Mission: The Permanente Journal is published for physicians, practitioners, and salaries to create and to deliver superior health care through the principles and benefits of Permanente Medicine.

Permanente Medicine is preventive, innovative, evidence-based, population care practiced by a multispecialty group, using an electronic, health and medical record, and focused on patient relationships and outcomes.

Circulation: 25,000 print readers per quarter, and accessed by 539,000 unique Web readers in 2009 from 164 countries of the world.

Original Research & Contributions

4. Patients’ Perspectives on Nonadherence to Statin Therapy: A Focus-Group Study

Veki Fung, PhD, Fiona Sinclair, PC, MD; Huifan Wang, PhD, Diane Dailey, MD; John Hsu, MD, MBA, ABCE; Ruth Stuber, MD

Nonadherence to statin therapy is associated with poor cardiovascular outcomes. Study participants, with a one- to six-month gap in drug supply, identified factors that contributed to their discontinuing therapy: nonadherence; including concerns on experiences with adverse effects; uncertainty about the benefits or importance of statins for their overall health, and lack of convenience. Participants desired more information about statins.

11. Alcohol and Lung Airways Function

Tatlin T Sia, MD; Natalia Udaltsova, PhD; Carla Johansen, MD, PhD; Arthur L Klatsky, MD

Limited data suggest that moderate alcohol drinkers may have better lung airways function than abstainers. The authors studied the relationship in 177,721 members of a comprehensive health plan. For each measure studied—FEV1, FVC, and FEV1:FVC—persons reporting two or fewer drinks per day or three to five drinks per day had better airways function than nondrinkers (p < 0.001), but heavier drinkers had worse function.

19. The Extended Surgical Time-Out: Does It Improve Quality and Prevent Wrong-Site Surgery?

Arthur L Klatsky, MD; Carlos Iribarren, MD, PhD; Stanton T Siu, MD; Natalia Udaltsova, PhD; Ruth Shaber, MD; John Hsu, MD, MBA, MSCE; Huihui Wang, PhD; Diane Dai, MD; Vicki Fung, PhD; Fiona Sinclair, PA-C

The authors considered the extended surgical time-out (STO) before anesthesia induction as a successful intervention to eliminate wrong-site surgery. How-ever, STO placed the responsibility on the surgical team and system, rather than with the individual surgeon.

24. Obesity: Problem, Solution, or Both?

Vincent J Politi, MD, FACP; Kathy Lekites; Victoria Pepper, MD; Albert Kay, MD

The authors are convinced that obesity is widely misunderstood, as is the usual program they have operated safely and effectively for more than a quarter century, involving prolonged absolute fasting, with the use of a supplement, and a lengthy and complex group program to explore the basis of each participant’s enormous compulsive use of food. Addressed are safety, observed origins of obesity, treatment programs, and outcomes.

32. Reviewing Manuscripts for Biomedical Journals

Cazi M Carmel, MD, FACEP, FAEM

Writing for publication is a complex task. Authors have varying emotions related to the process of writing for scientific publications. This article discusses the review process within the biomedical literature, the importance of reviewers to the scientific process, responsibilities of reviewers, and qualities of a good review and reviewer. This article also describes essential elements of a submitted manuscript, with the hopes of improving scientific writing.

Multiple Case Study

41. The Prayer Prescription.

Gerald Salzman, MD

Many patients welcome a chance, at the conclusion of their office visit, to say a prayer for their well-being, which is a socially accepted expression of care and, for the internist author, an expression of empathy, hope, and gratitude. The author has prayed with people from various religious backgrounds—Christian, Native American, Hindu, Buddhist, and Jewish.

ON THE COVER

“Tall Trees” by Suzanne Ackley, MD. These magnificent trees are Giant Sequoias in the General Sherman Giant Forest in Sequoia National Park, Sierra Nevada, California. Dr Ackley took advantage of the misty appearance created by the controlled burns set by the National Park Service to aid the ecological balance of the area. Photography continues to be an ongoing passion for Dr Ackley, which she pursues with her husband on tours of the National Parks. Dr Suzanne Ackley is an Orthopedic Hand Surgeon with Southern California Permanente Medical Group in Orange County. She lives in Newport Beach, CA.

Communication: Your Most Important Tool for Practicing Medicine

Why It’s the Outcomes!

- Create successful and efficient patient visits
- Overcome challenging conversations
- Use HealthConnect effectively
- Find local classes

Visit the Clinician Patient Communication Web site: http://apex kp.org/comm

The University of New Mexico Health Sciences Center, Office of Continuing Medical Education and The Permanente Journal present

The ELEVENTH ANNUAL Taos Writing Retreat for Health Professionals

August 1-7, 2010 at the historic Mabel Dodge Luhan House in Taos, New Mexico
www.taoswritingretreat.com

Register early—conference is limited to 15 attendees.
For more information about registration, call Lois Montoya at 505-272-3942 or e-mail mmontoya@salud.unm.edu.

For complete conference details and registration information, please visit www.meetingsbydesign.com or call 510-527-8800.

Register early—conference is limited to 15 attendees.
For more information about registration, call Lois Montoya at 505-272-3942 or e-mail mmontoya@salud.unm.edu.
CLINICAL MEDICINE

46 Image Diagnosis: Interesting Plain Film Radiographs from the Emergency Department.
Gus M Garmel, MD, FACEP, FAAEM

Two traumatic injuries are displayed: an adult distal radius fracture (obvious) and distal radioulnar joint dislocation (often missed); and a common distal radial torus or buckle fracture in a child, often missed because extremely subtle.

47 The Use of Problem-Knowledge Couplers in a Primary Care Practice.
Charles Burger, MD

The unaided human mind has limitations in decision making when faced with a complex set of data. The author describes how he and associates integrated “problem-knowledge couplers”—the clinical decision tool developed by Lawrence Weed, MD—into their Internal Medicine practice in Portland, ME.

Corridor Consult

51 The Hoarse Patient: Asking the Right Questions.
Ji-Eon Kim, MD; Barry Rasgon, MD

Patients describe hoarseness as a change in the quality of their voices. Common among patients in the ambulatory care setting, its causes—anatomic, functional, neurologic, infectious, environmental, and neoplastic—can be benign and self-limited or life threatening. The management of two cases is presented.

54 Working with the Noncompliant Patient.
Fred Kleinsinger, MD

Compliance here refers to the mutually negotiated physician–patient shared decision and agreement. This article offers practicing clinicians tools for working with the noncompliant patient—mirroring, “I” statements, developing and reinforcing self-efficacy, and enlisting support—and offers approaches to denial, depression, dementia, cultural issues, drug or alcohol dependence, and cost of treatment.

COMMENTS

61 A Physician Prescription for the Nursing Shortage.
John H Cochran, MD, FACS

The Colorado Permanente Medical Group, a large multispecialty physician group in Denver and Boulder, embarked upon the “Preferred Clinical Partner Program” to leverage physician leadership to participate in solving the nursing shortage through working clinical partnerships and funding initiatives: nursing scholarships, advanced training, and building and expanding nursing simulation laboratories.

64 Evidence-Based Medicine and the Physician-Patient Dyad.
Howard I Kushnert, PhD

Evidence-based medicine (EBM) can serve as a valuable tool when properly understood, but should not be regarded as the all-encompassing panacea for the future of medicine. As with the promiscuous and often exaggerated labeling of a variety of relatively benign behaviors and conditions as risk factors, uncritical reliance on EBM can result in serious side effects.

NARRATIVE COMMENTARY

78 Exploring Health Care and Medical Tourism in a Modernizing Society: Journey in Chennai, India.
Janani Krishnaswami, MD

A young student returns to the site of childhood family vacations to complete a medical “rotation” in the clinic of a renowned physician who blends alternative and allopathic medicine. She gains insight into the dichotomy created by a country that is tackling basic deficiencies in public health indicators while supporting an “extreme makeover” of health care worth nearly 15 billion rupees to support over 150,000 patients who fly in from around the world to receive comparatively lower-price treatment or escape long waiting lists.

Soul of the Healer

Original Visual Art

18 “The Cafe”
C Shore

31 “Three Mushrooms, Latourell Creek”
David S Emmons, LCSW

69 “Tropical Paradise”
Lester DR Thompson, MD and Pamela A Thompson, MFA

77 “Forest Innocence”
Robert W Hogan, MD

Book Reviews

Page 90
Patients’ Perspectives on Nonadherence to Statin Therapy: A Focus-Group Study

Vicki Fung, PhD
Fiona Sinclair, PA-C, MHS
Huihui Wang, PhD
Diane Dailey, MD
John Hsu, MD, MBA, MSCE
Ruth Shaber, MD

Abstract
Context: Nonadherence to statin therapy is associated with poor cardiovascular outcomes.
Objective: We explored factors and perceptions that contribute to statin therapy nonadherence.
Design: We conducted a qualitative study that was based on three patient focus groups using a structured discussion guide to explore factors related to statin therapy nonadherence, information sources, perceptions of statins and cardiovascular risks factors, and suggestions for improving adherence.
Participants: We enrolled 18 adult patients of an integrated delivery system who had been newly prescribed a statin between November 2006 and August 2007, with a subsequent one- to six-month gap in drug supply as documented by automated pharmacy data.
Measures: We performed content analysis of verbatim focus-group transcripts to assess themes within each domain.
Results: Study participants identified many factors that contributed to their statin therapy nonadherence, including concerns or experiences with adverse effects, uncertainty about the benefits or importance of statins for their overall health, and lack of convenience. Concerns about the adverse effects of statins were a dominant theme. Although most participants believed that having a high cholesterol level is unsafe, many were unsure about their personal need for statins if they were making other lifestyle changes or had only borderline high cholesterol levels. Participants suggested that systematic follow-up, as well as greater information about the risks and benefits of statins and the merits of alternative approaches for lowering cholesterol, could have improved their adherence to therapy.
Conclusions: Many patients reduced statin use because of concerns about adverse effects and desire for more information about statins. Effective interventions that address patients’ underlying concerns and perceptions are needed to improve statin therapy adherence.

Introduction
Hydroxymethylglutaryl–coenzyme A reductase inhibitors (statins) are the most commonly prescribed medications for decreasing lipid levels. In 2005, 29.7 million individuals in the US were prescribed statin therapy. There is considerable trial evidence that statins are effective medication therapy for reducing cardiac and cerebrovascular morbidity and mortality. Studies also suggest, however, that patients’ adherence to statin therapy is suboptimal and that persistence among those newly prescribed statins is poor. For example, one study found that 40% of elderly patients lacked adequate statin supply three months after receiving a prescription, and 60% lacked adequate supply after one year. Poor adherence to statin therapy is associated with adverse health outcomes, including higher hospitalization rates and increased nonpharmacy medical costs.

Earlier studies have identified patient characteristics associated with statin therapy nonadherence, such as younger age, female sex, fewer comorbidities, and greater out-of-pocket costs. Few studies, howev-
er, have examined underlying patient perceptions or attitudes that contribute to differential therapy adherence levels. A survey study reported in 2007 suggested that patients who were concerned about the adverse effects of statins or uncertain about the potential benefits were more likely to discontinue statin use.\textsuperscript{18} Gaining a better understanding of the range of underlying motivations for discontinuing therapy is critical for designing effective interventions. Identifying the types and sources of information patients use to learn about statins and their perceptions of cardiovascular risk factors could also improve clinician–patient communication about statins.

We conducted focus groups with patients of an integrated delivery system to examine these factors and to elicit suggestions for what could improve patients’ adherence to statin therapy. We focused on adult patients who had a gap of one month or longer in drug supply within the first six months of receiving a new statin prescription.

**Methods**

**Setting**

Kaiser Permanente Northern California (KPNC) is an integrated delivery system that provides comprehensive care, including inpatient, outpatient, and pharmacy services, to more than three million members. KPNC guidelines for adult cholesterol management recommend medication therapy for patients with low-density lipoprotein cholesterol levels >130 mg/dL, without established coronary artery disease (CAD). Medication treatment for dyslipidemia is also recommended for all patients with CAD or CAD risk equivalents, including cerebrovascular disease, peripheral arterial disease, abdominal aortic aneurysm, diabetes mellitus (age 40 years or older), and chronic kidney disease (stages 4 and 5). Simvastatin is recommended as first-line drug therapy and is available at the generic drug copayment level. The guidelines are available to all KPNC physicians and serve as recommendations but not requirements for clinical practice. Before the approval of generic simvastatin in June 2006, lovastatin was the preferred statin in the KPNC formulary; patients had generally low copayments for generic drugs ($0–$35 for a 100-day supply).

**Study Population**

We conducted focus groups with KPNC patients who received a new statin prescription and had a subsequent gap in drug supply. The target population included patients who received an index statin prescription between November 1, 2006, and August 15, 2007, with no statin dispensed during the preceding 24 months and drug supply gap of one to six months after the index prescription and the date of selection for the study population (August 15, 2007), allowing for carryover of remaining drug supply from month to month. All study participants were 18 years or older, with continuous membership and pharmacy benefits for 24 months before the index prescription and through the selection date (n = 7700).

**Recruitment and Focus-Group Protocol**

We contacted the clinicians of 1500 randomly selected patients from the target population for approval to phone their patients to invite participation. We confirmed that patients had not been taking statins as prescribed during the recruitment phone call. Patients could elect to participate in one of three focus groups that were conducted in two different locations, and they received a $50 gift card for participation. Recruitment for each group ended after 12 patients per group agreed to participate; this decision was based on our goal of including approximately 6 to 10 patients per focus group and estimated no-show rates that were based on the moderator’s previous experience with the KPNC membership. The protocol and informed-consent forms for participants were approved by the Kaiser Foundation Research Institute’s institutional review board.

All focus groups were conducted by a professional moderator in English, using a detailed discussion guide developed by the research team. We examined four main areas: 1) patients’ experiences with statins, including how they took or take them and reasons for not taking them as prescribed; 2) information patients received about statins from their physician, pharmacists, or other sources; 3) patients’ perceptions about statins, including the potential benefits and risks of statins; and 4) suggestions for what could have helped them take their statins and improved their adherence to therapy.

Each group was asked the same set of open-ended questions, and each focus-group session lasted two hours. Participants gave opinions on a voluntary basis, but all were asked to state why they stopped taking statins. The moderator also used probes included in the discussion guide to ask specific questions as needed, particularly about potential barriers to therapy adherence.

**Content Analysis**

The focus groups were audiotaped, and their discussions were transcribed verbatim. The study team identified major themes, and two researchers independently coded relevant passages into one or more of the themes;
new themes were added if appropriate. The rate of agreement between the two coders was 91%; cases of disagreement were discussed by a larger group and resolved by consensus.

**Results**

The majority of eligible study participants were prescribed lovastatin and had copayments of $\leq 15 for generic and $\leq 35 for brand-name medications (Table 1). The focus groups were conducted with a total of 18 participants with a mean age of 61 years; 14 participants were prescribed lovastatin and four were prescribed simvastatin. Seven participants were members of the health system’s hypertension registry, and three were members of the diabetes registry.

**Statin Use**

Patterns of statin therapy nonadherence varied across the focus-group participants: four patients did not take any statins after receiving the initial prescription; five took the statin for less than two weeks; six took their initially prescribed statin for a longer period of time (eg, more than two weeks) before stopping use; two participants took statins intermittently or at a lower dose than prescribed; and one participant did not provide this information. Seven participants reported that they told their physicians about the change in their statin use.

**Reasons for Therapy Nonadherence**

The participants identified a total of 15 reasons they did not take statins as prescribed (Table 2), which fall into four major categories: 1) concerns or experiences with adverse effects, 2) uncertainty about the benefits or importance of statins, 3) lack of convenience, and 4) other (being too ill to take statins; wanting to drink grapefruit juice, which they were instructed to avoid because it inhibits the metabolism of statins; and preferring to take a brand-name statin instead of the prescribed generic statin).

**Concerns About Adverse Effects**—Many participants expressed concerns about potential long-term effects of statins, including specific concerns such as liver and kidney damage and depletion of coenzyme (co) Q₁₀. In each of the focus groups, the participants talked extensively about the potential adverse effects of statins, and for many, these concerns were the primary reason they stopped taking statins. For example, one respondent expressed her specific concerns, whereas another noted his general fears about statins:

> "If you could get a cholesterol drug that didn’t degrade the muscles and didn’t endanger my kidneys or my liver, I think I would take it in a second."

> "I didn’t really like taking [lovastatin] because I had heard some negative things about it before. It was hard on your system in some ways. … It wasn’t good to take a lot of it for a long time. I can’t remember specifics; I just heard that it was kind of a powerful thing and better not to take it if you can avoid it."

In conjunction with their concerns about the adverse effects of statins, some patients expressed a preference for controlling their cholesterol via lifestyle changes, such as exercise and diet, or alternative therapies, including herbal remedies:

> "The pamphlet they gave me with the medication gave me all of the after effects, and I didn’t like those effects. One of them was [that] once I start taking [statins], I have to continue them … so I did not take it. I went on the oatmeal diet four to five days a week. I’m still on it."

A number of patients noted that they would like their physicians to discuss these options with them before prescribing statins:

> "I wanted options: A and B. Healthier options like work out, lose weight—those kinds of things—instead of just beading off to drugs."

---

**Table 1. Target study population characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>&lt;35</td>
<td>2.9</td>
</tr>
<tr>
<td>35–44</td>
<td>12.3</td>
</tr>
<tr>
<td>45–54</td>
<td>26.4</td>
</tr>
<tr>
<td>55–64</td>
<td>27.3</td>
</tr>
<tr>
<td>65+</td>
<td>31.0</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>49.4</td>
</tr>
<tr>
<td>Men</td>
<td>50.6</td>
</tr>
<tr>
<td>Generic name of statin on index prescription</td>
<td></td>
</tr>
<tr>
<td>Lovastatin</td>
<td>69.8</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>28.1</td>
</tr>
<tr>
<td>Atorvastatin calcium</td>
<td>1.5</td>
</tr>
<tr>
<td>Pravastatin sodium</td>
<td>0.6</td>
</tr>
<tr>
<td>Rosuvastatin calcium</td>
<td>0.1</td>
</tr>
<tr>
<td>Fluvastatin</td>
<td>0.0</td>
</tr>
<tr>
<td>Copayment</td>
<td></td>
</tr>
<tr>
<td>Generic, $0–$7; brand, $0–$20</td>
<td>30.3</td>
</tr>
<tr>
<td>Generic, $10–$15; brand $10–$35</td>
<td>51.3</td>
</tr>
<tr>
<td>Generic, $30–$35; brand $60–$120</td>
<td>14.8</td>
</tr>
<tr>
<td>Other</td>
<td>3.6</td>
</tr>
</tbody>
</table>

Note: All study participants were dispensed a new statin prescription between November 2006 and August 2007 (n = 7700). Age was calculated as of August 15, 2007, and copayment amounts are for a 100-day supply as of January 2007. Information was abstracted from automated pharmacy databases.
In addition, a number of participants noted that they dislike taking medications in general. For example, one said:

“It’s not just statins. I hate taking any drugs. You hear this stuff on the TV and the radio, and they pull it off the shelf, and you say, ‘Gee, am I killing myself?’”

Fewer than half of the participants noted that they stopped taking statins because of immediate adverse or side effects, including nausea, muscle pain, and allergic reactions. About half of these participants reported that they discussed these problems with their physicians, and many eventually resumed statin therapy. Notably, among participants who reported other primary barriers to therapy adherence (eg, concerns about long-term adverse effects, uncertainty about benefits of statins, inconvenience), none reported resuming statin therapy after their initial discontinuation. In addition, a number of participants who faced immediate problems with adverse or side effects decided to stop taking statins on their own, as this patient did:

“[Statins] made my heart race. I was suddenly agitated. I tried taking [them] at bedtime, and then I tried taking them in the morning instead of bedtime for the second week. I didn’t feel right taking them. I said, ‘I can do this on my own. I can lower my own cholesterol.’”

Uncertainty About Importance and Benefits of Statins—Some participants did not take statins as prescribed because they were unsure about the importance of statins for their health. Uncertainty about the need for statins was related to a number of factors, including the absence of obvious symptoms and lack of follow-up by their physicians.

“You have high cholesterol, but that doesn’t really manifest itself into anything tangible. You don’t have severe headaches or your vision isn’t necessarily blurred. There isn’t anything really that makes you stop and say, ‘Hey, I have to take my medication; this is serious.’”

“I had no side effects. I took it as prescribed, and I was never asked to come back to do a cholesterol check, so I never went back. … I didn’t get anything saying I needed to come back or I needed to follow-up or I needed to continue taking that drug.”

Lack of Convenience—A few participants noted that it was inconvenient to take the drug or obtain follow-up laboratory testing; however, this reason was uncommon. One respondent noted: “Initially I was prescribed to cut the tablet in half, and for some reason that just became so inconvenient, I would just put it off and just never took it.” In this insured population, no participants cited out-of-pocket drug costs as a barrier.

Sources of Information

Participants were asked to describe the kinds of information they received from their physician, pharmacist, or other sources. The majority of participants noted that they did not receive detailed information about statins from their physicians. One said:

“[The physician] just said, ‘I’m going to prescribe it. Go get the medication.’ He didn’t give me much details about it.”

The majority of patients noted that they were told by their physician that statins were prescribed to lower cholesterol levels but that they were not given information on the possible side effects, risks, or benefits of statins. Participants also described the information they received from pharmacists as limited and mainly focused on basic information about administration:

“I don’t remember anything about lovastatin that [the pharmacist] told me except just to take it once a day with food. Don’t take grapefruit, maybe.”

In addition, a number of participants commented that

### Table 2. Patient-identified reasons for nonadherence to statin therapy

<table>
<thead>
<tr>
<th>Concerns or experiences with adverse effects</th>
<th>Faced immediate problems with adverse effects (eg, nausea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerned about long-term adverse effects</td>
<td>Dislike taking medications in general because of concerns about risks</td>
</tr>
<tr>
<td>Preferred to use alternative methods (eg, lifestyle changes, herbal remedies)</td>
<td>Concerned about long-term use (ie, did not want to take the statin for rest of their life)</td>
</tr>
<tr>
<td>Uncertainty about the benefits or importance of statins</td>
<td>Believed statins to be unnecessary for their health</td>
</tr>
<tr>
<td>Uncertain whether statin should be continued, because of lack of clinician follow-up</td>
<td>Distrusted physician’s instructions</td>
</tr>
<tr>
<td>Lack of convenience</td>
<td>Inconvenient to get laboratory testing done</td>
</tr>
<tr>
<td>Inconvenient to take the medication</td>
<td>Did not want to wait at the pharmacy for a prescription to be filled</td>
</tr>
<tr>
<td>Forgot to take medication</td>
<td>Other</td>
</tr>
<tr>
<td>Wanted to drink grapefruit juice, which they were instructed to avoid</td>
<td>Too ill to take statins</td>
</tr>
<tr>
<td>Preferred to take a brand-name statin instead of the generic statin prescribed</td>
<td>Other</td>
</tr>
</tbody>
</table>

Note: list is based on content analysis of focus-group transcripts.
the pharmacy handout containing information on their prescribed statin raised concerns for them:

“If you read those sheets they give you, you wouldn’t take anything. It’s scary.”

Most participants noted that they received or sought information on statins from sources other than their physician or pharmacist. The most common sources were the experiences of family and friends, and lay sources, including the Internet and television programs. A number of participants sought information on alternative remedies for high cholesterol levels, including herbal treatments and dietary changes. Many participants also noted that they learned information on the risks of taking statins, but not information on the potential benefits of statins, from these sources.

“I read these herbal catalogs. … In one of them, it said that taking statins cut down the amount of co-Q₁₀ in your body. … co-Q₁₀ is very important because the doctor said you should take supplements. This doctor on Channel 9 … said you should take supplemental co-Q₁₀ when you get older.”

“I went on the Internet, and it turns out statin drugs scatter the Q₁₀ away from your kidneys, and there’s a lot of information out there that Q₁₀ is one of the best things you can do for your kidneys, and that’s one of the reasons I decided to try exercise.”

### Table 3. Patients’ suggestions for how to improve patient adherence to statin therapy

<table>
<thead>
<tr>
<th>Suggestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide additional or more detailed information about statins</td>
</tr>
<tr>
<td>Allow more time with the clinician to discuss the medication</td>
</tr>
<tr>
<td>Provide more information about the reason statins were prescribed and about the benefits and risks of statins</td>
</tr>
<tr>
<td>Provide written information about statins to describe risks, side effects, and medication administration</td>
</tr>
<tr>
<td>Provide classes to describe risks, side effects, and medication administration</td>
</tr>
<tr>
<td>Advise about possible drug interactions</td>
</tr>
<tr>
<td>Inform about or try alternative approaches first</td>
</tr>
<tr>
<td>Inform about the risks of drinking grapefruit juice while taking statins</td>
</tr>
<tr>
<td>Improve follow-up after initial prescription</td>
</tr>
<tr>
<td>Provide follow-up reminders (eg, mailing)</td>
</tr>
<tr>
<td>Provide follow-up by clinician</td>
</tr>
<tr>
<td>Improve convenience</td>
</tr>
<tr>
<td>Mail statins to patients</td>
</tr>
</tbody>
</table>

Note: List is based on content analysis of focus-group transcripts.

### Perceptions of Statins and High Cholesterol Levels

We asked participants about their perceptions about statins and high cholesterol levels. When asked by the focus-group moderator, the majority said that they felt that it is unsafe to have high cholesterol levels (eg, “high cholesterol means diabetes, stroke, heart attack—all the really bad stuff”) and believed that statins were effective at lowering cholesterol. However, a number also questioned their personal need for statins and appeared to have limited awareness of other cardiovascular risk factors. For example, some participants were unsure if they needed statins if their cholesterol was only borderline high:

“Statins seem to help some people that have really had cholesterol. I think of mine as not that high. I’m suspicious that that’s the best way to fix the problem.”

Participants’ views on whether other risk factors, such as family history of heart disease, were important reasons to take statins were mixed. Some stated that these factors did not affect their perceived need for statins:

“No doctor said to me that it was that important. They didn’t make it seem important. So … do I really need [statins]?”

Other patients noted that these factors concerned them, but many also felt that the potential risks of taking statins outweighed the potential benefits.

### Suggestions for Improving Therapy Adherence

Participants were also asked what might have helped them take their statins as prescribed (Table 3). The participants’ suggestions were closely related to their reasons for not adhering to statins, and many centered on the need for more information about statins or high cholesterol levels. One participant noted:

“Sometimes doctors say, ‘This is what you have to do.’ … Tell me why. Tell me what’s going to be good for me, what the possible side effects are.”

Although most participants preferred to have more time to discuss statins with their physician or suggested discussions with other health care professionals (eg, nurse practitioners), a few noted that providing additional information in written format might have also helped them understand the need for statins or helped them remember what was discussed during the appointment.

Others suggested that more systematic follow-up by clinicians or reminder systems might have helped them adhere to statin therapy. One participant compared the lack of follow-up regarding her statin pre-
Patients’ Perspectives on Nonadherence to Statin Therapy: A Focus-Group Study

Discussion

We conducted focus groups to validate existing hypotheses and identify additional reasons for nonadherence to new statin therapy. Patients identified a wide range of factors that contributed to their discontinuation of statins; the majority cited concerns about the risks of taking statins and uncertainty about the benefits of importance of statins as primary reasons for stopping. Patients expressed a strong desire for more information about statins, to better understand the risks and benefits of the medication, and also suggested that systematic follow-up after receiving the prescription could have improved their therapy adherence.

Most patients believed that statins effectively reduce cholesterol levels and that having a high cholesterol level is unsafe; however, many also questioned their personal need for statins. A number of participants felt that their cholesterol levels were close enough to target thresholds that statins might not be of much benefit to them. In addition, many patients had unfavorable perceptions of the safety profile of statins and noted that concerns about potential long-term harms were a primary factor in their decision to discontinue therapy. Although some patients cited specific concerns, such as liver and kidney damage, many also expressed general fears about taking statins and other medications. Of concern, most participants did not discuss these fears with their physician or a pharmacist. These findings agree with those of other studies that have examined underlying perceptions that contribute to poor statin therapy adherence, as well as other chronic drug therapies, and further highlight an important need to identify effective and efficient ways of providing patients with more information about statins.

Dissatisfaction with the amount of information received about statins from physicians and pharmacists was a dominant theme in the focus groups. A recent study found that some physicians hesitate to discuss potential side effects with their patients because they worry about contributing to patient fears and therapy nonadherence. The patients in our focus groups, however, sought this information from alternate sources, such as the Internet and television. The information gathered from these sources might not be clinically reputable and appeared to focus on the risks of statins rather than the benefits of statins or of lowering cholesterol levels. Stressing the benefits of statin therapy at time of prescribing, as well as discussing potential adverse or side effects, the likelihood of experiencing them, and their seriousness, may improve how patients filter information they receive from other sources. In patients with more moderate cholesterol levels but with other risk factors for cardiovascular disease, such as diabetes mellitus, it may be particularly valuable to explain in detail why the statin is being prescribed.

Because the time available to discuss statins with patients may be limited, providing clinically accurate and easily accessible written information online, as handouts, or in health education classes may also present important counterpoints to other sources patients might consult. Work is needed to determine the most effective ways of delivering this information. Patients also suggested that receiving simple postcard or telephone reminders after they began statin therapy would reinforce the importance of therapy and improve their adherence to it.

This was a qualitative study with a small sample size. Although we identified a wide range of patient-reported reasons for therapy nonadherence and found similar themes repeated throughout each focus group, there might have been unidentified barriers. Patients might have had incomplete or inaccurate recall of their experiences with statins or the information they received. In addition, patients who were not able to participate in the focus groups (because of, for example, illness, cognitive impairment, or language barriers) likely face additional barriers to adherence. We did not assess the clinical appropriateness of the statin prescription for each participant, nor did we collect information about why patients were prescribed statins. This study was conducted within a single integrated delivery system, and all study participants had a pharmacy benefit with modest copayments. No participants cited costs as a need to identify effective and efficient ways of providing patients with more information about statins.

Dissatisfaction with the amount of information received about statins from physicians and pharmacists was a dominant theme in the focus groups. A recent study found that some physicians hesitate to discuss potential side effects with their patients because they worry about contributing to patient fears and therapy nonadherence. The patients in our focus groups, however, sought this information from alternate sources, such as the Internet and television. The information gathered from these sources might not be clinically reputable and appeared to focus on the risks of statins rather than the benefits of statins or of lowering cholesterol levels. Stressing the benefits of statin therapy at time of prescribing, as well as discussing potential adverse or side effects, the likelihood of experiencing them, and their seriousness, may improve how patients filter information they receive from other sources. In patients with more moderate cholesterol levels but with other risk factors for cardiovascular disease, such as diabetes mellitus, it may be particularly valuable to explain in detail why the statin is being prescribed.

Because the time available to discuss statins with patients may be limited, providing clinically accurate and easily accessible written information online, as handouts, or in health education classes may also present important counterpoints to other sources patients might consult. Work is needed to determine the most effective ways of delivering this information. Patients also suggested that receiving simple postcard or telephone reminders after they began statin therapy would reinforce the importance of therapy and improve their adherence to it.

This was a qualitative study with a small sample size. Although we identified a wide range of patient-reported reasons for therapy nonadherence and found similar themes repeated throughout each focus group, there might have been unidentified barriers. Patients might have had incomplete or inaccurate recall of their experiences with statins or the information they received. In addition, patients who were not able to participate in the focus groups (because of, for example, illness, cognitive impairment, or language barriers) likely face additional barriers to adherence. We did not assess the clinical appropriateness of the statin prescription for each participant, nor did we collect information about why patients were prescribed statins. This study was conducted within a single integrated delivery system, and all study participants had a pharmacy benefit with modest copayments. No participants cited costs as a need to identify effective and efficient ways of providing patients with more information about statins.

Dissatisfaction with the amount of information received about statins from physicians and pharmacists was a dominant theme in the focus groups. A recent study found that some physicians hesitate to discuss potential side effects with their patients because they worry about contributing to patient fears and therapy nonadherence. The patients in our focus groups, however, sought this information from alternate sources, such as the Internet and television. The information gathered from these sources might not be clinically reputable and appeared to focus on the risks of statins rather than the benefits of statins or of lowering cholesterol levels. Stressing the benefits of statin therapy at time of prescribing, as well as discussing potential adverse or side effects, the likelihood of experiencing them, and their seriousness, may improve how patients filter information they receive from other sources. In patients with more moderate cholesterol levels but with other risk factors for cardiovascular disease, such as diabetes mellitus, it may be particularly valuable to explain in detail why the statin is being prescribed.

Because the time available to discuss statins with patients may be limited, providing clinically accurate and easily accessible written information online, as handouts, or in health education classes may also present important counterpoints to other sources patients might consult. Work is needed to determine the most effective ways of delivering this information. Patients also suggested that receiving simple postcard or telephone reminders after they began statin therapy would reinforce the importance of therapy and improve their adherence to it.

