease treatment should begin with “diet and exercise” changes, before medications are considered.

In 2009 the American College of Preventive Medicine hosted a blue ribbon panel meeting to establish core competencies in lifestyle medicine for primary care physicians (see table 1) [2]. When patient care is approached from this foundation, it looks far different than what is being taught in typical medical school and residency curricula.

Basic Physician Skills

To practice lifestyle medicine, once a physician has a solid knowledge base he or she must develop several basic skills. In performing an effective lifestyle assessment, the physician gains a detailed understanding of the patient’s underlying health habits and risks, not just the series of illnesses, medications, and health system interactions that

Table 1. Lifestyle medicine competencies [2]

A practicing primary care physician should possess the following knowledge, skills, attributes and values.

- A. **Leadership** (2 competencies)
 - 1. Promote healthy lifestyle behaviors
 - 2. Practice healthy lifestyle behaviors
- B. **Knowledge** (2 competencies)
 - 1. Demonstrate knowledge that lifestyle can positively affect health outcomes
 - 2. Describe ways in which physicians can effect health behavior change
- C. **Assessment** skills (3 competencies)
 - 1. Assess social, psychological, and biologic predispositions
 - 2. Assess readiness to change
 - 3. Perform lifestyle medicine focused history, physical and testing
- D. **Management** skills (4 competencies)
 - 1. Use nationally recognized practice guidelines
 - 2. Establish effective relationships with patients
 - 3. Collaborate with patients and their families to develop specific action plans like lifestyle medicine prescriptions
 - 4. Help patients manage and sustain healthy lifestyle practices including referrals as necessary
- E. **Office and community support** (4 competencies)
 - 1. Have the ability to practice in interdisciplinary and community teams
 - 2. Apply office systems and technologies to support of lifestyle medicine
 - 3. Measure processes and outcomes
 - 4. Use appropriate community referral resources to support implementation of healthy lifestyles

person has had. Physicians must invest enough time learning about how their patients are eating, exercising, resting, and achieving social support to understand their core lifestyle patterns and therefore the full picture of their health risks. Often extra time and effort invested in understanding events that may predispose or trigger a patient towards poor lifestyle choices can be valuable shortcuts to recognizing when that patient's health is threatened.

Prescribing lifestyle interventions begins with possessing a clear health behavior-change skill set that includes comfort with tools such as motivational interviewing, positive psychology, and cognitive behavioral therapy. Successful health behavior change requires that patients be ready to take charge of their own health, be driven by their inner strengths and energy rather than external factors, and understand small specific steps they can take to improve. The skill set physicians need to help a patient get in touch with these resources can be, and sometimes is, acquired in medical school and residency. More education is needed, however, to assure that all physicians are familiar and comfortable with these tools.

Once a patient's risks are assessed and he or she is directed toward health behavior, lifestyle prescriptions should be written with the same level of detail as medication prescriptions [4]. Telling a patient to exercise more or to eat less fat is too vague to be helpful. Giving him or her a specific, customized written prescription for an improved health behavior is much more likely to achieve real lifestyle change (see table 2). Lifestyle prescriptions must take into account each patient's circumstances and, ideally, should include each element of a SMART objective (i.e., be specific, measurable, attainable, realistic, time-specific).

| Table 2. Examples of specific customized lifestyle prescriptions |
|--|
| <p><u>Exercise</u> Frequency: four times each week Intensity: heart rate between 100 and 140 Time: at least 30 minutes each session Type: walking</p> |
| <p><u>Nutrition</u> Type: cruciferous vegetables such as broccoli, kale and brussels sprouts Amount: 1 serving (1/2 cup cooked, 1 cup fresh) Frequency: once daily</p> |

Intensive Therapeutic Lifestyle Change

The most successful health behavior change programs are those that provide intensive therapeutic lifestyle change (ITLC) [5]. ITLC programs entail intensive, group-based support and can be offered in a community, office, or residential setting. Community-based programs are ideal in many circumstances because they can be located near or within a patient's normal living environment and can incorporate other people important to a patient's behavior. They have a strong record of success [6], but even the least expensive can bring economic challenges for some patients. The most successful community-based ITLC is the Comprehensive Health Improvement Program (CHIP), which has graduated more than 50,000 participants [7].

Offering evidence-based ITLCs in the physician office setting is a developing opportunity that promises significant value to patients, physicians, and health insurance companies. Successful office-based ITLCs rely on a physician's ability to understand and facilitate group visits [8]. Training in group dynamics and an understanding of group-visit billing procedures are core competencies required for running successful office-based ITLC programs. It's also essential to recognize that group visits represent a culture change for both the health care system and the patient that can be challenging.

In certain circumstances, patients who must make significant health behavior change do best in residential ITLC programs run by experienced lifestyle medicine specialists [9, 10]. Although there is currently not a market for many residential ITLCs across the country, knowing where such programs currently exist, how they operate, and which patients will benefit the most from them is valuable.

Living Lifestyle Medicine

Physicians who practice lifestyle medicine must also live healthily themselves. A doctor can offer greatest help to patients when he or she knows what it's like to make nutritious food choices, stay physically active, prioritize rest and life balance, and consistently pursue healthful relationships and support systems [11]. Patients are more likely to follow the advice of a physician who leads by example and can share from personal experience about what it's like to successfully make consistent healthy life choices [11]. The core physician leadership position needs to be one of foundational healthful living.

Lifestyle medicine is much more than working with patients individually or in groups. It also entails recognizing that physicians who want to change the way members of our society eat, exercise, sleep, and relate to each other must involve themselves in changing our culture locally, nationally, and globally. Currently, the convenient food choice is frequently the unhealthful choice. This is in large part because food availability and commercial development in our communities is market driven with little government intervention. Lifestyle medicine physicians who want to change society must be willing to speak out about food taxes, crop subsidies, food manufacturing and labeling regulations, and other politically and economically driven agendas.

Each individual's health is tied to multiple factors. To successfully change our epidemics of chronic, lifestyle-related diseases, all physicians need to know how to counsel individual patients around specific, customized changes they can make in their current health-affecting choices. Physicians must also assist patients in interacting with their existing environments to decrease health risks and must advocate for social change. Achieving adequate lifestyle medicine training at the medical school, residency, and continuing medical education levels should be a high priority for those interested in real health care reform.

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STATE OF THE ART AND SCIENCE

Health Span Extension through Green Chemoprevention

Jed W. Fahey, ScD, and Thomas W. Kensler, PhD

Prevention of disease is by nature not glamorous. Metrics of success are ephemeral and hard to quantify. An averted death or prolonged good health does not enlist advocates or boost the credibility of health care professionals in the way that curing a potentially fatal or disfiguring disease or eliminating its symptoms does. Only 5 years ago, this journal [commented](#) on health promotion in medicine in the context of physician responsibilities [1]. In the [same issue](#) attention was given to the fact that, in 2002, preventive medicine specialists represented only 0.8 percent of the physician workforce and 0.5 percent of medical school faculty were trained in public health, preventive medicine, or related subspecialties [2].

It is not surprising that disease prevention has garnered such a small fraction of American health care dollars. For example, only 6 percent of the National Cancer Institute's budget is devoted to prevention [3], and the fraction of national health care expenditure devoted to prevention is even smaller [4]. Classically, the primary prevention of disease has involved both active strategies (e.g., vaccination, exercise), and more passive avoidance strategies (e.g., protection from excessive sunlight, tobacco), as well as regulatory or governmental intervention (e.g., attempts to control food- and water-borne carcinogens and pathogens). We discuss herein the rationale for the additional approach of secondary prevention that seeks to impede, block, or reverse the early steps in disease progression, including the molecular steps involved in its initiation.

The Global Cost of Disease

As the world has changed over the past century, the scourges of starvation and of many infectious diseases have been dramatically reduced in the industrialized nations, and progress is being made on these fronts in the developing world. However, as the lifespans of just a few generations ago are doubling, these conditions are rapidly being replaced by chronic, noncommunicable illnesses such as cardiovascular disease, cancer, chronic obstructive pulmonary disease (COPD) and other respiratory diseases, stroke, obesity, Alzheimer disease, and diabetes. Lifespan is increasing, but health span (the enjoyment of good health, or aging with minimal handicap and near full function for the duration of a vigorous and productive natural life) is not increasing commensurately. The chronic diseases of aging are overwhelming the health care system of the United States. In this country we spend almost \$2.7 trillion on health care annually [5], three-quarters of it on chronic disease treatment [6]. This expenditure represents about 18 percent of our gross domestic

product and about 20 percent of the federal budget [5, 7], but only 4 percent of this figure goes towards public health and prevention programs and policies [4].

Worldwide, there are about 12.7 million new cases of cancer each year, and 7.6 million deaths, at an annual cost (calculated to include years lost from ill health, disability, or early death) of about \$900 billion [8]. This cost exceeds estimates for all other disease costs: heart disease, \$753 billion; cerebrovascular disease, \$298 billion; road accidents, \$204 billion; HIV/AIDS, \$193 billion; lower respiratory infections, \$126 billion; cirrhosis of the liver, \$93 billion; malaria, \$25 billion [8]. Collectively, the cost of these noncommunicable diseases is estimated to represent 48 percent of the global GDP [9]. These, and similar statistics for other chronic diseases (especially the cardiovascular and neurodegenerative diseases), are progressively defining medicine by its ability to deliver long-term health care, but not as a tool for extending health span.

Last year’s United Nations 65th World Health Assembly conference set a goal of reducing the probability of premature mortality from noncommunicable diseases by 25 percent by the year 2025, prompting the fitting reuse of the old aphorism “It’s not just a matter of life and death, it’s more important than that” [10]. It is the prevention of these chronic and degenerative diseases, which have been most closely associated with both affluence and aging, upon which we shall dwell in the next few paragraphs. Most of our examples focus on the prevention of cancers, a suite of diseases the World Health Organization (WHO) estimates will claim 70 percent of its victims in the developing world by 2030 [11].

The Proximal Common Mechanisms of Chronic Disease

The cellular and physiologic mechanisms by which most of the chronic and degenerative diseases of aging do their damage can be traced in large part back to a very limited number of causal factors: infection with pathogens, inflammation, exposure to electrophilic chemicals, oxidative damage, radiation, and the interaction of one or more of these factors (see figure 1).

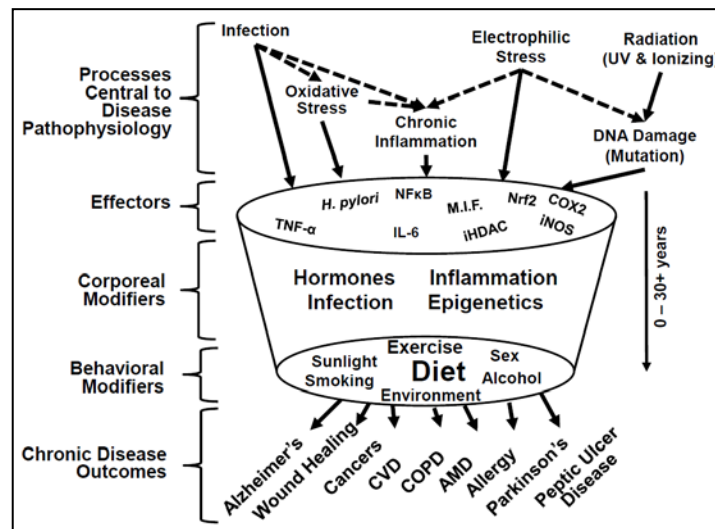


Figure 1. Protection and prevention with dietary agents.

For prevention to be practical, it is ultimately the intelligent and effective targeting of these factors that we must address. The first of these, infection by pathogens, is estimated by the WHO to be the causative factor in about 22 percent of cancers in low- and middle-income nations (6 percent in high-income nations), with hepatitis B and C viruses, human papilloma virus, *Helicobacter pylori*, and a number of waterborne parasites high on the list of responsible infectious agents [8]. Elimination of infection may directly reduce attributable cancer risk and inflammation, which may add to the protective effect. Though beyond the scope of this article, the mechanisms by which inflammation, electrophile and oxidative damage, and radiation initiate and propagate the disease process continue to be the subject of extensive investigation. (A few general reviews are suggested for the interested reader [12-14].)