This was a qualitative study with a small sample size. Although we identified a wide range of patient-reported reasons for therapy nonadherence and found similar themes repeated throughout each focus group, there might have been unidentified barriers. Patients might have had incomplete or inaccurate recall of their experiences with statins or the information they received. In addition, patients who were not able to participate in the focus groups (because of, for example, illness, cognitive impairment, or language barriers) likely face additional barriers to adherence. We did not assess the clinical appropriateness of the statin prescription for each participant, nor did we collect information about why patients were prescribed statins. This study was conducted within a single integrated delivery system, and all study participants had a pharmacy benefit with modest copayments. No participants cited costs as a need to identify effective and efficient ways of providing patients with more information about statins.
Conclusion

Patients identified a wide range of reasons for stopping their statin therapy, and most emphasized concerns about adverse effects or uncertainty about the benefits of statins. They expressed a desire for more information about the benefits and risks of statins and believed that such information might have helped them take their statins as prescribed. These factors should be systematically assessed in a larger population to identify the most effective strategies for improving statin therapy adherence.

Disclosure Statement

Pfizer, Inc provided financial support to Kaiser Permanente for this study. However, Pfizer, Inc exercised no control over the Kaiser Permanente researchers who designed and conducted the study, performed the analysis, and prepared the manuscript. There are no other relevant financial disclosures.

Acknowledgment

Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References


3. Mehta JL, Bursac Z, Hauer-Jensen M, Fort C, Fink LM. Concerns about adverse effects or uncertainty about the benefits of statins. They expressed a desire for more information about the benefits and risks of statins and believed that such information might have helped them take their statins as prescribed. These factors should be systematically assessed in a larger population to identify the most effective strategies for improving statin therapy adherence.


Alcohol and Lung Airways Function

Abstract

Background: Limited data suggest that moderate alcohol drinkers may have better lung airways function than abstainers. Because few studies have fully accounted for confounders (including smoking and coronary disease), and some might have been biased by the inclusion with nondrinkers of alcohol drinkers who quit because of illness, we performed a cross-sectional analysis in a large free-living population.

Methods: We studied the relation between alcohol and airways function in 177,721 members of a comprehensive health plan. An item on a questionnaire administered as part of a health examination asked for “usual number of drinks in the past year.” Respondents were asked to lump “wine, beer, whiskey, and cocktails” together. Health history queries included 47 items indicative of possible cardiorespiratory (CR) illness; participants with one or more positive response (61.0%) were classified as “CR yes.” Lung function measurements were part of the health examination; we studied one-second forced expiratory volume (FEV₁), forced vital capacity (FVC), and FEV₁/FVC by analysis of covariance and FEV₁/FVC ≤ 0.7 by logistic regression. Nondrinkers were the referent for alcohol categories; covariates were age, sex, ethnicity, smoking, education, body mass index, and CR composite yes/no.

Results: For each measure studied, persons reporting two or fewer drinks per day or three to five drinks per day had better airways function than nondrinkers (p < 0.001), but heavier drinkers had worse function. This J-shaped relation was consistent across multiple strata, including CR “yes” or “no.”

Conclusion: Independent of smoking and evident lung or heart disease, light to moderate drinkers of alcohol had better FEV₁, FVC, and FEV₁/FVC than abstainers did. Although this association does not prove causality, drinking moderate amounts of alcoholic beverages may have some benefit for lung function.

Introduction

Alcohol reaches the airway passages both by the bronchial circulation and by direct inhalation. Thus, an effect on airway flow is plausible with implications for bronchial asthma and chronic obstructive pulmonary disease (COPD). It has long been thought that alcohol might be beneficial in persons with asthma. Some data, mostly from small studies, suggest that low doses of alcohol may have a bronchodilator effect by relaxing smooth muscle tone. Even if ethyl alcohol is beneficial for asthma, nonalcohol components of alcoholic beverages, such as congeners, may cause bronchoconstriction in susceptible persons with extrinsic asthma. Also, alcohol metabolites such as acetaldehyde may trigger asthma attacks in persons, mostly Asian Americans, with genetic alcohol dehydrogenase polymorphisms.

Although the analyses were not always clearly independent of smoking, cross-sectional reports consistently show impaired lung airway flow (LAF) in heavy drinkers. Population studies of chronic LAF among light to moderate drinkers of alcohol show conflicting results. A study of 2539 free-living adults found no evidence for an independent association of alcohol intake with LAF. Another study of 3800 study participants in Arizona found alcohol-associated decreased LAF independent of smoking status. A survey of 1555 random residents of western New York State showed no overall relation between alcohol and LAF, but function was better among wine drinkers, especially drinkers of white wine. A large study compared the prevalence of LAF with alcohol intake in 15,294 representative US adults; the data demonstrated no relation with light to moderate intake of alcohol but did show increased airflow obstruction in former heavy drinkers.

Limited longitudinal analyses of the relations of alcohol drinking to LAF are also conflicting. A report about 1067 male veterans revealed no independent association.
Alcohol and Lung Airways Function

The extensive health history inventory inquired about current or past symptoms or illnesses. We judged 60 items as indicative of possible cardiorespiratory (CR) illness. From these, a composite CR “yes” or CR “no” covariate for analytic models was constructed, as described in the next section.

Analytic Methods

We studied mean values of FEV₁, FVC, and FEV₁/FVC ratio by analysis of covariance, yielding adjusted means and p values. By logistic regression, we also studied two arbitrary cutoffs of FEV₁/FVC ratio, <0.7 (vs ≥0.7) and persons in the lowest decile (vs upper 90%), yielding odds ratios (ORs), 95% confidence intervals (CIs), and p values. Covariates in the analytic models included age (continuous), sex, ethnicity (white, African American, Asian American, other), body mass index ([BMI] <25, 25–29, ≥30 kg/m²), education (no college, some college, college graduate), cigarette smoking (never-smoker, ex-smoker, two to four categories of current smoking in various models), alcohol (nondrinker, two

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean FEV₁ ± SD</th>
<th>Mean FVC ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>3.13 ± 0.91</td>
<td>4.07 ± 1.00</td>
</tr>
<tr>
<td>No alcohol</td>
<td>2.90 ± 0.63</td>
<td>3.78 ± 1.03</td>
</tr>
<tr>
<td>≤2 drinks</td>
<td>3.24 ± 0.89b</td>
<td>4.18 ± 1.00b</td>
</tr>
<tr>
<td>3–5 drinks</td>
<td>3.09 ± 0.87b</td>
<td>4.04 ± 0.98b</td>
</tr>
<tr>
<td>≥6 drinks</td>
<td>2.94 ± 0.86b</td>
<td>3.93 ± 0.96b</td>
</tr>
<tr>
<td>Unknown</td>
<td>3.02 ± 0.90b</td>
<td>3.96 ± 1.00b</td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>2.24 ± 0.65</td>
<td>2.85 ± 0.72</td>
</tr>
<tr>
<td>No alcohol</td>
<td>2.07 ± 0.63b</td>
<td>2.63 ± 0.70</td>
</tr>
<tr>
<td>≤2 drinks</td>
<td>2.33 ± 0.64b</td>
<td>2.95 ± 0.71b</td>
</tr>
<tr>
<td>3–5 drinks</td>
<td>2.19 ± 0.62b</td>
<td>2.83 ± 0.70b</td>
</tr>
<tr>
<td>≥6 drinks</td>
<td>2.09 ± 0.63</td>
<td>2.74 ± 0.68b</td>
</tr>
<tr>
<td>Unknown</td>
<td>2.16 ± 0.62b</td>
<td>2.78 ± 0.69b</td>
</tr>
</tbody>
</table>

*Usual number of drinks per day in the preceding year; unknowns gave no response or a conflicting response.

p vs nondrinkers <0.001.

FEV₁ = one-second forced expiratory volume; FVC = forced vital capacity.

Based on the extensive health history inventory ... 47 items showed a relation to FEV₁/FVC ratio of <0.7.

during a five-year interval. A study of 8765 Danish study participants⁸ found a relation between alcohol drinking and accelerated loss of LAF. A ten-year study of 378 French policemen⁹ showed no decline in LAF associated with alcohol intake or a liver enzyme marker. A four-year study of 307 young Dutch persons¹⁰ suggested better LAF in women than men, and also showed a relation to extensive health history. Few items showed a relation to the FEV₁/FVC ratio, a relation to extensive health history. FeV₁/FVC ratio <0.7.

The extensive health history inventory included an extensive health history questionnaire. Starting in 1964, the Kaiser Permanente Medical Care Program of Northern California has provided comprehensive medical care to patients in the San Francisco Bay Area. Except for underrepresentation of the indigent and very wealthy, the subscribers are socially and ethnically diverse. For much of its existence, the Oakland and San Francisco facilities of the program offered an automated multiphasic health checkup to adult subscribers as a periodic health appraisal¹⁷ that included an extensive health history questionnaire. Starting in 1964, the collected data were stored on computers. The examinees passed from station to station, where a variety of tests were administered and measurements were made. From July 1964 through December 1973, the tests included spirometric determination of one-second forced expiratory volume (FEV₁) and forced vital capacity (FVC). A Collins spirometer was employed from July 1964 through May 1966, after which date a wedge spirometer was used. These measurements were satisfactorily completed among 177,721 persons of known sex, age, and ethnicity.

Questionnaire data included demographic data, current symptoms, and past health history. One query asked, “In the past year did you drink any alcohol?” and provided check-sheet answer choices of “yes” and “no.” The next item was “If yes, how many alcoholic drinks did you usually have (wine, beer, whisky or cocktails)?” with these four check-sheet options: “2 or less a day, 3 to 5 a day, 6 to 8 drinks a day, total of 9 a day or more.” Responses classified alcohol intake in the 177,721 examinees as “none” (21.4%), two or fewer drinks per day (60.7%), three to five drinks per day (8.0%), and six or more drinks per day (2.3%). The remaining 7.6% gave no response, responded yes but gave no amount; these were classified as having “unknown” alcohol data. Table 1 includes distributions of selected traits of the study population.

**Table 1. Unadjusted FEV₁ and FVC in liters by alcohol and sex**

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean FEV₁ ± SD</th>
<th>Mean FVC ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>3.13 ± 0.91</td>
<td>4.07 ± 1.00</td>
</tr>
<tr>
<td>No alcohol</td>
<td>2.90 ± 0.63</td>
<td>3.78 ± 1.03</td>
</tr>
<tr>
<td>≤2 drinks</td>
<td>3.24 ± 0.89b</td>
<td>4.18 ± 1.00b</td>
</tr>
<tr>
<td>3–5 drinks</td>
<td>3.09 ± 0.87b</td>
<td>4.04 ± 0.98b</td>
</tr>
<tr>
<td>≥6 drinks</td>
<td>2.94 ± 0.86b</td>
<td>3.93 ± 0.96b</td>
</tr>
<tr>
<td>Unknown</td>
<td>3.02 ± 0.90b</td>
<td>3.96 ± 1.00b</td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>2.24 ± 0.65</td>
<td>2.85 ± 0.72</td>
</tr>
<tr>
<td>No alcohol</td>
<td>2.07 ± 0.63b</td>
<td>2.63 ± 0.70</td>
</tr>
<tr>
<td>≤2 drinks</td>
<td>2.33 ± 0.64b</td>
<td>2.95 ± 0.71b</td>
</tr>
<tr>
<td>3–5 drinks</td>
<td>2.19 ± 0.62b</td>
<td>2.83 ± 0.70b</td>
</tr>
<tr>
<td>≥6 drinks</td>
<td>2.09 ± 0.63</td>
<td>2.74 ± 0.68b</td>
</tr>
<tr>
<td>Unknown</td>
<td>2.16 ± 0.62b</td>
<td>2.78 ± 0.69b</td>
</tr>
</tbody>
</table>

*Usual number of drinks per day in the preceding year; unknowns gave no response or a conflicting response.

p vs nondrinkers <0.001.

FEV₁ = one-second forced expiratory volume; FVC = forced vital capacity.
or fewer, three to five, six or more drinks per day), the CR composite (yes/no), and appropriate unknown categories.

To construct the CR composite, we selected 60 potential queries and introduced each into a separate logistic model. There were 47 items that showed a relation (p < 0.05) to FEV1/FVC ratio of <0.7. All of these were included in the composite. The queries involved current or past indicators of possible cardiac or pulmonary conditions (eg, heart attack, angina, stroke, high blood pressure, diabetes, abnormal findings on chest radiographs or electrocardiograms, bronchitis, asthma, emphysema, tuberculosis), symptoms of cardiac or pulmonary conditions (eg, chest pain, shortness of breath). A positive response to any one (or more) of these 47 queries was made by 108,400 (61.0%) study participants; these were classified as CR “yes.” The 69,321 (39.0%) participants with no positive responses to any of these items were classified as CR “no.”

The composite included 19 queries about events and symptoms “before one year ago,” 7 related to “the past six months,” and 20 related to “the past year.”

We performed analyses involving all persons and of multiple strata, including the sexes, ethnic groups, smoking categories, and CR-yes and CR-no groups. With the large number of study participants involved, small numeric differences produced impressive p values. Therefore, in this article, we define p < 0.001 as “statistically significant.”

**Results**

**Mean Values**

Unadjusted mean values for FEV1 and FVC for men and women are presented in Table 1, with evident higher values for light to moderate drinkers of alcohol. Because adjusted models consistently showed similar alcohol relations for these measures and for the FEV1/FVC ratio, we present only data about the mean ratio in other tables. The mean FEV1/FVC ratio for all 177,721 study participants was 0.779, of whom 33,532 (18.9%) had a ratio <0.70 and 17,764 (10.0%) had a ratio <0.63. Data showing adjusted mean FEV1/FVC ratios are

<table>
<thead>
<tr>
<th>Trait</th>
<th>Number (%)</th>
<th>Mean FEV1/FVC</th>
<th>p &lt; 0.001</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>177,721 (100)</td>
<td>0.779</td>
<td>—</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>96,223 (54.1)</td>
<td>0.787</td>
<td>Versus men</td>
</tr>
<tr>
<td>Men</td>
<td>81,498 (45.9)</td>
<td>0.771</td>
<td>Versus women</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;40</td>
<td>83,485 (47.0)</td>
<td>0.794</td>
<td>Versus each other bracket</td>
</tr>
<tr>
<td>40–49</td>
<td>36,871 (20.8)</td>
<td>0.783</td>
<td>Versus each other bracket</td>
</tr>
<tr>
<td>50–59</td>
<td>32,001 (18.0)</td>
<td>0.775</td>
<td>Versus each other bracket</td>
</tr>
<tr>
<td>60–69</td>
<td>18,864 (10.5)</td>
<td>0.760</td>
<td>Versus each other bracket</td>
</tr>
<tr>
<td>≥70</td>
<td>6,500 (3.7)</td>
<td>0.745</td>
<td>Versus each other bracket</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>136,997 (77.1)</td>
<td>0.768</td>
<td>Versus each other ethnicity</td>
</tr>
<tr>
<td>African American</td>
<td>26,409 (14.9)</td>
<td>0.786</td>
<td>Versus white, other</td>
</tr>
<tr>
<td>Asian American</td>
<td>7,248 (4.1)</td>
<td>0.783</td>
<td>Versus white</td>
</tr>
<tr>
<td>Other</td>
<td>7,067 (4.0)</td>
<td>0.779</td>
<td>Versus white, African American</td>
</tr>
<tr>
<td>Smoking history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>67,608 (38.0)</td>
<td>0.790</td>
<td>Versus each, except unknown</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>30,338 (17.1)</td>
<td>0.782</td>
<td>Versus each, except unknown</td>
</tr>
<tr>
<td>&lt;1 ppd</td>
<td>37,875 (21.3)</td>
<td>0.775</td>
<td>Versus each, except unknown</td>
</tr>
<tr>
<td>≥1 ppd</td>
<td>37,623 (21.2)</td>
<td>0.763</td>
<td>Versus each, except unknown</td>
</tr>
<tr>
<td>Unknown</td>
<td>4,277 (2.4)</td>
<td>0.786</td>
<td>Versus &lt;1 ppd; ≥1 ppd</td>
</tr>
<tr>
<td>Alcohol in past year—drinks per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>38,074 (21.4)</td>
<td>0.779</td>
<td>Versus each other, except ≥6</td>
</tr>
<tr>
<td>≤2</td>
<td>107,827 (60.7)</td>
<td>0.787</td>
<td>Versus each other, except 3–5</td>
</tr>
<tr>
<td>3–5</td>
<td>37,875 (21.3)</td>
<td>0.783</td>
<td>Versus each other, except 2–6</td>
</tr>
<tr>
<td>≥6</td>
<td>4,084 (2.3)</td>
<td>0.773</td>
<td>Versus 3–5, ≤2</td>
</tr>
<tr>
<td>Unknown*</td>
<td>13,471 (7.6)</td>
<td>0.772</td>
<td>Versus each other, except ≥2</td>
</tr>
<tr>
<td>Body mass index (kg/m2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;25</td>
<td>88,146 (49.6)</td>
<td>0.774</td>
<td>Versus each other</td>
</tr>
<tr>
<td>25–29</td>
<td>50,599 (28.5)</td>
<td>0.783</td>
<td>Versus each other</td>
</tr>
<tr>
<td>≥30</td>
<td>15,321 (6.6)</td>
<td>0.790</td>
<td>Versus each other</td>
</tr>
<tr>
<td>Unknown</td>
<td>23,655 (13.3)</td>
<td>0.769</td>
<td>Versus each other</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No college</td>
<td>86,712 (48.8)</td>
<td>0.773</td>
<td>Versus each, except unknown</td>
</tr>
<tr>
<td>Some college</td>
<td>49,770 (28.0)</td>
<td>0.780</td>
<td>Versus each other</td>
</tr>
<tr>
<td>College graduate</td>
<td>36,243 (20.3)</td>
<td>0.786</td>
<td>Versus each other</td>
</tr>
<tr>
<td>Unknown*</td>
<td>4,996 (2.8)</td>
<td>0.769</td>
<td>Versus each, except no college</td>
</tr>
<tr>
<td>Possible baseline cardiorespiratory illness*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>108,400 (61.0)</td>
<td>0.770</td>
<td>Versus no</td>
</tr>
<tr>
<td>No</td>
<td>69,321 (39.0)</td>
<td>0.789</td>
<td>Versus yes</td>
</tr>
</tbody>
</table>

*Analysis of variance; covariates were age, sex, ethnicity, body mass index, education, smoking, alcohol, and baseline illness composite.

*Nonresponse or conflicting response.

*Any of 47 medical history or symptom items in “yes.”

FEV1 = one-second forced expiratory volume; FVC = forced vital capacity; FEV1/FVC = ratio of FEV1 to FVC; ppd = pack(s) per day.
presented in Table 2. As expected, the mean FEV1/FVC ratios became lower with increasing age and with increased smoking. The lower mean ratios among those with high BMI, with less education, and with CR history and/or symptoms were also expected. In this study population, men had a lower mean FEV1/FVC than women, and white persons had lower mean ratios than African Americans or Asian Americans. For the alcohol drinking categories, the highest mean FEV1/FVC ratio was among the large number of drinkers reporting having two or fewer drinks per day, followed closely by those reporting having three to five drinks per day. Thus, the mean FEV1/FVC ratios for both abstainers and the heaviest drinkers (six or more drinks per day) were lower than for the intermediate alcohol categories. With the large numbers in this study population, most of the apparently small differences in mean ratios had p values <0.001. The relation of mean FEV1/FVC to reported alcohol intake presented in Table 1 was generally consistent in analyses among multiple stratified groups.

### Logistic Models for Low FEV1/FVC Ratio

Adjusted logistic models with the FEV1/FVC ratio dichotomized as <0.7 and ≥0.7 showed that compared with nondrinkers, persons reporting two or fewer drinks per day and those reporting three to five drinks per day were less likely to have low ratios (Table 3). This finding was consistent in most subgroup analyses, with persons younger than 40 years being a noteworthy exception. In the various age strata, the largest apparent reduction (35%) in low FEV1/FVC ratio among the light drinkers was in those who were 60 to 69 years old.

Using the more stringent cutoff point of lowest 10% of ratio, with FEV1/FVC <0.63, the U-shaped relation of alcohol drinking to reduced FEV1/FVC ratio had a slightly deeper nadir. With this definition, the ORs (95% CI) versus nondrinkers were as follows: two or fewer drinks per day = 0.79 (0.75–0.82; p < 0.0001); three to five drinks per day = 0.87 (0.81–0.94; p = 0.0002); and six or more drinks per day = 1.11 (0.99–1.23; p = 0.07).

The relations of selected covariates to OR of FEV1/FVC ratio <0.7 are shown in Table 4. The strongest relations were with increasing age (ORs were more than double at ≥70 years vs <40 years), smoking (ORs were 71% higher for smokers of one or more pack per day vs never-smokers), and for the CR composite (ORs increased 45% for CR “yes” vs “no”).

### Stratified Models for Cardiorespiratory Composite “Yes” or “No”

Figure 1 and Table 5 show the ORs of FEV1/FVC ratio <0.7 stratified into CR composite “yes” and “no” groups. Table 5 presents data for the alcohol categories of two or fewer and three to five drinks per day in a number of selected groups.

### Table 3. Adjusted odds ratio of FEV1/FVC <0.7 in selected groups according to alcohol intake

<table>
<thead>
<tr>
<th>Group</th>
<th>n (percentage of total 177,721 with FEV1/FVC &lt;0.7)</th>
<th>≤2 drinks per day</th>
<th>3–5 drinks per day</th>
<th>≥6 drinks per day</th>
<th>OR versus nondrinkers (nondrinkers were referent; OR = 1.00)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>33,532 (18.9)</td>
<td>0.82&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.88&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.04</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>16,694 (20.5)</td>
<td>0.83&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.87&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.08</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>16,838 (17.6)</td>
<td>0.81&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.91</td>
<td>0.91</td>
<td></td>
</tr>
<tr>
<td>Age &lt;40 years</td>
<td>11,237 (13.5)</td>
<td>0.96</td>
<td>1.08</td>
<td>1.35&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Age 40–49 years</td>
<td>5,809 (15.8)</td>
<td>0.83&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.93</td>
<td>1.02</td>
<td></td>
</tr>
<tr>
<td>Age 50–59 years</td>
<td>5,629 (17.6)</td>
<td>0.69&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.83</td>
<td>1.05</td>
<td></td>
</tr>
<tr>
<td>Age 60–69 years</td>
<td>4,217 (22.4)</td>
<td>0.65&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.66</td>
<td>0.91</td>
<td></td>
</tr>
<tr>
<td>Age &gt;70 years</td>
<td>1,730 (26.6)</td>
<td>0.73&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.80</td>
<td>1.45</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>26,991 (19.7)</td>
<td>0.83&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.88</td>
<td>1.05</td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>4,155 (15.5)</td>
<td>0.83&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.91</td>
<td>0.98</td>
<td></td>
</tr>
<tr>
<td>Asian American</td>
<td>1,197 (16.5)</td>
<td>0.86</td>
<td>0.92</td>
<td>1.20</td>
<td></td>
</tr>
<tr>
<td>Other ethnicity</td>
<td>1,239 (17.5)</td>
<td>0.88</td>
<td>1.02</td>
<td>1.37</td>
<td></td>
</tr>
<tr>
<td>Never-smoker</td>
<td>10,620 (15.7)</td>
<td>0.83&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.92</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>5,561 (18.3)</td>
<td>0.75&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.77</td>
<td>0.98</td>
<td></td>
</tr>
<tr>
<td>Smoke ≤1 ppd</td>
<td>7,241 (19.1)</td>
<td>0.89</td>
<td>0.92</td>
<td>1.06</td>
<td></td>
</tr>
<tr>
<td>Smoke ≥2 ppd</td>
<td>9,384 (24.9)</td>
<td>0.87&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.94</td>
<td>1.22</td>
<td></td>
</tr>
</tbody>
</table>

<sup>aVersus FEV1/FVC ≥0.7 by logistic regression among 177,721 examinees for age, ethnicity, body mass index, education, smoking, alcohol, and cardiorespiratory composite.</sup>

<sup>b p < 0.001</sup>

FEV1/FVC = ratio of one-second forced expiratory volume to forced vital capacity; OR = odds ratio; ppd = pack(s) per day.
The reduced proportions of low ratios among drinkers were slightly greater in the groups without the CR composite. Thus, study participants without a history of possible baseline cardiovascular or lung problems had slightly deeper nadirs to the curve relating alcohol drinking to low FEV/FVC ratios, but this disparity was substantially due to the data for women. For men, the reduction in OR for low FEV/FVC at two or fewer drinks per day was 17% in both strata; whereas in women, it was 24% lower among those in the CR “no” group and 16% lower in the CR “yes” group. Other strata showing deeper U curves within the CR “no” stratum were persons ≥50 years old, never-smokers, and study participants with a BMI <25 kg/m².

### Discussion

The main finding of our study is that light to moderate drinkers of alcohol have better LAF than alcohol abstainers. Although this difference is modest in absolute magnitude, the p values, the consistency in stratified subgroup analyses, and the independence from strictly defined baseline illness make a chance difference unlikely. However, because these data are cross-sectional, interpretation of better LAF as a possible causal benefit of alcohol drinking requires great caution.

One important problem of alcohol categorization relevant to this study, known as the “sick quitter” hypothesis, is present in analyses that use all nondrinkers as the referent group. Such categorization fails to separate ex-drinkers from lifelong abstainers. Because ex-drinkers include some who quit drinking because of alcohol-related or other medical problems, this could increase the likelihood of illness among the non-drinker category and make light to moderate drinkers spuriously appear healthier. This issue has been raised for observational studies that show less coronary artery disease risk among light to moderate drinkers than among abstainers. Although the alcohol-coronary instance is refuted by studies that use lifelong abstainers as the referent, alcohol data for the present analysis of LAF does not enable such direct refutation.

We attempted to deal with the “sick quitter” problem by studying...
the subcohort with no evidence of CR disease. A caveat is that because many healthy persons have nonspecific CR symptoms, a proportion of persons in the CR “yes” group were probably free of actual CR disease. In creating this CR composite, we intended to be inclusive in order to derive a group truly free of CR disease. We reason that the “no CR” group, with negative responses to all queries, was unlikely to have quit drinking because of cardiovascular or lung disease. Thus, the better LAF in light to moderate drinkers in this subgroup adds substantial credibility to a possible lung function benefit of light drinking.

The broadness of the category of two or fewer drinks per day precludes ascertainment of a possible threshold. These persons composed more than half of study participants, and, even assuming truthful reporting, include a range from occasional drinking (less than one drink per month) to intake of two large drinks daily. Furthermore, the group almost surely includes heavier drinkers who underreport. By inclusion of some heavy drinkers as “light to moderate” drinkers, underreporting, in a situation where light but not heavy drinking has a possible benefit, diminishes the apparent benefit. In this connection, the decreased prevalence of impaired LAF among those reporting having three to five drinks per day strengthens the validity of our main finding.

These measurements were performed with equipment that was technically inferior to more modern lung-testing machines. Thus, technical factors might be partially responsible for the relatively low FEV$_1$ and FVC numbers we obtained (Table 1). However, the implausibility of a systematic relation of technical test aspects to alcohol drinking habits leaves these data valid for the analyses we did.

The FEV$_1$/FVC ratio is widely used as a screen for COPD. Because COPD is primarily a disease of smokers, the strong relationship between smoking and drinking$^{20,21}$ makes it difficult to eliminate confounding when analyzing the possible role of alcohol in this condition. Thus, the lesser likelihood of a low FEV$_1$/FVC among never-smokers in our data (Table 4) indicates independence of the finding from confounding by smoking.

A few reports have suggested a possible benefit by light to moderate alcohol intake for COPD. A retrospective autopsy study among male veterans showed an inverse relationship of alcohol consumption to emphysema.$^{21}$ The Lung Health Study in 5887 Canadian smokers with airways obstruction$^{25}$ found a significant protective effect of moderate drinking in men, but not women, for both hospitalizations and deaths. A 20-year mortality study among 2953 middle-aged men from several European countries$^{24}$ showed a U-shaped relation between alcohol and COPD mortality.

Speculative mechanisms of potential benefit for LAF by moderate alcohol drinking include anti-inflammatory effects,$^{22}$ improved mucociliary clearance,$^{1,25}$ direct bronchodilation,$^{1}$ and antioxidant effects.$^{12}$ Antioxidants in alcoholic beverages are most plentiful as nonalcohol phenolics, especially in red wine.$^{20,27}$ A report of possible specific benefit for LAF by wine drinking$^{1}$ found slightly more

---

**Table 5. Adjusted$^a$ odds ratio of FEV$_1$/FVC <0.7 for drinkers reporting ≤2 or 3–5 drinks per day stratified by cardiorespiratory history**

<table>
<thead>
<tr>
<th>Group</th>
<th>History “Yes”$^{bc}$</th>
<th>History “No”$^{bc}$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤2 drinks per day</td>
<td>3–5 drinks per day</td>
</tr>
<tr>
<td></td>
<td>vs nondrinkers</td>
<td>vs nondrinkers</td>
</tr>
<tr>
<td>All</td>
<td>0.84$^c$</td>
<td>0.89$^c$</td>
</tr>
<tr>
<td>Men</td>
<td>0.83$^c$</td>
<td>0.86$^c$</td>
</tr>
<tr>
<td>Women</td>
<td>0.84$^c$</td>
<td>0.95$^b$</td>
</tr>
<tr>
<td>Age &lt;40 years</td>
<td>0.95</td>
<td>0.98$^c$</td>
</tr>
<tr>
<td>Age 40–49 years</td>
<td>0.82$^c$</td>
<td>0.91$^c$</td>
</tr>
<tr>
<td>Age 50–59 years</td>
<td>0.80$^c$</td>
<td>0.88$^c$</td>
</tr>
<tr>
<td>Age 60–69 years</td>
<td>0.76$^c$</td>
<td>0.75$^c$</td>
</tr>
<tr>
<td>Age ≥70 years</td>
<td>0.71$^c$</td>
<td>0.73$^c$</td>
</tr>
<tr>
<td>White</td>
<td>0.85$^c$</td>
<td>0.90$^c$</td>
</tr>
<tr>
<td>African American</td>
<td>0.85$^c$</td>
<td>0.90$^c$</td>
</tr>
<tr>
<td>Asian American</td>
<td>0.92</td>
<td>1.00$^c$</td>
</tr>
<tr>
<td>Other ethnicity</td>
<td>0.87</td>
<td>0.93$^c$</td>
</tr>
<tr>
<td>Never-smoker</td>
<td>0.86$^c$</td>
<td>0.89$^c$</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>0.73$^c$</td>
<td>0.77$^c$</td>
</tr>
<tr>
<td>Smoke &lt;1 ppd</td>
<td>0.90</td>
<td>0.96$^c$</td>
</tr>
<tr>
<td>Smoke ≥1 ppd</td>
<td>0.88</td>
<td>0.94$^c$</td>
</tr>
<tr>
<td>BMI &lt;25 kg/m$^2$</td>
<td>0.90$^c$</td>
<td>0.96$^c$</td>
</tr>
<tr>
<td>BMI 25–29 kg/m$^2$</td>
<td>0.77$^c$</td>
<td>0.88$^c$</td>
</tr>
<tr>
<td>BMI ≥30 kg/m$^2$</td>
<td>0.80</td>
<td>0.90$^c$</td>
</tr>
</tbody>
</table>

$^a$Versus FEV$_1$/FVC ≥0.7 by logistic regression models for age, ethnicity, BMI, education, smoking, alcohol, and CR composite.

$^b$Reply of yes to any of 47 history and/or symptom items. The “yes” group included 108,400 study participants—22,993 (21%) with a ratio of <0.7; the “no” group included 69,237 study participants—10,539 (15%) with a ratio of <0.7.

$^c$p < 0.001.

BMI = body mass index; FEV$_1$/FVC = ratio of one-second forced expiratory volume to forced vital capacity; ppd = pack(s) per day.
benefit for white than for red wine. We have no data in our study cohort about beverage choice. Although benefit by alcohol is one possible explanation for our data, the numerous well-established harmful effects of heavy drinking include impaired lung defenses, with resultant increased susceptibility to infections. This disparity between the possible effects of moderate and heavy drinking must be kept in mind when considering advice to individuals or the general public.

Conclusion
Our study in a large, free-living, multiethnic population found better LAF among light to moderate drinkers than among abstainers, independent of smoking and evident lung or heart disease. Drinking moderate amounts of alcoholic beverages may have some benefit for lung function.

Disclosure Statement
This work was supported by a Community Budget grant from the Kaiser Permanente Medical Care Program.

Acknowledgment
Katharine O’Moore-Kemp, ELS, of KOK Edit provided editorial assistance.

References
soul of the healer

“The Cafe”
Oil on canvas
24 x 36”

By C Shore

Ms Shore studies under the tutelage of Richard Morris, at the University of California Los Angeles, at international workshops, and with Nan Rae Parker at her Pasadena Studio. Ms Shore is a Kaiser Permanente member. She has been an educator in the Los Angeles Unified School District, employing all forms of art within the classroom. She found that being bilingual and using art throughout the curriculum were successful tools to teach subject matter to limited English proficient students. Ms Shore continues to advance her education in art and language.

More of Ms Shore’s art may be seen on her Web site: www.fineartbycarolyn.com.
The Extended Surgical Time-Out: Does It Improve Quality and Prevent Wrong-Site Surgery?

Steven L Lee, MD

Abstract

Purpose: To review the initial results of implementing an extended surgical time-out (STO) in pediatric surgery.