Making Chemoprevention Green

Cancer chemoprevention refers to the use of drugs or natural compounds (e.g., phytochemicals) to prevent cancer. Michael Sporn, who was instrumental in developing the field of chemoprevention, frames the development of cancer as a continuum, likening its latent, frequently invisible development to a smoldering barn full of hay that, before it bursts into flames, is *not* a safe place to be. In a recent discussion of chemoprevention he describes it as “the arrest or reversal of the progression of premalignant cells towards full malignancy, using physiological mechanisms that do not kill healthy cells” [15]. Stephen Hecht, another pioneer in the field, further suggests that we need to target susceptible individuals for interventions “including chemoprevention using nontoxic or dietary agents with demonstrated efficacy” and avoid “fleeting, flamboyant approaches” in favor of dealing “with lifestyle factors that link cause and prevention” [16]. The last 25 years have provided an abundance of quantifiable evidence to underpin a concept already supported by an ever-more-robust body of epidemiologic evidence—that specific diets can reduce the risks of and protect against cancer and other chronic diseases. The novelty of this approach is rooted in the concept that ingesting certain phytochemicals from specific plants can boost the intrinsic defensive mechanisms of cells that protect against oxidative damage, inflammation, and DNA-damaging chemicals—some of the fundamental causes of chronic disease and aging [17, 18].

We have recently suggested that the practice of “green chemoprevention” begets more frugal medicine and can serve rich and poor alike [19]. We point to the fact that the use of dietary means to deliver protective phytochemicals makes good sense and that chemoprevention by whole foods, or simple extracts of whole foods, presents unprecedented opportunities to solve unmet global problems. It is a frugal and realistic strategy that is economically sustainable in the U.S. and in the underserved and economically deprived populations that are already moving toward more chronic illnesses. And finally, we make the case that proof of the validity of the concept is already available: clinical studies demonstrate the effectiveness of phytochemicals derived from teas (polyphenols), berries (anthocyanins), broccoli sprouts (sulforaphane), garlic (sulfur compounds), and others [19]. Widespread regulatory ambiguities complicate the marketing of green chemoprevention products (e.g.,

should whole food or extracts be regarded as foods, medical foods, dietary supplements, or even drugs?). Large-scale production and standardization of such chemopreventive food products is complex, but clinical studies are currently under way on all of these.

There are a number of questions specific to the target populations that will need to be addressed in delivering these interventions. We have discussed them previously [19-21] but they bear repeating: Are there countervailing health or ecological risks associated with the intervention? What is to be the delivery vehicle (fresh food or processed food or drink products)? Can the food product or intervention be manufactured or grown locally and sustainably? Can farmers or consumers afford the costs? Is the intervention culturally appropriate? Are there any contraindications? Can the actual cost effectiveness be determined as the intervention is implemented? And finally, will people comply? Adoption of healthier diets is of course an uphill battle, and the effect size will likely be small if efforts to encourage more healthy eating are not based on sound science, but progress is being made. Approaches were recently reviewed in a special issue of the journal *Science* [22-24].

A very straightforward starting point for this paradigm shift is for physicians to prescribe preventive diets for their at-risk patients. The food system in the U.S. can readily facilitate the delivery of such diets, but our medical and graduate schools must do a far better job of teaching new physicians and biomedical scientists about human nutrition and the role of diet in disease prevention, and those newly trained professionals must in turn be proactive with their patients and counselees. They must make prevention as much the order of the day as cure. Food—chemopreventive diets—should be, and can be, the daily “multivitamin” of our immediate future.

How Much Does Prevention Cost?

Chemopreventive strategies, in particular dietary approaches, make enormous sense. They are intuitively the most logical, sustainable, ethical, and responsible way to deal with the epidemic of chronic and degenerative disease. They may also be among the most cost-efficient, certainly compared to treatment of frank disease. However, it is very difficult to estimate the true costs and benefits of such approaches, since the impact of preventive measures must be measured over a long time. One must make a number of assumptions about the costs of a dietary prevention strategy, which will most likely involve education, social interventions, and the development of dietary alternatives. One must also make certain assumptions about the degree of protection one can expect to see. In other words—how much of an impact will the intervention have on the disease burden of the target population? And one must assume that even a small risk reduction may have a meaningful impact.

Current methodologies do not enable us to measure reliably the effects of a dietary intervention on future rates of any of the major cancers, but we can measure biomarkers of specific dietary components and of their effects, in particular those that pertain to hepatocellular carcinoma and aflatoxin exposure [20] and air pollutants [25, 26]. Nonetheless, from the perspective of increasing the meager levels

of government funding allocated for this approach, it is incumbent on physicians and scientists to assist policy makers in developing an economic understanding of the road to applied chemoprevention.

The authors of recent studies suggest that economic studies of the cost effectiveness of a core set of strongly recommended preventive services examined in 2006 by the National Commission on Prevention Priorities “consistently report that evidence-based clinical preventive services offer high economic value” [27, 28]. (At its simplest, cost effectiveness is a ratio of the cost of an intervention to a measure of health gain such as quality-adjusted life years [QALY], a metric commonly used by insurers and health care providers). Published calculations for preventive approaches range from \$69 per year of life saved for mandatory seat belt laws [29] to \$12,000 for cervical cancer screening [30] to \$100,000 for automobile airbags [31], when quality of life is not taken into account. It is reasonable to assume that the cost effectiveness of any adequately funded chemoprevention program ought to be comparable to many other widely funded prevention services and most likely under the threshold of \$50,000 per QALY that is often used in cost effectiveness calculations. An adequate level of funding for such a program might be expected to range upwards from the \$55 million spent annually by the CDC on their National Heart Disease and Stroke Prevention Program [32]. Although it is beyond the scope of this short paper to identify the costs of a dietary preventive strategy, we strongly endorse the need for robust and defensible cost calculations with which the efficacy of such strategies can be meaningfully evaluated.

Conclusions

The evidence is mounting and is viewed by many as irrefutable. The challenge for the next decade(s) and for new health professionals is how to convey what has been learned directly to patients and to the general public. Social scientists, the entire spectrum of stakeholders in the food industry (e.g., from farmers to retailers), medical, nursing, and public health schools, government (e.g., regulatory and research branches), and primary and secondary school educators will all need to become invested and involved. The new drivers of this revolution will be not the drug companies but the food and agricultural interests because they will stand to profit greatly from introduction of new foods, new plant cultivars, and the reintroduction of “old foods” into new markets. They should thus be expected to provide a larger share of the funding for chemoprevention research as well as for effective public outreach. The road to longer health span will of course be rocky, but we cannot afford to ignore a strategy of diet-based prevention without putting our health care system in even more severe jeopardy than it already is.

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STATE OF THE ART AND SCIENCE

Health Coaching

Amireh Ghorob, MPH, Rachel Willard-Grace, MPH, and Thomas Bodenheimer, MD

Four principles undergird the ethical provision of health care: beneficence, nonmaleficence, respect for autonomy, and justice [1]. We believe that these golden rules cannot be implemented for every patient in our current system of health care. In particular, the stresses engulfing primary care thwart attempts to comply with the four principles. A new model is needed to transform primary care so that these ethical obligations can be met. This new model creates a paradigm shift that we call “health coaching.”

Our Failure to Provide Universal Ethical Care

Beneficence is the obligation of health care professionals to do everything possible to improve people’s health. Commonly, beneficence is equated with the provision of evidence-based medicine. However, evidence-based medicine has serious limitations. For many clinicians, evidence-based medicine is a three-step process: (1) research uncovers the evidence, (2) clinicians learn the evidence, and (3) clinicians use the evidence in creating care plans for their patients. For patients to benefit, however, clinicians must also (4) make sure that patients understand the evidence and (5) do everything possible to encourage patients to incorporate the evidence into their lives [2].

We will use the highly prevalent conditions of diabetes, hypertension, and hyperlipidemia to ground this discussion in reality.

Evidence-based medicine steps (4) and (5)—which take considerable time—are impossible in the rushed 15-minute visit that dominates primary care. In the United States, half the patients with hypertension, 43 percent of people with diabetes, and 80 percent of people with hyperlipidemia have not reached the clinical goals set by national practice guidelines [3-5]. If everything possible were being done to improve people’s health, greater proportions of the population should be reaching those goals. On a population level, beneficence is not universally achieved.

Nonmaleficence is the duty of health care professionals to do no harm. Harm comes from errors of commission and also of omission. Millions of people have not met their evidence-based glycemic, blood pressure, and lipid goals and are at elevated risk of severe and fatal cardiovascular complications. Harm is being done by omission of maximal efforts to make sure that all patients understand the risks of uncontrolled blood sugar, blood pressure, and cholesterol and are properly counseled on how to minimize those risks.

Autonomy is the right of persons to choose and follow their own plans of life and action. Patients have the right to choose whether or not to accept the health care being offered them. Yet, according to a study of more than 1,000 audiotaped visits with 124 physicians, patients participated in medical decisions only 9 percent of the time [6]. While half of patients surveyed preferred to leave final decisions to their physician, 96 percent wanted to be offered choices and to be asked their opinion [7]. Patient autonomy is exercised in the medical context through informed patient consent or refusal of the treatment alternatives offered. Typically, physicians give patients a care plan without consideration of patient exercise of autonomy. Moreover, 50 percent of patients do not even understand the medical options that are offered them [2]. As a result, patients do not know why they should follow their care plans, are not involved in creating them, and exercise their autonomy by not adhering to them. Only one-third of patients with diabetes adhere to recommended guidelines for lifestyle changes [8]. If patients were adequately informed to make these life-affecting decisions, adherence to lifestyle changes and medications would be greater [8].

Justice refers to treating everyone fairly and equitably. The pervasive health disparities haunting our health system demonstrate that justice is not being achieved. For hypertension, diabetes, and hyperlipidemia, lower-income patients and those who are part of historically marginalized groups have poorer outcomes than higher-income patients [9]. In part, these disparities are associated with poorer communication between higher-income, well-educated physicians and lower-income patients who have less opportunity to acquire health literacy and other forms of education [10].

To implement the basic ethical principles more fully, a new model is needed that moves beyond the 15-minute physician-visit syndrome. Such a model requires that health care workers—called health coaches—with a collaborative style, good training, and ample time are available for patients who have inadequately controlled chronic conditions. In the remainder of this paper we explore how health coaching can improve our health care system's performance on the four ethical principles.

What Is Health Coaching?

Health coaching can be defined as helping patients gain the knowledge, skills, tools, and confidence they need to become active participants in their care so that they can reach their self-identified health goals. The familiar adage “Give a man a fish, and he eats for a day. Teach a man to fish, and he eats for a lifetime,” demonstrates the difference between rescuing a patient and coaching a patient [11]. For chronic conditions, patients make the salient decisions every day: what will I eat, will I exercise, will I take my medications? Patients with chronic conditions need to learn how to fish.

Health coaching could be performed by clinicians (physicians, nurse practitioners, physician assistants), but the 15-minute visit makes that impractical if not

impossible. Thus health coaching is best done by another member of the primary care team. Health coaches might be RNs, pharmacists, health educators, trained medical assistants, or other patients called peer coaches. Health coaches must have the training and protected time to provide this essential service and must be on the clinician's team so that the clinician and health coach coordinate their messages to the patient. Health coaching has the potential to assist the health care system to perform better in the four domains of medical ethics.

The Content of Health Coaching

Some people understand the term “coaching” to mean a supportive activity in which the coach's main job is to encourage the patient to do better. Indeed, providing emotional support and motivation is an important part of coaching. But true health coaching does far more, offering patients assistance in five concrete areas: understanding, knowing their numbers, shared decision making, behavior change, and medication adherence.

Understanding

In a 2003 study, when physicians asked patients to restate the physician's instructions, the patients responded incorrectly 47 percent of the time [12]. Fifty percent of patients, when asked to state how they are supposed to take a prescribed medication, did not understand how the physician had prescribed the medication [13]. While physicians frequently attribute medication nonadherence to patient behavior, in fact, 3 of 4 physicians in one study failed to give patients clear instructions on how to take their medications [2]. Low health literacy, more common in lower-income patients and those from historically marginalized groups, is associated with greater lack of understanding of clinician instructions [10].

A key function of health coaching is to make sure that patients understand the care plan made by the clinician. This function is carried out by “closing the loop,” also known as “teachback.” To close the loop, the coach asks the patient: “Just to be sure we were clear, how will you be taking your medication starting tomorrow?” The patient then states the clinician's instructions in his or her own words. If the information is incorrect, the coach corrects the patient and asks again. This is repeated until the patient can accurately state what the clinician's instructions were. In a study of patients with diabetes, those whose coaching included this technique had better HbA1c levels than those whose coaching did not [12].

The understanding step in the coaching process enhances beneficence and nonmaleficence by improving patient outcomes. Because understanding is a greater problem for lower-income patients, and because health coaching is more often performed in safety-net settings, this coaching function can also reduce health disparities and bring more justice to health care.

Knowing Your Numbers

Most patients with diabetes do not know their actual HbA1c number or their HbA1c goal [14]. A randomized controlled trial has demonstrated that patients with diabetes who are taught their actual HbA1c level and their HbA1c goal improve their glycemic control more than a control group [14]. Diabetic patients with low health literacy have worse glycemic control than those with adequate health literacy [15]. A central function of health coaching is to teach patients their ABC numbers—A for A1c, B for blood pressure, C for cholesterol (specifically LDL-cholesterol). Coaches also teach patients their ABC goals (for example A1c of 7, blood pressure of 130/80, and LDL cholesterol of 100), and explain how patients can get from their current numbers to the goals—generally by healthful eating, physical activity, and taking medications. Because knowing your numbers improves outcomes and because knowing your numbers improves health literacy that is often inadequate in lower-income populations, this health coaching function enhances beneficence, nonmaleficence, and justice.

Shared Decision Making

Clinical outcomes improve when patients are involved in clinical decisions, i.e., when the principle of respect for autonomy is honored. A participatory relationship between patient and physician is one of the most decisive factors in promoting healthy behaviors [16, 17]. In a study of 752 ethnically diverse patients, information giving and collaborative decision making were associated with better adherence to medications, diet, and exercise [18]. In an intervention study, patients who were encouraged to participate more actively in the clinical visit reduced their average hemoglobin A1c levels from 10.6 percent to 9.1 percent, while hemoglobin A1c levels in the control group increased from 10.3 percent to 10.6 percent [19]. For patients with diabetes, significant associations exist among information giving, participatory decision making, healthier behaviors, and better outcomes [20-22].

Because clinicians often lack the time to engage in shared decision making, this crucial medical care function can be provided by health coaches. Health coach training begins with the concept of ask-tell-ask: rather than telling patients information that they may already know or may not be interested in learning, good coaches ask patients what they want to learn, what choices they want to make, whether they agree with the clinician's instructions, and what behavior changes they are motivated to make. If there is one fundamental principle of health coaching, it is shared or collaborative decision making with patients. Health coaches are trained not to tell patients what to do.

One common situation that arises in coaching is that clinicians tell patients what to do, then coaches ask patients what they are willing to do, and coaches must then go back to the clinician and say that the patient will not do what the clinician instructed. For that reason, everyone providing health care, clinicians included, should be trained using the coaching paradigm. Getting mixed messages does not help patients.

Behavior Change

It is commonly believed that information alone promotes healthy behavior change, but telling a patient that eating less fat will reduce LDL cholesterol and prevent heart attacks rarely has the desired result. While information is necessary, it is not sufficient. A review of diabetes patient education found that in 33 of 46 studies, education improved patients' knowledge about their condition, but in only 18 of 54 studies did patient education improve glycemic control [17]. Sixteen randomized controlled trials of patient education on hypertension found that education alone is not associated with reductions in blood pressure [23]. Nor does education by itself increase the extent to which patients take prescribed medications [24].

In helping patients adopt healthier behaviors, two things seem to work: shared decision making and realistic goals. These two things form the basis of behavior-change action plans, also known as goal setting. Action plans are central tools in a health coach's toolbox. First, patients—after learning their numbers, their goals, and how to get from their current number to their goal—are assessed for their motivation to get from their number to their goal. If motivated, the patients are asked to choose which behavior they would like to work on; the most common choices are healthful eating, physical activity, and medication adherence. Once the patient has made this choice, he or she is encouraged to make an action plan for a behavior change—for example walking for 15 minutes per day or eliminating sodas and substituting water—that the patient is confident he or she can succeed at. Action plans are a stark contrast to the unrealistic instructions clinicians often give: “You need to stop eating sweets and need to walk 30 minutes each day.”

A recent randomized controlled trial demonstrated that goal setting using action plans was effective. Patients were randomly assigned to traditional patient education or goal setting with action plans. The group doing action plans had a significant reduction in HbA1c compared with the patient education group, whose A1c levels did not change [25]. The success of properly performed health coaching is bolstered by evidence. Moreover, the replacement of the doctor's order by the shared decision making displayed in collaborative goal setting and action planning enhances patient autonomy.

Medication Adherence

Approximately one-third of patients take all their medications, one-third take some of their medications, and one-third take almost none of their medications [26]. Many studies and reviews address the issue of improving medication adherence. A participatory relationship—shared decision making—between patient and physician appears to be the most significant factor in medication adherence. The more actively the patient is involved, the higher the level of adherence [26, 27]. Health coaching focuses a great deal of energy on medication adherence, since medications for diabetes, hypertension, and cholesterol are highly effective in assisting patients to reach their clinical goals. This effort enhances all four ethical principles.

Summary

Faithful adherence to the four principles of medical ethics is not possible in the rushed, 15-minute primary care clinician visit. Health coaching—performed by other members of the health care team—can increase the chances that the ethical tenets will be followed for every patient. The coaching must assist patients to understand their care plan; know their current state of disease control, their goal, and how to get from here to there; engage patients in shared decision making, which increases the likelihood of good clinical outcomes; help with realistic behavior change that the patient agrees with; and work with patients to overcome barriers to medication adherence.

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HEALTH LAW

Oreos, Big Gulps, and Nicotine: Legal Challenges to Government Lifestyle Interventions

Valarie Blake, JD, MA

The battle to improve the American public's health is often staged in the courts, as legislators, political figures, and activists look to law as a primary way to regulate and curtail unhealthy behaviors. The legislative efforts typically come in either of two forms: (1) bans that proscribe a particular substance or activity (e.g., trans fat and soda bans or bans on smoking indoors) and (2) labeling requirements that seek to indirectly discourage an activity or use of a particular substance by raising awareness about potential harms (e.g., calorie counts posted on menus or graphic warnings on cigarettes packages). Both bans and label requirements face strong legal opposition from industry and ignite furious public debate about the role and limits of government intervention in American lifestyles. This article highlights two of the most recent controversies: the infamous "soda ban" in New York City and the new Food and Drug Administration (FDA) law requiring graphic images on cigarette cartons.

Bans on Sugary Drinks in New York City

In 2012, New York City's Board of Health approved a law that a "food service establishment may not sell, offer, or provide a sugary drink in a cup or container that is able to contain more than 16 fluid ounces" [1]. (The industry standard that you currently see lining the shelves is 16.9 ounces). The law does not apply to alcoholic beverages, beverages with greater than 50 percent milk or milk substitute (think Starbucks or milkshakes), or beverages with fewer than 25 calories per 8 ounces; and it does not stop an individual from buying more than one 16-ounce beverage at a time [1]. The law, controversially, does not apply to convenience stores that sell both packaged foods and foods for immediate consumption because these are under the authority of the state and not the city [2]. Thus, under this law, the 7-Eleven "Big Gulp" lives on.

Lauded by some as a heroic measure against the rising tide of obesity or at least a good first step, the law was criticized by others for being an infringement of citizen rights or, at the very least, likely to be ineffective at reducing obesity rates given its many loopholes.

A disparate crew of plaintiffs (ranging from the National Restaurant Association and American Beverage Association to soft drink worker unions, Korean grocer organizations, the Hispanic Chamber of Commerce, and movie theater owners) challenged the law in the New York courts for targeting local and small businesses,

overstepping the city's authority, and infringing on individual rights [3]. Specifically, they argue that the City Board of Health cannot implement social policy (because this is the role of the state legislature)—comparing it to *Boreali v. Axelrod*, in which the New York Court of Appeals held that the State Public Health Council did not have the authority to establish smoking bans in public areas [3]. Thus the new rule violates the separation of powers (a constitutionally mandated division of labor between executive, judicial, and legislative branches) and the city has overreached its authority. Moreover, the plaintiffs argue that the ban is arbitrary and capricious (or basically an unjustified abuse of power by the city) [3]. To support this stance, they point to the many high-calorie beverages the law doesn't reach (e.g., milkshakes, alcohol, high-calorie coffee drinks), the wide range of environments it does not apply to (such as convenience stores), and the lack of scientific evidence to support drawing the line at 16 ounces of 25 or more calories per ounce [3]. Soft drink makers also argue that the alteration of the industry standard (from 16.9 ounces per container to 16 ounces) will create expensive and unjustified burdens, such as the need to generate new factory equipment and new bottles for one small geographic piece of the soft drink market [3].

The city disagrees that its action is an overreach of power, arguing that the New York State legislature granted New York City's Board of Health the authority to regulate all health-related matters (including control of chronic disease and oversight of the city's food supply) and that, unlike the State Public Health Council in *Boreali*, the city board is quasi-legislative, meaning that it has been granted some power to make social policies [2]. Further, the city responds that its reasons for enacting the law are reasonable and not arbitrary or capricious and cites scientific data in support of the claim that, where larger portion sizes are available, consumers will select them [2]. Moreover, the consumption of sugary drinks offers no nutritional benefit, people who drink sugary drinks do not adjust by consuming fewer calories at meals, and sugary drinks are a known leading contributor to the obesity epidemic [2]. The city also highlights the particular overconsumption of soft drinks by socioeconomically marginalized groups [2].

While loopholes exist in the ban, they mainly allow for drinks that have nutritional value (like milk-based drinks) or drinks that are outside of the city's authority (like alcohol and convenience store sales). And while consumers could buy more than one 16-ounce beverage at a time, data show that most consumers gravitate towards a default option and often choose convenience, so this limit would mean consumers would have to make an effort to consume more than 16 ounces [2].

On the eve of the soda ban becoming enforceable, the judge struck down the law as arbitrary and capricious because its many loopholes effectively defeat its purpose—it does not apply to many high-calorie beverages or to a variety of suppliers, and it would be unevenly enforced “within a particular City block, much less the City as a whole” [4]. Moreover, the judge opined, the city overreached its powers [4]. The judge reviewed historical examples in which the Board of Health was granted more expansive powers, and concluded that these were all related to control of

communicable, infectious, and pestilent diseases, not chronic disease [4]. The city has already filed an appeal, suggesting that a resolution to this case could be long in the making [5].

When compared with the soda ban case, it is important to note that long and drawn-out legal battles are not the only way to bring about changes in food industry practices. Sometimes the threat of legal and public relations problems can be enough. In 2005, for example, an activist group brought suit against Kraft, demanding that it lessen or remove trans fats from Oreo cookies or desist from marketing and selling them to children under the age of ten. Kraft quickly settled the suit by agreeing to remove trans fat from its cookies and replace it with nonhydrogenated vegetable oil [6]. (Oreos are also vegan!) Kraft then launched a healthful food marketing campaign, ensuring and advertising that Wheat-Thins, Jello pudding snacks, pizza crusts, crackers and many of its other products were made without trans fats [6].

Graphic Warnings about Nicotine

Restrictive labeling aims to achieve the same goal of changing behavior, but by educating consumers rather than banning products.

One of the more recent and dynamic examples of controversy about labeling was a legal challenge to a new FDA rule mandating that all cigarette packages and advertisements bear one of nine warning labels, all of which contain text warnings, graphic depictions of the harmful health consequences of smoking, and the National Cancer Institute's tobacco cessation quit line telephone number [7]. The ads must cover 50 percent of a cigarette package or 20 percent of a cigarette ad and depict images of mourning family members and persons suffering the ill effects of smoking [7, 8]. The images were selected following an 18,000-person Internet study commissioned by the FDA to determine which photos were most effective in (1) educating the consumer and (2) encouraging quitting or refraining from smoking [9]. A notable number of countries have also included graphic labels on cigarettes, among them Australia, Belgium, Brazil, Canada, Switzerland, the United Kingdom, Turkey, and Thailand [9].