Methods: Starting in January 2006, all members of our surgical team implemented and used an extended STO, confirming the patient’s identity, technical and anesthetic details, administered and available medications, and need for blood products and special equipment. To avoid disrupting work flow, the STO was initially after anesthesia induction. Starting in October 2007, the STO was done before anesthesia induction. Initial results, elapsed time to incision, and surgical team surveys were reviewed before and after implementing the preinduction STO.

Results: The elapsed time to incision was similar for elective and urgent operations before and after implementing the preinduction STO. All antibiotics were administered and confirmed during the STO. Four significant equipment findings were detected, altering the planned procedure (two before and two after implementing the preinduction STO). Operating room staff felt more confident and prepared for the operations because communication was improved. One near-miss occurred during the postinduction STO. One wrong-site operation occurred despite the preinduction STO, because of inadequate marking. Root-cause analysis demonstrated that this was due to a systems error.

Conclusions: Using the extended STO before anesthesia induction improved communication among the surgical team members and did not disrupt workflow. An extended STO may also have broader value, such as confirming timely antibiotic administration or meeting other quality measures. The extended STO did not eliminate wrong-site surgery. However, implementation of the STO placed the responsibility for wrong-site surgery with the whole team and system, rather than with the individual surgeon.
and procedure by the preoperative nurse, with marking
of the surgical site by the preoperative nurse or
surgeon; 2) confirmation of the patient’s identity and
the procedure by the circulating nurse before enter-
ing the operating room (OR); and 3) a pause by the
surgeon just before making the incision, to confirm the
patient’s identity and the procedure. Starting in Janu-
ary 2006, our facility added an extended STO to this
safety process. The purpose of the STO was to mimic
the safety practices of the aviation industry, specifi-
cally to improve communication and level the play-
ing field for all members of the surgical team. Before
implementation of the extended STO, multiple joint
sessions with all members of the surgical team were
conducted to promote and review the importance
of communication and teamwork to improve patient
safety. To avoid disrupting work flow, the extended
STO was initially done after anesthesia induction,
with all of the previous steps remaining the same. All
members of the surgical team, which included the
surgeon, anesthesia team, circulating nurse, and scrub
technician or scrub nurse, participated in the extended
STO. The extended STO consisted of confirmation of
the patient’s identity, the procedure, technical details
of the procedure, the anesthetic plan, administered
medications, possible medication needed during the
operation, blood product availability, and need for
special equipment (Table 1). Starting in October 2007,
the time for doing the extended STO was switched; it
is now performed before anesthesia induction. Initial
results, time to incision, and surgical team surveys
were reviewed before and after implementing the
preinduction STO. Our study focused only on pediatric
surgical patients. Statistical analysis was performed
using the Student’s t-test, with a p value <.05 being
considered significant.

**Results**

The elapsed time to incision when using the ex-
tended STO before anesthesia induction was similar
to that for using the extended STO after induction for
elective surgery (24 ± 3 min; n = 195 vs 25 ± 8 min,
respectively; n = 156; p = 0.33) and urgent surgery (36
± 7 min; n = 114 vs 32 ± 16 min; n = 118, respectively;
p = 0.25). With respect to surgical quality measures,
all prophylactic antibiotics were administered at the
appropriate time and confirmed during the extended
STO. Four significant equipment findings were de-
tected that altered the planned procedure. Two of
these findings were discovered when the extended
STO was performed after anesthesia induction. In one
case, the laparoscopic pyloric spreader was
missing and the operation was performed open. In
the second case, the appropriate coagulation device
and instruments to perform laparoscopic Nissen
fundoplication were not available, necessitating an
open procedure. Because both of these problems
were discovered before an incision was made, lapa-
roscopy was avoided altogether and only the open
procedure was performed. Two significant problems
were also detected when the extended STO was
performed before anesthesia induction. The first was
that the laparoscopic pyloric spreader was broken.
Because this was discovered early, we had enough
time to locate a second spreader and proceed with
laparoscopic pyloromyotomy. In the second case,
we was noted that the desired tunnelled catheter was
not available. Again, because this was discovered
early, the catheter was located (in the interventional
Radiology Department) and we were able to proceed
with the operation without delay.

**Table 1. Patient safety briefing checklist (before anesthesia induction)**

<table>
<thead>
<tr>
<th>Surgeon</th>
<th>Discussed</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address patient and explain briefing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirm patient identity and procedure (chart, consent, armband)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plan for surgery (type, duration, position, potential challenges)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special equipment and special needs (implants, grafts, Foley catheter)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiology (images, fluoroscopy)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anesthesia provider</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergies reviewed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of anesthesia (potential challenges)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prophylactic antibiotics administered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative issues (pain, ventilation management)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Circulator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information on the whiteboard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirm correct patient, site, side</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirm position</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirm implants and special needs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirm preoperative medications given</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirm intraoperative medications and fluids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scrub technician or scrub nurse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical equipment in the operating room</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special equipment and instruments available and functioning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All solutions available and labeled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All medications available and labeled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other concerns?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
One near-miss occurred when the extended STO was done after anesthesia induction. Because the intended procedure involved right open hernia repair, laparoscopic left groin exploration, and possible left inguinal hernia repair, both groins were marked. Without the briefing, the procedure would have started on the incorrect side. Of note, transinguinal laparoscopy showed that the patient did not have a hernia on the left side. One wrong-site surgery was performed when the extended STO was done before anesthesia induction. The patient was scheduled for right inguinal hernia. The patient was marked on the correct side, but the marking was not visible after draping the patient. The patient was examined while under anesthesia and noted to have a left inguinal hernia. Despite the briefing and pause, the patient underwent a left inguinal hernia repair; near the completion of this procedure, it was noticed by the surgical team that this was the incorrect side. The right side was then repaired. If the surgeon had not been notified of this finding, the right side would not have been repaired. A root-cause analysis was performed, and because all of the safety steps, including the briefing, were performed by the surgeon, this error was deemed a major systems issue caused by the inadequate marking process.

Team surveys demonstrated that OR staff felt more confident and prepared for the procedures because of improved communication. Hospital surveys also showed that 95% of OR staff felt actively involved with improving patient safety, compared with 55% of the rest of hospital staff.

**Discussion**

To prevent patient harm in the form of wrong-site, wrong-procedure, and wrong-person surgery, the Joint Commission implemented the Universal Protocol. Despite ongoing protocols, checklists, and surgical briefings, the effectiveness of these safety measures is still not known. The purpose of our study was not to debate the validity of the Universal Protocol or to argue whether the STO should be used to incorporate quality measures but rather to highlight some of the unique features of implementing an extended STO in pediatric patients.

Before January 2006, patient and procedure verification included confirmation of the patient and procedure by the preoperative team, with marking of the surgical site by the preoperative nurse or surgeon, confirmation of the patient’s identity and the procedure by the circulating nurse before entering the OR, and a pause by the surgeon just before making the incision to confirm the patient’s identity and the procedure. Starting in January 2006, an extended STO was added to this safety process. The rest of this discussion focuses on the extended STO because the other steps remained the same. The first decision was to determine what to include in the extended STO. Given that all of the procedures in children are performed in general hospitals as part of the same system and not in a children’s hospital, our institution elected to continue the same process as in adults. All pediatric surgeons were required to perform the extended STO. It was decided to use the extended STO as a briefing to improve communication, quality, and safety. Thus, all members of the surgical team, including the surgeon, anesthesia team, circulator, and scrub nurse, were involved. All had specific roles and all were expected to participate equally. The surgeon again confirmed the patient’s identity and the procedure, the diagnosis, the plan for surgery (duration, position, potential challenges), special equipment, and need for radiology and/or blood products. The anesthesia team reviewed the allergies, type of anesthesia, prophylactic antibiotics, and postoperative issues, including pain management and possible ventilator needs. The circulator had all of the information on the whiteboard and confirmed the patient’s identity, the procedure, the side to be operated on, position, available blood products, administration of preoperative medications, and intraoperative medications and fluids. The scrub nurse confirmed that the surgical equipment, special equipment, and all solutions and medications were available and labeled. To minimize disruptions in work flow, we initially performed this extended STO after anesthesia induction. Another pause, just before incision, was also used, to confirm the patient’s identity, the procedure, and the proper side for the procedure.

Because of the success with the extended STO as well as its universal acceptance across all surgical subspecialties, our institution elected to perform the extended STO before anesthesia induction with the patient awake (all surgical subspecialties switched to the preinduction STO). Doing the extended STO before anesthesia induction allowed more time to cor-
The Extended Surgical Time-Out: Does It Improve Quality and Prevent Wrong-Site Surgery?

In the new process, the surgeon must mark the site in the preoperative area ... The mark must be visible after preparation and draping the patient for the procedure.
The Extended Surgical Time-Out: Does It Improve Quality and Prevent Wrong-Site Surgery?

Medical teams must continue to implement, refine, and research interventions to minimize and possibly eliminate these events.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

Acknowledgment
Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References

On the Surgery
The things relating to surgery, are—the patient; the operator; the assistants; the instruments; the light, where and how; how many things, and how; where the body, and the instruments; the tie; the manner; the place.

— Hippocrates, 460-400 BCE, Greek physician known as the father of modern medicine
Since 1982, the Southern California Permanente Medical Group’s Positive Choice Weight Loss Program in San Diego has treated more than 30,000 adults, predominantly middle-aged, for obesity—some successfully, some not. This has been an extraordinary experience and provided us with numerous counterintuitive observations. We now are convinced that obesity is widely misunderstood, and we realize that the unusual program we have operated safely and effectively for more than a quarter century is often misunderstood as well. There is growing interest in our program and in using our approach as a model for other Kaiser Permanente (KP) Regions. We therefore share an overview here of our experience with this specific program. Consequently, most referenced works in this report are publications emanating from our program, sometimes contrasting those findings with conventional views on the subject.

The Positive Choice Weight Loss Program has two integrated components:

- Prolonged absolute fasting, with the use of a supplement to support health and to prevent death from such fasting.
- A lengthy and complex group program to explore the basis of each participant’s unconscious compulsive use of food, as well as to explore the hidden benefits of obesity for that individual.

Given that the average weight loss of someone completing our 20-week program is 62 lb (28 kg) and that approximately 5000 patients each have lost more than 100 lb (45 kg), we realize we have challenged the belief systems of some who assume either that such weight loss cannot commonly be achieved or that the process of supplemented absolute fasting must be dangerous. In fact, the process has been notably safe, and major improvements in biomedical outcomes have been the norm. This article addresses four basic issues:

1. The safety of properly supplemented prolonged absolute fasting in obesity
2. The observed origins of obesity, and their implications
3. The components of a relevant treatment program
4. Outcomes of the Program.

Overview of Unsupplemented Starvation

The Irish hunger strikers of the early 1980s illustrated the outcome of unsupplemented, prolonged, absolute fasting. They only drank water, and it was clear after six weeks that all involved had sustained significant weight loss and were mortally ill. By seven weeks, all were dead. They died because of profound potassium and magnesium deficiency, with consequent lethal cardiac arrhythmia. Had they received electrolyte supplementation and had the hunger strikers been obese, they could have lived for several months longer before dying because of major protein deficiency. Supplementing two essential fatty acids and the essential amino acids needed for anabolic protein turnover would have prevented such a death. Had this been done, the hunger strikers would have died toward the end of a year because of beriberi, pellagra, and scurvy. Preventing these diseases by vitamin supplementation would be straightforward. To simplify the example, we have left out the problem of calorie deficiency in these nonobese individuals. In obese individuals, body fat stores of course resolve this problem; the metabolism of these fat stores is obviously the basis for weight loss. Details of unsupplemented starvation can be found in the famous work of Ancel Keys, described in his two-volume *Biology of Human Starvation.*

Vincent J Felitti, MD, FACP
Kathy Jakstis
Victoria Pepper, MS
Albert Ray, MD

Kathy Jakstis is the Manager of the Positive Choice Wellness Center for the Southern California Permanente Medical Group. E-mail: kathy.m jakstis@kp.org.
Victoria Pepper, MS, is the Marketing and Promotions Health Educator for the Positive Choice Wellness Center in the San Diego Area of the Southern California Region. E-mail: vicki.x.pepper@kp.org.
Albert Ray, MD, is Assistant Chief of the Department of Family Practice at Kaiser Permanente in San Diego and is an elected Director of the Southern California Permanente Medical Group. E-mail: albert.x ray@kp.org.
Safety of Supplemented Fasting

The nutritional supplement Optifast 70 was created by Sandoz Pharmaceuticals to supply electrolytes, amino acids, two essential fatty acids, and vitamins. At 420 cal/d in five feedings, this superbly designed product allows a sufficiently morbidly obese individual to cease eating all food and caloric beverages for at least a full year. In our entire experience, no death or biomedical harm has occurred in any of these individuals.

During a year of supplemented absolute fasting, a weight loss of approximately 300 lb (136 kg) will occur (Figure 1). To the degree that this does not occur, it means that the patient is consuming food, regardless of denial. Surprisingly, hunger is not a problem. However, the desire to eat is variable, ranging from minor to uncontrollable. Interestingly, this desire to eat is an issue separate from hunger. Indeed, it attests to the profound psychoactive benefits of food, as illustrated by a commonplace observation that is even built into our language: “Sit down and have something to eat; you’ll feel better.” There is truth for many in the phrase “comfort food.”

Origins of Obesity

In the early years of the Weight Program, we naively were taking morbidity obese individuals down 300 lb (136 kg) at a time, a rate of loss distinctly exceeding that of bariatric surgery. The striking results perhaps understandably led us to believe that we understood what we were doing. Counterintuitively, some of our most successful patients forced us to realize we were merely in possession of a powerful technology and had no idea what we were doing in other regards. They did this by demonstrating that massive weight loss could precipitate divorce, severe anxiety, and sometimes suicidality. Some patients, sensing these outcomes early, fled their own success in the Program. Surprisingly, our high dropout rate was mainly limited to patients who were successfully losing weight. By contrast, we had other patients who were eating during the Program, routinely denying it, and losing no weight while paying a fairly significant fee, seemingly to accomplish nothing. With these patients, it took some time for us to realize that we were supplying an important support system with our group approach. It turned out that many of our obese patients had no functional support systems at home.

The striking and frankly annoying conflict between our ability quickly and safely to reduce a person’s weight and what patients appeared capable of tolerating emotionally led us to detailed exploration of the life histories of 286 of our patients. Here, we unexpectedly discovered that histories of childhood sexual abuse were common, as were histories of growing up in markedly dysfunctional households. It became evident that traumatic life experiences during childhood and adolescence were far more common in an obese population than was comfortably recognized. We slowly discovered that major weight loss is often sexually or physically threatening and that obesity, whatever its health risks, is protective emotionally. Ultimately, we saw that certain of our more intractable public health problems such as obesity are often also unconsciously attempted solutions to problems dating back to the earliest years but hidden by time, by shame, by secrecy, and by social taboos against exploring certain areas of life experience. The antecedent life experiences of the obese are quite different from those of the always-slimmer. Eventually, these Program findings led to the 17,000-member Adverse Childhood Experiences (ACE) Study, in which we established that the developmental damage initially discovered in our obese patients was broadly applicable to many aspects of everyday medical practice.

Ultimately, we learned from our patients that in obesity, we are dealing with two core problems:

- The unconscious, compulsive use of food for its psychoactive benefits
- The unrecognized and unspoken benefits of obesity

These two core problems are markedly at variance with conventional thinking about obesity, starting with the government’s food pyramid. Worse yet, these two basic problems are uncomfortable to deal with. In reviewing the medical literature, one quickly notes that most articles purporting to discuss the causes of obesity quickly switch to describing the unhealthy consequences of obesity and never pursue their stated goal. One also notes the tendency to confuse intermediary mechanism with basic cause. For instance, several years ago, leptin deficiency was proposed as the cause of human obesity. Although that idea has now been discarded, someday the “real leptin” will be discovered, but it will no more be causal than increased levels of epinephrine are the cause of anxiety. Each is a necessary intermediary mechanism, not a basic cause. Understanding the difference is as essential to progress in treatment as it is to primary prevention.

Any physician choosing to validate in his patients the points being made here will be in the position of asking about topics that we have all learned are not discussed by polite
people. Incest, rape, family suicides, and parental brutality are not readily brought up. That being the case, we physicians typically have no basis for opinions on the frequency or rarity of such life experiences. We documented these experiences as surprisingly common among our patients, but we did not know that before we began routinely inquiring about them. Counterintuitively, we learned that discussion of these experiences is usually not uncomfortable to those who have had them, if they are supported by someone comfortable with their discussion. Patients often find a great sense of relief in discussing their life experiences. As one patient wrote, “The shame, guilt, and pain for the abuse and molestations of childhood, and being raped, was so great that I had to come forward or die. If your questionnaire had been put in front of me, it would have shown me that people existed in the medical profession who knew about the sad things that happen to some people.” This poignant statement imposes a huge responsibility on us that we can of course avoid by falling back on lack of time or lack of training as being the factor that precludes our inquiry.

The now internationally recognized ACE Study was initiated to determine the prevalence and outcomes of ten categories of such life experiences in more than 17,000 consecutive adults from KP’s San Diego population. These experiences are common, and their consequences are devastating in terms of emotional damage, biomedical disease, and the costs of health care. Like a child’s footprints in wet cement, the consequences are lifelong. Putting it plainly in regard to obesity, we have seen that obesity is not the core problem. Obesity is the marker for the problem and sometimes is a solution. This is a profoundly important realization because none of us expects to cure a problem by treating its symptom.

Treatment

Given the nature of our observations about the causes of obesity, repeatedly documented in thousands of responses to our preprogram questionnaire (See http://xnet.kp.org/permanentejournal/spr10/PreprogramQuestionnaire.pdf to view the questionnaire) and in more than 50 videotaped interviews, it was inevitable by the early 1990s that we revise our program to fuse two separate goals: weight loss by supplemented fasting, and helping patients identify and resolve the life experiences underlying obesity. By far the easier of the two goals is the medical management of supplemented absolute fasting. Weekly checks of potassium levels, blood pressure measurements in patients taking antihypertensive medications, and blood sugar levels in patients with diabetes are our most common tracking measures other than weight itself. Other details of biomedical management are equally straightforward but are not the point of this article. Chronic disease is not a reason for exclusion from the Program; most such patients should actually be sought for Program inclusion if obese. Our only absolute exclusions are pregnancy and recent myocardial infarction or stroke. Optifast 70, drunk five times daily for a total daily intake of 420 cal, is a remarkable material that makes biologically safe the otherwise unthinkable. The remainder of the day’s caloric needs come from body fat stores as long as those fat stores exist. It is important to understand that Optifast 70 has one function only: the prevention of death from prolonged absolute fasting. It does not take weight off people; not eating does that. And it has nothing to do with whether lost weight is regained or kept off; that outcome is solely a function of what is accomplished or not accomplished by the group work of the Program.

By contrast with the simplicity of fasting, the weekly two-hour group meetings of the Program are a complex endeavor that is difficult for some patients to engage in and is difficult to train staff to pursue vigorously. By the mid-1980s, we had learned that our initial goal of teaching people to “eat right” was totally irrelevant to obesity, although it seemed a reasonable thing to do when we did not know what to do. In retrospect, we

Figure 1. Patient who lost 277 lb in 51 weeks
should have known better because most of us knew that overweight, middle-aged women commonly know enough about calorie content to give a dietitian a run for his or her money any day of the week. Nutrition is an interesting and important subject that has no more relationship to obesity than it does to anorexia. The role of the Program is to help people recognize and find an acceptable alternate solution or resolution to the underlying problems being treated with food. We are at an early stage of success; the work is difficult because it is resisted by some patients and can awaken personal ghosts in staff, but we have clearly established a beachhead on the right beach and slowly are moving inland.

In the course of detailed interviewing of about 2000 obese patients over the past 20 years, in-depth and often repetitively over time, we have noted several recurrent findings:

- It is rare for anyone to be born obese. In 2000 adult obese patients, only one individual was born overweight, at 14 lb (6 kg), to a 550-lb (250-kg) mother, and she was slender throughout childhood and adolescence until age 20, when she married an alcoholic and suddenly began massive weight gains, ultimately matching her mother’s weight. “Born fat” is a defensive concept.
- A significant minority of our Program participants are born at subnormal weight because of prematurity.
- Obesity indeed runs in families, as does speaking the same language. It is the distribution pattern of body fat deposition that is genetically determined, not its presence.
- Major weight gain is typically abrupt, episodic, and life-event related.
- The forces underlying extreme morbid obesity are relatively easy to discern for those seeking them. They are qualitatively similar to those underlying mild overweight, though they are much harder to discern in the latter.
- The age at which weight gain first began is critically important because it allows one to inquire why it began then. Some patients will know and others will not want to know, but this is an essential point not to be dropped because of patient avoidance.
- Obesity commonly is beneficially protective: sexually, physically, and socially. This is an uncomfortably difficult point for many nonobese individuals to accept.
- Major weight loss may present a significant threat, usually to the person involved, but sometimes to others.
- Emotional support from others for major weight loss is uncertain.

With adequate medical monitoring, there is no biologic risk to supplemented absolute fasting. Supplemented fasting has two treatment advantages:

- When large amounts of weight are to be lost, it reduces weight quickly enough to provide positive and supportive feedback.
- By removing eating as a major coping device, we expose the underlying issues that are being treated by the psychoactive properties of food.

The main work of the Program enters personal territory that is comfortably off-limits to polite people. It is therefore difficult and demanding, though conceptually simple. Doing the work in groups is essential because of the implicit support of the group and because participants quickly learn from each other’s self-observations. To the degree that counselors pose meaningful questions to their groups, and insist on answers to the questions asked and not to some enfeebled version of their questions, they are successful. To the degree that they teach by lecturing, they fail. In actual fact, our task is to help the participants discover what they already know at some level, and then to use that discovery for their own benefit. To illustrate the process, some seemingly simple questions may be offered for our readers to try, understanding that this works best in small groups and initially will be stressful for the group leader:

1. Why (not how) do you think people get fat?
2. How old were you when you first began putting on weight? Why do you think it was then and not a few years earlier or later?
3. Sometimes people who lose a lot of weight regain it all, if not more. When that happens, why do you think it happens?
4. What are the advantages of being overweight?

Patients’ answers to these questions are staggeringly counterintuitive to conventional thinking about obesity. Moreover, their answers have been consistent over the many years we have posed these questions in group sessions. For instance, answers to question 1 routinely are: “stress, depression, people leave you alone, men won’t bother you.” There are of course occasional escapist responses like “I just like food.” In that case, the following response to the answer given for question 2 is helpful: “Really? Can you tell us why you suddenly liked food more at 22 when you first began putting on weight?” Responses to question 3 always are versions of “If you don’t deal with the underlying issues, the weight will come back.” About 60% of the time, someone in a group

The Permanente Journal/ Spring 2010/ Volume 14 No. 1

ORIGINAL RESEARCH & CONTRIBUTIONS
will also propose that regain occurs because major weight loss is threatening. Answers to question 4 repeatedly fall into three categories: obesity is sexually protective; it is physically protective (eg, “throwing your weight around”); and it is socially protective—people expect less from you.

Ultimately, we were forced to recognize that patients in a supportive setting speak of things that we ourselves may find it easier not to know. This embarrassing recognition exposes the tempting opportunity that a physician or group leader has to become part of the problem by authenticating as biomedical disease that which is actually the somatic inscription of life experience onto the human body and brain. The frequent reference to “the disease of obesity” is grossly in error, diagnostically destitute, and apparently made by those with little understanding of the antecedent lives of their patients. Obesity, like tachycardia or jaundice, is a physical sign, not a disease.

What we have learned about obesity has been more widely applicable in everyday medical practice than we would ever have contemplated. The general principles underlying the unconscious, compulsive use of food as a psychoactive agent are common to any of the addictions. We unwittingly recognized this at some level in the early years of the Program by giving as gifts, coffee mugs bearing the inscription, “It’s hard to get enough of something that almost works.” The psychoactive benefits of food are profound though not curative: “Sit down and have something to eat; you’ll feel better.” Hunger is not at issue in that saying. Whether we are talking about the next mouthful, the next drink, the next cigarette, the next sexual partner, or the next dose of whatever psychoactive chemical we might buy on the street, the concept is equally applicable: It’s hard to get enough of something that almost works.

Slowly, we have come to recognize that overeating is not the basic problem. It is an attempted solution, and people are not eager to give up their solutions, particularly at the behest of those who have no idea of what is going on. Nor is obesity the problem. Obesity is the consequence, the marker for the problem, much in the way that smoke is the marker for a house fire. Often enough, obesity is even the solution—to problems that are buried in time and further protected by shame, by secrecy, and by social taboos against exploring certain areas of human experience. A memorable response comes to mind from 1985 when a patient, going with us through a timeline of her life in which weight, age, and events were matched, told us that at age 23 she was raped and that in the subsequent year she gained 105 lb (48 kg). Looking down at the carpet, she then muttered to herself, “Overweight is overlooked, and that’s the way I need to be.” Not knowing how to respond at the time, we said nothing. A few weeks later when she had lost 35 lb (16 kg), enough to be noticeable, she abruptly disappeared for 2.5 years, quickly regaining the weight. When she attempted to rejoin the Program after that hiatus, we discovered that she had no recollection of this conversation. Prompted by this to look into the issue of amnesia, we found in a sample of 300 consecutive obesity program patients that 12% acknowledged a history of focal amnesia, typically for the few years antecedent to the onset of weight gain. Amnesia is a high-grade marker for dissociation, which is a high-grade marker for abuse.7

Just as no one becomes amnesic because of good experiences, no one becomes fat out of joy. Depression is common in the Program and is a major stumbling block to weight loss. Not surprisingly, until the recent advent of pharmacologic blockers of fat absorption, every single “diet pill” save one has had potent antidepressant activity. The exception was fenfluramine, whose potent antianxiety activity was linked with the antidepressant phentermine as the first component of fen-phen. These medications can play a useful supportive role, but it should be understood that what is being treated is depression or anxiety, the consequences of antecedent life experiences, and not obesity per se. Overall, we have found and documented that the antecedent life experiences of the obese are quite different from those of the always-slimmer.8

Subsequent to the 20-week weight-loss phase of the Program, we have a 12-month Maintenance Phase. Initially thinking that this was necessary to teach people how to eat right, we slowly came to see that Maintenance indeed is essential, but for other reasons: to provide group support when major weight loss is threatening, usually to the person involved but sometimes to those who are close. Some of our patients regain all their weight, and others do not. The question we posed was: What are the differences between those who regain and those who do not? We have identified two major predictors of regain: a history of childhood sexual abuse and currently being married to an
alcoholic. The latter can probably be generalized into having a significantly dysfunctional marriage, but that concept was too nebulous to study as an outcome.

Today the prevalence of obesity is rapidly increasing in children. Although our experience with obese children is quite limited, we are impressed by the number of adults who date the onset of their initial weight gain to coincide with parental loss in childhood, usually by divorce. Our most obese female patient, weighing 840 lb (381 kg) at age 29, was born weighing slightly less than 2 lb (0.9 kg) and was thin until her parents divorced when she was 11 years old and she never again saw her father. By age 17, she weighed 500 lb (227 kg). This correlation with parental divorce has escaped general attention, although a search in Google Scholar using the phrase childhood obesity divorce quickly indicates its presence in the literature. Given the high prevalence of divorce in the US, we suspect that "McDonald’s" may be a more comfortable explanation for childhood obesity, although it obviously misrepresents mechanism as cause.

Bariatric surgery has been increasing in popularity since its initiation in 1967 by Edward Mason, the remarkable Iowa surgeon who introduced gastric bypass surgery to the US. Our own experience in the Program with bariatric surgery is biased because we see a disproportionate number of cases where "the surgery failed" and patients consequently enter the Weight Loss Program. We have found alternate explanations that are not usually considered. An unexpectedly clear insight was provided by a recent patient comment: "The antidote [sic] to bariatric surgery is Karo Syrup." The psychological implication is blatant; the physiologic insight is ingenious. One may not be able to chew one’s way through a lot after bariatric surgery, but the ability to ingest highly caloric liquids is unlimited. The question, of course, is: Why would a patient do that? A different take on bariatric surgery is depicted in a brief video clip of an interview with a patient available at: http://public.me.com/vjmfdsdca. These comments from patients are, once again, counterintuitive to conventional views about obesity. We have slowly learned that our average patient on the one hand wants very much to lose weight but on the other hand often has significant unconscious fear of the changes that major weight loss will bring about. In keeping with this unexpressed conflict, it is worth remembering that opposing forces are routinely present in biologic systems.

### Outcomes

We have measured our Program outcomes in three categories:

- Weight loss
- Maintenance of weight lost
- Benefits of weight loss.

The average weight loss in one 20-week cycle of our program has been 62 lb (28 kg). The most anyone has ever lost in our former 26-week cycle was 157 lb (71 kg). This was a highly motivated man with a large underlying muscle mass.

Eighteen months after completion of the Program, half of our patients are keeping off 60% or more of the weight lost. These are old data and have probably improved with the revised Program, but we have not restudied the point. Instead, we have studied the differences between those who regain and those who do not. Our ability to predict regain offers the possibility for preventive treatment in advance.

The biomedical benefits of such major weight loss have been dramatic. Of 400 consecutive patients taking medication for hypertension who completed the Program, 62% were able to discontinue all medication and no longer had hypertension. Of 400 consecutive patients with hypercholesterolemia, the average starting cholesterol level was 285 mg/dL; the average cholesterol level for those completing the Program was 204 mg/dL. Most impressively, of 320 patients with Type 2 diabetes who completed the Program, 71% were able to discontinue medication and had normal fasting blood sugars. In terms of health care economics, there is a 25% reduction in physician office visits while patients are in the Program and a 40% reduction in such visits in the subsequent year. Certainly, some of this is due to a reduced disease burden, but we suspect that a significant portion is due to reduced emotional distress in patients who have been helped in supportive settings to speak of the worst secrets of their lives and have been enabled to emerge feeling still accepted as human beings.

### Summary

We have had an unusual opportunity to become deeply involved in the treatment of major obesity since 1985. What we have counterintuitively learned from that experience is that obesity, though an obvious physical sign and easily measured, is not the core problem to be treated, any more than smoke is the core problem to be treated in house fires. Supplemented absolute fasting is a highly effective treatment for obesity, but only if it is combined with a meaningful program that is designed to help patients explore the psychodynamic issues that underlie overeating as a
coping device, as well as exploring the possible protective benefits of obesity itself. The work is difficult because it threatens social conventions and beliefs and often awakens personal ghosts in staff. This can lead to nonalignment of purpose and reminds us of Michael Balint’s famous comment, “Patients see doctors because of anxiety, while doctors see patients because of disease. Therein lies the problem between the two.”

Although our work with obesity is difficult to carry out, we have nevertheless found that the work we have described can be done and that the benefits are major.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

Acknowledgment
Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

The Boston Tea Party
To say that obesity is caused by merely consuming too many calories is like saying that the only cause of the American Revolution was the Boston Tea Party.

— Adelle Davis, 1904-1974, American author and nutrition pioneer

References
8. Felitti VJ, Williams SA. Long-term follow-up and analysis of more than 100 patients who each lost more than 100 pounds. Perm J 1998;2(3):17–21.
“Three Mushrooms, Latourell Creek”
photograph

By David S Emmons, LCSW

David S Emmons, LCSW, is a Mental Health Triage Therapist at the Interstate Medical Offices in Portland, OR. He is a serious amateur photographer working in slide and print film, and he divides his subject matter between the urban and the natural world.
Reviewing Manuscripts for Biomedical Journals

Gus M Garmel, MD, FACEP, FAAEM

Abstract

Writing for publication is a complex task. For many professionals, producing a well-executed manuscript conveying one’s research, ideas, or educational wisdom is challenging. Authors have varying emotions related to the process of writing for scientific publication. Although not studied, a relationship between an author’s enjoyment of the writing process and the product’s outcome is highly likely. As with any skill, practice generally results in improvements. Literature focused on preparing manuscripts for publication and the art of reviewing submissions exists. Most journals guard their reviewers’ anonymity with respect to the manuscript review process. This is meant to protect them from direct or indirect author demands, which may occur during the review process or in the future. It is generally accepted that author identities are masked in the peer-review process. However, the concept of anonymity for reviewers has been debated recently; many editors consider it problematic that reviewers are not held accountable to the public for their decisions. The review process is often arduous and underappreciated, which is one reason why biomedical journals acknowledge editors and frequently recognize reviewers who donate their time and expertise in the name of science. This article describes essential elements of a submitted manuscript, with the hopes of improving scientific writing. It also discusses the review process within the biomedical literature, the importance of reviewers to the scientific process, responsibilities of reviewers, and qualities of a good review and reviewer. In addition, it includes useful insights to individuals who read and interpret the medical literature.

Introduction

Writing for publication is a complex task. For many professionals, producing a well-executed manuscript conveying one’s research, ideas, or educational wisdom is extremely challenging. Authors, clinicians, scientists, and researchers have varying emotions related to the process of writing for scientific publication. Although the issue has not been studied, a relationship between an author’s enjoyment of the writing process and the outcome is highly likely. As with any skill, practice generally results in improvement, which in turn results in increased satisfaction and comfort with the process. In addition, authors can consult literature that focuses on manuscript preparation and the art of reviewing manuscripts. Accordingly, this article describes essential elements of a manuscript and the review process, in hopes of simplifying the creative and review process and improving scientific writing. It is generally accepted that authors’ identities are masked during the peer-review process. Similarly, the majority of journals guard their reviewers’ privacy during the process. This protects reviewers from direct or indirect author demands during the review or in the future. However, reviewer anonymity is under debate; many editors consider it problematic that reviewers are not held accountable to the public for their decisions about whether to recommend manuscripts for publication.

The review process is often arduous and underappreciated, which is one reason why biomedical journals acknowledge editors and frequently provide public recognition of reviewers who donate their time and expertise in the name of science. This article also discusses the importance of reviewers to the scientific process, reviewers’ responsibilities, and qualities of a good review and reviewer. In addition, it includes insights useful to individuals who read and interpret the medical literature.

Definitions

According to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (Uniform Requirements), an author is someone who has made substantial intellectual contributions to a published study. An editor of a journal is the person responsible for its entire content. These requirements state that editors must have full authority for determining the journal’s...
editorial content. Finally, the International Committee of Medical Journal Editors, which produced these requirements, describes the peer-review process as an intrinsic part of all scholarly work, including the scientific process. It is the critical assessment process of each manuscript submitted to a journal by unbiased, independent experts who are not part of the editorial staff. For this article, the term manuscript is used for materials not yet published; article refers to published manuscripts.

**Protections**

Protection of an author's intellectual property (data, theories, conclusions) must be maintained at all times by those involved in the publication process. Author and reviewer confidentiality must be maintained for blinded peer review, although the editorial staff should be able to identify all parties if necessary. This is important if allegations of fraud or dishonesty occur or if there are accusations of professional misconduct by any (or an outside) party. In addition to the ongoing debate as to whether reviewers should remain anonymous, whether to publish their comments is also argued. Whatever details exist regarding these questions, they must be unambiguous and available in advance to authors and journal readers. Reviewers should be held accountable to these established guidelines.

**Reviewer Responsibilities**

Once reviewers agree to review a submitted manuscript, they generally agree to complete their work within a set time frame. Reviewers may either express interest in the manuscript and recommend publication or convey concern that the submission is not suitable for that particular journal (ie, they recommend that it be rejected). It has become more common for reviewers to encourage revisions from an author before committing to a publication decision, especially given the recent increase in submissions to English-language journals by researchers whose first language is not English. This is not unreasonable, although the reviewers' comments should be composed in a manner that is helpful to the author. This nondecision should neither falsely inflate an author's hopes for publication of an article within that journal nor delay an author's chances for publication elsewhere. Reviewers should seriously consider the manuscript after the author has made the suggested revisions.

All reviewers have personal biases. These must be acknowledged and limited as much as possible when reviewers consider manuscripts for publication. Reviewers are more likely to favor submissions with interesting titles likely to grab readers' attention. They are also more likely to prefer manuscripts that are clearly written with favorable results and meaningful, unique, or creative ideas. Conversely, reviewers may be more likely to reject manuscripts with negative results (referred to as publication bias); that neither describe nor discuss novel ideas or novel results; that contain numerous and/or egregious grammatical, syntax, or spelling errors; and that would not be interesting to readers. Because bias is impossible to exclude entirely from the decision (referee) process, editors-in-chief should work to build an editorial staff and establish a group of expert reviewers who consider submissions with thoroughness and reflection. Deliberate reviewers, editors, and staff who work well together and have discussed these issues in advance strengthen final manuscripts. This improves not only the quality of the journal but also the quality of medical literature in the aggregate.

It is important for authors to incorporate reviewers' suggested changes whenever possible. Ignoring suggestions by editorial staff or reviewers to improve a manuscript or to make it more appropriate for that journal without explanation is not recommended. Most reviewers see subsequent manuscript revisions and may review for other journals similar in scope. This may prove problematic for authors if they decide to pursue publication elsewhere. Depending on the number of submissions a journal receives, fewer manuscripts are accepted for publication than are rejected. It has been estimated that 1 in 5 manuscripts are accepted for publication, although it is difficult to know this with certainty because manuscripts are submitted to more than one journal once the initial decision to reject has been made. Authors who do not follow submission instructions carefully or who elect not to incorporate reviewers' comments or answer reviewers' queries provide legitimate reasons to reject even a good manuscript.

A cover letter from the primary author addressing specific reviewer or editor queries, with explanations why some were not addressed, is appropriate, expected, and appreciated. This is especially true if the elapsed time between review and revision is months.

Numerous challenges are inherent with reviewing manuscripts for scientific publication. First, an editorial staff must have confidence in the abilities and skills of a reviewer. It is not always necessary for reviewers to have expertise in a particular area, because they can still submit useful comments.
In this circumstance, however, the reviewer has an obligation to point out this lack of expertise to the editor-in-chief. Thorough reviews take time, and individuals qualified to review manuscripts likely have their own commitments and deadlines. Reviewers must be professional in their critiques, using comments that would be unlikely to offend an author. Often, reviewer comments are filtered through the editor-in-chief or one of the assistant or associate editors, providing an opportunity to soften negative criticisms and maintain the journal’s professional reputation and integrity.

Despite donating their time, reviewers represent the journal for which they review. This also allows the editors to review the reviewers. Because manuscripts are not submitted to multiple journals at once, it is expected that once reviewers agree to review a manuscript, they adhere to a strict, predetermined timeline so that authors promptly learn if there is interest in their submission and how much revision is necessary. Often, it is difficult for administrative or editorial staff to identify appropriate reviewers for a submission. This may be due to a lack of available reviewers (especially common during the summer or the months before grant or national meeting deadlines) or to the nature of the topic (narrow in scope, advanced, or unique). It is possible that the journal’s review board may not possess the requisite number of reviewers for a particular area of research. Occasionally, reviewers’ recommendations differ to such an extent that additional reviewers are needed to evaluate a manuscript. When this occurs, a high-level editor must increase his or her involvement in the review process. In addition, authors may be asked by the editor-in-chief or editorial staff to suggest potential reviewers.

It is incumbent on the editor-in-chief to make final decisions about the articles published in a particular issue, including publication order within the journal, on the basis of content, timing, space availability, and numerous other issues. Often, editors choose to rush or hold manuscripts accepted for publication to produce theme issues, to get certain topics to press before competing journals do (especially for breaking medical news), or to improve balance within an issue given the subject matters of other manuscripts being published in that issue.

**Essentials of the Review Process**

A number of elements comprise a good review of a submitted manuscript. Reviewers are essential to editors, as they assist them with decisions about which articles to publish; to authors, as they provide expert advice about their ideas and the manner in which they are described; and to readers, as they are expected to help confirm scientific validity and research methodology rigor. Additionally, statistical reviewers may identify more appropriate statistical tests or methods—or even study designs—that better suit the data collected and the research question being investigated. Most reviewers are not statisticians; reviewers should, however, have some familiarity with common statistical measures and general concepts used in research.

Reviewers must have a sharp eye for detail. Generally, the editorial staff (and perhaps editors) will preview all submissions to make sure they possess appropriate merit to justify review. Editorial staff should make certain that tables, figures, font, layout, and submission rules have been followed. If not, they can quickly respond to the authors, asking them to resubmit their manuscript in the appropriate format. Tables and graphs should have legible labels, be numbered sequentially, and be of good quality for reproduction. Sections within the manuscript should follow each other in a sequence standard for that journal, with each section containing appropriate content. Although the references should be relevant and current (one of many responsibilities assumed by expert reviewers), editorial staff can perform a quick check to confirm that references are in the correct format.

Reviewers should be as specific as possible in their comments to the authors. These comments should include suggestions, requests for clarification, and statements that instruct authors to correct or change something. Comments should be detailed enough to assist authors in making necessary edits or modifications, but not so detailed that the manuscript is rewritten. Some journals have professional copy editors on staff; many use freelance copy editors. This allows reviewers to focus more on content, methodology, and conclusions than on grammar and syntax. This is especially important for manuscripts submitted in English by authors whose first language is not English. If a sentence, paragraph, or concept is unclear to an expert reviewer, it will likely be ambiguous to the journal’s readers.

Reviewers should agree to provide a useful, quality, timely, and unbiased assessment of submitted manuscripts. The review does not have to be lengthy. However, it should be sufficiently detailed that authors can understand what the reviewer is looking for or expecting in the revision, and can thus
improve subsequent drafts of their manuscript. A useful manner in which to proceed includes providing general comments, both favorable and negative, related to the entire manuscript and the reviewer's overall impression, and then addressing each essential component of the manuscript (Table 1).

Components of Manuscript Reviews

Reviewers should consider each section individually on its own merit. It may not be necessary for reviewers to comment on each section; in fact, the absence of comments related to a section may indicate the absence of problematic issues in the reviewers’ opinions. However, reviewers should address both information within these sections that requires correction and any lack of information.

The IMRAD (introduction, methods, results, and discussion) structure is a direct reflection of the scientific discovery process; thus, both observational and experimental manuscripts are encouraged to follow this format. Additional sections or subheadings include Title, Abstract, Limitations, References, and Figures (with legends). Editorials, commentaries, case reports, review articles, and other nontraditional research manuscripts are unlikely to share this format. Author names and degrees, affiliations, conflicts of interest, and funding support must be provided for all submissions and reviewed by editorial staff because reviewers are not given these. Each journal’s format will dictate where, how, and to whom this information is provided. Authors and reviewers should be familiar with the CONSORT (Consolidated Standards of Reporting Trials) Statement for reporting randomized trials, and with the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network for reporting medical research.

A reviewer should first consider the manuscript’s title. Is it interesting? Catchy? Relevant? Does it give away the conclusions of the research? Does it contain a mnemonic that might garner attention? If so, is the mnemonic appropriate? Is this a negative study with a negative title? Does the title draw the reader into the study itself? The manuscript’s title may provide the first opportunity for a reviewer to share his or her opinion with the author (or editorial staff).

The abstract provides the overall information about the research and the setting in which it occurred. It should include brief background material, methods, findings, and conclusions. Each journal’s abstract format may differ, including word count limitations and required components. Abstracts are important for readers (and journals) because they are often the only section of the article read. Furthermore, abstracts may be the only portion of an article indexed in electronic databases. Therefore, it is vital that authors accurately represent their findings in the abstract.

The introduction of an article presents the topic to readers. It includes background information, the context and reason for the study, the significance of the topic, and the incidence and prevalence of the issue being investigated. Occasionally, descriptions of the study design and findings may appear in this section, despite this not being the appropriate area of the manuscript. When this occurs, the reviewer should alert the authors. The research question under investigation and the purpose of the study should be clearly stated within this concise section.

<table>
<thead>
<tr>
<th>Table 1. Checklist for reviews: areas for comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Research question—importance, relevance, and utility</td>
</tr>
<tr>
<td>2. Originality</td>
</tr>
<tr>
<td>3. Strengths and weaknesses of methodology, experimental design, statistical approach, and interpretation of the results</td>
</tr>
<tr>
<td>4. Writing style and clarity</td>
</tr>
<tr>
<td>5. Presentation of figures and tables</td>
</tr>
<tr>
<td>6. Ethical concerns—animal, human, conflicts of interest</td>
</tr>
</tbody>
</table>


The materials and methods (or methods) section tends to be rather complex and detailed. However, this is expected for a scholarly manuscript resulting from rigorous research. This section describes all planned activities prior to data collection. Inclusion and exclusion criteria for study participants ensure the safety of group members, increases the homogeneity of the groups, and improves the likelihood for reproducibility and applicability of the study in another setting. These criteria are provided in painstaking detail. How randomization was performed; who enrolled patients; when (and how) they were enrolled; how data were collected; the data variables themselves (ie, continuous, ordinal, dichotomous); and which equipment, drugs, doses, administration techniques, and settings were used are key elements discussed within this section. The methods section should be written as the recipe for a study’s design, so that others can reproduce the research in a different (or the same) setting. How the data were analyzed, by whom, and using which statistical tests of significance are crucial elements of this section as well. Many novice readers skim this section or skip it entirely. However, it is one of the most important sections of the manuscript. Therefore, it
is the responsibility of reviewers to see if they can correctly reconstruct the study given the information provided in this section. If they cannot, they must request more detail from authors for this section. Because the study has already been conducted, the study design itself will not change on the basis of reviewers’ comments. However, the manner in which the section is reported can be modified to provide readers with a greater understanding of the complexities of the authors’ methodology. Furthermore, reviewer concerns about the materials and methods employed by the authors in the study may disclose several limitations that authors can report.

For manuscripts that review a clinical or health care topic, the methods employed by the authors to identify articles (including the time frame and databases searched), selection criteria used for those included, how data from those articles were abstracted and synthesized, and which articles were excluded in the research and why are essential elements in this section.

The results section includes the research findings. These can be presented as text, although tables, graphs, and illustrations help emphasize important findings. It is not necessary that all data be presented in figures. Whenever possible, images should not greatly interrupt the flow of text. Figures that are less essential to this section, or to understanding the main results from the study, may be added at the end of the manuscript as appendices or published on the journal’s Web site if print space is an issue. Data from tests of statistical significance should be reported here as well. Authors should not interpret their results in this section; interpretation of results occurs in the discussion section.

The discussion section of an experimental study briefly summarizes the main research findings. The discussion can emphasize unique aspects of the study and the conclusions that can be drawn. This section should try to explain how and why these results were obtained, along with their significance. References to similar studies are included in this section, in which brief reports of those studies’ findings are made, including comparisons with and contrasts to study design and results. Here, authors offer possible explanations for differences between their study and other studies. Implications and possible future research directions are appropriate to include in this section.8

A limitations section is not included in every article, because not every article has a need for this. For example, an editorial or review article would not require such a section. Not every journal or published article includes this section, unfortunately. In this section (or within the comments or discussion section), authors present to readers what they consider to have been limitations of their study design, such as problems with enrollment, outcomes, endpoints, or biases. Often, reviewers request that authors include limitations they had not considered but were identified during review of the manuscript. These limitations are not attributed to the reviewers in the final version of the article, and the anonymous reviewers’ suggestion of additional limitations is not acknowledged in print. The limitations section should be thorough and insightful. As all studies have flaws, listing a number of limitations in no way decreases the impact of the research findings. In fact, many scholars believe that a well-prepared limitations section strengthens the authors’ conclusions.

The author’s conclusions are summary-type statements that pull together the research question, findings, and implications at the end of the manuscript. This is an opportunity for the authors to share with readers the significance of their research. Authors should be careful not to overstate their conclusions or make claims that are unsupported by their results. Statements that suggest new directions for research or potential implications of this research (especially related to health care costs or other financial issues, if not studied) should be clearly stated as hypothetical or suggestive, not as fact. This section is generally concise and uses direct language, without theory or grandiosity. Reviewers should determine to the best of their ability whether the authors’ stated conclusions are supported by their data. These conclusions should neither overstep nor overreach the results presented in the research provided by the authors.

An acknowledgment section (if provided) should be reviewed to determine its appropriateness for publication. Not all journals include such a section.

The references section should follow the expected pattern of the journal in style, format, and sequence. Most journals prefer consecutive citations, although some prefer references provided alphabetically (and therefore not numbered sequentially). Whatever the instructions for references are for that journal, authors should follow them carefully, and reviewers should make note of this in their comments. References should be relatively current, important, and found in quality primary sources. Although personal communications or unpublished data as references may be relevant, these should be kept to a minimum (if used). If reviewers sense that references are from inappropriate sources, this may influence decisions related to
publication. Publications from an author or research group should be cited if the research is similar; however, if authors cite themselves to the exclusion of other articles or research, this should raise red flags for the reviewers. If possible, reviewers or someone from the editorial staff should randomly check citations for accuracy, because misrepresented information used once is often repeated in subsequent publications by different authors. This is especially true with background information found in the introduction section.

Many journals now include appendices to reduce the length of the article’s body, improve the flow of information presented, and allow the reader to access information without needing to skip over it. These appendices commonly include additional information about methodology (eg, from a prior publication) or information related to the outcome of randomization. This is often referred to as Table X, where two groups are compared against each other to demonstrate that the randomization process of an experimental investigation was indeed random. Because these tables tend to demonstrate that the two groups were equivalent, and that comparisons between these groups reached statistical significance, simply stating this in the body of the manuscript but including the details in a traditional table format has become common. Reviewers should make the effort to scan appendices to confirm that this information belongs in an appendix and not in an article’s body.

Tables and figures typically follow the last part of the submission, with clear legends. Authors can insert placeholder text (eg, Table X or Figure B) in the body of their text, because embedded tables or figures make it difficult for reviewers to follow the flow of the manuscript. Embedding figures may also be difficult for authors because of word-processing skills and software availability. Authors are generally given the instruction that each figure, table, and graph should be separate, clearly numbered, and clearly labeled so there is no confusion for the editorial team. These tables and images should be easy for the reviewers and editorial team to view and to include in the final layout and publication. Requisite permissions to use published material (including that from the Internet) should be obtained in advance by authors and attached to these figures. Reviewers or editorial staff should confirm that these permissions are appropriately constructed.

Review Process

After careful review of a manuscript’s individual sections and overall merits, reviewers are expected to provide editors with recommendations regarding the manuscript’s suitability for publication. Manuscripts can be accepted without revision (although rare, this does occur, especially for invited editorials or submissions), accepted with minor revisions, accepted with major revisions (often referred to as “conditionally accepted”), or rejected outright. A category of decision pending revisions is possible, although not all journals do this because many authors want to know what will likely occur once they take the time to make revisions. As the number of scientific manuscripts submitted grows, a streamlined peer-review process and a talented editorial staff assume additional influence on the journal’s reputation and impact factor.29

Reviewers have a number of responsibilities to both authors (Table 2)30 and editors (Table 3),30 and, ultimately, the journal’s

<table>
<thead>
<tr>
<th>Table 2. Reviewers’ responsibilities to authors</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Provide written, honest, and unbiased feedback in a timely manner</td>
</tr>
<tr>
<td>• Express a critical opinion about the manuscript, as experts in the field, in a collegial and constructive manner</td>
</tr>
<tr>
<td>• Comment on the style of writing, especially its clarity</td>
</tr>
<tr>
<td>• Rate the work’s detail, methodology, relevance, accuracy, and originality</td>
</tr>
<tr>
<td>• Avoid comments or criticism of a personal nature</td>
</tr>
<tr>
<td>• Maintain professionalism and confidentiality, especially given the competitive nature of research, funding availability, and publication</td>
</tr>
<tr>
<td>• Refrain from directly contacting authors without permission from the editor, unless the journal stipulates otherwise</td>
</tr>
</tbody>
</table>

Adapted with permission from Jordan K, Pederick R. Guidelines for reviewers [cited 2009 Jul 18]. Available from: http://people.bath.ac.uk/liskmj/living-spring/journal/reviewgd.htm.29

<table>
<thead>
<tr>
<th>Table 3. Reviewers’ responsibilities to editors</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Respond to the editors promptly if unable or unavailable to review a manuscript</td>
</tr>
<tr>
<td>• Recommend names of other experts as potential reviewers if unavailable</td>
</tr>
<tr>
<td>• Determine the scientific merit of the submission, with recommendations for acceptance or rejection</td>
</tr>
<tr>
<td>• Identify possibilities to improve the manuscript to the authors</td>
</tr>
<tr>
<td>• Point out potential ethical concerns about research methodologies or similarities with other papers or ongoing research</td>
</tr>
<tr>
<td>• Acknowledge personal or author conflicts of interest and inform the editor of these</td>
</tr>
</tbody>
</table>

Adapted with permission from Jordan K, Pederick R. Guidelines for reviewers [cited 2009 Jul 18]. Available from: http://people.bath.ac.uk/liskmj/living-spring/journal/reviewgd.htm.29
Reviewing is a skill that takes time to develop; it develops in part from reading, writing, researching, and practice. Peer review is an integral part of the publication process.

Table 4. Reviewers’ responsibilities to the readers

- Ensure that published articles adhere to journal standards, as well as to standards of scientific practice
- Protect readers from incorrect or flawed research
- Identify missed references or erroneous citations (including misquoting or misinterpreting an author’s findings)

Table 5. Ten qualities of a good reviewer

1. Competence (and/or expertise) in the field
2. Consistency (within and between reviews)
3. Confidentiality
4. Responsibility in feedback (constructive, educational, unbiased)
5. Knowledge of the scientific process (research and writing)
6. Integrity
7. Impartiality
8. Timeliness (punctuality)
9. Detail orientation
10. Outstanding language skills


be challenging. Perhaps it is less stressful to offer feedback on and make decisions about someone else’s work than receiving it on your own. Yet reviewers assume tremendous responsibility to the authors and the medical community, given the authority of their position. This creates stress and challenges for reviewers that most contributors do not recognize. Reviewing is a skill that takes time to develop; it develops in part from reading, writing, researching, and practice. Peer review is an integral part of the publication process. In addition to being expert in a field for which they review manuscripts, good reviewers possess traits that make them valuable to their journal, including fairness, courteousness, and punctuality. Good reviewers and reviews allow authors to remain positive about their manuscripts and their submission experience. Reviewers provide recommendations to editors about the merits of a manuscript and the appropriateness of the submission for the journal; it is the editors who make final decisions about publication. Editors should take an active role in reviewing their reviewers and provide feedback to them on the quality and timeliness of their reviews.33,35,36 Reviewers and editors who treat their authors and their manuscripts well enhance the quality of their journal, its articles, and the medical community as a whole.

**Disclosure Statement**

*The author(s) have no conflicts of interest to disclose.*

**Acknowledgments**

I am grateful to Doris Hayashikawa of the Kaiser Santa Clara Health Sciences library for her resourcefulness during research for this article and for other scholarly projects.

Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

**References**

27. equator-network.org [homepage on the Internet].
Medical Journalism

There never was a time when medical journalism was so enterprising as now, nor its pages so filled with valuable instruction, and there never was a time when a physician could so soon fall behind and be lost sight of as now.

— John Hamilcar Hollister, 1824-1911, physician, author, and professor of medicine
MULTIPLE CASE STUDY

My First Patient

My first patient of the day was Tina. She was referred to me by the physician-in-chief of my medical center because she was a “challenging patient.” I had been asked to assume her care because she had visited the Emergency Department (ED) every month for the past six months for neurologic symptoms including slurred speech, falling, and focal weakness of an arm or leg. A computed tomography or magnetic resonance imaging scan of her head was obtained at every visit to the ED and its results would be read as normal. Tina would leave the ED upset because she believed that she had multiple sclerosis and was not being treated. She would write angry letters of complaint after every encounter with the ED. She reiterated her symptoms when I first met her, and she was forthright about what she wanted—1 g of intravenous (IV) steroids—because that was what her recently retired neurologist had given her despite the lack of objective evidence of multiple sclerosis. She sat there expectantly awaiting my response. As I pondered how to reply, I noticed a golden cross shining against her chest, reflecting the bright light from the overhead fluorescent fixture, and suddenly it occurred to me how I might help her.

Healing and Spirituality Conference

Coincidentally I had attended a conference on healing and spirituality the weekend before at the Kalsman Institute in Los Angeles. More than 200 caregivers had been there—mainly nurses and hospice workers; fewer than 5% were physicians. The vast majority were women, although there were a few men, and I had felt out of place as a male physician. I participated in some workshops on music and healing because this is an interest of mine, and I deliberately shied away from anything to do with prayer. I was traditionally trained with a background in biochemistry—so how could I incorporate prayer into my medical practice, which was based entirely on the scientific model? However, as I listened to what some of the speakers reported back from the workshops on using prayer in the examination room or in hospital room settings, the role of prayer no longer seemed so foreign to me. I still thought that prayer would never be something I would employ unless I felt I had no other option to solve a clinical dilemma, and I was aware that the offering of prayer is for the benefit of the patient and not for the clinician.

Many polls have indicated that Americans are highly religious. It is well known that prayer can help people cope with illness, and many believe that prayer contributes to physical healing. In a 2008 PEW national survey of more than 36,000 Americans, 92% reported a belief in God or a universal spirit. More than half of Americans polled pray at least once daily. Whether prayer actually heals or instead works as a placebo, it has been administered for hundreds of years. It has few adverse side effects; it is low cost; and it can be provided safely in multiple doses. Understanding all of this, I began to think that maybe prayer was worth more consideration.

A Personal Breakthrough

I was feeling challenged in my visit with Tina, and I felt that I needed to provide her with a safer and more acceptable alternative than 1 g of IV steroids. I asked her what she used for spiritual support, and she confirmed that she prayed on a regular basis. I acknowledged that I heard her request to treat her with IV steroids, but in good conscience I could not give her a medication without objective evidence of what I was treating, particularly a medication such as steroids with serious side effects. At the conclusion of our visit, I gingerly asked her if she would like to say a prayer with me. Tina readily agreed. I held her hands, and while we faced one another, we each closed our eyes. With full sincerity, I said a prayer for her well-being and recovery and wished her strength to cope with her “illness.” At the conclusion of the prayer, I opened my eyes and detected her smile. I felt that I had made a personal breakthrough not only in helping Tina but also in my own evolution as a physician and care provider.

Gerald Saliman, MD, is an Internist and Chief of Patient Education at the South San Francisco Medical Center, and has served as a communication coach and led training sessions in Northern California communication skills workshops. E-mail: gerald.saliman@kp.org.
I saw Tina every one to two months; at the conclusion of each visit, I said a prayer for her, and she in turn recited a prayer for me. Tina never asked again for steroids following her initial encounter with me. She stayed out of the ED for more than nine months, until she fell taking out her garbage and broke her leg. This time, after her visit to the ED, she did not write a letter of complaint to the hospital administration.

Office Visit Prayer

Since that day with Tina, I have discovered that prayer is an important component in many patients’ lives and that they welcome a chance to say a prayer at the conclusion of their office visits. I have prayed with people from various religious backgrounds—Christians, Native Americans, Hindus, Buddhists, and Jews. The only time a religious division came up was when I asked Mary, a Jehovah’s Witness, if she wanted to say a prayer. She asked me what my religion was, and because it was different from hers, she declined my offer to pray for her. Although it was the first time that I had seen her as a patient, she remarked that her visit with me was the best visit she had experienced with any physician. I suspect that my simply asking her about her spiritual beliefs inspired her trust in me.

It is sometimes difficult for physicians to convey the message of how much we care for our patients, and I have found that holding patients’ hands and praying for their well-being can be a socially accepted expression of care in some cases. There is another benefit as well. I can directly instill my therapeutic recommendations by asking God to provide them the strength to quit smoking or asking God to help them with other modifiable behaviors.

When other family members join in prayer, I feel a sense of special bonding that goes beyond the traditional physician–patient relationship. I have a patient who is a 30-year-old black woman with sickle cell C disease. At the conclusion of each visit with her, I offer a prayer. When her mother joins us to make a threesome, I am always thrilled because she chants the most divine supplicating prayer in response—likely well rehearsed from having prayed intensely her entire life for the welfare of her daughter.

More Case Examples

Here are three other examples of patients with whom I have prayed. Following this section are examples of patients who have declined.

Rodolfo

Rodolfo is an elderly man with severe angina and inoperable coronary disease who came to see me more than one year ago with complaints of having to take nitroglycerin tablets frequently. I made some adjustments in his medication, and I said a prayer for him at the conclusion of our visit. When I saw him back in the office six months later, he wore a broad smile and profusely thanked me for the “prayer that worked”—because he no longer needed to use nitroglycerin. I was worried that he attributed all of his improvement to prayer and I encouraged him to be sure to continue to take all of his medicines. I gave him another dose of prayer to tide him over to his next visit. When I closed the exam door behind me, I couldn’t help but feel a sense of awe about his improvement.

Hector

Hector came to see me in July 2008, terribly depressed because of the economy and his near financial ruin. He was crying in my office, but fortunately was not suicidal. He had lost his home to foreclosure, but he still had a job doing auto repair work. I prescribed an antidepressant for him and made an appointment for him to see a psychologist within one week. By exploring with him what emotional and spiritual resources he had available, I discovered that prayer was an integral part of his life. He was both surprised to learn that a physician would say a prayer for him and eager to experience it. He failed to keep his psychotherapy appointment but showed up to see me a few months later for an unrelated knee problem. No longer depressed, he appeared completely transformed from his earlier visit with me. This time, he had tears of appreciation for me instead of the tears of sadness that he had cried previously. The simple prayer that I said for him had made him shift his focus from all he had lost to the things that he was fortunate to have in his life. He had begun doing volunteer work in South San Francisco, helping others who had gone through foreclosure. He said that my prayer for him had healed him, and after only one dose, he stopped taking the antidepressant that I had prescribed. I, too, felt stunned at how transformative my prayer was. The effect was quicker than I had ever witnessed from antidepressants or psychotherapy. Physicians often wonder why some patients stop taking their medicines without informing their physician; one explanation might be that some patients find an alternative or complementary
therapy, such as prayer, acupuncture, or nutritional supplements, about which they are too embarrassed to inform their physician.

Christina

Christina came to see me for a routine physical. She was feeling well except for being distraught because her 95-year-old mother had recently broken her elbow. Christina was unusual for a person her age in that she did not take any prescription medicine; she had healthy eating and exercise habits. The medical portion of her encounter with me was therefore short, and we used the time to address her emotional needs and share prayers. Christina prayed to God to grant her mother patience, and she prayed for everyone who was unfortunate and disabled. She beseeched God to help both the victims of crime and the perpetrators of crime. She prayed for those who were hospitalized, for those who had injuries from accidents, and for the poor and the hungry. I mentioned to her after she said her final words that this was one of the finest prayers I had heard. She responded that her prayers were authentic because they came directly from her heart. In his book *How to Know God*, Deepak Chopra, MD, the well-known author who has written extensively about God and spirit, describes the experience Christina and I shared: “In this place the patient is not a stranger, nor is she removed in space. You and she are joined in a place where the boundaries of the body no longer count.” 2 This special phenomenon as we experienced it was just as Dr Chopra described. Her appointment for a physical examination with me was holistic. The use of prayer served as one of the components of providing comprehensive care for the body, mind, and spirit.

Patients Who Declined

There have been only four instances out of my more than 100 offers of prayer in which patients declined. My high response rate most likely stems from asking many of my patients what resources they typically use for spiritual and emotional well-being, rather than going directly to “Do you pray?” When I short-circuit this process, I run into awkward moments. Mary, whom I mentioned earlier, declined because of a difference in religious beliefs. The three following examples illustrate the importance of care and sensitivity in assessing a patient’s spiritual beliefs before inviting prayer.

Arthur

Arthur, a church deacon, lost his son due to sepsisemia from a cortisone injection to the shoulder. I jumped to the conclusion that it would be natural for a church deacon to want to pray, but I had failed to inquire if prayer was a means of emotional support for him. He politely declined my offer to say a prayer.

Sidney

Sidney is an elderly man whom I have known for almost 27 years. He has severe mitral regurgitation, but he is otherwise coping well with the physical limitations of his heart condition. I was in a rush one day, and it occurred to me that I had never asked Sidney if he wanted to say a prayer. I failed to ask him what he did for spiritual support or even if prayer played a role in his life. He was suddenly taken aback when I offered to say a prayer for him, remarking good-naturedly, “Are you trying to tell me something?” I had no intention of implying that his death was imminent, so I carefully backed out of that faux pas. We ended up having a good chuckle together.

Vivian

Vivian, whom I have treated for many years for high blood pressure and anxiety, came to see me for an urgent appointment in a state of profound grief because her younger brother had died unexpectedly after a heart attack. We usually end each visit with a prayer, but at the end of this particular encounter, she uncharacteristically declined. She was angry at God for having taken her brother from her. Strangely enough, expressing her anger to God appeared to be therapeutic. She declined my offer to refer her for grief counseling.

Boundaries

There are boundary issues whenever one enters a patient’s private space. Here is how I think about it. Just as I always ask permission before I physically examine patients, consider asking permission before holding someone’s hands. One must understand what is considered “safe touch” and what isn’t; approach an inquiry about spirituality and prayer in a way that makes it safe for the patient to say “no thank you,” without fear of alienating the physician or risking the relationship. If nonverbal clues indicate the patient is hesitant, it is important to say to the patient, “It’s okay to decline, my feelings won’t be hurt.”
Be aware that the offering of prayer is for the benefit of the patient, not the clinician.

Much of what transpires in physician-patient encounters is nonverbal, and part of being a sensitive caregiver is paying attention to nonverbal clues. This is not a situation where written consent is obtained because it is a natural outgrowth of conversation with selected patients. Just as we ask permission when we invade a person’s physical space by touching, we need permission to invade a patient’s spiritual space as well.

I hope that sharing my experience of praying with patients adds a practice perspective that will enable other caregivers and their patients to have that occasional “wow” encounter. This is a path that has proven effective with selected patients, but it may not be a technique that works for all physicians. There is nothing about this that is easy, and this may be why it took me almost 20 years of practicing medicine before I had the courage to pray with my first patient.