Several challenges to the constitutionality of the mandate were heard in federal courts, which were split in their decisions. In one case, a number of tobacco manufacturers and sellers sued the FDA for violation of First Amendment free speech in the U.S. Court of Appeals Sixth Circuit [10]. Free speech is the right to speak or to refrain from speaking, and the government can only mandate certain speech (e.g., a compulsory warning label) if it has a substantial interest in regulating that speech and evidence that the regulation directly advances that interest [9]. In holding that the graphic warning label was constitutional and not a violation of free speech, this court emphasized that the purpose of the First Amendment is to protect the flow of accurate information—companies have an interest in conveying truthful information about their legal products, and adult consumers have a corresponding interest in receiving truthful information [10]. Thus a company's constitutionally protected interest in not providing factual information is minimal. The text of the

graphic warnings is factual—it relates the proven medical harms of tobacco. The government’s use of labels that convey factual information about the harms of tobacco are reasonably related to a goal of preventing consumer deception [10]. Even facts which might disconcert or provoke a strong emotional response, remain facts and not opinions, and the question turns on whether the labels are providing facts for the public, not on whether they are controversy-provoking [10]. Thus, to the Sixth Circuit court, the graphic image law is constitutional [10].

In a case with the opposite outcome, RJ Reynolds Tobacco Company sued the FDA, arguing that the new labeling requirement violated its First Amendment right to free speech, and the U.S. Court of Appeals for the D.C. Circuit sided with the tobacco company [9]. While the FDA might have a substantial interest in reducing smoking rates among Americans (and particularly youth), the court did not believe the FDA had adequate evidence to show that these graphic warnings would actually reduce smoking [9]. The labels might increase thoughts about quitting smoking, but the court was not convinced that those thoughts necessarily translated into actual quitting [9]. The court pointed to evidence that, while smoking rates dropped in Canada after the introduction of graphic warnings, there was not sufficient proof of a causal link between the warnings and smoking reduction [9]. Thus, the FDA did not provide the compelling evidence needed to trump First Amendment free speech rights and allow certain images and information on cigarette labels and ads [9]. The FDA has decided not to appeal this latter case, which struck down the graphic label warning. Instead the FDA intends to “undertake research to support a new rule-making consistent with the Tobacco Control Act” [11].

Whether through bans or labeling requirements, regulating American health behaviors remains a legally challenging (and somewhat unpredictable) activity. And as evidence linking lifestyle choices to chronic disease mounts, the challenges will only intensify.

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POLICY FORUM

Cigarette Marketing and Packaging

Andrew A. Strasser, PhD, and Lynn T. Kozlowski, PhD

The Family Smoking Prevention and Tobacco Control Act (FSPTCA) of 2009 gave the United States Food and Drug Administration (FDA) authority to regulate tobacco products in several ways, including restricting cigarette packaging, requiring the inclusion of graphic warning labels (section 201 d), banning misleading descriptors such as “light” and “low tar” (section 911 a-b) that imply the product is less harmful, setting standards for nicotine content in cigarettes, and banning flavorings [1, 2]. The graphic warning labels were released in June 2011 with an original implementation date of September 2012. However, recent litigation by several tobacco companies (e.g., *RJ Reynolds Tobacco Co. v. United States Food and Drug Administration* [3]) has delayed the initiation of the graphic warning labels, on the grounds that the graphic warning labels violated the companies’ First Amendment rights and would be too costly and that the shocking color graphics did not deliver factual, noncontroversial messages [4, 5].

Cigarette descriptors such as “low tar,” “light,” and “mild” were successfully banned in June 2010 under the FSPTCA (section 911 a-b), although the effectiveness of this initiative remains unclear [6, 7]. Prior to the descriptor ban taking place, the tobacco industry manipulated package coloring, and supplied informational materials to retailers, so that the color coding implicitly replaced them [7, 8]. Many smokers did not notice the descriptor ban [6] and appear to have adopted the tobacco industry’s use of package colors as a way to infer “risk” level [6, 7]. These types of countermeasures and the challenges to graphic warning labels raise questions of how far the FSPTCA will actually be able to advance tobacco control for the protection of public health.

One can anticipate other possible challenges to forthcoming regulations. For example, a provision within the law formally discourages the adoption of product standards that would create significant demand for contraband or other tobacco products. Some of the most significant possible changes to tobacco products could be challenged by this provision. For example, the Tobacco Products Scientific Advisory Committee notes that banning menthol may be of benefit to the public health, yet also acknowledges that contraband markets of menthol cigarettes would likely exist and the origin and safety of these products would be difficult to determine and monitor [9].

Cigarette smoking remains the largest single, preventable cause of death and disability in the United States [10], and, from the perspective of discouraging this

deadly activity, a classic skull and crossbones-type poison symbol along with graphic images of the disease effects would seem warranted on packaging. The tobacco industry knows the utility of cigarette packages as a communication vehicle about its product. As noted by Philip Morris executive Mark Hulit in May 1994 to the Corporate Affairs Conference in Manila,

Our final communication vehicle with our smoker is the pack itself. In the absence of any other Marketing messages, our packaging—comprised of the trademark, our design, color and information—is the sole communicator of our brand essence. Put another way—when you don't have anything else—our packaging is our Marketing. Therefore, regulations that infringe upon and distort our fundamental packaging designs must be fought with all the resources and energy Corporate Affairs can muster. Government required warnings placed on the largest packaging panel, often called the front and/or back, are the biggest marketing threat to all of us in Asia. The size, type weight and number of countries requiring such warnings seems to be concentrated particularly here in Asia—and this is a very big concern not only in our Region but right around the world [11].

The cigarette package is clearly an excellent channel for information and has been used to mitigate smokers' risk and harm perceptions, formulate product expectations, and convey brand image by the tobacco industry [12-14]. Mutti and colleagues [15] reported that, in an international survey of over 8,000 smokers, those whose cigarettes came in light-colored packs (e.g., gold, silver, blue) were more likely to believe their cigarettes to be less harmful than were smokers of cigarettes in dark-colored packages, such as red or black.

There is also ample evidence that the cigarette pack is an opportunity to improve smokers' decisions about smoking and risk beliefs. Research spanning several countries and regulatory environments that measured warning label salience on cigarette packages generally supports the hypothesis that labeling increases knowledge of smoking harms and intent to quit and more negative and emotional thoughts about continued smoking [16, 17]. And an empirical study on the effect of graphic warnings and package features on cigarette preference indicates that both graphic warnings and plain packaging can reduce the appeal of a cigarette brand [18]. A recent review by Hiilamo and colleagues observed that, as the salience of health warnings on packs increased, the tobacco industry response moved from a position of "relatively innocuous" to increasingly litigious [19].

Graphic warning labels elicited negative responses to smoking in U.S. smokers [20], increased reported intention to quit smoking when Canada adopted graphic warnings [21, 22], and increased perceptions of smoking dangers in a four-country survey [23]. Some researchers have found population-level effects of graphic warning labels on smoking behaviors. Azagba and Sharaf [24] found decreased smoking prevalence and increased quit attempts; Hammond and colleagues [22] found that 20 percent of

smokers self-reported smoking less. Of course, some of these effects could be complicated by concurrent tax increases or antismoking media campaigns that coincide with the introduction of new warning labels [17, 21]. However, the results of two experimental studies designed to examine the effectiveness of FDA-approved graphic warnings are supportive of the labels [25-27]. Increased emotional and cognitive responses, high recall of the graphic warnings, and improved beliefs about the dangers of smoking were reported in a survey of over 10,000 respondents [25]. More recent research conducted by the Annenberg Public Policy Center added insight into how specific features of the warnings increase efficacy (color, phrasing consistency) and identified individual characteristics associated with responsiveness to graphic warnings [26, 27].

A recent laboratory study examined how smokers viewed a graphic warning label embedded into a print advertisement. In that study, how quickly viewer attention was drawn to the text and duration of viewer attention to the graphic image were significant predictors of their ability to recall the content of the warning [28]. Those randomly assigned to the graphic warning were significantly more likely to recall the content of the warning than those who viewed the text-only version, suggesting that graphic warning labels are superior to text warnings at conveying information by both drawing and sustaining attention. In this study, the graphic warning label was embedded in a Marlboro print advertisement. Of relevance to this discussion, those who were Marlboro brand smokers, verified by presenting their own packs to investigators, were less likely to correctly recall the warning label than smokers of other brands. This difference in recall and viewing patterns could be influenced by brand preference and indicative of how branding- and health-relevant information may battle for consumer attention in the advertisement arena. Research conducted in the United Kingdom by Munafo [29] supports this observation, as removal of brand information improved viewing and attention of the graphic warning label.

Summary

The FSPTCA ostensibly provides a means to enact important health policy improvements to a significant health problem, but the legal challenges to the implementation of the graphic warning provisions raise questions about the future of regulatory tobacco control in the United States. Graphic warning labels have been shown to be effective, low-cost, and capable of conveying important information at the relevant times—purchase and use. Several lines of empirical research conducted by the tobacco industry and health researchers provide converging results to support that cigarette packaging is an optimal vehicle of communicating risk. Research from around the world repeatedly demonstrates that graphic warning labels improve health by decreasing the likelihood of initiating smoking; improving understanding, beliefs, and knowledge of health risks; and increasing the likelihood of trying to quit smoking [20, 21, 30]. There are now more than 55 countries that have mandated that some version of image and text be affixed to cigarette packs to provide health information and discourage smoking [31].

Opponents to the implementation of graphic warning labels in the United States cite infringement of free commercial speech, that the health harms are already known, and that including graphic warnings on cigarette packs is costly. It is imperative that these arguments are weighed against the magnitude of the problem. Nearly 20 percent of adult Americans are daily cigarette smokers [32], there are nearly 400,000 smoking-attributable deaths annually, and approximately 2 million Americans, most of whom are between 12 and 18 years of age, initiate cigarette smoking each year [33]. Cigarette smoking affects a great deal of the population, and its health consequences are significant. It is therefore crucial to better inform and routinely remind the public about the dangers of cigarette smoking, to improve the accuracy of their beliefs about the risks of smoking, and to provide support for them to seek cessation, such as through the inclusion of 1-800-Quit-Now in the warning labels. An important communication device to help achieve these goals is effective implementation of graphic warning labels on cigarette packages in the United States.

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POLICY FORUM

Unintended Consequences of Obesity-Targeted Health Policy

Andrew W. Brown, PhD, and David B. Allison, PhD

L'enfer est plein de bonnes volontés et désirs. [Hell is full of good wishes and desires.]

Saint Bernard of Clairvaux [1]

The conflict between individual freedom of choice and a government's obligation to protect its citizenry from threats to public health is often at the center of health policy debates. This has played out in New York City, for instance, with freedom of choice being the rallying cry of those opposed to a citywide ban on large containers of beverages [2], while saving lives through health-motivated policies is offered as the justification for the regulations [3]. However, several other ethical concerns exist related to the creation or implementation of public policy. Herein, we will discuss a catalog of ethical concerns identified by M. ten Have et al. [4] related to policies intended to prevent or treat obesity.

We discuss these ethical concerns in light of two key issues: (1) Under which circumstances does obesity merit being considered a *public*, as opposed to simply a common, health concern? Whether or not obesity is considered a public health concern is important in deciding whether impinging on individuals' rights may be warranted. (2) How plausible is it that a given policy or program will have negative unintended consequences? These consequences are important to consider when deciding if a policy should be implemented. We then suggest strategies for minimizing ethical and other unintended adverse consequences of obesity-targeted health policies.

Ethical Concerns in Obesity-Targeted Health Policies

In "Ethics and Prevention of Overweight and Obesity: An Inventory," Marieke ten Have and colleagues identify ethical concerns posed by 60 actual or proposed public policies, corporate initiatives, and behavior recommendations intended to prevent or treat obesity [4]. One group of ethical concerns comprises direct negative consequences of a program, including physical and psychosocial harm, dissemination of inadequate information, and creation or exacerbation of inequalities. The other group of ethical concerns encompasses disrespect for individuals and their rights and values, including transgressing personal and cultural values of eating, invading privacy, assigning fault for obesity, and abridging freedom of choice. Typically, more than one of these concerns exist with varying degrees of severity for any proposed policy or recommendation, but often the debate is

dichotomized as a desire to promote health versus a desire to preserve individual liberty.

The complexity of ethical considerations in obesity policymaking can be demonstrated by a policy that would allow the government to remove an obese child from his or her home (see table 1). Note that the pros and cons listed in the table are not necessarily weighted by importance because importance is dependent on individual perspectives and specific situations. Here, the assumed benefit of the policy is that removing the child from the home will improve his or her weight and therefore health, though that assumption is itself contentious [5]. As the table shows, the ethical considerations are far more complex than health vs. freedom of choice. To add to the complexity, a given individual may consider one specific ethical concern more important than all others: for health advocates the physical health implications may outweigh all other concerns, while for the parents the sanctity of the parent-child relationship may be paramount [6].