Discussion

Nine years ago, I said my first prayer with a patient almost out of desperation; since then, it has become an integral part of my practice. I have been reluctant to share my experiences with other physicians for fear that I would not be seen as a “real physician.” In the absence of a physician role model in using prayer, I have made a few mistakes along the way as I learned how to pray with patients. As with any prescription or intervention we use as health care providers, I have tried to learn by experience. In a hectic day of seeing patients one after the other or responding to one patient message after the next, taking a moment to have a spiritual encounter with a patient reminds me of the rewards of being an internist. I gain a sense of higher purpose by combining my problem-solving skills with an awareness of the divine. This in turn promotes the mind–body connection, helps achieve quality outcomes, and serves as a valuable contribution in clinical management. I suspect this is because “Prayer may return a sense of balance in life, and faith offers a relief from physical burdens of stress and worry. If we have faith, we are more accepting of our human condition, our human frailties, and our destiny in life.”

I had the opportunity to speak to a former ED physician. He has found that when a physician first contemplates praying with a patient, there is usually a distinctive patient encounter that triggers the response to pray. He described a seminal experience with a patient that was strikingly similar to my own. After informing a patient that she had metastatic cancer to her brain, he was compelled to pray with her when his attempts to provide medical reassurance failed to comfort her. “Praying with Ms Martinez [not her real name] felt so completely right.” In the intervening years, he has become a full-time chaplain at the Stanford University Medical Center and trains medical students in spiritual care.

Clearly one does not have to be a hospital chaplain to pray with patients. Larry Dossey, MD, is a physician who has written extensively about connecting prayer, health, and healing. In his book Healing Words, he states, “I emphatically do not believe that physicians should impose their spiritual beliefs on their patients. For the physician who feels the need to do something that goes beyond the physical means, however, prayer perhaps is the best method.” When I first began to pray with patients, it was not based on any specific religious principle, but it has become for me an expression of empathy, hope, and gratitude. For those who may be considering praying with patients, it does help to understand one’s own spirituality and to have a conviction that everything cannot be explained by science alone. Probably the most essential ingredient for praying with someone is the desire to seriously connect in a way that becomes spiritual. Many of my patients have shared that they include me in their daily prayers, and I feel humbled to be a part of their thoughts. The relationships that I have formed remind me that in addition to providing standard medical treatment, I also have the ability to profoundly affect my patients’ lives using the power of prayer.

... as we ask permission when we invade a person’s physical space by touching, we need permission to invade a patient’s spiritual space as well.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgment

Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.
Magnificence

For me the practice of medicine has become the pursuit of a rare element which may appear at any time, at any place, at a glance. It can be most embarrassing. Mutual recognition is likely to flare up at a moment’s notice. The relationship between physician and patient, if it were literally followed, would give us a world of extraordinary fertility of the imagination which we can hardly afford. There’s no use trying to multiply cases, it is there, it is magnificent, it fills my thoughts, it reaches to the farthest limits of our lives.

— William Carlos Williams, MD, 1883-1963, physician and poet
Clinical Medicine

Image Diagnosis: Interesting Plain Film Radiographs from the Emergency Department

Gus M Garmel, MD, FACEP, FAAEM

Figure 1. Traumatic left wrist injury: AP and Oblique

On clinical evaluation, there is obvious deformity and swelling of this adult’s left wrist. The important finding here is identifying two injuries: fracture at the distal third of the radius (obvious) and dislocation of the distal radioulnar joint (obvious in these images but often missed). A line through the distal portion of the ulna should intersect the pisiform bone. These two injuries comprise a Galeazzi’s fracture (fracture-dislocation), which requires open reduction and internal fixation (ORIF). Injury to the Anterior Interosseous Nerve (AIN) may occur, but is commonly missed because this nerve has no sensory component. Injury to the AIN (branch of the median nerve) results in a loss of the pinch ability between the thumb and index finger.

Figure 2. Traumatic right wrist injury in a child: AP and Lateral

Note the slight wrinkle (bulge) in the distal portion of the radius, approximately 2 cm from the unfused (normal) epiphysis. Known as a torus or buckle fracture, this fracture is common in children and often missed because it can be extremely subtle (and often identified in only one view). Additional clues to the diagnosis include a small amount of soft tissue swelling and swelling within the fascial planes near the fracture. Despite overlap of the radius and ulna on lateral view, the smooth contour of the distal radius changes to an abrupt angle at the site of the fracture.

Gus M Garmel, MD, FACEP, FAAEM, is a Senior Emergency Medicine Physician at the Santa Clara Medical Center, CA. He is also the Co-Program Director of the Stanford/Kaiser Emergency Medicine Residency Program, and Clinical Associate Professor of Emergency Medicine (Surgery) at Stanford University. E-mail: gus.garmel@kp.org.
The Use of Problem-Knowledge Couplers in a Primary Care Practice

Charles Burger, MD

In the Summer 2009 issue of The Permanente Journal, Lawrence Weed, MD, outlined the philosophy behind the development of the problem-oriented medical record and the subsequent development of the clinical decision tool called problem knowledge couplers. In this article, I describe how my associates and I have integrated the use of problem knowledge couplers into our Internal Medicine practice.

Background

Our practice consists of two full-time physicians and one nurse practitioner with the equivalent of 3.5 support staff per clinician. A family therapist is integrated into our practice, although she also maintains an independent practice. We are located in Bangor, ME, and are part of Martin’s Point Health Care, a diversified health care company offering both health plans and health care centers.

I was introduced to the problem-oriented record and system developed by Dr Weed as a second-year medical student. It is useful to remember that Dr Weed’s first article in the US—“Medical Records that Guide and Teach,” published in the New England Journal of Medicine—did not appear until 1968, so I had the opportunity to live through the revolution that that innovation in recordkeeping and thinking caused.

In 1971, after a residency in Internal Medicine and two years in the US Army, I joined Harold Cross, MD, and John Björn, MD, in their revolutionary practice in Hampden, ME. Both of these men had been trained by Dr Weed. It is impossible to overstate the contribution these men made to the acceptance and spread of the problem-oriented system. At that time, this was a revolutionary concept and was heartily resisted by the medical establishment. Besides the fact that it required clinicians to be clear and explicit about their thinking, it was thought to be impractical and not applicable in a practice setting. Drs Cross and Björn showed it could be done. The success of that practice put that straw man to rest, and the monograph they wrote about their experience became a medical best seller.

By 1984, I had established my own practice, and I began working with computerized problem knowledge couplers in a minor way. By 1993, my associates and I had begun using our own problem-oriented electronic medical record (EMR), and with a local area network in place, we extended our use of the couplers into all aspects of the practice.

We currently use the Centricity EMR (GE Healthcare, Fairfield, CT).

The Problem Knowledge Coupler System

The Problem Knowledge Coupler system was developed by Dr Weed to help overcome the inherent limitations of the human mind in decision making when faced with a complex set of data, the norm in most medical situations. Cognitive psychologists have long recognized this deficiency when the number of variables exceeds about seven. Since 2000, there has been a flurry of books in the popular press discussing our limitations in this regard (eg, The Black Swan, How We Decide, Predictably Irrational, Everyday Irrationality). They point out that subconscious biases distort our decision-making processes and occur instantly in all situations of everyday life. We know, for example, that left to our own devices, clinicians will form a hypothesis within 30 seconds of listening to a patient. From then on, we tend to exclude information that discredits that hypothesis and seek information that confirms it. So much for the scientific method!

The coupler principle is simple: gather a large number of variables (medical history findings, physical examination findings, laboratory data) and use a computer to sort them into all the diagnostic or treat-
The coupler principle is simple: gather a large number of variables ... and use a computer to sort them into all the diagnostic or treatment possibilities for that patient’s unique clinical situation.

The current list of couplers covers the majority of clinical problems and functions in a primary-care office: wellness, screening, diagnosis, and management. They are meant to be used routinely, not just with difficult cases. Routine use of couplers provides a critical standardization of input.

Coupler content is reviewed and updated every six months and downloaded electronically into our system. All current guidelines are incorporated, but their application is tailored to each unique patient situation. Feedback from users is encouraged.

Getting Started: Leadership, Vision, and Quality Management

The implementation of this computerized technology in our practice, as with any major technologic innovation, required a clear statement of purpose from the practice leadership, mobilization of the entire staff to that end, and adequate training and practice time. Accepting this way of thinking about medical problems is a truly transformational experience.

All staff members have to understand the principles of couplers, and workflow has to be changed to use the software most effectively. The greatest source of failure for any software implementation is to not change workflow to take advantage of the new software. Because process improvement and workflow redesign are constants in our practice, we have found it useful to first train our staff in the principles of quality management (systems thinking, continuous improvement, customer focus, and understanding variation) to help them absorb these changes and implement them quickly.

Getting Couplers Done

The process for diagnostic couplers starts with our triage coupler. This is a custom coupler that I have been developing since the late 1980s for use by our patient service representatives. When a patient calls with a new medical problem, the patient service representatives use this coupler to review a series of questions that will allow them to determine 1) whether the patient needs to be seen in the office, and if so, how soon; 2) how much time should be allowed for the visit; and 3) whether any testing should be done before the visit. In many cases, patient service representatives can provide advice and treatment to be followed at home, saving the patient an office visit. Patients with life-threatening symptoms may be told to go directly to an Emergency Department.

This tool is a perfect example of continuously updating and refining knowledge that then is made available to all users. It allows the patient service representative to act directly to assist patients without having to pass through the filter of the clinicians.

If the patient has a new complaint for which there is a coupler and is to be seen in the office, s/he is directed to a Web portal to complete the medical history portion of the coupler and e-mail it back to us. That is loaded into the office coupler system. Patients who are unable to complete the medical history from home are instructed to come in before their appointment to complete their portion of the coupler in the office. Using the patient’s time for this process is key to gathering the detailed, standardized database for the couplers and saves staff and clinician time. If this process fails, the medical-history portion of the coupler can be completed by clinical staff in an examining room.

As already noted, the triage coupler also defines the amount of time for the visit. Because our goal is to make quality the constant and time the variable, we want to match the amount of work with the appropriate amount of time.

Our goal is to review the appropriate management coupler for all chronic problems yearly. There are management couplers for most chronic problems (hypertension, cholesterol, chronic obstructive pulmonary disease, coronary disease, asthma, migraine, etc). The process for completing the management coupler is the same as for the other couplers: have the patient complete the history portion at home or, more often, complete the coupler in the examining room with the patient at the time of the visit. As with the diagnostic couplers, the guidance options are presented in a structured array, starting with things the patient can do and ending with medication options, including the pros and cons for each drug. In essence, we have created a complete care plan for that particular problem.
The patient leaves with rich information about each option selected.

**Using Couplers in the Examining Room**

In the examining room, our clinical support staff brings up the coupler with the already-entered patient input and the EMR on the computer screen. Because the coupler system is not integrated with the EMR, users are required to toggle between the two programs. Integration of couplers in an EMR is possible and essential.

The clinical support staff takes the history of the present illness and vital signs, entering the information on the latter into the coupler, along with any appropriate laboratory data. At this point, much of the work of the visit has been done, allowing the clinician to focus primarily on decision making. Collection of all of the pertinent information before engaging in clinical decision making is essential to avoiding the biases noted earlier. The clinician reviews the medical history findings for accuracy, annotates where appropriate, and then completes the coupler-specific physical examination. The program couples the data, and patient and provider are ready to consider the options for that problem in this unique patient situation.

All diagnostic possibilities suggested by a positive finding in the coupler are displayed, even if uncommon or rare. They are grouped into broad categories that help guide the analytic process. For instance, rapidly progressive or life-threatening diagnoses may be grouped first, those for which a single finding makes the diagnosis a consideration may be grouped next, and so on.

The clinician and the patient then consider the diagnostic options. The final decision can be made with the patient, considering his or her concerns and values in conjunction with the clinician’s clinical judgment. The patient participates in the process to the degree s/he is able and willing. Some want to participate and some do not, but all are given the opportunity. My experience is that they are more willing to do this with the management couplers.

The options selected are then flagged and the coupler session is saved. Each patient has a coupler record that is separate from the EMR. All coupler sessions run for that patient are saved in that electronic record. If there is pertinent new information, the clinician only needs to bring up the original stored coupler, enter the new data, recouple, and review the updated options without having to repeat the entire process. This is particularly useful for the management couplers when initial therapeutic choices may not be working and others must be considered.

**Couplers and the Medical Record**

When the coupler session is saved, the user is presented with a comment dialogue box. I use that to summarize my option choices and the next steps for evaluating the problem. The final document is then saved in the patient coupler record. The subjective and objective findings with the diagnostic or management options selected for consideration, plus my plan summary, may then be displayed as an encounter report. It is a simple step to copy this report into the EMR under the history of present illness and vital signs. There is no dictation, and typing is minimal. The patient leaves with a copy of that note and the printed options information that we selected.

**The Straw Man of Time**

The goal is to make quality the constant and time the variable. A concern might be that patient care “takes too long.” This was a common complaint about the problem-oriented medical record system also. However, as the old management saying goes, there is never enough time to do it right but always enough time to do it over. All of the couplers can be completed in the context of a 15- or 30-minute office visit. The most time-consuming part of the process is completed by patients themselves, and the system redesign allows us to complete the process within that time frame. As an added benefit, most coupler sessions can be coded at a high level because they include an extensive and detailed medical history and physical examination, and complex decision making is involved in sorting through the options. One can do well while doing good!

**What Have We Achieved?**

We have successfully integrated a sophisticated clinical support system into our busy primary-care practice with no loss of productivity. This has been achieved by a combination of system process redesign, engagement of the patient directly in the process, and a highly trained support staff. We have standardized inputs at the front end (itself a quality gain), with the variation occurring in the outputs (options) generated by each unique patient situation. We have minimized the chances that the rare or unusual case will be missed, and we are able...
The Use of Problem-Knowledge Couplers in a Primary Care Practice

We have shown that it can be done. We can finish the day knowing that in those situations where the coupler system has been used, we have given ourselves the best shot at practicing the best medicine possible. The only question is whether the profession is willing to minimize the limitations of the human mind to deal with complex data through the use of new tools.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

Acknowledgment
Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References

Progress
An able physician is more useful to a patient than the most devoted friend, and progress in medical knowledge does more for the health of the community than ill-informed philanthropy.

—Bertrand Russell, 1872–1970, British philosopher, mathematician, logician, and historian
Introduction
Case 1
A man, age 64 years, reports that he has had hoarseness and throat pain for the preceding three months. His symptoms have been constant and gradually worsening in intensity. He has lost approximately 15 lb (6.8 kg) and reports a 60 pack-year history of smoking, in addition to consuming three to four alcoholic drinks daily for the preceding 40 years. How would you treat this patient?

Case 2
A woman, age 56 years, reports that she has had intermittent hoarseness for six months that seems to be worse when she wakes up in the morning. In addition, she states that she feels as if a lump is stuck in her throat and she is constantly clearing her throat. She says that she does not smoke or drink alcoholic beverages excessively but reports that she experiences heartburn “every once in a while.” She is very anxious and concerned because her uncle died from cancer of the throat. How would you treat this patient?

Discussion
Hoarseness is the term often used by patients to describe a change in the quality of their voices. It is a common complaint among patients presenting in the ambulatory care setting. Possible causes of hoarseness are numerous and stem from many sources: anatomic, functional, neurologic, infectious, environmental, and neoplastic. Many common causes of hoarseness, such as voice abuse or viral laryngitis, can be benign and self-limited, but other causes, such as laryngeal cancer, can be life-threatening. These factors make the evaluation and treatment of a hoarse patient challenging and, at times, downright daunting.

Adding to the difficulty of diagnosis is the inability to easily examine the larynx. In a clinic, usually only an otolaryngologist has the ability and resources to perform flexible fiberoptic laryngoscopy or indirect laryngoscopy with a mirror. Although the mirror laryngeal examination can be extremely helpful, most primary-care physicians are not properly trained or adept in the technique. This often leads to reluctance in taking on the challenge of evaluating a patient with hoarseness.

Early training instills in most physicians the mantra “A good history is 90% of the diagnosis.” Although this may not always be true, a good history is essential in the evaluation of a patient with hoarseness. At the very least, a carefully directed set of questions can greatly narrow the differential diagnosis. It also enables the primary-care physician to better assess the need for specialty referral, which in turn leads to improved patient counseling and satisfaction. The following are some key issues to bring up when evaluating a hoarse patient.

Onset of Hoarseness
The onset of hoarseness can be broadly categorized into acute versus chronic. Many causes of acute hoarseness, such as viral and bacterial laryngitis, are self-limited or medically responsive. Others are accompanied by characteristic symptoms, such as the high fevers, sore throat, and drooling found in epiglottitis, or follow a sentinel event such as surgery or ingestion of a foreign body.

Chronic hoarseness has many possible causes, including voice abuse, smoke exposure, gastroesophageal or laryngopharyngeal reflux, and neoplasm. As the onset is usually insidious and progression gradual, recovery can often be gradual as well, which is important in counseling patients. Any patient with a significant history of smoking and drinking alcoholic beverages who has unremitting and worsening hoarseness accompanied by throat pain should be considered to have laryngeal cancer until it is proven otherwise and should be referred to an otolaryngologist.

Timing of Hoarseness
The timing of a patient’s hoarseness is revealing. Some patients complain that their hoarseness is worst in the morning; others notice
a gradual worsening as the day progresses. For some patients, the hoarseness is constant (ie, “all the time”); for others it is intermittent. Hoarseness that is worst in the morning often can be attributed to gastroesophageal or laryngopharyngeal reflux. Sometimes, a history of heartburn, regurgitation, or globus can serve as reinforcing findings to suggest reflux. However, the results of several studies have indicated that the majority of patients with laryngopharyngeal reflux may not have some of the classic findings of gastroesophageal reflux such as heartburn.\(^2\)\(^-\)\(^4\) Hoarseness that progressively worsens throughout the day can usually be attributed to voice abuse, especially in someone who speaks a lot or in the presence of a neurologic problem such as myasthenia gravis.\(^5\)

Hoarseness that is constant usually indicates an anatomic deficit, such as benign vocal cord lesions (eg, nodules, polyps) or malignant lesions (eg, squamous-cell carcinoma of the larynx). Traumatic injury to the vocal cords can also produce a constant hoarseness. Rarely, behavioral disorders such as functional aphonia\(^6\) can cause a constant change in the quality of the voice. Intermittent or fluctuating hoarseness, however, can be found in patients with periodic voice abuse, as exemplified by the improved Monday-morning voice of someone whose weekday job requires frequent voice use. Postnasal drip can also cause intermittent hoarseness.

**Voice Quality**

Careful observation of the patient’s voice quality can reveal the source of hoarseness. A voice shaken by tremor can often be found in a patient with Parkinson disease or essential tremor. A rough or harsh voice can result from a lesion of the vocal cord, either benign or malignant. A patient with vocal cord paresis or abductor spasmodic dysphonia will speak with a breathy or weak voice as the vocal cords fail to meet at midline. Adductor spasmodic dysphonia will produce a tense, high-pitched voice with frequent breaks. A patient with laryngitis will often talk with a whisper because of the pain and discomfort associated with it.

**Medical History**

When determining an obvious cause of hoarseness is difficult, a detailed medical history can sometimes help point to that elusive diagnosis. Many medical conditions are known to cause a change in the voice. Hypothyroidism is an often-overlooked cause of hoarseness.\(^7\) Several autoimmune disorders, such as rheumatoid arthritis,\(^8\) gout, and systemic lupus erythematosus,\(^9\) can cause fixation of the cricoarytenoid joint; other inflammatory disorders, such as amyloidosis,\(^10\) sarcoidosis,\(^11\) and Wegener granulomatosis,\(^12\) can cause deposits or growth of lesions in the airway, leading to hoarseness. A detailed neurologic history can often expose neurodegenerative disorders, such as myasthenia gravis and diabetic neuropathy. As already mentioned, gastroesophageal or laryngopharyngeal reflux disease is a very common cause of hoarseness.

**Surgical History**

One important fact to remember is that any surgery requiring an endotracheal tube or laryngeal mask airway\(^13\) can lead to hoarseness by causing vocal cord immobility. Many times, such hoarseness is caused by direct trauma to the vocal cords (ie, scarring of the cords or subluxation of the cartilage structures), but sometimes it is due to pressure-induced neurapraxia to the recurrent laryngeal nerve, highlighting the common misconception that only a traumatic intubation can lead to hoarseness. Rarely, esophageal stethoscopes or nasogastric tubes can also cause hoarseness.\(^14\) The majority of hoarseness due to intubation is of short duration (usually less than two weeks). However, if a patient reports persistent or unrelenting hoarseness after intubation, an otolaryngology referral is warranted.

Another cause of hoarseness related to surgery is direct injury to the recurrent laryngeal nerve during a procedure. The nerve has an extended anatomic course, starting from the skull base above and extending down around the aortic arch (on the left) and finally entering the larynx at approximately the cricothyroid notch. Understandably, any surgery involving these areas, such as thyroid surgery, can lead to injury to the recurrent laryngeal nerve or vagus nerve (see Sidebar), which can lead to permanent hoarseness. It is important to note, however, that even when the recurrent laryngeal nerve is preserved during surgery, temporary paresis and hoarseness frequently occur and ultimately resolve within six months.

**Common surgeries that can cause vocal cord paralysis from injuries of the recurrent laryngeal or vagus nerve**

- Carotid surgery
- Neck dissection
- Thyroid/parathyroid
- Mediastinal surgery
- Cervical spine surgery

---

*Sidebar: Common surgeries that can cause vocal cord paralysis*
Social History
Practitioners of certain professions are predisposed to voice overuse. Teachers, public speakers, singers, and people who work in a noisy environment and have to speak loudly often develop hoarseness, with some developing vocal nodules or polyps. Many of these patients report voice fatigue as the day progresses. The proper treatment for these patients is voice rest, but this often conflicts with their work schedule. Adding to the difficulty in treatment is that many of these patients develop unhealthy voice habits that predispose them to further hoarseness. Excessive tobacco use is also well known to cause hoarseness, but, perhaps more important, it can significantly increase the risk for laryngeal carcinoma.

Management of Case Scenarios
Case Scenario 1
Several findings for this patient suggest the possibility of cancer. The patient's age and sex should not be ignored, just as his extensive history of smoking and alcohol use should not. The presence of pain, its constant nature, and constitutional symptoms should immediately alert physicians to the possibility of malignancy. Such patients should be referred to an otolaryngologist, who will conduct laryngoscopy and biopsy that will confirm the diagnosis.

Case Scenario 2
Although it is important to note that a suspicion of malignancy should never be dismissed, no matter how slight, this patient has several findings that warrant considering gastroesophageal reflux disease. The intermittent nature of hoarseness (periods of normal voice) and the salient lack of pain are findings that seem to point the diagnosis away from malignancy. In addition, the presence of globus, frequent throat clearing, lack of smoking history, and occasional heartburn heavily favor gastroesophageal reflux as the most likely diagnosis. Such patients should be taught about proper dietary and sleep habits, and their clinicians should consider providing medical therapy using proton-pump inhibitors or H2-blockers. With close monitoring, these patients will start to experience symptom relief at anywhere between four and eight weeks of treatment.

Conclusion
Knowing the right questions to ask a hoarse patient will not only improve the chances of a correct diagnosis but will also improve physicians' ability to design a more appropriate treatment plan. In many cases, obtaining a detailed history alone will greatly narrow the differential diagnosis and enable physicians to know when to treat and when to refer. For any patients who have unremitting hoarseness as well as risk factors for malignancy, a timely referral to an otolaryngologist is important.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

Acknowledgment
Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References
Introduction

For the Fall 2003 issue of *The Permanente Journal*, I wrote an article entitled “Understanding Noncompliant Behavior: Definitions and Causes” (xnet.kp.org/permanentejournal/fall03/behavior.html). It discussed the various underlying causes of more seriously noncompliant behavior (NCB) with the goal of understanding that noncompliance is not a unitary entity but has a differential diagnosis. Use of this differential diagnosis, it was stated, could lead to more effectively working with the noncompliant patient. The goal of this article is to offer the practicing clinician tools for working with the noncompliant patient.

Background

The initial article treated NCB as an aberration in the physician–patient alliance. In the few years since the publication of that article, there has been increased attention in the medical literature to this problem. The publications on this topic largely fall into two groups: articles on medication noncompliance, often dealing with related issues such as causes of noncompliance, and articles on disease-specific noncompliance, such as noncompliance in chronic pulmonary obstructive disease or asthma or noncompliance in patients with diabetes. What is apparent in most of these articles is that NCB is much more widespread than it was thought to be and that it has a serious, deleterious effect on health outcomes and medical costs.

...even clinical trials report average adherence rates of only 43 to 78 percent among patients receiving medication for chronic conditions... Cramer et al, reporting on a meta-analysis of compliance in diabetes, hypertension, and dyslipidemia, noted that “only 59% of patients [take] medication for more than 80% of the [prescribed doses] in a year.” Even in the case of serious and symptomatic disorders, such as acute myocardial infarction, a study has shown that as many as one in eight patients discontinue all three medications of the commonly prescribed combination of β-blocker plus aspirin plus statin within one month of hospital discharge. These patients have an 80% higher chance of dying within the first year after discharge compared with patients taking all three classes of medication.

...and that of “all medication-related hospital admissions in the United States, 33 to 69 percent are due to poor medication adherence, with a resultant cost of approximately $100 billion per year.”

...that NCB is epidemic and not just an aberration. NCB is likely one of the most common causes of treatment failure for chronic conditions, though this is not widely or consistently recognized.

Noncompliance names a series of behaviors that fall on a continuum of severity, ranging from the trivial to the catastrophic. It would be a mistake to lump these together. Because I was unable to find a noncompliance rating scale in my literature review, I am proposing the tool shown in Table 1 to allow us to identify and compare differing intensities of NCB.

My goal in this article is to focus on individual clinicians and their relationship with the noncompliant patients of greater degrees of severity (stages 2 and 3) in their clinical practice. Lesser degrees of NCB are more common and also detrimental to effective medical care. Given their frequency, these may require a systems approach rather than relying on the individual clinician. A detailed discussion of these approaches is beyond the scope of this article, but at least in terms of medication compliance, certain simple tools have been shown to be effective. These include simplifying medication regimens, using once-a-day dosing whenever possible, providing pillboxes for patients, using combination tablets when possible and appropriate, and using computerized tracking systems for prescription refills.

...multi-faceted and of real but limited efficacy. McDonald et al conclude that “current methods of improving adherence for chronic health problems are mostly complex and not very effective, so that the full benefits of treatment cannot be realized.” Few...
articles in the literature deal with helping the physician with noncompliance. One useful article by Haynes et al. makes a number of practical suggestions, including simplifying medication regimens, providing rewards and recognition for the patient’s efforts, and enlisting social support from family and friends.

The same physician tools described in the following sections that are useful in more severe cases of NCB are also relevant to the milder degrees (stage 1 and early stage 2). Because so many of our patients are in this category, it can be difficult for the busy clinician to find time to deal with these issues. For some of these patients, however, identifying and countering a single and simple barrier to compliance can be readily accomplished.

### Dealing with Noncompliance

#### General Principles

In the modern clinical era, there has been a change in modes of physician–patient interaction and agreement. The more traditional authoritarian approach is transforming toward a collaborative partnership between patient and physician that is based on mutual goals and a shared understanding of problems and their potential solutions. A widely used current model is *shared decision making*, in which physician and patient, after discussion, agree on the nature of the problem in question and proposed steps toward its management. In a case discussion, Bodenheimer wrote, “A participatory relationship between patient and physician appears to be the most important factor promoting medication adherence” and that “the more actively the patient is involved, the higher the level of adherence and the greater the chance that the patient engages in healthy diet and exercise behaviors.”

Trust between physician and patient is also a factor. Greater trust facilitates improved compliance. NCB can be understood as a breakdown in the physician–patient alliance and the implied or explicit contract between physician and patient. Understanding that this is a common phenomenon, and being aware of its possibility in a given clinical situation, is the first step toward dealing with this.

The physician must realize the possibility that NCB is occurring in the given context with the particular patient—Sometimes this is apparent, as in the case of the patient who misses multiple appointments and who does not fill or refill prescriptions. Occasionally the patient will bring this up, but more often it requires a high index of suspicion and some detective work on the part of the physician. Given how common NCB is, it should be looked for in most cases of failure to meet treatment goals. How often do we add a third antihypertension medication when the patient in reality is not taking the first two regularly?

**The physician should raise this question with the patient in a problem-solving and nonjudgmental manner**—“I see you haven’t refilled your antihypertension medications recently. Have you been taking them as prescribed? It’s important to maintain good blood pressure control.”

<table>
<thead>
<tr>
<th>Stage number</th>
<th>Stage name</th>
<th>Stage description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None to minimal</td>
<td>Takes 80%+ of regular medications for condition, most monitoring parameters indicate acceptable control, and makes and keeps regular appointments</td>
</tr>
<tr>
<td>1</td>
<td>Mild</td>
<td>Takes 60%–80% of medication doses, is seen at least twice yearly, and monitoring parameters indicate acceptable control</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
<td>&lt;80% medication compliance with unsatisfactory control of at least one monitoring parameter; regularly misses or fails to keep appointments</td>
</tr>
<tr>
<td>3</td>
<td>Severe</td>
<td>Erratic medication compliance and/or visit compliance, highly unsatisfactory control of one or more monitoring parameters for the given condition, and/or does not comply with minimal standards of monitoring</td>
</tr>
</tbody>
</table>

### Noncompliance Versus Nonadherence: What's in a Name?

In my first article, I chose to use the term noncompliance instead of nonadherence for a number of reasons, principally because noncompliance is the term used most widely by physicians, the primary audience for this article. Many current articles on this topic use the terms as synonyms. Compliance has pejorative overtones, as it historically has referred to compliance with physician decrees rather than to shared agreements between physician and patient. As shared decision making has become a standard of practice since the 1990s, we can now see compliance as referring to the mutually negotiated physician–patient agreement or contract, which rehabilitates the term from its previous negative associations.
Physician-patient conflict-resolution tools are very effective:

- “What could I do differently to help you with this?”
- “How could we approach this problem more effectively?”
- “What are the obstacles that have prevented our dealing with this more successfully?”

The very act of asking these questions can help reframe the situation from a more combative one to a more collaborative one. Be aware that guilt, shame, or a sense of failure is common when NCB is seriously threatening the patient’s health. Your open, nonaccusatory, and problem-solving stance will help defuse these negative emotions.

**Physician–Patient Conflict-Resolution Tools**

Though NCB is often not a direct manifestation of physician-patient conflict, communication tools that have proven effective in conflict situations can also

---

Table 2. Checklist: tools for working with noncompliant patients

<table>
<thead>
<tr>
<th>1. Establish that noncompliance is present</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ask patient about compliance</td>
</tr>
<tr>
<td>• Use prescription refill data</td>
</tr>
<tr>
<td>• Review visit frequency, missed appointments, monitoring parameters</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Review the patient’s understanding and agreement with diagnoses and treatment goals and recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ask the patient to describe how s/he understands his or her medical disorder in his or her own words</td>
</tr>
<tr>
<td>• Ask if the patient understands the purpose of treatment and the consequences of ineffective treatment</td>
</tr>
<tr>
<td>• Have the patient explain the specific treatment recommendations you are agreeing on in detail</td>
</tr>
<tr>
<td>• Using open-ended questions, ask if the patient feels confident in following the treatment recommendations and if the patient sees any problems</td>
</tr>
<tr>
<td>• Work to mutually find solutions to any problems with compliance that are identified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. When discordance or disagreement is evident, use physician–patient conflict-resolution tools to clarify and resolve the disparities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Use mirroring and “I” statements to identify and defuse conflicts.</td>
</tr>
<tr>
<td>• Work to make noncompliance a mutual problem, not a power struggle</td>
</tr>
<tr>
<td>• Build patient self-esteem and self-efficacy by using an incremental approach, with interim goals</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. When causes of noncompliance are not apparent:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Screen for the four D’s:</td>
</tr>
<tr>
<td>- Denial</td>
</tr>
<tr>
<td>- Depression</td>
</tr>
<tr>
<td>- Dependence (alcohol and drug)</td>
</tr>
<tr>
<td>- Dementia</td>
</tr>
<tr>
<td>• Look for cultural issues that may affect care</td>
</tr>
<tr>
<td>• Ask if cost of treatment is a problem</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Enlist support from:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The patient’s family and friends</td>
</tr>
<tr>
<td>• Colleagues</td>
</tr>
<tr>
<td>• Case managers</td>
</tr>
<tr>
<td>• Behaviorists</td>
</tr>
<tr>
<td>• Outside agencies</td>
</tr>
</tbody>
</table>
be very useful in working with NCB. These tools have been developed primarily in nonmedical settings but can be very readily adapted for clinical use.

**Mirroring**—Sometimes the simple act of mirroring what the patient says to you can defuse a difficult situation, even when you do not agree with the position the patient is taking. It also helps ensure that you correctly understand what your patient is telling you. By mirroring, I mean primarily verbal mirroring, in which the physician repeats back to the patient a summary or even a paraphrase of what the patient has been saying:

**Patient:** I think this is all a waste of time. I'll never lose weight, I hate sticking my finger all the time, and I'm too busy and stressed to eat the way I know I should be.

**Physician:** I see that you're very frustrated with how hard it's been to live with your diabetes and that you feel that it's been hard to do the finger sticks and to follow your diabetic diet. Did I get this right?

Try to be as nonjudgmental and empathic as possible in your mirroring statement. Successful mirroring shows patients that they have been heard and understood, which is a prerequisite to moving toward new solutions.