Table 1. Ethical concerns of an example policy in which the government is allowed to remove obese children from homes. The ethical concerns are not necessarily equally prevalent and do not necessarily carry equal weight.

| Ethical concern [4] | Pro-policy view | Anti-policy view |
|--------------------------------------|---|--|
| Physical health | Improved health if professionals can affect weight. | There may not be the resources or knowledge to improve the health of the removed child in the long term. |
| Psychosocial well-being | Obesity is associated with psychological disorders. | Removing children from parents may be more traumatic than the obesity. |
| Equality | All children have the right to a healthy childhood and life. | Obesity affects the poor and minorities to a greater extent, so this policy will disproportionately target these groups. |
| Informed choice | X | Parents are no longer able to make decisions for their child. |
| Social/cultural values | The social value placed on fitness and health is upheld. | The social value placed on parent-child relationships is violated. |
| Privacy | X | The family's and child's privacy may be compromised. |
| Attribution of responsibility | Responsibility for the child's obesity is shared among society and medical professionals. | The parents are directly or indirectly blamed for the obesity and stigmatized. |
| Liberty | X | The parent's and child's liberties are violated. |

Under Which Circumstances Should Obesity Be Considered a Public Health Concern?

The example in table 1 has ramifications for specific individuals in specific circumstances and particularly focuses on minors, who are broadly considered not

fully responsible for their own actions. The justifications and ramifications of broad health-targeted policies affecting ordinary adults are quite different.

Before proceeding, we must distinguish between two distinct uses of the phrase “public health” as a prefix to terms such as “problem,” “concern,” or “issue.” The phrase is often used merely to convey that the problem affects a large number of people. The term “population health” is emerging to express this idea [7]. But in debates about policies that may impinge on individual rights and values, the phrase is used more specifically to denote health problems in which individuals’ actions may not be sufficient to protect them from ill health and collective action may offer such protection. Examples of the latter definition include certain infectious diseases from which protection can be afforded by mass vaccination and toxins in public drinking water supplies, which can be minimized by a variety of government policies.

Using the more specific definition, it is not clear that obesity qualifies as a public health concern in all circumstances [8]. When considering some putative contributors to obesity, such as adenovirus 36 or environmental endocrine disruptors [9], the definition does seem to apply: individuals generally cannot fully detect and protect themselves from exposure to these factors by their own action, and collective action at a societal level mandated by government policies might do so. However, when considering some other putative contributors to obesity such as ingesting excess energy or being insufficiently active, there generally are not external unavoidable *constraints*, as opposed to *influences*, on individuals. Thus, collective action to protect individuals from undetectable or unavoidable contributing factors is not required in such cases.

At this point, we should address a related argument. This is perhaps the most commonly used argument to justify policies about obesity: obesity is costly to society, largely through the healthcare system, and this justifies collectively infringing upon individual liberty to decrease obesity. We do not agree with this argument. Regardless of the cost of obesity, that cost itself does not necessarily justify society’s imposing such policies. The fact that one party (society in this case) voluntarily takes on an obligation to cover some costly benefit to a second party (individual citizens in this case) does not necessarily give the first party the right to dictate the behaviors of the second party. There are several alternatives which include society’s not volunteering to take on the obligation, society’s taking on the obligation but distributing the costs equitably to its members (e.g., charging obese persons more for health coverage), or society’s voluntarily accepting the obligation and then simply agreeing to be “magnanimous” and bear the additional expense of costly behaviors in the interests of preserving individual liberty.

This is not to say that obesity is not a problem. Obesity is associated with many chronic diseases, decreased productivity, and psychosocial difficulties. But if a health policy targeting a putative cause of obesity does not address an issue in which individuals’ actions are insufficient to protect themselves from obesity, then the policy may be unwarranted regardless of cost.

Good Intentions, Unintended Consequences

Various policy advocates insist that obesity needs to be addressed by public policy, either because they reject the definition of public health provided above or because they believe action must be taken despite obesity's not specifically being a public health concern. Innumerable policy recommendations have been proposed or enacted in an effort to reduce obesity, from "sin" taxes [10] and "psychic" taxes [11] to information campaigns [12] and alterations to the built environment [13]. In some cases, the scientific evidence demonstrates fairly clearly that the recommendation will not substantially reduce obesity, which means these policies not only raise ethical concerns but may have no beneficial outcome; other recommendations are simply equivocal—the potential exists for benefits and harms—and the balance between ethical consequences and health benefits is thus uncertain [14].

When the outcomes of a particular proposal are uncertain, especially for interventions grounded in "common sense," one could ask, "How could it hurt to try?" Some ways various policies could hurt, despite good intentions, were previously highlighted [15]. Such negative consequences include direct negative effects and encroachment on individual freedom like the list from ten Have et al. but also include direct costs of resources, damage to scientific and political credibility, and distraction from more promising efforts and policies. In fact, direct, unintended negative consequences of some policy proposals have been demonstrated (table 2).

Table 2. Unintended consequences of actions intended to affect obesity

| Action | Good intention | Documented unintended consequence |
|---|--|--|
| Tax sugar-sweetened beverages (SSBs). | Decrease energy intake to decrease weight. | Increased consumption of beer beyond the decrease in sugar-sweetened beverages [17]. |
| Alert patients to their heavy weight status. | Make the patient aware of a problem as a first step in addressing it. | Patients may feel stigmatized, become depressed and eat more, and avoid future appointments [16]. |
| Labeling calories on vending machine beverages. | Awareness of calories will result in decreased consumption. | Purchases of SSBs increased in some settings [18]. |
| Label "unhealthful" foods with messages that encourage consuming fruits and vegetables. | Increase "healthful" behaviors and decrease "unhealthful" behaviors. | Increased selection of an "unhealthful" snack [19]. |
| Describe certain restaurants and foods as more "healthful" and "low-calorie." | Decrease caloric consumption and shift consumption toward "healthful" foods. | Consumers consumed more calories in side dishes and beverages, and underestimated total meal calories when choosing "healthy" restaurants or main dishes [20]. |

| | | |
|--|--|--|
| Labeling calories and removing value pricing on menu items. | Awareness of calories and eliminating value pricing will decrease energy consumption. | Men ate more calories [21]. |
| Discourage chocolate consumption. | Decrease caloric consumption. | Chocolate consumption increased for some women in some circumstances [22]. |
| Encourage children to consume fruits by incorporating them into games. | Children prompted to eat fruits will increase consumption of “healthful” foods and decrease caloric consumption overall. | Children ate as many calories when prompted by fruit games as when prompted by energy-dense-snack games, did not increase fruit consumption, and ate more overall than when not prompted by food [23]. |

For instance, the “common sense” impetus behind informing patients that they are obese may be the old maxim, “the first step in solving a problem is admitting you have one.” Yet, there is evidence that clinically relevant words to describe a patient’s weight (e.g., morbidly obese and obese) are considered stigmatizing, which patients state may make them avoid future appointments [16].

It is important to note that the good intentions and unintended consequences in the table represent hand-picked examples and these interventions may not be negative in all circumstances. For instance, there is some evidence that the effects of menu labeling on consumer choice can be inconsistent or even positive if delivered in specific ways, including whether or not educational information is included and whether the participants are male or female [21, 24, 25]. Thus, the selected examples in table 2 bring up yet another ethical concern: if a policy intervention benefits one subset of the population but harms another, what action should be taken? One could argue against implementing a policy so as to do no harm to one group, while another could argue that failing to act is tantamount to harming the group that stands to benefit [26, 27].

Minimizing Negative Ethical Consequences in Reversing Obesity

Marieke ten Have and colleagues raise an important complementary point to ethical concerns over policy recommendations: “The fact that objections are raised does not automatically imply that a programme should not be implemented” [4]. When considering an obesity-targeted public health policy, we propose six recommendations:

1. Evaluate whether the proposed policy addresses an exposure that can truly be considered a public health concern [8].
2. Be honest about the quality and quantity of evidence about the policy [14].
3. Generate sufficient, high-quality evidence before implementing the policy and have plans in place to generate quality evidence about the effectiveness of the policy once instated [28].
4. Do not assume there is negligible or no harm from the policy (see table 2).

5. Do not assume that achieving a health benefit overrides respect for other values and ethical principles [4, 29].
6. Given a choice between two or more plausible policies, choose the policy that least compromises ethical values [29].

These guidelines should help prevent us from paving the roads to health with good wishes but unintended consequences.

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MEDICINE AND SOCIETY

Uncle Sam in Your Kitchen: Using Population Approaches to Improve Diet

Kristina H. Lewis, MD, MPH, SM

Despite considerable evidence of harm from poor dietary choices, many Americans continue to make them. The reasons for our collective unhealthful diet are complex and probably vary considerably among individuals. For some Americans, poor diets may stem from a lack of access to better options [1]. For others, there may be a component of addiction-like behavior driving their intake [2]. Most of us would probably assert, though, that our diets reflect conscious choices about what we like to eat and what's most convenient for us.

Regardless of the reasons for poor diet, the consequences of our consumption patterns are significant. In the past few decades, there has been explosive growth in the rates of two conditions directly linked to overconsumption of calorie-dense foods—obesity and diabetes. Once developed, these conditions are difficult to treat with medication or lifestyle changes, and affected patients may increasingly require invasive and expensive procedures previously reserved for only the most extreme cases. In order to ensure that the U.S. population is healthy and productive, and to avoid further crippling our economy with ballooning medical costs from diet-related disease, comprehensive and sustainable changes to American dietary habits are needed.

Changes can be attempted in a number of ways, but in general there are two possible approaches: those that target the *individual* and those that target the *population* [3]. Individual-level interventions are tailored to one person or family's needs; for example, a dietitian's teaching a client what kinds of foods to eat in order for her to lose weight and prevent diabetes, or, more extreme, a bariatric surgeon resecting the patient's stomach to achieve the same goals. Population-level interventions, on the other hand, target the behavior of an entire group of people through policy changes, without specific attention to individual circumstances.

Millions of Americans are at risk of developing chronic disease due to their dietary habits or are already affected—can you imagine using longitudinal, tailored medical approaches to successfully change the behaviors of each of these people? That kind of intervention would require enormous amounts of time and funding, neither of which is currently in abundant supply [4]. Purely individual-level approaches to preventing and ameliorating the effects of diet-related disease are not likely to be cost-effective, which suggests that population-level or policy approaches would increase the efficiency with which resources are used [5, 6]. Developing food policy, however, is not merely an issue of feasibility or effectiveness. It is also necessary to

examine the ethics of using population-level approaches to solve what many politicians and citizens believe to be an individual-level behavioral problem.

In order to do this, it's worth separating food policies into two general categories, each with very different ethical implications. First are policies that *rely on active behavior change* by individuals in order to be effective (we'll call this the "loose" end of food policy), and second, those that *automatically change behavior* (we'll call this the "tight" end of food policy). Loose policies could take the form of educational interventions like ad campaigns and school-based programs that provide information to everyone regardless of personal behavior or beliefs, but ultimately rely on individuals to both understand and comply with the message (i.e., it still comes down to the notion of "personal responsibility" and an active choice). Even something like a soda tax could be considered a loose policy; I can still buy a sugary soda if I want one, but the slightly higher price tag might make me think twice about it.

Policies on the tight end of the spectrum, in contrast, remove the option for personal choice, putting responsibility entirely in the hands of the government or other mandating body. New York's ban on trans fats in restaurants or the removal of red dye #3 by the FDA in the early 1990s are two examples of using a "tight," mandatory policy to change eating behavior. Rather than requiring action by individuals to be effective, these policies required action at the level of the food producer or supplier, thereby removing the opportunity for individual choice.

The Ethics of "Loose" Dietary Policies

Loose policies that are limited to educational initiatives, particularly if the messages are framed positively (e.g., "Drink more water" instead of "Don't drink soda") tend not to generate much friction from an ethical or personal liberties standpoint. Even the most ardent libertarian would argue that consumers' rights are not violated by the provision of information in order to facilitate good dietary choices. Unfortunately, purely educational policies that generate little political resistance are also likely to generate little change (see figure 1) [6-8]. Providing consumers with information about their dietary choices is an important step, but it's unlikely to succeed on its own.