**“I” Statements**—Contrast in your mind the impact on the patient of the following two approaches to the same problem:

**Physician:** You're doing a very poor job controlling your diabetes. Don't you know this could lead to serious complications?

**Physician:** I'm worried that if your diabetes isn't better controlled, you could develop some serious complications.

Using statements that start with the word “I” and that express your genuine positions and concerns are much easier to hear and accept and foster a problem-solving versus a critical and blaming tone. Patients already often feel self-conscious and defensive when they are noncompliant. We want to break this cycle, and the physician's working to sound more human and less authoritarian can enhance this possibility.

**Developing and Reinforcing Self-Efficacy**—Many noncompliant patients have tried the best they can and feel like failures. Failure begets failure (just as success begets success) and stimulates feelings of despondency, depression, and denial. Breaking complex problems down into simpler components and then working on them one at a time and slowly can help combat this cycle of failure and defeat and encourages self-esteem and self-efficacy.

**Physician:** I see that it's been very hard for you to do all the things you need to get your heart failure under control. Between now and our next visit, why don't we focus on just one of the problem areas. We've identified that you're having trouble taking your medications on time, following a low-salt diet, and doing regular exercise. Which would you like to focus on first?

As physicians, we want the patient to answer “all of the above.” Yet the patient would not have become noncompliant if s/he had been able to accomplish this. We have to trust ourselves, in the possibility of slow progress over time, in the power of our strengthening relationship with the patient, and that this approach can facilitate the patient’s increasing sense of mastery and control. Some physicians may be concerned about potential medicolegal problems if the patient experiences an adverse consequence while being given permission to focus on limited areas of treatment at any one time. Good documentation of the treatment plan and its rationale make such problems unlikely.

**Enlisting Support**—Most of our patients do not exist in a vacuum. They have their own formal and informal networks of support, including family, friends, associates, and other health care professionals. In many cases it can be helpful and appropriate for physicians to encourage patients to use other people in their lives to help improve compliance and self-care.

In refractory cases of noncompliance, family members and friends can be enlisted in the campaign for better health. Patients can be asked, “Is there anyone in your life who could help you with this?” Could a spouse or partner or an adult child remind them to take their medications or to keep their appointments—without creating problems or tension in the relationship? This process must be with the consent of and under the control of patients; otherwise, we risk setting up a conflictual or codependent relationship. Patients can be asked to bring pertinent family members or friends to the medical appointment to discuss these issues. Sometimes these individuals will also have additional insights into the nature of the noncompliance problem that were not otherwise discoverable.

In some health care settings, the physician has other colleagues who can be called on for assistance, including chronic-disease managers, case managers, nurse practitioners, and behavioral-medicine specialists. These individuals may have more time available per encounter than the physician, and their motivational and teaching skills can be extremely helpful in complementing the physician’s approach.
Physicians themselves often feel stymied and frustrated in working with highly noncompliant patients and can benefit from discussions with colleagues, consultation with behavioral-medicine specialists, or by making use of a variety of practice-support settings such as Balint groups, should these be available.

**Approaches to Specific Causes of Noncompliant Behavior**

In the first section of this article, I described and identified specific causes that sometimes underlie NCB. There are targeted approaches to NCB that are based on the suspected etiology of these behaviors that can supplement the more general approaches just described.

**Denial**

Denial, as a defense from the stress and worry of living with a chronic condition, can have a positive value. However, when denial interferes with getting necessary care, it can become a common cause of NCB. Fear often underlies more pronounced forms of denial. Gently inquiring how the patient understands his or her illness, its likely course, its possible complications, or the effects of treatment can lead to a beneficial discussion in which the concept of denial can be introduced if it seems relevant.

In my experience, talking about denial in a nonjudgmental way often leads to a useful and clarifying discussion. Enlist patients' support in working with their denial. Most patients have heard of the term denial and can be asked if they think this is playing a role in how they are dealing with their disorder. Frontal assaults on denial, however (“You'll die if you don't take better care of yourself”), feed and strengthen the denial. Feeling overwhelmed also breeds denial. Identifying these feelings and simplifying medical regimens whenever possible (see the “Developing and Reinforcing Self-Efficacy” section earlier in this article) can lessen the impetus to denial as well.

**Depression**

Part of the experience of being depressed is the loss of optimism, of self-worth and self-efficacy, and a lowering of energy. These can all interfere with chronic illness care and lead to NCB. Depressed patients are three times more likely to be noncompliant with medical treatment recommendations than are nondepressed patients.18 Because depression itself is common, especially among the chronically ill, the clinician should be alert to this possibility and use depression screening tools such as the nine-item depression scale of the Patient Health Questionnaire (PHQ9) (Pfizer, Inc, New York) (and others) readily with noncompliant patients. Treatment of depression may well facilitate medical compliance.

**Dementia**

Dementia, especially early in its onset, can both be nonapparent to the clinician and yet subtly impair the skills needed for medical compliance.19-21 In select patients with NCB, use of dementia screens like the Mini-Mental Status Exam (Psychological Assessment Resources, Lutz, FL) may reveal unsuspected subtle cognitive impairments that interfere with compliance. When this is recognized, the clinician, in collaboration with the patient, can seek the assistance of other persons or agencies that can assist with care, as well as with undertaking the evaluation and potential treatment of the cognitive decline.

**Cultural Issues**

The greater the discrepancy between the cultural background of the physician and the patient (and the patient’s family), the greater the likelihood for miscommunication and NCB. Cultural differences can affect more than the understanding of the meaning and causes of illness. They also affect one’s understanding of how symptoms or illnesses should be managed and how physician and patient should communicate. Dealing with these crosscultural issues is beyond the scope of this article, but the issue has been widely discussed in the medical literature. Recommended general approaches include:

- Being aware of the potential impact of cultural issues on the treatment process.
- Being willing to engage the patient in a collaborative and nonjudgmental manner regarding these issues.
- Seeking clarification regarding these issues from the medical literature, from programs aimed at understanding cultural diversity in medicine, and from colleagues with expertise in these issues.

**Drug or Alcohol Dependence**

Misuse of alcohol or recreational drugs impairs compliance.22-23 Screening for these problems is advisable for patients with NCB and can be rapidly accomplished using the CAGE tool for alcohol abuse and by asking the patient about drug use. Asking, “What drugs have you ever used occasionally?” may be helpful. Remember that alcohol and drug abuse is found in all sectors of the population. Whether identifying and treating substance abuse improves compliance has not been
thoroughly studied. Because uncovering substance abuse is generally considered to be beneficial in its own right, it certainly makes sense to do this when evaluating NCB even if we cannot prove its benefits in this arena at present. Counseling the patient regarding these disorders and making appropriate referrals to chemical-dependence programs may affect NCB and is worth doing for many other reasons.

Cost of Treatment

When patients cannot afford their medical care, as is all too common in the US given our lack of universal health care and the high costs of treatment, this is not, technically, noncompliance. The economic barriers to medical care are the primary factor here, not the actions or inactions of a given patient.

Having stated this, I must add that there are also many cases in which the relative affordability of treatment affects degrees of compliance in patients who are able to pay at least some of their medical expenses. In a study of Medicare enrollees completed before Medicare Part D was implemented, 13% of Medicare patients (and 29% of disabled Medicare patients) reported cost-related noncompliance.24 Asking patients if the cost of treatment is a problem for them should be done widely in evaluating NCB. If this proves to be the case, strategies include using generic and less-expensive medications when possible and reducing visit frequency for patients with stable diseases. Patients can be referred for various forms of financial assistance that may be available as well.

Summary and Conclusions

Using the diagnostic and therapeutic approaches outlined in this article, reviewed in Table 2, can improve your success rate in dealing with NCB and can reduce both your and your patients’ tension and frustrations. It can help align you and your patient toward a shared framework and collaboration rather than blaming and mistrust. Being open, nonjudgmental, and inquisitive can only be beneficial here and may well reveal causes of noncompliance that are not mentioned in this article. A sample dialog with a stage 2 noncompliant patient using communication tools described here may be viewed on The Permanente Journal Web site at: http://xnet.kp.org/permanentejournal/spr10/app/WorkingWithTheNoncompliantPatient.pdf

Taking a holistic and strategic approach to NCB can also help the physician reframe these encounters, so that they become a stimulating therapeutic challenge. Being thoughtful, patient, and believing yourself in the possibility of long-term incremental change in NCB can help develop your own self-esteem and self-efficacy in working with these challenging and difficult patients.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgment

Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References

Divergent Aims

The ordinary patient goes to his doctor because he is in pain or some other discomfort and wants to be comfortable again; he is not in pursuit of the ideal of health in any direct sense. The doctor on the other hand wants to discover the pathological condition and control it if he can. The two are thus to some degree at cross purposes from the first, and unless the affair is brought to an early and happy conclusion this divergence of aims is likely to become more and more serious as the case goes on.

— Art and Science in Medicine, Wilfred Batten Lewis Trotter, 1872-1939, British surgeon and sociologist
A Physician Prescription for the Nursing Shortage

John H Cochran, MD, FACS

Abstract
In 2003, the Colorado Permanente Medical Group (CPMG), a 780-member, multispecialty physician group that provides ambulatory and hospital care principally in metropolitan Denver and Boulder, embarked upon a multifaceted program to leverage physician leadership to address the nursing shortage. Designated as the “Preferred Clinical Partner Program” (the PCP Program), CPMG sought to participate in solving the nursing shortage by engaging in a number of initiatives. Through an initial fund of $1 million, over $350,000 was used to fund nursing scholarships, over $150,000 was used to provide advanced training to a select group of health care professionals in a program that may be the first physician-partnered MA-to-LPN and RN-to-BSN initiative, and over $500,000 was devoted to building and expanding nursing simulation laboratories. Currently, the accelerated nursing program graduates approximately 32-35 nurses each year and has admitted its seventh cohort of students. Student retention has been excellent.

Introduction
In 2003, the Colorado Permanente Medical Group (CPMG), a 780-member, multispecialty physician group that provides ambulatory and hospital care principally in metropolitan Denver and Boulder, embarked upon a multifaceted program to leverage physician leadership to address the nursing shortage. Designated as the “Preferred Clinical Partner Program” (the PCP Program), CPMG sought to participate in solving the nursing shortage by: a) funding nursing scholarships, b) building nursing education capacity by funding and developing educational programs, c) utilizing physicians as faculty and mentors, d) clarifying leadership and partnership expectations for physicians, and e) developing physician-nurse relationship training programs. The strategy of the PCP Program was to be comprehensive and innovative in the drive to stimulate interest, develop capacity, and offer opportunities for nurses and other future health care team members. The development of the PCP Program is explained more fully in Physician as Healer, Leader and Partner: Tackling the Nursing Shortage. Six years later, we look back to assess the impact of the PCP Program in helping to address the nursing shortage in Colorado.

Background
The shortage of nurses has severe implications for affordability, accessibility, and the quality of health care. In 2000, the US Department of Health and Human Services (DHHS) identified Colorado as one of 30 states with a nursing shortage. The 2000 supply-versus-demand comparisons by DHHS projected a shortage of 11% (3656 nurses) by 2007 compared with the national nursing shortage trend at 6%. The shortage was expected to grow slowly until 2010, at which time demand was expected to accelerate and exceed supply in 2020 by 31%. DHHS anticipated a 40% increase in demand for RNs between 2000 and 2020 with growth of this labor pool at a modest 1.7% annually.

In 2000, CPMG physicians began to experience the effects of an acute and, in some situations, crippling shortage of nurses—aggravated by local geography. Patients were being diverted away from CPMG’s urban partner hospitals and four new hospitals under construction on Denver’s periphery posed an additional challenge as they vied for nurses who preferred to work closer to home. Classified advertisements in local newspapers showed some urban hospitals were offering an additional per diem of $50—simply for driving to work. This impending crisis caused CPMG to take action to maintain high-quality, affordable care.

The Preferred Clinical Partner Program in Action
Rather than sit back and let others “fix” this increasingly severe problem, CPMG decided to be a part of its solution. CPMG’s Board of Directors authorized a contribution of $250,000 to provide scholarships and other financial assistance to help prospective nursing students and to build the educational infrastructure necessary to accommodate them.
With this commitment in hand, matching grants were obtained from Kaiser Foundation Health Plan of Colorado and Exempla Healthcare. Thus, what began as a relatively small scholarship program grew into a fund of more than $1 million. Funds obtained through the generosity of these institutions have been put to good use over the past six years. See Table 1 for a summary of the disposition of the funds.

**Scholarships**

Over $350,000 was used to fund nursing scholarships. These scholarships were awarded to an ethnically diverse and deserving population of prospective nurses. More than 130 individuals who might not have had the opportunity to pursue nursing careers have been able to do so because of these scholarships. In addition, the recognition and publicity that these students obtain in connection with the award of these scholarships has generated interest in nursing well beyond the scholarship recipients alone.

Over $150,000 was used to provide advanced training to a select group of health care professionals. In a program that may be the first physician-partnered MA-to-LPN and RN-to-BSN initiative, professionals who already had dedicated themselves to the health care field were able to advance their skills, increase their scope of practice, and obtain higher paying jobs. The ability to envision a robust career path has led to improved career satisfaction, which will lead to lower nurse turnover and fewer nurses abandoning the health care field. Thus far, this program has seen 128 nursing students receive BSN degrees, and 32 MAs receive LPN licenses.

Currently, the number of graduates from the accelerated nursing program has stayed consistent at approximately 32-35 graduates each year. The program has admitted its seventh cohort of students. Student retention has been excellent. To date, a total of two students did not complete the program; a third is returning this spring following withdrawal last year. Consequently, the program has generated an impressive attrition rate of only approximately 1.5%.

**Nursing Education Infrastructure**

In 2007, US nursing schools turned away 40,285 qualified applicants due to lack of faculty resources and funding. Educational capacity is one of the chief obstacles to entry into the nursing profession. There are simply not enough teachers, educators, or facilities to train the number of nurses needed. And every time a nurse steps away from the bedside and into a classroom, a critical hospital bed may become unavailable for patient care. Funds must be used in creative ways to provide needed infrastructure without “stealing from Peter to pay Paul.”

By devoting over $500,000 to build and expand nursing simulation laboratories, the PCP Program accomplished this end. Nurses can learn how to insert an IV or a chest tube or practice birthing procedures using this simulation equipment. Such equipment enables more students to practice needed skills, and requires fewer educators to supervise the training. This, in turn, enables our most senior nurses to remain at the bedside, caring for our most critically ill patients.

**Colorado Center for Nursing Excellence**

Finally, the funds were used to help open the Colorado Center for Nursing Excellence (the Center) and a CPMG physician leader was on the founding Board of Directors. Today, the Center creates public awareness of the nursing workforce shortage and stimulates attraction to the profession, ensures statewide access to capacity-building, lifelong learning opportunities for nursing personnel, promotes innovation that increases workforce retention and professional satisfaction, and provides a sustainable resource for the public and the health care community. It works to expand and enhance nurse recruitment and retention efforts, expand the capacity of the academic nursing education system, strengthen the

<table>
<thead>
<tr>
<th>Table 1. Contributions to the CPMG Education Fund between 2003 and 2008 to support nursing education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician-supported nursing education</td>
</tr>
<tr>
<td>Student scholarships</td>
</tr>
<tr>
<td>Nursing education simulation equipment and construction</td>
</tr>
<tr>
<td>Colorado Center for Nursing Excellence</td>
</tr>
<tr>
<td>Accelerated nursing degree programs</td>
</tr>
<tr>
<td>Funds recently donated but not yet allocated</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

CPMG = Colorado Permanente Medical Group
collaboration between practice settings and education systems, and consistently monitors, reports, and evaluates the status of the nursing workforce. Working in partnership with the Center, CPMG established a clinical nurse scholar program that aims to increase the number of qualified nurse educators in the Region. CPMG continues to provide in-kind support annually. To date, these efforts have introduced hundreds of new nurses into the profession and touched thousands more who receive state-of-the-art training and education made possible by physician partnerships.

**Behavioral Issues**

Although financial support and community partnerships are critical to expanding the supply of qualified nurses and the capacity of the nursing educational infrastructure, another key component of the PCP Program was to drive a cultural change in the work environment for nurses in order to enhance the likelihood that nurses would remain satisfied in their work environments over time. The PCP Program commenced with evidence-based education for physicians on the impact of their behavior on their nursing partners. This work also included the funding of new positions, including a manager for the physician-supported nursing program, a director of program development who oversaw orientation and communication training, and a CPMG board-certified physician “coach” who consulted one-on-one with physicians who struggled with staff interactions. In addition, CPMG adopted a “zero-tolerance” policy—backed by a robust performance management system that included an annual review, with feedback provided by nursing colleagues. The combination of agreement on a set of principles and a rigorous management system to support those principles helped CPMG achieve its goals—nursing satisfaction increased, and nursing turnover declined. At the same time, overall physician satisfaction improved, and patient satisfaction scores reached all-time highs.

CPMG is continuing to support the formation and use of multidisciplinary clinical teams. Chronic care nursing coordinators, clinical pharmacists, and physicians work side-by-side to help chronically ill patients in a variety of disease management programs. Having these teams embedded in clinics is critical to improving overall quality, nurturing respect, creating a positive work environment, and building collaboration among professionals.

**Our Personal Stake in this Issue**

Like many persons of a certain age, I became a caregiver—not just to my patients—but also to my parents. As I sat at their bedsides in a Denver hospital, I had the bittersweet opportunity to see the art of healing that my nursing colleagues bring to their patients and to their profession. Now, each summer, my family gathers in the auditorium of that hospital to celebrate the lives of my parents, and to award a scholarship to a nurse in the oncology unit. I share this personal story to illustrate a much larger point. Let’s not wait until we watch a loved one suffer to value our nursing colleagues for their exceptional skills in carrying us through these painful experiences. Let’s recognize the leadership, education, and power we represent as physicians and not remain silent on the subject of the nursing shortage. CPMG’s initial physician prescription for the nursing shortage suggests there are three key ingredients—financial investments, community partnerships, and a focus on physician behavior—that may offer a lasting cure. Let’s opt in, fix ourselves, fix our systems, and extend a hand of support to our partners in the nursing profession. Our patients’ lives depend on it.

**References**


---

**Inferior to None**

The trained nurse has become one of the great blessings of humanity, taking a place beside the physician and the priest, and not inferior to either in her mission.

— Nurse and Patient, William Osler, MD, 1849-1919, physician, professor of medicine, and author
Evidence-Based Medicine and the Physician-Patient Dyad

Howard I Kushner, PhD

Introduction

As the current debates throughout the US attest, there are wide disagreements about the shape of future US health care delivery. Nevertheless, a general consensus has emerged about the need for more efficient interventions that are based on reliable scientific evidence. This need has been filled by evidence-based medicine (EBM), which employs meta-analyses and randomized controlled trials (RCTs) to examine the effectiveness of interventions on large populations. These findings are reviewed by the Cochrane Collaboration, a group of volunteers from around the globe who publish their findings quarterly in the Cochrane Database of Systematic Reviews.1,2

Although it seems difficult to deny the efficacy of statistically robust research, medical practitioners, especially those involved in primary care, are often skeptical about EBM, fearing that the physician-patient encounter will be undermined, and with it, the most appropriate mechanism to determine a diagnosis and treatment.3,4 These physicians are sometimes portrayed as representing an older, more traditional segment of the profession, but their hesitancy also represents more than fear of change. Increasingly sensitive to this resistance, advocates continue to reassure practitioners that EBM will not subvert the physician-patient encounter but instead will integrate “the values and preferences of the informed patient.”5 Certainly before EBM becomes legislated by agencies and insurance companies alike, it deserves the same careful examination that it claims to have made of specific conditions.

I argue that EBM must be closely evaluated and critically appraised because it is subject to its own set of defects. Such a revised EBM would be best implemented in a context that maintains sensitivity to individuality and to physician-patient interactions.

Background

The ascendency of EBM in North America and the United Kingdom has its roots in the exponential growth of medical scientific research in the post–World War II years.6 By the third quarter of the 20th century, medical research had become a scientific enterprise, whereas much of medical care remained an art. The goal of EBM was to transform the art of medical care into a science.7 However, as Kathryn Montgomery has recently argued so eloquently, despite its reliance on scientific knowledge and its use of technology, medicine is not a science. Rather, it is a science-using practice whose goals are to prevent illness and care for the sick.8,9

The issue remains of whether EBM enables physicians to more fully practice their craft or whether instead, as a number of authors whose works are discussed here indicate, EBM has created an additional barrier to doing so.10

EBM was envisioned as a division of labor in which scientific evidence would be generated by researchers at prestigious research and medical institutions and implementation would take place in practitioners’ clinics. In reality, many clinical trials are done in the private offices of specialist physicians who derive a significant amount of income from the pharmaceutical industry. Nevertheless, such a system, whether intended or not, has produced a growing schism between academic medicine and clinical practice that often finds expression in concerns over the impact of EBM on the integrity of the physician-patient relationship.3,4 This tension has its roots in the 1970s, when academic medicine, emphasizing its connection to research, began to distinguish itself from normal clinical practice. By the 1980s, it became clear that medical research was not easily translated into practice. Thus, research-based medicine was augmented by the establishment of professional clinical practice guidelines based on evidence gleaned from retrospective reviews of published RCTs. Practitioners, however, did not apply the...
Evidence-Based Medicine and the Physician-Patient Dyad

guidelines consistently, if at all. (Kaiser Permanente [KP] established the Care Management Institute in 1997 to summarize and disseminate "best practices" and to assist "in the care of KP members by synthesizing knowledge about superior clinical approaches including the creation, implementation and evaluation of effective care management practices."1) If clinical medicine were to become a science, statistically significant research findings would have to be translated in a user-friendly fashion for everyday practice.

**The Evidence-Based Manifesto**

This was the context for the EBM manifesto of the clinical epidemiology program at McMaster University in Canada published in the *Journal of the American Medical Association (JAMA)* in 1992.12 The manifesto called for the replacement of clinical decision making that was based on anecdotal and idiosyncratic physician experiences with scientifically informed and statistically significant findings from population-based studies.13 The most frequently cited definition of EBM is reliance on the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients," which is based on an integration of "individual clinical expertise with the best available external clinical evidence from systematic research."14 Evidence-based practices have been launched in general medicine and specialized fields.14,15 In 2001, the prestigious Institute of Medicine's Committee on Quality of Health Care in America endorsed "evidence-based, patient-centered, health care delivery" as essential to the quality of health care.16

Initially, EBM rejected medical practices that were based on anecdotal and idiosyncratic physician experiences in favor of statistically significant findings from population-based studies. Interventions based on individual cases or small cohorts were portrayed as suspect and quaint. Instead, practitioners were urged to apply findings from population-based studies to their own clinical practice. Not surprisingly, this stance resulted in more than a little resistance and much criticism from a number of practitioners. In response, advocates of EBM increasingly have attempted to portray it as complementary to clinical experience, and there have been calls for a more integrated approach.17

Nevertheless, as it has developed since 1992, EBM relies on the elaborate system of publication and peer review of medical research. It requires that clinicians keep themselves updated on new research findings, become skilled literature researchers and methodologists, learn how to apply and interpret sophisticated statistical analyses, and translate all these findings into everyday clinical practice.5,12 The challenge is to find time to do so, including interpreting and translating the findings as presented.6,18 Although practical concerns have been raised about physicians relying on electronic databases, their ability to determine the validity of the data that constitute EBM is more problematic.19 Moreover, as Timmermans and Mauck observed, in practice EBM "is loosely used and can refer to anything from conducting a statistical meta-analysis of accumulated research to promoting randomized clinical trials, to supporting uniform reporting styles for research, to a personal orientation toward critical self-evaluation."20

**Evidence-Based Authority**

Although there is no formal single EBM information authority in the US or Canada, in Britain the National Institute of Clinical Excellence (NICE) was established by the government in 1999 and expanded in 2005. NICE serves as an independent health authority responsible for producing evidence-based public health and clinical guidance for the National Health Service. Recently there have been calls for a similar body in the US.5,21

Tied as it is to external funding, EBM has been enthusiastically supported by medical school administrators, who judge and reward faculty by the number and dollar amount of their external grant funding. EBM has also gained much impetus from the pharmaceutical industry, which provides substantial funding for clinical trials.

EBM has transformed the transmission of medical knowledge. The disease mysteries and insights of the medical detectives that once populated medical journals have been relegated to the back pages. The patient increasingly has been replaced by the statistic. Patient narratives have become suspect and devalued as merely anecdotal. Moreover, human subject protection and ethics require that published cases be sufficiently altered so that the identity of a patient is not revealed.22 Thus published patient narratives are, of necessity, fictions. Such narratives now provide material for books, op-ed columns, films, and television programming, but not for EBM.

**The Critics**

EBM is not without its critics, who warn that the art of medical practice is in danger of being overwhelmed by disinterested science, on the one hand, and cost-cutting corporate bureaucrats, on the other.10,19 These concerns
have grown over the years, including those of David L Sackett, one of the authors of the McMaster manifesto. Sackett questioned the direction that EBM was taking and expressed frustration over what he considered the harmful effects of expert claims. Other critics have characterized reliance on data from population studies and clinical trials as Galenic scholasticism, in which the skills associated with close readings of texts have replaced the actual physician-patient encounter. In contrast, the physician’s familiarity with a patient's life history is portrayed as local knowledge that enables the clinician to tailor contextualized diagnoses, treatments, and advice that mesh with individual needs. Patient narratives serve as exemplars of what allegedly has been lost. These narratives are also literary devices that at once reveal the clinician's diagnostic and interpersonal skills, while exposing the danger of a mechanistic application of population studies. Case histories are presented as mirrors of the best of medical education in which individual cases are interrogated and, in the process, reveal why some patients fared well and others poorly when placed on similar regimens. What is at stake, these stories suggest, is nothing less than the clinical encounter itself.

Ghaemi reminds us that there is no such thing as “non-evidence-based” medicine, rather there are many levels of evidence, ranging from case series to double-blind RCTs. “In my reading of EBM,” writes Ghaemi, “the basic idea is that we need to understand what kinds of evidence we use, and we need to use the best kinds we can.” But how robust is the evidence produced even by gold-standard RCTs? Not very, according to a recent study published in the Annals of Internal Medicine. The investigation, conducted by the Ottawa Health Research Institute, found that 15% of “best evidence” recommendations were reversed in two years; in three years, 23% were reversed; and in five and half years, 50%. Commenting on the study, Groopman and Hartzband noted that “Americans have witnessed these reversals firsthand as firm ‘expert’ recommendations about the benefits of estrogen replacement therapy for postmenopausal women, low-fat diets for obesity, and tight control of blood sugar were overturned.” Who wants their care predicated on recommendations half of which are proven wrong within five years?

If clinical practice demands sensitivity, EBM, in contrast, requires specificity (reliability); each piece of data must be (as much as possible) identical to another. Thus, patients' complaints are evaluated in the context of the findings of population studies. However, according to Groopman, specificity can be misleading because patients present for treatment with combinations of conditions that do not match the evidence. For Groopman, EBM interferes with evaluating individual patient complaints because the physician is drawn toward statistical findings that seduce practitioners to cease listening even as their patients continue talking. Thus, EBM leads physicians to fail to incorporate the most important source of evidence, sensitivity to what their patients can reveal about their conditions. Paying attention to a patient’s narrative is crucial, argue EBM critics, because patients with similar signs and symptoms, even with the same diagnosis, often require different treatment. Added to this is Michael Balint's observation that “doctors see patients because of disease. Patients see doctors because of anxiety. Therein lies the problem between the two.”

**Evidence-Based Medicine and the Art of Medical Practice**

“There is one aspect of medicine that will surely survive, the need for a compassionate, competent person to help another confront the suffering of illness,” wrote Jerry Avorn of Boston’s Brigham and Women’s Hospital and author of *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs.* Whereas such sentiments reflect the Oslerian ideal of the medical encounter, one may reasonably wonder the extent to which these ideals reflect actual medical practices or nostalgia for a mythic golden age of physician-patient collaboration.

Some scholars, such as Australian medical ethicist Malcolm Parker, believe that there is no substantive reason for EBM to undercut the art of medical practice. Parker argues that such claims are based on “false dichotomies” because there is no necessary contradiction between medical science and medical art; that, in fact “EBM is a necessary condition for clinical freedom.” However, citing data from the NICE guidelines, Parker concedes that EBM has a number of structural weaknesses, not least of all that “rather than starting with health care priorities and setting the research agenda on that basis, the system tends to be inverted by EBM, with research often being performed as much for commercial as for scientific and health reasons.” Of course, here Parker is alluding to the influence of the pharmaceutical industry in shaping the research agenda of EBM in the United Kingdom. As he notes, this agenda has a direct impact on patient care because “there appears to be little systematic inquiry into what areas are poorly researched, how research priorities are identified, and who runs research.”
Evidence-Based Medicine and the Pharmaceutical Industry

Despite the idealized claim that EBM would be the product of objective research conducted by disinterested medical researchers, pharmaceutical industry-sponsored clinical trials can have a corrosive impact both on physicians who derive substantial income from their participation and, in turn, on evidence claims themselves. Moreover, not all clinical trial results are published, especially those whose results fail to demonstrate the benefits of an agent in a pharmaceutical-sponsored trial.34

This situation has attracted the attention of a number of respected North American and British medical academics. They argue that pharmaceutical companies have infiltrated the medical research enterprise, hijacking the peer-review process into a vehicle for drug marketing. These critics believe the validity and veracity of peer-reviewed research is being undermined, subverting the foundation of EBM.35,36

According to Harvard University internist John Abramson, the pharmaceutical industry has inserted itself into every aspect of medical practice, from medical education to basic research and clinical care, endangering the integrity of the American health care delivery system and subverting the trust between patient and practitioner.24 Marcia Angell, former editor-in-chief of the New England Journal of Medicine, links the near collapse of health care in the US directly to the corrupting practices of the pharmaceutical industry.37 In Selling Sickness: How the World’s Biggest Pharmaceutical Companies Are Turning Us All into Patients (2005), British Columbia medical researchers Ray Moynihan and Alan Cassels argue that unfavorable research results are eliminated from or camouflaged in the texts of industry-influenced studies and that data often are remolded in ways that present favorable results when a more transparent analysis might reveal substantial risk for patients taking the “hyped” medications.38 British psychiatrist David Healy has written eloquently about the influence of the pharmaceutical industry in silencing and marginalizing even its most balanced critics.39

Building on these concerns, a special communication published in January 2006 in JAMA by a consortium of distinguished researchers, practitioners, and ethicists from eight of North America’s leading medical schools urged adoption of a series of measures aimed at insulating practitioners and academic medical researchers from what they believed to be the pharmaceutical industry’s corrosive effect on medical research and practice.40 These recommendations reveal the growing anxiety, at least among some highly regarded and influential medical faculty, that the pharmaceutical industry has placed the practice of medicine, especially EBM, at dire risk.

Thus, despite the logic of Parker’s analysis, the context of the current debate, framed as it is by the pharmaceutical industry’s influence over EBM, exacerbates practitioners’ suspicions. It is difficult, though perhaps not impossible, to imagine that an independent EBM could strengthen the physician-patient collaboration. However, EBM has not been liberated from pharmaceutical industry influence. Until it is, EBM, as practiced rather than as imagined, may continue to interfere with, rather than enable, the type of physician-patient collaborations that critics wish to nurture. Once—and if—industry influence is contained, the knowledge claims of an unfettered EBM may be reintegrated with the art of practice. Even then, physicians should be vigilant against the inappropriate reliance on population health studies for treatment of individual patients.

Valuable Tool versus All-Encompassing Panacea

Since the late 20th century, physicians and public-health researchers have understood the value of identifying risk factors as a prophylactic against a number of chronic conditions, including lung cancer, heart disease, and diabetes. As a number of recent studies have warned, however, risks can often be exaggerated in self-serving studies, presenting greater health hazards than the ones they putatively protect against.41–43 A similar danger is found with EBM. It can serve as a valuable tool when properly understood, but we should not regard it as the all-encompassing panacea for the future of medicine. As with the promiscuous and often exaggerated labeling of a variety of relatively benign behaviors and conditions as risk factors, uncritical reliance on EBM can result in serious side effects.44

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgments

I thank Vincent Felitti, MD, for his comments and suggestions and Carol Kushner for editorial assistance.

Katharine O’Moore-Klopf, ELS, of KOK Edit provided editorial assistance.

References

1. Bero LA, Grilli R, Grimshaw JM, Harvey E, Oxman AD, Thomson MA. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. The Cochrane Effective Practice and Organization of Care...
38. Moynihan R, Cassels A. Selling sickness: how the world’s biggest pharmaceutical companies are turning us all into patients. New York: Nation Books; 2005.
Lester DR Thompson, MD, is a Pathologist at the Woodland Hills Medical Center in Woodland Hills, CA. As a Pathologist, he looks through a microscope all day to try to separate colors and shapes into meaningful diagnoses. He finds that working with stained glass is a similar, though more creative, process.