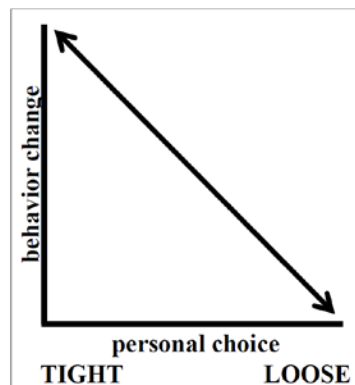


Figure 1. The inverse relationship between protection of personal choice and impact on behavior change as it pertains to food policy.

To achieve more widespread behavior change, informational policies may need to be augmented by more directive policies, such as taxing sugar-sweetened beverages (SSBs). Using SSBs as an example, a tax makes sense from an economic perspective: increase price to drive down demand (and therefore consumption) of products you don't want people to eat or drink. One can even justify the government's intervention in the marketplace by virtue of the externalities associated with SSB consumption (chronic disease, e.g.) that are not currently accounted for in the cost of these products [5]. From an ethical perspective, however, things are a little trickier. Whenever a soda tax is discussed, one of the reflex arguments against it is that it is unethical because it is regressive. Because sodas are disproportionately consumed by people of lower socioeconomic status, goes this argument, and because the beverages favored by economically better-off people will not be taxed, the poor will bear the burdens of the tax disproportionately. Alternately, even if the poor are not the main or only consumers of soda, the tax will be more likely to “work” on them—to dissuade them from drinking soda, depriving them of the pleasure their better-off fellows derive from it—than on those who are better off.

If we expand on the idea of so-called “sin taxes” to include junk foods such as candy, chips, and other calorie-dense, low-nutrient foods, we quickly find ourselves on a slippery slope where the notion of a regressive tax seems very concerning indeed. For people of low socioeconomic status (SES) who do not have good access to healthful foods, junk food may be the primary source of calories, and, while it is unhealthy for them in the long-term, it is necessary for survival in the short term. Furthermore, what might be an imperceptible price change to many could be a real shock for a person living in poverty. Thus, without ensuring that those living in poverty have access to healthy and affordable alternatives, policy makers might inadvertently make it harder for them to afford to feed their families by passing an ill-planned junk food tax.

The Ethics of “Tight” Dietary Policies

Mandates—dietary policies on the “tight” end of the spectrum—directly limit consumer choice by, for example, banning an ingredient or an entire product. Although such policies could have a profound effect on the population's diet, they are viewed by many as too extreme.

Opponents of dietary mandates state that it is not the government's place to interfere in the personal choices of consumers. They believe individuals should be able to eat whatever they want and that, if they are aware of the potential health consequences, their diets are their own responsibility. By this same logic, if individuals assume complete ownership of their dietary choices, they should also be held responsible for the consequences of those choices. If the healthy present-day “me” eats a dozen donuts every day for 20 years, the future sick “me” should not then expect society to bear the costs of my diabetes and coronary disease, right?

As a society and a profession, however, we've decided that those who cannot afford medical care should not die for lack of it, whether or not their condition is a result of

their own behavior. As long as that philosophy remains in place, the cost of caring for diet-related illness will probably continue to rise. Eventually, difficult choices will need to be made about what gets paid for and by whom. If the harm caused to society by limiting consumption on the front end is perceived to be less than that caused by limiting medical care on the back end, a resource conservation argument can be made for some dietary mandates (e.g., trans fat ban). It is important to keep in mind, though, the tension between protecting the public's health and the damage that can be done by removing an individual's freedom. Mandates are least likely to ruffle feathers when they're applied to substances that have clear adverse health effects if consumed in *any* amount (e.g., trans fats, as opposed to sodium), and those (e.g., red dye #3) for which there are available and comparable substitutes.

A related argument against the banning or direct limitation of certain products is that, while health consequences do result from the overconsumption of unhealthful items, not *everyone* overconsumes, and, of those who do, not *everyone* has health consequences. Stated another way—why should responsible, moderate consumers be prevented from drinking Big Gulps because others overconsume them? The same argument is often applied elsewhere—why should responsible gun owners be deprived of their weapons because other gun owners engage in criminal behavior? Why should individual children accept the risks of vaccination to ensure herd immunity? These sentiments express dismay at the prices we pay for living in a democratic society—sometimes what is good for the group might not be the thing we'd like best as individuals. Each of us has a different level of willingness to sacrifice personal liberties for our own good or the good of the population.

The Notion of Personal Freedom in Food Choice

So far, in discussing the various ways that dietary policy might infringe upon personal rights, I've been operating under the assumptions that most Americans' eating habits are based on free choice and that the food marketplace is structured merely to respond to consumer demand.

In reality, there are many Americans who don't have free choices about their diets. The most extreme case is that of children, whose parents and schools make dietary choices for them, and poor adults who live in food deserts and cannot access or afford to purchase nutritious food. Even the rest of us who supposedly "choose" to engage in dietary indiscretions aren't actually making completely free choices. As far as food products go, we're heavily influenced by advertising (hence the hefty budgets dedicated to it by food companies), by price (\$0.99 for a hamburger or \$3.50 for a salad?), and by the formulations of processed foods, which can appeal to a person's palate much more strongly than "whole" foods. Price is heavily influenced by the cost of ingredients, in turn influenced by agricultural policies from seed technology to subsidies. We eat a lot of corn syrup not because we love the stuff and demand that manufacturers give it to us, but because farmers know how to grow corn well, it's subsidized, and therefore corn syrup makes for a much cheaper way for food manufacturers to sweeten their products than using sugar cane.

So, think about it carefully. Is it really your choice to buy that corn syrup-laden candy bar in the grocery store checkout line, or is it an act of impulsivity due to convenience, cost, taste, and proximity (maybe even boredom)? What are your other options? When was the last time you saw an apple, banana or even a bag of trail mix sitting there in the checkout line next to the tabloids? In other words—when you decide what to eat, are you really buying what you want after considering all of your options, or are you just buying what someone else is selling you?

Conclusion

Although policy solutions will likely be necessary to facilitate population wide changes in diet, finding ethical solutions that help more than they harm is going to be complicated. As a policy rises on the effectiveness spectrum, it also generally moves further toward the “restrictive” end of the personal rights spectrum. The key for policy makers is finding the sweet spot between these two opposing interests. That spot will vary depending on what legislation is being considered. For something like trans fats, an intrusive but effective policy was probably justified due to the significant health risks trans fats posed, combined with the ready availability of substitutes. On the other hand, if the government were to try to rid the market of all sugar, there would be angry riots on the Capitol steps.

Before any honest discussion of infringing personal liberties can be entertained, however, the playing field must be leveled when it comes to consumer choice. Until healthful food is widely affordable and accessible to all people, any discussions of how policy might infringe on the right to choose may be misguided.

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HISTORY OF MEDICINE

Behavior Change in America: Public Health, Medicine, and Individual Counseling

Anthony L. Schlaff, MD, MPH

Behavioral counseling is a generally accepted component of primary care medicine. Few policy makers question the need for and wisdom of such practice. Indeed, with the growing burden of behaviorally mediated chronic diseases on population health and medical care costs, it seems increasingly important that physicians counsel their patients on such behaviors as good diet, exercise, safe sex, and the avoidance of tobacco, excessive alcohol, and illicit drugs [1]. A more thoughtful examination of the historical and ethical context of behavioral counseling by physicians, however, underscores a more complex reality. While physicians since Galen have recognized the strong connection between behavior and health, they have not wholeheartedly embraced the practice of behavioral counseling, nor have patients demanded it. In the past, most physicians saw their role as curing or treating diseases that had already developed. More recently, even as a science of effective prevention services has developed, physicians have done a poor job complying with performance of many of these recommended services [2-5]. Many Americans—particularly those who are arguably most in need of preventive services—do not seek them, and even fewer change their behavior on the advice of physicians [6-11]. This is one reason why some health economists and policy makers advocate for making such services free, as was done in the recently passed Affordable Care Act. Why is such a seemingly important activity honored more in the breach than in the observance?

One answer is that behavioral counseling by physicians is not automatically as necessary and logical an activity as it might appear. What prevents a disease and what treats it once it becomes manifest are not necessarily the same or even closely connected. Avoidance of certain behaviors might prevent the development of premature coronary artery disease, but treatment of a myocardial infarction requires a wholly unrelated set of technical skills—use of monitoring equipment, administration of parenteral medications, and procedures such as stenting or bypass surgery. Why should we expect those who have the latter set of skills to, of necessity, have the set of skills we now call motivational interviewing? Lester Breslow argues that our expectation comes in part from our culture's tendency to outsource responsibility for our health to professionals [12]. This is not necessarily a good thing: do we really need doctors to tell us how to live healthy lives? Arguably, this expectation is part of a broader societal trend to medicalize a host of well-being concerns that might be better addressed elsewhere and by other means. We will return later to the ethical dangers of such cultural beliefs and practices.

Historical Background

The preventive orientation of public health and the treatment paradigm of medicine first came together not to address the behavioral antecedents of chronic disease but to attack infectious diseases, the major killers in the United States up until early in the twentieth century [13]. Because many infectious diseases are contagious, treatment is a critical component of prevention. The surest way to prevent tuberculosis, for example, is to make sure no-one with active tuberculosis is present to cough the germ into the air that others breathe. The nineteenth-century sanitary movement was a precursor to integration of public health and medicine. Originally focused on environmental cleanliness, the sanitation movement led to the development of our modern water and sewer systems and evolved to the less politically challenging notion of teaching individuals proper hygiene. This change, partly driven by the science of bacteriology, was also more acceptable to the society at large in the increasingly conservative political environment of a country responding to a massive influx of new immigrants, mostly poor and often in ill health [14, 15]. The “New Public Health,” that emerged in the early twentieth century in response to the bacteriologic revolution resulted in the development of dispensaries and school health programs to identify and treat those who were infected.

Several historical events and trends converged in the early twentieth century to set new expectations for both public health and the medical profession [13, 16]. As the new public health system turned its focus to the individual, it came into conflict with private medical practitioners, and, in response to the expanding political power of that profession, the public dispensaries and school clinics dropped treatment and focused on screening and referring to physicians. In the meantime, the rise of corporations (and corporate jobs), the expansion of the insurance industry, and World War I produced powerful stakeholders who had an interest in screening individuals to separate those at risk for ill health from those who were well enough to be good investments for jobs, insurance, and military service. In response, the concept of screening for infection expanded to include other conditions.

The science behind this expansion of clinical preventive services was weak at best [13]. While studies from the military and insurance physicals showed high percentages of abnormalities which were used to launch major campaigns to have all Americans get a regular physical examination [13], the U.S. Preventive Services Task Force subsequently noted that there is no evidence that comprehensive periodic exams lead to interventions that improve health outcomes [17]. Nevertheless, the medical profession embraced the idea—for the business it could provide; the AMA did so formally in 1922 [13]. Having competed successfully to deny public health the responsibility for *treatment*, the medical profession now claimed for itself the responsibility for prevention, and it did so by embracing a purely individual and medical notion of what constitutes prevention.

Despite medicine’s embrace of prevention, neither the practice nor the promise of clinical prevention was fully realized. Numerous studies have shown physicians comply with recommendations for offering preventive services at low rates [2-5].

Patient adherence to recommendations from prevention counseling, which has been studied primarily in the setting of high-risk groups, tends to be low [6-8]. The effect of counseling is not particularly strong—at least not in the case of the best studied area of counseling: smoking cessation [9-11].

In the second half of the twentieth century, as concerns about health care costs and the need for evidence-based practice intensified, the assumptions behind clinical preventive services were reexamined. The potential for waste and harm in unnecessary screening tests was discovered. First Canada and then the United States organized comprehensive reviews of clinical preventive services [17, 18]. The U.S. Preventive Services Task Force (USPSTF), which published its first guide in 1996, developed a robust methodology for examining preventive services [18]. Although initially designed to assess the evidence for conducting screening tests, this methodology can be and was adapted by the USPSTF to look at preventive counseling as well. The recommendations of the USPSTF are both scientific and ethical: they seek to identify the scope and magnitude of both the benefits and harms of proposed services and to recommend services only when there is clear evidence that the benefits outweigh the harms.