Dr Thompson collaborated with his wife, Pamela, to create this piece to honor the 25th wedding anniversary of his sister-in-law and brother, Glynn M Thompson, MD, a physician in the Kaiser Permanente Mid-Atlantic Region.
Sustainable Food: A Conversation with Jamie Harvie—Executive Director, Institute for a Sustainable Future

Introduction

Jamie Harvie, PE, is a civil engineer and presently serves as Director of Health Care Without Harm’s Healthy Food in Health Care Initiative and as Executive Director for the Institute for a Sustainable Future, a not-for-profit organization based in Duluth, MN. He also serves on the steering committee for the Green Guide for Healthcare Construction—a best practices guide for healthy and sustainable building design, construction, and operations for the health care sector. Mr Harvie is an internationally recognized toxics expert and was instrumental in the negotiations with major pharmacy chains that successfully resulted in a national voluntary phase-out of mercury thermometer sales. In 2009, he was recognized as a “national thought leader” by the Natural Resources Defense Council for his leadership on sustainable health care food. His energy and vision are a driving force in changing the way food is produced and distributed so that it is not only nutritionally rich, but also environmentally sustainable. A Glossary of Terms used in this article may be found in the Sidebar: Glossary.

Motivated by impacts on poor nutrition, increased antibiotic-resistant bacteria, poisoned air and water, food-borne pathogens, and the potential health effects of climate change, leaders from the health sector are backing practices and policies that support sustainable agriculture and a healthier food system. In this interview, sustainable food system advocate Jamie Harvie addresses the big stake the health sector has in the way food is produced and distributed.

Sustainable Food and Health Care

Brian Raymond (BR): What is sustainable food and how does it pertain to health care?

Jamie Harvie (JH): What is my definition of sustainable food? It is food that is health promoting in the broadest sense.

The challenge with the question is that it suggests that there is one definition for sustainable food. For an individual, sustainable food may mean that it is nutritious, contains no toxic residues, and is affordable. For farm workers who harvest the food or others in the supply chain, it would also encompass issues of justice. Are the conditions in which they work safe? Can they make enough money to support themselves or their families? From the perspective of communities, does the production of the food promote the socioeconomic health of their community or the health of the local ecosystem? Globally, does the food system promote ecological health and resilience?

BR: Can you tell me about Health Care Without Harm and how its work in food system change got started?

JH: Health Care Without Harm is an international campaign of 480 organizations in more than 50 countries, working to transform the health care sector so it is no longer a source of harm to people and the environment. Our work began about 12 years ago when the US Environmental Protection Agency released a report that showed that medical waste incinerators were one of the largest sources of persistent bioaccumulative toxics, mercury and dioxin, to the environment. A variety of environmental and public health organizations recognized the inherent irony—that health care was inadvertently poisoning people and the planet—and came together to create this campaign for ecologically sustainable health care.

Much of our work involves education, which links health care practice to ecological health. Twelve years ago, hospitals had little understanding that the mercury blood pressure devices or mercury thermometers, which they used and accidentally broke could harm the short- or long-term health of their patients...
and staff and the environment. Once they saw the evidence, they began to act. Today, US health care is virtually mercury free.

Our work on health care food is only about three and a half years old and began with ongoing conversations with some of our health care partners trying to wrestle with the obesity crisis. From a strict economic perspective, this not only includes the cost of patient treatment, but the costs of lifting devices to move heavy patients, installation of new door frame sizes, as well as the occupational health costs associated with obese or overweight employees.

**Industrial Food and its Costs**

*BR: Most of us buy our food from supermarkets, but we don't really know where our food comes from or how it's produced. What's your take on this disconnect between Americans and their food?*

*JH: As you suggest, most people, regardless of socioeconomic background, have no idea where their food comes from. There's this belief that our farms are still bucolic places with grazing cows and the pretty red barn. Of course, nothing could be further from the truth. But, these images are marketed to consumers because they convey a sense of warmth and community. Could you imagine a large poultry processor marketing images in supermarkets of their massive factory-farmed poultry operations, or a multinational food giant providing images of pesticide drift moving from fields into school classrooms? Of course not. But at the same time maybe we American consumers don't want to know.

Americans are proud of being a modern, industrialized, technologically advanced nation. What would it mean if we acknowledged that our industrialized model of food production was inconsistent with the health of our nation? How would we reconcile this cognitive dissonance? American society is increasingly diverse and we have no one food culture that promotes food knowledge. Moreover, American culture is fast paced and we tend to promote quantity over quality. There are a host of factors that have gotten us to where we are today. But suffice to say, for the health of our nation, we are going to have to change our current industrial model of production.

*BR: Why is our highly industrialized food system a concern for health?*

*JH: Our current food system favors the production of animal products and highly refined, calorie-dense foods, rather than the fresh fruits and vegetables, whole grains, and a Public and political support for sustainable agriculture will not occur without greater awareness and understanding of how our industrialized food system is affecting human and ecological health.

---

**Table 1. Challenges and key issues for public understanding and involvement in food policy**

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Key issues for public understanding and involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obesity</td>
<td>Our current food system favors the production of animal products and highly refined, calorie-dense foods, rather than the fresh fruits and vegetables, whole grains, and other high-fiber foods important in prevention of obesity and related diseases.</td>
</tr>
<tr>
<td>Antibiotic-resistant bacteria</td>
<td>There is a strong consensus among experts that antibiotic use in agriculture contributes to rising drug-resistant infections in humans. An estimated 70% of all antibiotics consumed in the US are used as feed additives for poultry, swine, and beef cattle for nontherapeutic purposes. That is, antibiotics are used to promote growth and to compensate for diseases caused by poor animal husbandry.</td>
</tr>
<tr>
<td>Contaminated air, water, and food</td>
<td>Agricultural operations that confine large numbers of livestock to a closed area—concentrated animal feeding operations (CAFOs)—pose a hazard to soil, water, and air quality. Worker and public health concerns related to CAFOs include heavy metals, antibiotic resistance, pathogen bacteria, dust, mold, and volatile gases.</td>
</tr>
<tr>
<td>Fossil fuel consumption and climate change</td>
<td>Industrialized agriculture methods are fossil fuel intensive; the US food system accounts for an estimated 10.5% of the nation’s energy use and 19% of its fossil fuel consumption. The direct and indirect impacts of climate change on human health are substantial and include heat-wave fatalities, increased incidence of infectious diseases, and exacerbation of respiratory diseases.</td>
</tr>
<tr>
<td>Pesticide use</td>
<td>Reducing pesticide use is a key health priority given the many human health problems associated with pesticide exposure, as well as damage to other species.</td>
</tr>
<tr>
<td>Racial and ethnic health disparities</td>
<td>Low-income people and people of color face well-documented challenges to obtaining fresh fruits and vegetables and other nutritious foods; either they are not available in the neighborhood or the quality is poor and the price is high. Research shows that the scarcity of healthy foods makes it more difficult for residents of low-income neighborhoods to follow a good diet, compared with people in wealthier communities.</td>
</tr>
</tbody>
</table>

---

*Public and political support for sustainable agriculture will not occur without greater awareness and understanding of how our industrialized food system is affecting human and ecological health.*

and other high-fiber foods important in the prevention of disease. In addition, our food system is reliant on and supported by methods of production and distribution that hurt humans and our environment. We are already experiencing significant impacts in the form of poisoned air and water, food-borne pathogens, and collapsing rural communities (see Table 1). Consider the issue of antibiotic overuse. Approximately 70% of all antibiotics produced are given to healthy animals in their feed and water to promote growth and to compensate for stressful growing practices, not for the treatment of sick animals.

Every major medical, nursing, and public health association has suggested that if we want to protect our antibiotics toolkit, we’ll need to end agricultural overuse.2

BR: This sounds like a classic case of what economists call “externalized” costs.

JH: Exactly. Our industrial food system has become expert at externalizing its costs, and health care ultimately bears them. A number of years ago, Kaiser Permanente (KP) did an analysis of the cost of using a mercury blood pressure device, including the cost of clean up, patient room closure, etc. Using full-cost accounting, they found that the equally effective mercury-free device, with a slightly higher sticker price, was far less expensive in the end. What if we did this for meat and poultry production? A recent study estimated that antibiotic-resistant infections cost the US health care system in excess of $20 billion annually and that in addition, these avoidable infections result in more than $35 billion in societal costs and more than eight million additional days spent in the hospital.3 Some of these costs must be related to the routine feeding of antibiotics to healthy animals. Already, many hospitals are buying meat raised without antibiotics. With full accounting, the current incremental extra cost of some sustainable meats might be recognized as a health premium. The food system is highly energy intensive, and our health and health care is going to be on the frontlines of treating climate-related health impacts. What if these costs were internalized in food production?

BR: Tell me more about the climate change connection.

JH: Depending on which analysis and on what is included, the food system is responsible for 18% to 30% of global warming emissions. This is a sizeable contribution. We also know that with more sustainable farming practices we can minimize this impact.

Glossary

**Community-Supported Agriculture**
According to Suzanne DeMuth in *Community Supported Agriculture (CSA): An Annotated Bibliography and Resource Guide*, “in basic terms, Community-Supported Agriculture (CSA) consists of a community of individuals who pledge support to a farm operation so that the farmland becomes, either legally or spiritually, the community’s farm, with the growers and consumers providing mutual support and sharing the risks and benefits of food production. Typically, members or ‘share-holders’ of the farm or garden pledge in advance to cover the anticipated costs of the farm operation and farmer’s salary. In return, they receive shares in the farm’s bounty throughout the growing season, as well as the satisfaction gained from reconnecting to the land and participating directly in food production. Members also share in the risks of farming, including poor harvests [because of] unfavorable weather or pests. By direct sales to community members, who have provided the farmer with working capital in advance, growers receive better prices for their crops, gain some financial security, and are relieved of much of the burden of marketing.”

**Factory Farm**
From the *Sustainability Dictionary*: “A large-scale industrial site where many animals (generally chickens, turkeys, cattle, or pigs) are confined and treated with hormones and antibiotics to maximize growth and prevent disease. The animals produce much more waste than the surrounding land can handle. These operations are associated with various environmental hazards as well as cruelty to animals. The government calls these facilities Concentrated (or Confined) Animal Feeding Operations (CAFOs). The Environmental Protection Agency defines a CAFO as ‘new and existing operations which stable or confine and feed or maintain for a total of 45 days or more in any 12-month period more than the number of animals specified in categories that they list out. In addition, ‘there’s no grass or other vegetation in the confinement area during the normal growing season.’”

**Farm Bill**
From the Congressional Research Service: “The Food, Conservation, and Energy Act of 2008 (PL 110-246, ‘2008 farm bill’) is the most recent omnibus farm bill. It was enacted into law on June 18, 2008, and succeeded the 2002 farm bill. The farm bill governs federal farm and food policy, covering a wide range of programs and provisions, and, as noted above, undergoes review and renewal roughly every five years. The 2008 farm bill contains 15 titles encompassing commodity price and income supports, farm credit, trade, agricultural conservation, research, rural development, energy, and foreign and domestic food programs such as food stamps and...
So what does climate change have to do with health care? In 2003, as a result of a major heat wave, there were over 35,000 heat-stress-related deaths in Europe. Respiratory impacts such as asthma from worsened air quality, an increased range of infectious disease, death and injury from catastrophic weather events—these are just some of the many health issues that are predicted as a result of climate change. Unquestionably, health care is again going to be on the front lines dealing with the impacts of climate change. At the same time, the health sector can influence and mitigate these impacts.

In the United Kingdom (UK), the National Health Service Climate Action plan includes sustainable foods as part of the mitigation strategy. Because of the climate footprint associated with meat production they also announced a plan to eliminate meat from hospital menus. This is the UK, home of bangers and mash! The Swedish National Food Administration has created a food label system giving equal weight to climate and health. Climate change is a huge societal driver and obviously something that health care needs to be thinking about. We need to adopt food production methods that not only mitigate, but build resilience in our food system.

### Health Care and the Food System

BR: We see growing interest in sustainable food, but can we really grow enough food through organic or other sustainable practices?

JH: I like to think of this issue in terms of growing food in a better way, because if we continue to strictly think quantity we tend to forget quality, such as livelihoods of farmers and communities, or soil health and so forth. We already produce more calories than is necessary to feed the global population, yet we still have food shortages. Even in this country we have inner city and, surprisingly to most, rural communities without access to fresh fruit or vegetables. So much of this has to do with global food politics. That said, there is this perception that sustainable practices have low productivity. But if you look at the research, this is not the case. A recent United Nations study found that of 114 projects in 24 African countries had more than doubled their yields where organic or near-organic practices had been used. As global food demand explodes, we will have to consider changing both the kinds of food we eat and how we produce them.

---

**We already produce more calories than is necessary to feed the global population, yet still have food shortages.**

---

**Organically Grown/Certified Organic**

According to the Center for Urban Education about Sustainable Agriculture: “All products sold as “organic” must be certified. Certification includes annual submission of an organic system plan and inspection of farm fields and processing facilities to verify that organic practices and recordkeeping are being followed. Certification is carried out by organizations accredited by the USDA. Organic farmers are not allowed to use synthetic pesticides or fertilizers, genetically modified crops, growth hormones, or antibiotics. Organic meat and poultry can be fed only organically grown feed. Note: Some farmers adhere to accepted organic practices but are not certified. Possible reasons for not pursuing certification include the cost, time, or paperwork involved in certification, and/or a resistance to outside intervention. Under USDA law, farmers cannot call their produce organic unless they are certified.”

**Sustainable Agriculture**

According to the Center for Urban Education about Sustainable Agriculture: “Organic agriculture includes annual submission of an organic system plan and inspection of farm fields and processing facilities to verify that organic practices and recordkeeping are being followed. Certification is carried out by organizations accredited by the USDA. Organic farmers are not allowed to use synthetic pesticides or fertilizers, genetically modified crops, growth hormones, or antibiotics. Organic meat and poultry can be fed only organically grown feed.”

---

**Nontherapeutic Antibiotics**

From the Sustainability Dictionary: “Antibiotics administered to animals for purposes other than the treatment of existing illness. Factory farms routinely administer nontherapeutic antibiotics to their animals in order to boost growth rates and to prevent the outbreak of diseases which would otherwise run rampant within crowded, unsanitary factory farm facilities. The use of nontherapeutic antibiotics promotes the development of antibiotic-resistant bacteria, causing antibiotics used to treat humans to become less effective.”

**Food Miles**

According to Wikipedia: “Food miles is a term which refers to the distance food is transported from the time of its production until it reaches the consumer. Food miles are a single factor used when assessing the environmental impact of food.”

**Other nutrition programs, among other programs.”**


**Food miles**


**Organically Grown/Certified Organic**


**Nontherapeutic Antibiotics**


**Sustainable Agriculture**

Market Leadership

Health care organizations can make a difference by modeling good nutrition and adopting food purchasing policies and practices in their own facilities that steer the entire food system in a more positive direction.

- **Purchasing Power**—Hospital food is big business. In 2004, alone, the top health care Group Purchasing Organizations (GPOs) purchased approximately $2.75 billion of food. The total health care market for food and beverages is about $12 billion. Patient food receives some attention in the media, cafeteria and catered food actually make up the largest percentage of food in the hospital budget, accounting for approximately 55% – 70% of hospital volume. Hospitals and hospital systems are now becoming aware of their ability to use their purchasing dollar to affect change in the marketplace. Demand by health care facilities is creating momentum within the GPOs, which, until recently, were virtually unaware of food production issues. As a result of hospital-driven demand, GPOs and distributors are beginning to offer and label local products in food catalogues and are contracting for sustainable products.

- **Healthy Food in Health Care Pledge**—One action that health systems and facilities have taken is support for the Healthy Food in Health Care Pledge. Without encumbering facilities with mandates, the Pledge is a way to align hospitals with health food initiatives. As of early [2010, approximately 300] hospitals have signed the Pledge, thus sending an important signal to the marketplace and policy makers about their interest in local, nutritious, sustainable food.

Pledge signatories agree to initiate steps to:

1. **Work** with local farmers, community-based organizations, and food suppliers to increase the availability of locally sourced food
2. **Encourage** vendors and/or food management companies to supply food that is, among other attributes, produced without synthetic pesticides and hormones or nontherapeutic antibiotics
3. **Implement** a stepwise program to identify and adopt sustainable food procurement. Health care institutions are encouraged to begin where fewer barriers exist and where immediate steps can be taken, such as the adoption of rBGH-free milk, Fair Trade coffee, or introduction of organic fresh fruit in the cafeteria
4. **Communicate** to GPO interest in foods that are identified as local and certified
5. **Educate** and communicate within the system and to patients and the community about nutritious, socially just, and ecologically sustainable healthy food practices and procedures
6. **Minimize** or beneficially reuse food waste and support the use of food packaging and products that are ecologically protective
7. **Develop** a program to promote and [to] source from producers and processors that uphold the dignity of family, farmers, workers and their communities, and support sustainable and humane agriculture systems.

**References**


BR: I've heard about the Healthy Food Pledge. What exactly is it?

JH: We conceived the Healthy Food in Health Care Pledge when early on we discovered that a variety of hospitals we were working with were having difficulty getting the attention of their Group Purchasing Organization (GPO) or their distributors about changes they wanted to make in their food purchasing. Moreover, these facilities were interested in demonstrating their leadership in the marketplace. The voices of these leaders were getting lost in the din of the marketplace. A tool was needed that would help aggregate the health care voice around the issue and give it strength. Hence the Pledge, which is, as its title suggests, a formal commitment by a health care institution to initiate changes in their food service operations and a formal acknowledgement that healthy food is defined not only by nutritional criteria but by how it is produced and distributed.

From the institutional perspective it has been tremendously successful. Almost every facility that has signed the Pledge has received tremendous community support and media attention, locally and nationally. The GPOs have begun to offer new product lines and the distributors have also begun to respond. To date, we have approximately 300 hospitals that are Pledge signatories. We also created a separate Contractor Pledge for food service contractors when they each began knocking at our door trying to promote themselves as the most sustainable. The Contractor Pledge requires the contractor to support their clients’ sustainability interests and to provide reporting on a variety of criteria. We now have one national contractor who has signed this pledge and several regional companies.

BR: What role can health professionals play in the public policy process?

JH: Health professionals play a vital role in the policy arena because they are patient advocates; they are respected and bring moral authority to an issue. Historically, we have seen how health professionals' engagement has changed the policy debate when they advocate a public health issue—be it removing lead from paint and gasoline or antismoking campaigns. In the last two years, both the American Nurses Association and the American Medical Association have reviewed the science and adopted policy resolutions that call on their professions to support and advocate for nutritious, sustainable food systems.

How can a health professional get involved? First, educate yourself about an issue you feel passionate about. Food access, pesticides, genetic engineering, antibiotics overuse—there is no lack of issues or arenas for engagement. You might start by engaging your hospital administration to change hospital food purchasing policy by joining or supporting your hospital green team. You might petition your local and state professional organization to lend policy support. You might write opinion pieces in your local newspaper, or send letters to the editor. Health care professionals might lend their name and support to local, state, and federal policy initiatives by writing letters and calling legislators.

Two critical pieces of federal legislation—the US Food, Conversation, and Energy Act of 2008 (Pub L 110-234, 233 Stat 923) and the Child Nutrition and WIC Reauthorization Act (Pub L 108-235)—affect agricultural production, community food retail, school lunches, and more. The Farm Bill will be reauthorized in 2012, and includes hundreds of programs that exert tremendous influence on our food production and distribution. The Child Nutrition and WIC Reauthorization Act will be reauthorized within the next year. It includes programs such as WIC and school food programs. Ultimately, the key is to get involved.

Future Challenges and Opportunities

BR: What's the biggest challenge you see going forward?

JH: I think the biggest challenge is time. The United Nations’ Millennium Ecosystem Assessment report says that human activity is putting such a strain on natural ecosystems that we shouldn’t take for granted the ability of these systems to sustain future generations. Now that’s a wake up call.

BR: What are you optimistic about and why?

JH: I’m not sure I’d say I’m optimistic, but I’m definitely hopeful. We are in an interesting time, which is both exciting and terrifying. Our economic system is in crisis; we have a crisis in health care; and our climate is in crisis. It is in this turmoil, within this commotion and tumult, that we have the opportunity to make something new, but it won’t happen by watching from the sidelines. Our collective work makes sense, and I know I’m going to keep working to create models of resilience and health. My sense is that I am not alone.

Disclosure Statement
The author(s) have no conflicts of interest to disclose.
Wholesome Food

Many physicians appear to be too strict and particular in the rules of diet and regimen, which they deliver as proper to be observed by all who are solicitous either to preserve or recover their health … The common experience of mankind will sufficiently acquaint any one with the sorts of food which are wholesome to the generality of men; and his experience will teach him which of these agrees best with his particular constitution.

— Commentaries on the History and Cure of Disease, William Heberden, 1710-1801, English physician and author

References


Robert W Hogan, MD, is an Associate Clinical Professor at the University of California, San Diego School of Medicine and a Partner in the Southern California Permanente Medical Group (Family Medicine, La Mesa Medical Offices) in San Diego, CA. He is also an enthusiastic photographer who focuses on capturing natural beauty in his work. E-mail: rwhogan@cox.net.

This photograph was taken while hiking in the Canadian Rockies.
The Start of a Journey

I am riding in the front seat of a tiny Ford Icon, taking in the left-sided passenger view as we bump along narrow dirt roads. The driver is cheerfully unperturbed as he navigates various obstacles in our path: children, motorists, stray dogs, cycle rickshaws, carts of bright red tomatoes. By the end of my trip, my mind—and stomach—will be desensitized to the labyrinth of vehicles, pedestrians, and animal life constituting traffic in Chennai. But today is my second day; thus, I still shut my eyes in instinctive terror as our car swerves to avoid the mammoth trucks lurching toward us.

Chennai, India: A city in which I have never lived, but whose ancient culture shapes my roots. My memories of this south Indian city centered on its role as default destination of onerous family vacations. Back then, the sweltering summer weeks of bumpy rickshaw rides, obligatory extended-family visits and inevitable digestive woes felt more like forced medicine than my parents’ claim of “relaxation.” Yet these trips nurtured my subconscious appreciation for Indian culture, as I studied Sanskrit literature and trained as a student of Indian classical vocal music. Over the years, summer trips lessened in frequency, but my connection to Chennai grew tenacious as I pursued its art forms.

That connection had planted the seed for this trip. As an almost-physician, I was returning to Chennai with two specific goals: to provide medical service, while immersing myself in the culture inspiring my cherished hobbies.

Since my last visit (nearly a decade earlier), both of us had changed rather substantially. I’d moved across continents, worked for a behemoth investment bank and a tiny nonprofit agency, studied economics in England and parasitology in Texas—and now, months away from medical school graduation, was embarking on a future career in preventive medicine and public health. In India, transformation permeated society. A patriotic, pro-tradition movement had sparked a nationwide flurry of renaming Indian cities in indigenous language (Bombay to Mumbai, Calcutta to Kolkata, Madras to Chennai) even while popular media captured evidence of India’s resolute modernization: humble tea stalls replaced by Internet cafes, expansive rice fields now home to gleaming “tech parks,” mobile dosa-poori-masala stands juxtaposed near freshly painted Pizza Huts, bright yellow auto-rickshaws lost in the roar of sporty Honda Civics.

And so it was thus, on this occasion of visiting a home I secretly feared would seem rudely foreign, that I found myself cowering in the passenger side of a Ford Icon.

A Snapshot of Daily Life in Chennai

Chennai operates in a chaotic, stubbornly functional context. First, people are everywhere. Chennai’s 7 million people share a space of 180 square km, representing a population density of 24,231 people per square kilometer.1-4

Life in Chennai splashes boisterous color on the seemingly mundane. On the road, trucks groaning with loads of cargo are festooned with painted curlicues and canary-yellow paint jobs; shifting into reverse gear, they emit tinny renditions of various bhajans, Hindi film songs, or the national anthem. On nearly every corner, stores sell milk and pistachio (“pistha”) biscuits along with artists’ paintbrushes, crochet kits, an array of sketchbooks, and Fevicol-brand craft glue. Street vendors wheeling carts of fresh vegetables, sugarcane juice and customers’ folded laundry advertise their wares by shouting at the top of their lungs, creating a collective vocal cacophony that only a professional mother-in-law cooking in apartments above can interpret.

Everyone loves music, and fittingly, every street in Chennai pulses to a perpetual soundtrack: Bollywood, classical, bhajans, instrumental mandolin/veena/violin, drum beats

Janani Krishnaswami, MD

Janani Krishnaswami, MD, is a second-year resident completing a combined residency in Internal Medicine and Preventive Medicine at Kaiser Hospitals-San Francisco and the University of California-San Francisco. E-mail: jkswami@gmail.com.
of tabla and mridangam. And every December, the whole city celebrates the Chennai Music Season, a five-week festival featuring hundreds of heavily attended classical music and dance concerts, lectures, demonstrations, and performances.5

Religious diversity is often matter-of-fact on Chennai's streets, even as India's borders are caught in religious quaigamre. Travel down one road and you will see a prestigious convent school facing a billboard that proclaims Jesus Loves You, catercorner to a procession celebrating Ganesha Chaturti at a Hindu temple. On another corner, traditional Muslim prayer call echoes from a mosque tucked in between “Krishna Tailoring Stores” and “Muhammed and Sons Jewelers.” Turbans, burqas, saris, suits, dhotis, dresses, salwar kameez, pants and shirts (“pant-shirt” in Chennai-speak), and sometimes no shirts are all accepted Chennai attire. It can sometimes seem as though the city is in a state of perennial celebration of some festival or holiday, with the sight of a sequined, bedecked, palanquin-hoisting, hymn-chanting and dancing group in the street almost as commonplace as rush-hour traffic.

A Bit Lost

The address I've been given is “19, 12 Cross Street, Indira Nagar, Chennai.” The car meanders through increasingly pot-holed, nameless dirt roads; I wonder restlessly how we know where we're going. “Oh, 12 Cross Street,” my driver, Shekhar, had said confidently. “We'll get there, we'll get there. No problem.” Shekhar, of course, never said we couldn't do anything. Drive across town in 20 minutes during Chennai's rush hour, which makes Rockefeller Plaza at Christmastime look like Germany's Autobahn? “Of course, we'll get there, we'll get there. No problem.” Everything is possible for Shekhar.

Except, apparently, finding this clinic. The car slows to a pathognomonic I'm-lost pace, and I peer worriedly out the window. Still no street signs. Flat-roofed cement houses—pastel pink, lime yellow, mint green—line the road, each enveloped by lush green creepers and vibrant hibiscus and jasmine. In lieu of door numbers, each house features a name painted in neat white letters atop an iron-railing fence. Lakshmi Nivas. Swaathi. Sai Krupa. Despite this decidedly non-numerical pattern, we creep by in hope of finding number 19.

The car pulls to a stop in front of a turbaned man idly chewing a betel leaf. Shekhar rolls down the window and beckons. “Are, 12 Cross Street engu irruku theriyuma?” [Hey, do you know where 12 Cross Street is?] he calls. The man spits out the leaf, squints for a moment and points. “Angu left thirumbi, conju nenu pettu, inooru oru right…” [Turn left there, then go straight for a while, then another right …] I try to ignore the angry red betel stains on his teeth and instead concentrate on trying to understand the circuitous route. I'm lost after the first “left” and “right,” but Shekhar nods in apparent excellent understanding. And we're off once again, narrowly dodging the cow that suddenly is in front of us, plodding by turning its tail.

Surveying Chennai's Health

The context of health in Chennai is framed by a mammoth, decade-long rollercoaster ride of growth and development. As India expanded its information technology (IT) sector and liberalized foreign investment laws, wealth flooded into Chennai's economy. Chennai now serves as one of India's major IT and IT-related services exporter, with its newly constructed "IT Corridor" employing over 300,000 people. Upward mobility thus touches and transforms the lives of many once-poor Chennai residents.6-9 India's poverty rate declined over 50% from 1983 to 2007, and the 2006 South Asian Economic Report10 noted a “remarkable” reduction in the rate of absolute poverty in the region surveyed “primarily due to accelerated growth in India.” Among Indian states, Tamil Nadu ranks in the top five in terms of level of urbanization and literacy rate and has a lower-than-average poverty ratio. And in the 2009 Global Rankings Quality of Life Survey—covering 254 cities and conducted by the international human resources firm ECA International—Chennai was the top-ranked Indian city in which to live.11,12

Health care and health delivery are important beneficiaries of India's economic boom. The preceding decade's newfound wealth spurred grassroots efforts and nongovernmental organizations to fill basic public health needs: waste disposal, hygiene and sanitation, and access to clean water. Tangible examples include Friends of the Beach, an initiative in 1999 that installed garbage bins and public toilet facilities on Chennai's heavily polluted beaches and provides stable wages to slum-dwellers in exchange for beach cleaning and construction services.13 The World Bank-supported Tamil Nadu Health Systems Project is a hospital-centered public health effort; this five-year, $110 million project will roll out electronic information systems in the state's district hospitals, streamline disposal of hospital waste and construct 24-hour OB/GYN centers.16,17 And in
the realm of drinking water access, the successful completion of the Sai Ganga Water Project represented a milestone. This multimillion-dollar initiative provides safe drinking water to millions of Tamil Nadu citizens, including the very poorest communities and slum dwellers, via groundwater pipeline connections from the neighboring water-rich state of Andhra Pradesh.18

Such measures dent the devastating death toll wreaked by India’s endemic infectious agents. Tamil Nadu achieved a near-100% target vaccination rate from 2007-2008, and the death toll from six major vaccine-preventable diseases is zero.19,39 Even once-rampant, “classic” developing world conditions are declining: in Chennai, malaria’s incidence fell 43% between 2001-2008, and leprosy’s prevalence is currently less than 1/10,000 in Tamil Nadu.20,21 Expanding health care infrastructure also spurs dramatic increases in medical treatment and diagnosis. In 2008, Tamil Nadu’s patients obtained 19.4 million lab tests, 19,000 Pap smears, and 600,000 surgeries.22

Despite such advances, however, poverty and poor health still trouble many residents of Chennai. Almost ten times as many infants die at birth in Chennai compared to Beijing; the average Chennai female can expect to live only about 67 years. The city’s residents are served by about 1800 physicians, leading to a ratio of 42 physicians per 100,000. (In the US, the average is 286 physicians/100,000.)23-25 Even as enterprising students graduate from Chennai’s institutes of higher education, others drop out of poorly funded, deplorably run government schools where student and teacher attendance is optional, desks and chairs are a luxury, and basic infrastructure is in flux. For example, a recent study found 38% of these schools lacked proper toilet facilities for its students. The city’s overall literacy rate hovers at 73-78% (soaring from 46.7% in 1991), but literacy rates lag behind nearly 10-15% among poor classes, where sanitation, air pollution, and improper waste disposal hinders quality of life.26-30

The dichotomy between rich and poor is stark in gentrified locales like Besant Nagar. Here, idyllic gardens and glass-doored shopping malls featuring “export-only” clothing and goods cater to the area’s upper-middle class. One corner turn away on the paved road to the beach, however, is Oduma Nagar, a fishing colony and slum. In the slums of Chennai, populations exceeding the size of small European countries coexist on a few square kilometers. For slum inhabitants, mundane needs and activities—bathing, garbage disposal, drinking water, and defecation—are daily battles. Garbage and human waste invariably ends up in the same water used for bathing and drinking, promoting a vicious cycle of parasitic and communicable disease.34-35

Entering the Clinic

A khaki-uniformed security guard paces pensively by the wrought-iron gate encircling the cream-colored house. He pauses as we pull to a stop. “Idhu doctor veettu ah, doctor Krishna Raman?” [Is this Dr Krishna Raman’s house?] Shekhar questions the guard. I peer anxiously as the guard smiles and nods vigorously, briefly pondering the irony that the word for “doctor” in vernacular Tamil—a hybrid of Tamil and English—is “doctor.” Shekhar turns to me and nods with vigor and triumph; with good reason, as against all seeming odds, he’s successfully brought me to my destination. Although, I fret, this so-called “clinic” looks much more like a house.

I gingerly step down from the car, my relatively pampered muscles bruised from the jarring hour of swerving over Chennai’s obstacle paths. Then the reality of the moment floods over me. Here it is: the clinic of Krishna Raman, MBBS, FCCP, graduate of the BKS Iyengar Institute.34

Traveling down the inevitable extended-relative grapevine earlier, news of my medical “rotation” with Dr Raman had sparked much excitement. “Just one look at the frozen shoulder, and he knew exactly what to do: a few medicines, creams, and some yoga postures and I was completely back to normal,” my aunt had gushed. My grandmother had solemnly agreed. “Dr Krishna Raman, he’s a big name,” she said with hushed reverence. “He’s been on TV, helped many people … you’re lucky to be able to work with him.” Although I have grown accustomed to my relatives’ proclivity for exaggeration (eg, “air-conditioned” referring to “extra ceiling fan”), I figured at least some truth inspired this exuberant praise. A perusal of the clinic’s Web site and Dr Raman’s publications introduced me to his mission of providing quality health care to all patients regardless of socioeconomic status. And his treatment came with an added twist: allopathic medicine supplemented with an emphasis on lifestyle changes, including the incorporation of a personal practice of yoga.