The USPSTF Framework and Behavioral Counseling

In discussing preventive services, we need to distinguish between screening and intervention. A screening test by itself does nothing to prevent disease. Rather, it detects a condition or a high risk for a condition in order to inform a decision about whether preventive steps should be taken. A preventive intervention, in contrast, is designed to ward off the disease or alter its course early in order to prevent subsequent morbidity or mortality. Counseling is one form of intervention. Other forms of intervention include vaccines, medication, or technical procedures.

For a preventive service to be recommended by the USPSTF, it must meet several criteria [18]. The condition the service seeks to prevent must be of sufficient prevalence and severity to justify a population-based effort to identify those at risk. The service must do more good than harm. The benefit-harm balance is particularly of concern because preventive services, particularly if offered to an entire population, are almost certain to provide benefit to only a very small fraction. Everyone is exposed to the preventive intervention, however, and so even very small costs or harm done by the intervention, because they affect so many, may outweigh the benefit that accrues to a small number. Furthermore, the intervention must be shown to make a difference in outcome if applied early, prior to the time that the disease becomes clinically apparent and treatment is instituted.

Most preventive counseling services reviewed by the USPSTF are intended for the entire population or a specific age and gender group. Counseling can also be aimed at high-risk groups. In this model, risk is assessed either through a screening test or by history taking. Counseling is then provided only to those deemed higher-risk, sparing those less likely to benefit. This model exposes a small group to the counseling but exposes the entire population to a screening test. Screening by history

has few risks, although false negatives can result in false reassurance, false positives in unnecessary anxiety as well as subsequent exposure to whatever interventions and follow-up screening flow from the result, and the history taking itself can cause patients embarrassment or other distress. If a screening test is required to determine eligibility for counseling, other risks might be present from the testing procedure itself. A full treatment of the risks and benefits of screening tests can be found in the description of the USPSTF methodology [19].

For the general adult population, the USPSTF has reviewed behavioral counseling in regard to tobacco cessation, alcohol and other drug counseling, seat belt use, injury prevention, sexually transmitted disease prevention, and diet modification [20]. Only for tobacco cessation does the task force give a “category A” recommendation, confirming that there is good evidence that the intervention improves measurable morbidity and mortality at the population level. For most of the others, the task force could not find strong evidence that behavioral counseling by physicians produced significant and lasting changes in behavior sufficient to change outcomes at a population level. While in some cases evidence exists for short-term behavior change in at least a small percentage of patients counseled, evidence is lacking that the percentage so affected and the magnitude and duration of the change that resulted from counseling were sufficient to have significant impact on disease burden.

But can any harm come from physicians recommending to their patients that they eat properly or not smoke? Even if proof of efficacy is lacking, shouldn't counseling be recommended anyway, on the basis that at least some will benefit and no harm will be done? The task force agrees that harms from behavioral counseling were minimal and found little or no evidence of such harm. And, in most cases, it gives a qualified recommendation in favor of counseling on the rationale that we can infer that benefit is likely even if we do not have evidence, and that the harms we have not measured are likely to be small. It is important nonetheless to note that counseling can have negative consequences for the health of the public.

The first harm is opportunity cost. To the extent that behavioral counseling is ineffective (either because it is of no benefit or is misdirected to those who do not stand to benefit), it is a waste of resources—time that a physician might better spend on more useful actions or money that society might direct to other activities.

A second form of harm that can come from counseling occurs when the counseling is incorrectly done or improperly received or applied. Literature on this is again lacking, but an anecdote makes the point. I once treated an elderly Haitian woman who had recently come to the U.S. and who did not speak English. Through an interpreter, I gave her dietary counseling regarding her high cholesterol level. Three months later I received a call from the emergency room. She was being admitted to the hospital for dehydration and malnutrition. Respectful of my authority, but unable to figure out what she should and shouldn't eat, she had given up most eating and drinking completely, making herself quite ill as a result. In this case, harm was, indeed, done.

Even when counseling is “successfully” administered and patients understand and follow the directives, a third harm may come to those who do change behavior at no benefit to themselves. This harm may be nothing more than forgone pleasure—but presumably the need to actively change behavior on advice of the physician means a new pattern of behavior that is less preferred by the individual making the change. If the benefit of the behavior change is small and accrues only to a small number, is it worth the negatively perceived change that a much larger number of people must make?

There is scant literature documenting this kind of harm, but another anecdote may make the point. For many years, I delivered wine to my mother, who lived in elderly housing. She also ate whatever she wanted, having decided that the quality of her remaining years was more important than the quantity. Both she and I frequently heard her octogenarian neighbors who, on seeing her with a glass of wine or with a pat of butter on her bread, would complain bitterly how their physicians had forbidden them such pleasures and how jealous they were. Did these elders truly benefit from, or were they harmed by, their physicians’ advice?

Collectively, these concerns about behavioral counseling do not mean we should refrain from doing it. They do, however, point to the ethical obligation to consider the potential harms and well as benefits of any intervention and to conduct counseling as we should any other intervention: when there is evidence of benefit, when the benefit outweighs the harm, and when we can do it in such a way as to minimize the risks of harm.

Behavioral Counseling and Broader Ethical Concerns

There is a final, and more serious, ethical dilemma in physician behavioral counseling, and it flows from the historic tensions and competition that developed between medicine and public health, described briefly above. Public health research into chronic disease and behavior change over the past half century has made clear that behavior is most effectively changed not by education or counseling, but by altering the conditions in which the behavior occurs, so that people can make the change more easily [21]. This is true in every society and with every behavior studied. I can touch on only a few examples of this phenomenon here.

It has been hypothesized that twentieth century Americans keep themselves cleaner than their ancestors, not because they are taught to be cleaner, but because they have access to heated water systems and easy-to-clean cotton clothing that earlier generations did not have [22]. Raising the price of cigarettes and regulating exposure to secondhand smoke have had much more powerful effects on smoking rates than has physician counseling or even community-based education [23, 24]. Diets are heavily influenced by culture and by what is available, familiar, and affordable, with perceived quality or healthfulness playing a much smaller role [25, 26]. People walk more when their communities are designed for walking. Public health interventions directed at such social determinants have been shown to have significant effects.

This does not by itself mean we should not do individual counseling. There is no need for either-or, so can we not simply pursue both public health and clinical approaches? What, then, is the ethical dilemma?

While we can and probably should do both, we as a society have drastically underinvested in public health efforts at changing the conditions in which people behave. We are a profoundly individualistic society that lives comfortably with the idea that we each determine our own health, and to the extent that it is subject to external control, that control comes almost exclusively from our physicians and from our access to health care. These are myths and are demonstrably not true. At their worst, they lead to a blame-the-victim mentality and lack of coordinated or group intervention [27-29].

This brings us back to the ethical concerns with physician counseling. There is a hint of paternalism in the notion that patients need physicians to speak to them about the harm caused by smoking, diet, lack of exercise, and excessive use of alcohol or drugs. The relationship between knowledge and behavior change is exceedingly complex, but we have learned that knowledge alone does not change behavior [30, 31]. While physician counseling might increase patients' motivation, patients may be motivated but still incapable of making the suggested changes. The root causes of many health behaviors of concern for many people are deeply embedded in the culture and lifestyle of our society, and using a counseling model that assumes exclusively individual control, autonomy, and responsibility for these behaviors can mean that patients feel hectored instead of helped by the advice. The negative emotional response may create yet another form of potential harm: that done to the patient-physician relationship that may in turn adversely impact adherence to physicians' advice on more pressing clinical matters or disinclination to see a physician at all.

The medical profession has both claimed for itself and been granted by society the role of health expert, and both passively and at times actively the profession has accepted that role and perpetuated the myths that individuals control their health destinies and that individual counseling is the one and only method by which behavior is changed. It is in this setting of shared delusion between the public and the medical profession as to the sources of health and well-being that behavioral counseling by physicians poses an ethical problem. To the extent that the reliance on behavioral counseling as the primary mechanism of behavior change perpetuates these beliefs, in some sense it crowds out the far more promising potential of public health modalities to change behavior and improve health.

If behavioral counseling were done properly, with adequate attention to risks as well as benefits, and if the medical profession were fully involved and invested in making sure that counseling was only part of the effort to improve health behaviors to a degree commensurate with its relative efficacy, there would be no ethical dilemma. But this is not the world as it is. So while we should encourage good practice and the

use of effective clinical preventive strategies including behavioral counseling, let us do so with understanding of its historic roots, its limitations, and its ethical challenges. And let us consider how to construct systems—environmental, social, and political—in which healthy behavioral choices are the easiest and most natural choice to make, and so they are made and acted upon.

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HISTORY OF MEDICINE

Development of the Biopsychosocial Model of Medicine

Micah R. Sadigh, PhD

Dennis Novack writes, “Despite broad endorsement of the biopsychosocial model by medical educators, United States medical education is predominantly biomedical in focus. Partly because of that biomedical focus, the United States health care system is in crisis” [1]. Because the biomedical model of disease has been the prevailing one in our lifetimes, it may appear that the biopsychosocial model of health is a new concept, at odds with the more widespread “magic bullet” approach to treatment. But, as we will see, medicine has been considering the interaction between disease processes and the patient’s life circumstances for a long time.

History is a most valuable teacher, the conveyer of much wisdom; learning about the evolution of ideas and the development of a discipline can show us much that is relevant in our time. The role of psychological factors in the onset of disease should not be viewed as anything new to the field of medicine. Indeed, we might more accurately see this as an extension of the wisdom of the physicians of long ago who taught the importance of first gaining a more comprehensive view of the patient than merely focusing on the symptoms or manifestations of disease. To Socrates is attributed the exhortation that “neither ought you to attempt to cure the body without the mind; and this...is the reason why the cure of many diseases is unknown...for part can never be well unless the whole is well” [2]. “It is far more important to know what person the disease has,” Hippocrates told us, “than what disease the person has” [3]. More than a thousand years after Hippocrates, this admonition came to play a significant role in the works of the physician and philosopher Galen, who made a decisive connection between temperament and disease [4].

Relevant concepts of health can be found in the teachings of twelfth-century ethicist and physician Moses Maimonides. Maimonides’s view of patient care was inspired by wisdom found in the pages of the Talmud and the teachings of Hippocrates, Aristotle, Galen, and others [5, 6]. Through the integration of such wisdom and by emphasizing the multidimensional nature of each patient, he added to the science of medicine the art of administering it [7]. Sidney Bloch describes Maimonides’s teaching thus: “whereas the study of a medical text is straightforward, the art of its application is intrinsically challenging. The doctor is faced with a particular patient, with a particular bodily constitution, and at a particular point in time” [5]. Instead of making the disease the main focus of treatment, the patient as a whole should occupy that central place. Maimonides cautions, for example, about the role of negative thoughts regarding either the future or the past in the exacerbation of symptoms; emphasizes that behavioral changes can add to the success of the treatment; and

identifies social influences, both positive and negative, as important to proper treatment [8]. An integrated, multidimensional conceptualization of disease and patient care thus emerges in the teachings of Maimonides, which capture the essence of the biopsychosocial model [6].

The emerging germ theory of disease held the attention of Louis Pasteur and many of his protégés in the mid-nineteenth century. This was the foundation for the power of the biomedical model throughout most of the twentieth century. At the same time, though, one of Pasteur's contemporaries, Claude Bernard, suggested that for the germ to grow the "terrain" of the body must be first prepared [9]. This proposition added an interactive dimension to the linear germ theory model. Indeed, it has been reported that, late in his life, Pasteur had arrived at a similar conclusion: he repeated to himself, even on his death bed, "Bernard avait raison. Le germe n'est rien, c'est le terrain qui est tout" (Bernard was right. The germ is nothing, the soil is everything) [9]. Decades later, in the early twentieth century, Hans Selye, the father of stress research, demonstrated how excessive stress just did that: it prepared "the terrain of the body" so that disease could grow [10].

Selye presented ample evidence that stress may act as a major contributor to a variety of disorders [10]. The importance of recognizing the interaction between the body and its surroundings that guided Selye's work was earlier proposed by another giant in the field of physiology, Walter B. Cannon, whose seminal 1932 work, *The Wisdom of the Body*, shed new light on the dynamic interactions between the body and its surroundings [11]. Cannon proposed the existence of homeostasis—a variety of biochemical changes through which the body has the capability to maintain its internal integrity in spite of external changes such as heat and cold. Yet maintaining homeostasis in the face of excessive external demands may result in the derailment of vital physiological functions, contributing to breakdown and disease [10]. Fifty years later, a more expanded and comprehensive concept of this phenomenon suggested changes in behavior occurred to cope even with anticipation of demands (physical or psychological), perhaps contributing to maladaptive behaviors and the ensuing pathophysiology, and termed the mechanism allostasis [12].

Another important contribution to the development of a broader understanding of medicine took place in the early decades of the twentieth century, when the role of the unconscious and personality factors were demonstrated in the etiology of many disorders in what came to be known as psychosomatic medicine. Psychosomatic medicine introduced an indispensable dimension to the practice of medicine, especially in terms of better diagnosing idiopathic conditions that were refractory to a variety of interventions [13].

In the early 1920s, the pioneering work of German neurologists Oscar Vogt, Johannes Schultz, and Wolfgang Luthe provided us with an in-depth understanding of psychophysiology that demonstrated how mental states can directly affect physiological processes [14]. Such discoveries became the very essence of a psychophysiological self-regulation technique known as autogenic training that is

taught in many European medical schools as an adjunctive treatment for a variety of medical disorders [15]. Autogenic training focuses on reducing the activity of the central nervous system through the repetition of phrases that promote bodily relaxation. Decades of research have provided consistent evidence that this and other self-regulation techniques can have clinically positive effects on conditions such as hypertension and certain forms of headaches and may be helpful in the management of chronic conditions, such as chronic pain [15]. Such discoveries brought forth a better understanding of stress-related disorders and the role of psychological states in better managing them.

This brings us to the contributions of the physician and visionary George Engel [16] and the now commonly recognized biopsychosocial model of medicine. Engel's conceptualization adds the critical psychological and social factors to the traditional, linearly conceived biomedical model. Engel wrote that "the biopsychosocial model is a scientific model constructed to take into account the missing dimensions of the biomedical model. To the extent that it succeeds it also serves to define the educational tasks of medicine" [17].

This model brings together decades of empirical research that point to the need for the development of a more integrated, system-oriented view of health and disease. It is important to note that the biopsychosocial model does not contradict the time-tested biomedical model; it simply adds to it the missing psychological and social variables that are essential to effective diagnosis and treatment. These psychosocial variables offer a more individualistic, less mechanical approach to patient care. While the biological mechanisms may appear nearly identical from person to person, emotions, cognitive factors, and the presence or absence of social support add uniqueness to each patient. Considering these factors can lead to better understanding of the patient's condition and to interventions that are likely to expedite the amelioration of symptoms and, more importantly, promote well-being. As Borrell-Carrio and colleagues wrote, "George Engel's most enduring contribution was to broaden the scope of the clinician's gaze. His biopsychosocial model was a call to change our way of understanding the patient and to expand the domain of medical knowledge to address the needs of each patient" [18].

Conclusions

Although the premises of the biopsychosocial model are, indeed, very sound, its potential has not been fully realized, particularly in medical training. According to Novack, most medical schools dedicate only a handful of hours to training in the biopsychosocial model [1]. This despite the steady stream of studies that have provided consistent support for the immense benefits of this integrative approach to the practice of medicine. Time and again, great medical minds proposed a dynamic, integrated approach to the diagnosis and treatment of the patient. Above all, and most importantly, they warned against the dangers of fragmenting the patient into parts, for, in so doing, symptom amelioration becomes the focus of treatment, the integrity of the patient is compromised, and the healing process is derailed—the patient becomes a mechanical structure in need of repair. Repair and healing are not

one and the same; the former focuses on the “broken” parts and proceeds to attend to such parts in isolation, while the latter promotes integration of all the systems that are critical in achieving well-being and reestablishing health and healthy function.

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OP-ED

The Physician's Role in Nutrition-Related Disorders: From Bystander to Leader

Neal D. Barnard, MD

More than 100 million Americans currently have diabetes or prediabetes. While the financial cost of diabetes, estimated at \$116 billion in 2007 [1] and rising every year since then, is a growing burden on insurers, government health programs, and businesses, the personal costs are incalculable. Diabetes leads to heart attacks, blindness, amputations, renal failure, and loss of more than a decade of life, on average [2]. Many people with diabetes also have high blood pressure, abnormal cholesterol levels, and obesity, all of which require additional treatment and lead to additional complications.

What is the role of the physician in a disease that is caused mainly by poor diet and lifestyle habits? Do we have a right to push patients to make major lifestyle changes? Do we have obligations toward those who are at risk but have not sought our help?

Some useful lessons come from the war on tobacco. In 1980, I was an intern at the George Washington University Hospital in Washington, D.C. Walking into the hospital gift shop to buy a pack of Merit Menthols, I often ran into one of our senior surgeons buying Marlboros. Shocking as it may sound today, many doctors smoked back then. The physicians' lounge had air you could have cut with a knife. Our hospitalized patients were free to smoke, too—in bed even, so long as open oxygen was not flowing.

We were not fools. We knew that smoking caused cancer. But we had stressful lives and told ourselves that cancer was a long-term process. We imagined that we could take our time in quitting.

Today, that scenario has changed dramatically. When I quit smoking in 1984, lung cancer incidence among men was 102 per 100,000; by 2006, it had dropped to 71 per 100,000, and it keeps spiraling downward year by year. In women, lung cancer rates have finally plateaued, reflecting the later rise in tobacco use among women [3]. Today, it would be tough to find a physician who puts match to cigarette.

How did this change occur? First, physicians and the public became aware that the smoker was not the only one at risk. The dangers of secondhand smoke to children, spouses, and co-workers added urgency to the call for action. Second, doctors realized they were more effective at counseling patients to quit smoking if they no longer had tobacco stains on their own fingers. Third, as hospitals began to ban

smoking, businesses and government offices followed suit. In other words, doctors went from being bystanders—or even enablers—to leading the fight against smoking. By making the conscious decision to address a deadly epidemic, the medical community has saved countless lives.

If the previous generation battled tobacco, the current generation faces an even bigger fight against unhealthful food. Here are the battle lines:

In 1909, the U.S. Department of Agriculture began tracking what Americans eat. Over the following century, annual per capita meat consumption soared from 123.9 pounds in 1909 to over 200 pounds in 2004. In the same interval, annual cheese intake rose from less than 4 pounds per person to well over 30 pounds. That extra 75 pounds or so of meat and 30 pounds of cheese—per person per year—have contributed a load of fat, cholesterol, and calories that are joined by more calories from sugar, the intake of which has surged as well [4].

Although some may be tempted to blame our girth on sloth, some studies show that a lack of exercise has played virtually no role in the recent rise in obesity [5]. The obesity epidemic and the ill health that has come along with it have been fueled by unhealthful food.

Who is at particular risk? Among the most consistent findings of nutritional epidemiology is that populations that have made meats and dairy products their staples have higher risk of diabetes, obesity, hypertension, cardiovascular disease, and several forms of cancer, among other problems, than those whose diets are based on vegetables, fruits, whole grains, and legumes. A 2009 study zeroed in on 60,903 Seventh-Day Adventists—a population chosen because nearly all avoid tobacco and alcohol, while varying in dietary patterns. Meat eaters turned out to be the heaviest group. Those who limited their meat intake to fish were somewhat slimmer, on average, than the meat eaters, but were nowhere near as slim as full-time vegetarians. And the only group that stayed well within the boundaries of a healthy weight were those who avoided animal products altogether. Diabetes risk followed the same gradient. It was common in meat eaters (7.6 percent of adults over age 30) and rare in people who avoided animal products (2.9 percent) [6]. Many other studies have made similar findings, showing that meaty diets are risky, while plant-based diets are potent for preventing obesity, lipid disorders, and diabetes [7-9].

Consequent to these population studies, plant-based diets have been put to the test in randomized clinical trials. In 1990, Dr. Dean Ornish published the results of a study in which patients with coronary disease were asked to begin a low-fat vegetarian diet, along with other healthful lifestyle changes. Cholesterol levels fell decisively, as did body weight. After 12 months, angiograms showed reversal of atherosclerotic lesions in 82 percent of participants. After 5 years, coronary events were cut to less than half the rate seen in a control group [10, 11]. Our own research team has used a similar regimen to address other conditions [12], most notably diabetes [13], leading the American Diabetes Association to accept this approach for type 2 diabetes

management [14]. Plant-based diets are the nutritional equivalent of quitting smoking.

What does this mean for doctors? Do we need to share this information with patients? Do we need to change our own diets? Where do we begin? From studies of diet and health, several key points emerge:

1. Like smoking, unhealthful eating habits affect the whole family. When parents eat poorly, their children do, too. Obesity, hypertension, diabetes, and cardiovascular disease spread around a family like a foodborne illness and represent not so much shared genetic traits as shared recipes. Just as doctors maintain a high level of suspicion about child abuse and other often-hidden problems, so they should be vigilant about unhealthful eating habits that put family members at risk.
2. When doctors take care of themselves, it shows. A 2011 survey of 500 primary care physicians showed that those at a healthy body weight were much more likely to recognize obesity and to feel confident in addressing weight issues in their patients than physicians who were overweight [15].
3. Medications are no substitute for dietary interventions. While medications can counter some of the effects of risky dietary habits, it is essential to address the underlying nutritional causes of diabetes, lipid disorders, and hypertension. Rather than viewing pharmacological interventions as “conventional” and nutritional interventions as “alternative,” these views should be reversed: Medications for these conditions should be considered “alternative” treatments when nutritional improvements have not gotten the job done.
4. Pessimism is not justified. Yes, there are challenges in changing any sort of longstanding habit. But recidivism was a problem in smoking cessation, too. Many patients stutter-stepped their way to abstinence. With continued support, they got there. The same is true when the lure of burgers, brie, and sugared beverages overpowers patients’ resolve. When the going gets tough, the tough get another good pep talk from a caring physician.
5. *Every* patient has food issues. While it is tempting to send only those with high cholesterol or an elevated body mass index for diet counseling, the fact is, nutrition is an issue for everyone, whether it manifests as obesity, diabetes, coronary disease, or colorectal cancer. Studies of casualties during the Korean War showed that heart disease was common even in young, normal-weight, physically fit American soldiers. Of 300 men autopsied, 77 percent showed significant atherosclerosis [16].
6. Practice must be evidence-based. Just as our prescribing practices must be founded on solid evidence, the same is true for dietary advice. Hunches, fads,

and one's own personal preferences are no basis for guiding therapy. Not only is there abundant evidence of the effectiveness of dietary interventions, there is also evidence regarding their acceptability. In clinical trials, a low-fat vegan diet is as acceptable to participants as any other therapeutic diet, and considerably more effective clinically [17].

7. Delegate. Many clinicians feel ill-informed on nutritional issues [18, 19]. While they are well aware that type 2 diabetes is not caused by a metformin deficiency, they are hard-pressed to know how to tackle the food habits that are at its core. Little matter. Primary care physicians do not take their own X-rays or run their own urinalyses, and they do not need to do their own diet counseling either. That is the job of a good dietitian. The physician simply needs to know that nutrition is important and must communicate this clearly to the patient while providing a solid referral.

So, do we doctors need to change our own diets? Do we need to share diet information with patients? Doctors not only need to encourage patients to make major lifestyle changes, they have an obligation to do so, and must include in their consideration those family members who may not be in the examination room but who are put at risk by bad food habits. Here is how to begin:

- Turn waiting time into learning time. Patients pacing around examination rooms scour the fine print on the certificates and diplomas and flip through old magazines while waiting for their doctor to arrive. Clinicians can turn that time to advantage with nutrition-oriented posters and booklets. More than one smoker was motivated to quit by a booklet in a medical office, and the same may be true of people who need a dietary improvement.
- Talk with patients about the power of foods, and be ready with a dietetic referral.
- Invite patients to an after-hours nutrition class held in your waiting room. Patients with diabetes, weight issues, or other diet-related problems can be efficiently taught in groups by a qualified dietitian.
- Make our hospitals exemplary. Just as hospitals made the conscious decision to go smoke-free, healthfulness should be the rule for foods served to patients and visitors, food vendors renting space on hospital grounds, and wellness programs offered to employees.

It is time for doctors and hospitals to make the transition from being bystanders in food-related illnesses to becoming role models and leaders in the fight for health. If it sounds like a tall order to reform our own diets and to guide our patients to do the same, the payoff is enormous. Like the successes enjoyed in the war on tobacco, victory over unhealthy foods will save more than money. It will save countless lives.

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