Brushing beads of sweat off my forehead, I leave my slippers outside the door—the custom in Chennai—and step barefoot onto the mosaic-tiled floor of the clinic. The
room is empty, except for the clamoring rattle of a fan, which seems to be producing more noise than breeze. A bare light bulb flickers overhead, casting feeble light over a wooden table placed in the center of the room. Five chairs are neatly lined in a row, empty except for a stack of magazines and newspapers: *Time. India Today. The Hindu.*

“Welcome!” I am greeted by a trim, elderly gentleman wearing a light green polo shirt and cleanly pressed khaki pants. Dr Raman ushers me inside to give me the one-room clinic tour. It’s short: there’s the waiting room, which I’ve already seen, and the combined exam-room/physician’s office featuring familiar fixtures of outpatient medicine—a Dell computer station, exam table and the less familiar x-ray viewing box.

Dr Raman shows me the day’s schedule, explaining that he routinely sees between 40-50 patients a day. Most come in with a chief complaint of musculoskeletal pain. “There are sometimes significant social issues,” he says in lightly accented English. “Some women come with carpal tunnel syndrome from rolling chapattis all day for 20 in-laws, for example. It’s impractical to tell them to stop cooking, when it’s what everyone—including the patient—expects.” I nod, wondering how anyone could tolerate standing even slightly near heat-generating kitchen equipment in the searing 100-degree-plus weather, especially in 9 yards of a silk fabric sari. “But I get patients from all backgrounds,” he continues, leaning back in his chair as I take a seat in front of the desk. “Muslim, Hindu, Sikh, Christian, Tamil, Hindi, Telugu, Marwari. There are those who can’t afford to pay—the care is free for them. Others are successful businessmen and women; they pay the regular fees.” (Regular fees, I find out, are anywhere from 250—800 rupees [INR], $6-$12.)

Dr Raman also eagerly expounds on the aspect of yoga and lifestyle education interwoven into his clinic services. “These days, the nine-to-five tech jobs … so many people are sitting, no such walking or activity as they had in the past. Only a decade ago, people walked more. Activity was built into their lives: walk three miles to school, to go to the temple and to do 40 pradakshinams. Now it’s staring at the computer screen.”

“So naturally,” he continues, “muscle pain complaints are the biggest part of my practice. Herniated disks, osteoarthritis, carpal tunnel syndrome, chondromalacia. A lot of it, of course, is sedentary lifestyle and being overweight. For these people, I do give allopathic treatment for the pain and swelling. But that cannot change lives. A daily yoga practice, however, can—it improves flexibility, lean muscle mass, peace of mind all in one,” he concludes triumphantly.

I had half-expected an introductory discourse on Chennai’s clinical epidemiology covering topics such as Pott’s spine, leishmaniasis, leprosy; my mind now shifts gears in the face of a medicine demographic echoing my patient encounters in the US. Dr Raman turns to his computer and, with a few mouse clicks, brings me even closer to home as he pulls up the ubiquitous blue screen of a Microsoft PowerPoint presentation. “Here, you can take a look at some MRIs and x-rays of some of my patients,” he explains as we click through slides containing radiologic proof of patients’ suffering and photos of patients (without faces blackened out as in my lectures back home) trying out yoga. There are sari-clad women holding onto a wall and twisting their spine; somewhat pot-bellied men stretching up valiantly to the ceiling; “before” and “after” MRIs that show the progression of a herniated disc back into its rightful place after a year of yoga. I’m impressed.

Dr Raman looks up abruptly at the clock. “Well, it’s 8:30. Let’s see our patients.”

**The Rise of Chennai’s Medical Tourism Industry**

As India tackles basic deficiencies in public health indicators, another phenomenon transpires in parallel: the explosion of an elite private health care sector worth nearly $15 billion. Catering to the upper-class segments of Indian society with “five-star” hospitals, this emerging industry is responsible for India’s “extreme makeover” of health care.35

Each year, over 150,000 patients fly in from around the world to receive comparatively lower-price treatment or escape long waiting lists. Their stories are featured in op-ed pieces and magazines: Bill W from California, denied health insurance because of a high PSA and suspected cancer, paying cash to receive a transurethral resection of the prostate (TURP) in New Delhi’s Fortis Hospital for a quarter of the cost back home; Mohammed S from Kuwait, undergoing an eight-hour removal of a glioblastoma in Chennai’s MIOT hospital only a few days after receiving his diagnosis at home.35,36

Nearly 50% of patients treated in Chennai travel from outside Tamil Nadu. Chennai’s hospitals go to great lengths to attract this lucrative group of patients, offering city tours, swanky hotel rooms for guests, airport pick-up and drop-off, and hours of one-on-one time with staff physicians. All with calculated
reason, for the industry is forecasted
to grow at a rate of 15% per year
for the next six years, eventually
constituting 3% to 5% of the health
care delivery market and contribut-
ing $1-$3 billion additional revenue
for tertiary care hospitals.10,35,37,38

The medical tourism industry in
India traces its roots to Chennai—
specifically, the Apollo Hospitals
group, a private entity, which opened
its first international branch in 2007. Navigating the traffic-
chocked streets of Chennai, it is
hard to miss the handsome, coffee-
colored marble building with its
gold-emblazoned “Apollo” moniker,
towering above the hand-painted
shops and stalls. Apollo’s success
inspired the creation of private hos-
pitals and “super-specialty” centers
in Chennai offering everything from
lipsuction to laparoscopic, mini-
mally invasive joint replacement.
There is the Shankara Netralaya Eye
Institute; MV Hospital for Diabetes
and Diabetes Research Center; Ma-
stras Ear Nose & Throat Research
Foundation, Heart Institute and
Institute of Cardiovascular Diseases,
all of which are privately owned
and nationally recognized.39-42

These hospitals steered India’s
most lucrative health trends, in-
cluding telemedicine and medical
outsourcing, and have received criti-
acclaim as the home of various
medical “firsts” in Asia and India.
Examples include the first success-
ful transmyocardial revascularization
laser surgery in 1994, the concept of
magnetopexy in 1988 and the first
successful heart-lung transplant in
1995, to name a few.40,41 The effect of
modernized medicine is seen even
in such seemingly low-tech places
such as the Chennai Central railway
station, where there is a telemedicine
facility complete with EKG machines
and virtual consultation stations for
those passengers who suddenly feel
a bout of chest pain along the main
concourse.45

Glamour and wealth in Indian
health care transpire primarily in
the private sector, which generates over
70% of all health care revenue (or
6% of GDP in 2005). Highlighting
the regional dominance of health
care by the private sector, the South
Asian Economic Report notes that
“the proportion of private health
expenditure to total health expendi-
ture in the South Asian region
surpasses that of most countries in
the world.”45,46 Contrast this with the
US, where the government’s share
of per capita health care spending
tops 50%.

The private sector’s starring role
in India’s health care stems from the
dynamics of supply and demand: Private providers’ domain en-
compases services from x-rays and MRIs
to treatment of childhood diarrhea
and malaria to prescription drugs.
In contrast, government spending
on health care actually decreased
over the past decade.10,43 Paucity of
funding sustains inefficiency in gov-
ernment hospitals, where shortages
of drugs, supplies, and personnel
persist. One article describes Chen-
nai’s Government General Hospital,
which sees 10,000 patients per day,
as having a workforce “not even
adequate to cater to a fourth of these
numbers.”45 Such basic deficiencies
prompted an acrid editorial com-
ment in the city’s major newspaper,
The Hindu: “It is an ironic outcome
of neo-liberal economic reforms
that in spite of fundamental policy
failures in public health, India is
increasingly seen as an attractive
international health care destination.”38

**First Encounter**
The couple walking into the
room comprises an elderly man
and woman who instinctively seem
to lean on each other for support.
The woman is slightly heavyset,
with salt-and-pepper hair loosely
threaded into a braid and secured
with jasmine flowers that have be-
gun to brown in the midday heat.
She absenthly pats these flowers as
she looks up respectfully at Dr Ra-
man. Her husband, a stocky, dark
gentleman wearing a white dhoti
and a rather ill-fitting button-down
shirt, is carrying a bulky briefcase
that he sets down before cupping
his hands together. “Vanakkam,
docor,” he says with genuine rever-
ence and enthusiasm. It is only
two words—hello, doctor—but the
undertone of hope in his voice is
almost palpable.

Because there isn’t an extra chair,
I am trying to stand as incon-
spicuously as possible under
the x-ray viewing box. I wonder
what patients will think of my rather
random presence as they discuss
their aches and pains. Would they
request that I leave? Demand an
introduction? Should I introduce
myself—exposing my broken,
American-accented Tamil—or wait
for Dr Raman to take the lead?

As I find out, introductions are
apparently unnecessary. Patients
seem to think that as long as Dr
Raman accepts my presence, they
don’t need to know who I am,
or what my qualifications are for
listening to their concerns. Indeed,
throughout my rotation here only
one patient actually looks at me
directly and asks, “And so, who
exactly are you?” It’s somewhat
of a relief in a sense; part of me
fears that by opening my mouth
and talking too much, my status as
foreigner will instantly be revealed.
Throughout the rotation, I grow
used to my place as a nameless
physician-in-training, nodding in
sympathy during the discussions of
pain and suffering, hanging up x-
rays on the lightboard, helping frail
patients climb down from the table.

Now, Mr Vasu launches into a description of his wife’s agonizing back pain. A few sentences in, however, Dr Raman stops him. “She’s the one with the pain?” he asks in Tamil. Both nod hesitantly, and Dr Raman motions to the lady. “Then you talk,” he says pointedly. Mrs Vasu looks taken aback for a second, reaching up to her jasmine flowers for support. But she begins, after a moment, to describe the dull ache in her lower back that has disturbed her for the past two years, now intensifying to the point where she can no longer sleep. Dr Raman nods in understanding and is already scribbling down something on a prescription pad. “Let’s see the x-ray?” he half-asks, half-commands as he signs the pad with a flourish.

Mrs Vasu looks at her husband expectantly; he readily pulls a large Manila envelope from his briefcase. Across the front is stamped in faded gray print: “Swaminathan Scans, Ltd.” Across the front is stamped in faded gray print: “Swaminathan Scans, Ltd.” The envelope contains a glossy x-ray of what is apparently Mrs Vasu’s spine. As I will discover throughout the month, even the poorest of patients come to clinic with “high-definition” radiologic images capturing their anatomy. Obtaining a computed tomography scan or x-ray is as easy as going into a neighborhood stall and paying a few dollars, depending on where the scan is obtained. Meanwhile, if a patient is not able to afford these prices, Dr Raman has agreements with specific x-ray and MRI centers that will perform the tests free of cost.

Dr Raman and I look at Mrs Vasu’s x-ray. He asks me what I see; I gesture, with weatherman-style vagueness honed during third-year rotations, over an area with joint-space narrowing. He nods thoughtfully, studies the scan for a few more moments and then switches off the viewing light. “Right,” he tells the couple, who seem to be hanging on his every word. “Absolutely nothing to worry about. No TB, no infection. Take these medicines, and I will give you some exercises; it will become all right.” He slides over a prescription (for what looks like an NSAID, PPI, and a topical muscle relaxant) as Mr and Mrs Vasu nod vigorously in tandem, relief evident in both their faces.

Dr Raman stands up. “Also, you will need to lose five kilos,” he says bluntly. “You’re overweight, and your pain will improve if you lose this weight.” Mrs Vasu and her husband look genuinely surprised, almost as though the concept of having “too much” weight is foreign. Dr Raman briskly continues as he hands her a card. “My dietician—Jyotsna—she is very good. You can make an appointment with her, and she will give you a diet. Then come and see me day-after-tomorrow. I will show you some yoga exercises to help the pain.” She mouths agreement, looking at her husband with a slightly bemused expression.

**Side Effects of Modernization: New Challenges to India’s Disease Burden**

As the lifestyle of material success touches more of India’s citizens, so does the sobering impact of a new set of health conditions. They are a cohort of “lifestyle” diseases: metabolic syndrome, Type II diabetes, coronary artery disease, obesity, and tobacco and alcohol addiction.

In 2004, almost half the disease burden in South Asia consisted of noncommunicable diseases, a 10% increase over the past decade. Over the next decade, these “lifestyle” diseases will comprise an estimated 57% of India’s total burden of disease—with heart disease rising as India’s number one killer—whereas infectious diseases’ share will sink below 24%.49

Heart disease already kills 15% of India’s population each year, whereas over a third have metabolic syndrome. The Public Health Foundation of India notes: “India tops the world list in terms of the disability burden due to heart and blood vessel disease (more than all industrial countries put together).”50 Tobacco use persists as a major killer, responsible for India’s world dominance in oral cancer prevalence. And noninsulin-dependent diabetes mellitus (Type II Diabetes) is also a health scourge for Indians: With over 12% of its adult population developing the disease each year, India is the “diabetes capital” of the world, housing more diabetic patients than any other nation.10,48-50

The changing disease demographic is rooted partly in lifestyle transitions—urbanization, sedentary behavior, changing food choices—which escalate classic risk factors causing diabetes and heart disease. Where Indian residents once feared undernutrition, they are now caught in a growing epidemic of overnourishment: obesity, and its anvil of chronic disease. A large cohort study found nearly half of Chennai’s urban population was obese by a standard of BMI > 25; adopting a waist-circumference-based definition (waist size greater than 90 cm) placed even more Chennaites—55% of Chennai females—in this category.51 Another study identified 16% of urban Indian schoolchildren as overweight, with close to a third demonstrating insulin resistance (a precursor to diabetes).52 Misra et al comment that "the rapid nutritional and lifestyle transition in urbanized areas … are prime reasons for increasing prevalence of obesity and the metabolic syndrome."50
More evidence supports a coupling of urbanization and lifestyle disease. In urban Chennai, high socioeconomic status was found to be an independent, statistically significant predictor of being overweight or obese. Lifestyle may also be partly responsible for hypertension in nearly a third of Chennai’s urban residents; a Madras Medical Institute cross-sectional study of 2007 Chennai-based volunteers found that higher monthly income correlated positively with blood pressure. In this study, belonging to a middle-class classification or higher increased the chance of having high blood pressure by 150%.

Hastened by obesity and metabolic syndrome, diabetes is a particularly problematic component of the “lifestyle epidemic” in urban India. A large cohort study from Chennai’s MV Diabetes Center (Chennai Urban and Rural Epidemiologic Study, CURES) found that diabetes prevalence in urban Chennai increased by 72.3% from 1989 to 2004. Although this increase arises partly from improved methods of detection and earlier diagnosis, lifestyle factors are also contributors. The Diabetes Prevention Program underscored the role of obesity, lack of physical activity, and poor diet in exacerbating cardiovascular disease and diabetes. Various epidemiologic studies even quantify this effect, suggesting obesity is responsible for up to 90% of the risk of acquiring type 2 diabetes. As the incidence of obesity and impaired glucose tolerance rises in a younger Indian population, the number of Indian diabetic patients inevitably increases.

Urbanization has clearly transformed India’s health, but new evidence suggests genes may also contribute to Indians’ growing burden of chronic disease. Of note, India has a higher prevalence of diabetes and cardiovascular disease than other Asian industrializing nations. Factors hastening cardiovascular disease—high cholesterol, cell markers of inflammation, obesity and overweight, endothelial dysfunction (disruption in the lining of blood vessels leading to formation of artery-clogging plaques), thrombosis (clots which can block blood flow, leading to heart attacks), glucose intolerance (a precursor to diabetes)—affect a greater proportion of South Asians than Caucasians, with onset in Indians occurring 10 to 15 years earlier. Nearly half of all cases of heart disease are detected in Indians younger than age 50—and over half of all cardiovascular deaths occur in people <70 years in India, compared with 22% in developed countries.

Several studies extricate the genetic component to lifestyle diseases in India. One study by the International Diabetes Epidemiology Group showed that Indians’ risk of acquiring diabetes increased at lower levels of body mass index (BMI) compared with Europeans—and is more sensitive to smaller increases in BMI. The National Urban Indian Survey found central obesity had a higher prevalence (50%) among Indians; even lean-BMI individuals tended to have central obesity and high percentages of body fat. This is particularly significant as central adiposity—the so-called “apple shape”—carries the strongest relationship to impaired glucose tolerance in Indians. In fact, the “unique” Indian overweight and obesity patterns prompted the Association of Physicians of India to issue revised 2009 guidelines for obesity and metabolic syndrome, aimed at identifying more at-risk Indians and staying off disease through early prevention strategies. In sum, such research supports a theory that Indians may have inherent genetic susceptibility to diabetes and cardiovascular disease, now unmasked by lifestyle changes accompanying India’s urbanization and industrialization.

Co-pay

As the Vasus stand to leave, Mr Vasu asks, “Evlovu, Doctor?” [How much, Doctor?] Dr Raman waves them off. “You can pay me later; it will be 500 rupees.” Mr Vasu cups his hand once more in respect, and the couple exits the room. I am struck by this trust-based system of accounting—when exactly is “later”?—as I begin straightening the room for our next patient.

Paying for India’s Modernizing Health Care

Most citizens pay out of pocket for health care (40% of the $27 per capita health spending in 2002). Talking to various patients during my rotation, I gleaned that a typical middle-class Chennai household (mean income INR 10,000) generally finds outpatient medical care at a government hospital to be affordable: A clinic visit costs anywhere from $0.50 to $5; a knee x-ray can be obtained for $4; a week’s supply of antibiotics will run less than $3.

Unfortunately, current trends in health and social demographics are already driving up prices, threatening to render an era of affordable healthcare obsolete. First, as private tertiary care hospitals flourish in the wake of the medical tourism goldmine, state-of-the-art procedures and facilities demand increasingly prohibitive prices. Second, as the prevalence of “lifestyle” diseases increase, so also does the cost of receiving treatment. In contrast to times when disease treatment entailed an empiric course of relatively...
cheap chloramphenicol, today’s urban diseases demand expensive antidotes—cardiac catheterizations and stents, a multidrug regimen of blood pressure- and cholesterol-lowering medications, coronary bypass procedures, and total knee replacements.

Thus, staying healthy is getting expensive in urban India. A five-year cohort study of 556 diabetic patients found that total household expenditures on health care—constituting 34% of median annual income—increased 113% during a five-year period, with the highest increase in percentage outlay occurring in the lowest socioeconomic group.

Another study found that 50% of patients hospitalized in 2004 faced hospital expenditures exceeding 10% of annual household spending. Reaching deeper into their pockets to receive medical care, India’s citizens often must sell their assets or borrow to meet costs—as was the case for 40% of Tamil Nadu’s inpatients in 2007.

Debriefing

When Dr Raman and I sit down later to debrief, I ask him if he thinks his patients will take the medications he prescribes, make the appointments he recommends or follow-up on his instructions. “Oh, they do,” he tells me matter-of-factly. “It is a different doctor-patient relationship. Patients here take these appointments very seriously. It is almost never the case that a patient will not schedule a follow-up appointment or fail to obtain the scans needed or ignore the prescriptions. They want to get better, of course, and they believe that will come from listening to the doctor.”

I think back to my small repertoire of patients encounters as a medical student in Michigan: the hour spent answering the questions of a pneumonia-ridden businessman who is concerned about taking a new antibiotic, explaining to an irate sickle-cell patient the rationale for capping her morphine dosage, reiterating to a frustrated patient that her work-up to date has not yet revealed a specific etiology to “fix.” As I will find throughout the month, it is a different world here. Dr Raman does very little explaining; the patients, in turn, question and challenge very little. They accept the added medications, the reassurance that “it will become all right,” the exhortation to “get an MRI scan and follow-up in a week,” almost as if it is a duty. The inherent trust they place in Dr Raman’s opinion is, perhaps, reflective of the prevailing cultural attitudes toward physicians. As a patient stated: “For the majority of us, a doctor is virtually God—one who is beyond questions or doubts and has solutions to all our ills.”

Reflections: The Future of Indian Health Care

The opulent luxury of private-sector hospitals, juxtaposed with creeping improvement in basic health indicators, hints at the dichotomy of health care in India. Even as efforts abound to quash pathogens and parasites—the vestiges of underdevelopment and poverty—India’s private health care industry flourishes, bringing with it the promise of profits. This twin agenda operates at polar opposites of socioeconomic class, two seemingly disparate foci running in parallel. Is it sustainable—and equitable? The Asian Development Bank’s South Asian Economic Report warns, “Although medical outsourcing will give impetus to economic growth in the region, it could also distort the availability of medical care away from South Asia’s poor as the health systems cater to clients from the developed world.”

Growing evidence supports the troubling emergence of a two-tier system, whereby quality health care caters to and becomes the de facto privilege of the upper class, and the average citizen depends on underfunded, understaffed public facilities. This, in turn, portends a spiral of suboptimal health for the nation’s poor and middle class, carrying somber ramifications for goals of public welfare and social equality.

The dramatic changes in India’s health environment and shift of the disease profile presage an economic and social transformation in health care delivery. On the one hand, the nation’s newfound riches promote certain types of health, effacing the disease-ridden India stereotypes of middle-school geography books and quaint Rudyard Kipling tales—where epidemics of cholera and polio consumed millions and curable infectious diseases terrorized the lives of city inhabitants. But even as strides are made in the realm of hygiene and hospital infrastructure, new health challenges emerge in the shifting face of disease, cost containment, and health care access. Such challenges carry relevance to health care in the developing world, as they represent the prototypical public health needs of a nation straddling the realities of persistent poverty and the heady success of breakneck growth.

Reflections: The Beginning of a Journey

I am waiting for takeoff. It is pitch black outside—approximately 1:30 am, Indian Standard Time—and my head is heavy with fatigue. The dry Lufthansa cabin air keeps forcing me to sneeze, thwarting half-hearted attempts at sleep. My mind also appears to be part of the plot...
to keep me awake, buzzing with a flurry of thoughts and impressions of a summer in India.

I revisit the trepidation that pervaded my first bumpy car ride to Dr Raman’s clinic. I had imagined—and feared—the rapidly urbanizing, technology-championing, café-laden “new” Chennai would serve as a rude shock, alien from the “Madras” of childhood visits. I had wondered if any trace of my heritage—the culture that sparked my passion for art, music, and dance—might remain in this revamped, modernizing pantheon of software outsourcing. And, with quavering hope and resolve, I had entered this city with the goal of serving in a medical capacity, of understanding the city’s unique health needs.

Chennai had changed. There were glitzy new stores, air-conditioned restaurants, new highways, the flood of bright matchbox Fords and Hondas. There existed a growing sense of empowerment: young professional women confidently rode to work on scooters and mopeds in the midst of rush-hour traffic; billboards heralded the grand opening of new technology parks; newly installed garbage cans on street corners exhorted in Tamil: “Don’t Litter: Keep Chennai Beautiful.” And, of course, there were momentous changes in health care. Multistorey hospitals towered over dilapidated clinics; clean public restroom facilities emerged as reliable fixtures in malls and restaurants. Complex surgeries no longer necessitated expensive trips abroad; instead, medical tourism now brought thousands of foreigners and a steady stream of profits to Chennai’s hospitals each year.

And yet, in Chennai much remains the same. The ancient temples I had visited on trips past are still as ancient as ever. The homemade patgava and cardamom milk from my favorite (non-air-conditioned) dairy store still tastes as divine as I remembered it, and unfortunately is still as sattening. Cows still lazily ruminate as they always have on pot-holed side roads, unperturbed as surrounding cars unleash a blaring cacophony of honks. The unique aroma of incense, spices, humidity, car exhaust, roasted peanuts, and coffee powder still hangs in the air—it’s simply mixed with more exhaust fumes.

Chennai’s health also sadly carries echoes of the past. Beggars still cry for food on street corners; slums still spill human filth and suffering. Public health initiatives have mitigated—but not eliminated—one epidemic communicable diseases. India still carries the world’s greatest burden of patients with tuberculosis, and must face the challenge of emerging multidrug-resistant strains. Polio and measles may no longer consume lives in Chennai, but HIV/AIDS and malaria persist as important health concerns; infectious diarrhea still kills an unacceptable number of children each year. The battle to provide fundamental public health needs is still not won, and it must not be ignored in favor of the haute trend of elite health care.

India’s paradox of constancy and change—epitomized by its health care—serves as Chennai’s major theme. As a student in Dr Raman’s clinic, I interacted with a truly diverse socioeconomic, cultural, and religious cross-section of Chennai society, many of whom were crippled by pain exacerbated by a sedentary lifestyle, excess weight, and poor dietary habits. Often, patients had no idea that they were overweight—or that lifestyle could potentially undermine their health. Several patients were unfamiliar with the concept of a “heart-healthy” diet, or unaware that they could modify their risk for diabetes and heart attacks with simple dietary and activity modifications. Here lies a crucial area for future medical service in Chennai: public health education, enabling its citizens to understand—and practice—the elements of a fundamentally long and healthy life.

The plane revs up its engines in preparation for the final rapid acceleration before takeoff. As we rise smoothly above the twinkling lights of Chennai, I peer out the window, straining for a final view of the city and its roads (which are, even at this hour, packed with cars), exhalting a wave of nostalgia as the city lights fade, covered by growing patches of clouds and mist. I press my face against the cool window, imagining I can still see a twinkling light or two.

As the last visible light disappears from view, I realize it is only a matter of time before I return. For the past month has introduced me to a challenge—a medical need that speaks to my interests in public health, service, and culture—that I am determined to revisit and tackle as a physician.

Even with all its chaos and inefficiency, Chennai somehow, miraculously, inexplicably, stubbornly, still works. It’s reassuring, for I know it will still be working when I fly back at some point in the future into the humid air surrounding Anna International Airport.

I wave goodbye one last time before pulling the window cover shut. “Paarkalam,” I whisper, to no-one in particular. It’s a promise: See you soon.
a Prakshinam: walking around the temple in a sign of respect—40 prakshinams, depending on the size of the temple, can equal several miles!

b High-funda: a slang term used to capture the idea of “high-tech,” “new-age,” or “chic”—as in: “That’s one high-funda Lexus IS Coupe you’re driving!”

Disclosure Statement
The author(s) have no conflicts of interest to disclose.

References
Exploring Health Care and Medical Tourism in a Modernizing Society: Journey in Chennai, India


29. Tamil Nadu and Kerala [monograph on the Internet]. Ontario, Canada: York University Department of Environmental Studies; 2003 Dec 15-17.


52. Mohan V, Shanthirani S, Deepa R, et al. Intra-urban differences in...


Dreams of Living Men

If there is one place on the face of earth where all the dreams of living men have found a home from the very earliest days when man began the dream of existence, it is India.

— Romain Rolland, 1866-1944, French writer and art historian, winner of the 1915 Nobel Prize for Literature
BOOK REVIEW

The Heart Speaks: A Cardiologist Reveals the Secret Language of Healing
by Mimi Guarneri, MD, FACC

Are doctors human? Not really, says Mimi Guarneri, founder and director of the Scripps Center for Integrative Medicine. In The Heart Speaks: A Cardiologist Reveals the Secret Language of Healing, Guarneri argues that the American medical system produces physicians who are more in touch with their MRI scanners than the emotional life of their patients. This dehumanization imperils the health of patient and clinicians alike.

Guarneri, an interventional cardiologist at Scripps Clinic, studies the human heart as both a biological and emotional organ. She illustrates how stress, anger, and grief increase risk of heart disease, while optimism, gratitude, and forgiveness decrease it. Ignoring the emotional context in which cardiac abnormalities occur, physicians frequently miss the underlying etiology of a patient’s disease.

Guarneri aims at the lay public who will find this text accessible and persuasive and clinicians who, like readers of this journal, may be more skeptical. She represents a tradition of what might be called “humanistic” medicine, found lately in the writings of physicians such as Jerome Groopman, MD, and Arthur Kleinman, MD. Groopman and Kleinman agree with Guarneri on the problems with contemporary biomedicine, but their solutions are different. For Groopman, the key is teaching physicians to be more sensitive listeners. For Kleinman, recognition of the role of political, economic, and cultural forces is fundamental to improving medical care. Guarneri’s solution is the inclusion of spirituality in medical practice.

A manifesto for “alternative” or “integrative” medicine, this book draws on exemplars from Guarneri’s practice: the healing power of prayer, cellular memory, angelic visions, and energy healing. These represent what Guarneri calls “the ancient healing virtues of the past.”1,2,3 Guarneri does not explain how “spiritual” elements link to physical and emotional health and, although her examples are persuasive, they often have little in common except their exclusion from conventional biomedicine.

Alternative treatments may be valuable when clinically proven to have beneficial results. But Guarneri’s examples are difficult to translate among patients, not to mention populations. She is an excellent advocate, but even she admits her evidence consists of “interesting anecdotes.”4

Guarneri cites Krucoff’s MANTRA study as evidence that praying for patients can contribute to their recovery,5 neglecting his follow-up study, which found that prayer had no significant effect.6 Similarly, she describes herself as a practitioner of energy healing, without reference to experimental findings on its effectiveness; she neglects the findings of Schwartz and Simon7 and Harriet Hall’s critique.4 She does not mention Rosa’s canonical debunking of the “therapeutic touch.”8 Finally, Guarneri argues in favor of cellular memory—the idea that living tissues have the capacity to memorize their owner’s characteristics—by claiming that “[t]welve to 15 percent of heart-transplant recipients report added characteristics following transplant of their new hearts.”9 With a personal communication as her only source to support this claim, she acknowledges that medication and surgery may be in part responsible, leaving the reader uncertain about the phenomenon’s underlying mechanisms.

The Heart Speaks is not designed to withstand evidence-based scrutiny; it is a spiritual memoir that has as much in common with Augustine as with Groopman. Although at times it seems that for Guarneri spirituality is just another tool, she recognizes that belief operates under a different set of rules from randomized clinical trials and does not always give you what you want.

Ultimately, Guarneri references serious problems with medical care: physician lack of time, patient lack of money, American lifestyles and work environments. These issues are as much political and economic as spiritual.

References

Strong at the Heart: How it Feels to Heal from Sexual Abuse
by Carolyn Lehman

A physician interested in comprehensive health care for patients may not be able to put down Carolyn Lehman’s book, Strong at the Heart: How it Feels to Heal from Sexual Abuse. Its stories and photographs of emerging strength in the face of betrayal are riveting, as they capture the courage of survivors of childhood sexual trauma.

For a physician, these nine oral histories offer a shortcut to better understanding victims of sexual abuse from all socioeconomic and ethnic backgrounds. This book also needs to reach the nurses, therapists, counselors, teachers, ministers, parents, and friends of young people struggling to cope with experiences they may barely remember.

Carolyn Lehman has a remarkable ability to let the voices of her interviewees speak for themselves, with a natural directness that makes you want to be part of their lives.

From Jonathan, we hear how an eight year old could be drawn to, then violated by, the priest who showed such love for his whole family. After confusion, anger, drugs, a suicide attempt, and therapy, Jonathan was eventually able to heal enough to become, at seventeen, a guest speaker at high schools, reaching out to other kids. He says, “Other teenagers can see that I’m a kid just like them … that’s when people realize that sexual abuse isn’t just a story in a book or a scene from a movie. It’s something that happens every single day to people like them.”

From Kelly, we hear a chilling story of abduction and rape. Because of her remarkable memory for details, her rapist was caught, and evidence from her case led him to be charged with the rape and murder of a girl, age 14 years, one year earlier. Kelly tells about testifying at the trial, which she says, “was totally nerve-racking. But there is something incredibly valuable about getting to tell your story in your own words in an officially sanctioned room where the person who hurt you has to listen to you and so does everybody else.” After everything, Kelly can say, “I like the person I am now, and who I am has been influenced by the rape. It forced me to be strong, to get through it all. If I were to wish that experience away, I might be wishing away the source of my strength.”

The story of Tino presents us with a twisted grandmother. Remarkably, after years of alcohol abuse, nightmares, flashbacks, and near suicide, Tino is able to say, “Odd as it may seem, I bless my grandmother today. I’m not talking about that ‘forgive and forget’ b-s … [but] now I think of her with compassion.”

In terms of forgiveness, perhaps the most remarkable story is Akaya’s. Her father was an alcoholic who abused her on and off from the age of two through high school. Achievement and “going to the stars,” a kind of intellectual dissociation, were her escapes. Years later she recovered her memories of the abuse, confronted her father, and faced depression, therapy, and the need to heal. Even so, when her father collapsed and was on the verge of dying, she decided to look after him. “I found him a very good place to live. I started visiting him … I gave him the dignity I’d want any older person to have at the end of life.”

To understand where the resources come from for Akaya to care for her father, for Tino to bless his grandmother, and for all these remarkable men and women not just to survive but to thrive, you need to read this book.

This book ends with a photo from The Clothesline Project at Smith College, where members of SAFE (Survivors and Allies for Education on Childhood Sexual Abuse and Incest) hang up hundreds of t-shirts with inscriptions from survivors. On one sleeveless tank top embroidered with bright suns, we read, “You did not destroy me—you cannot. I am forever strong and proud because I am rooted in truth.”

For her earlier children’s book, Promise Not to Tell, Lehman won the Christopher Award. This book is likely to draw further honors and touch more lives. It belongs in every physician’s waiting room. After all, where are these once-abused boys and girls, now adults, going to appear if not their physician’s office and examining room? Whose help will they seek if not their physician’s—even when they bring their secret disguised as a symptom?

Reference
Clinical Emergency Medicine Casebook
by Joel T Levis and Gus M Garmel

Review by David Sklar, MD

I like puzzles, and I like people, which is probably partly why I chose Emergency Medicine as my specialty and why I enjoyed the book Clinical Emergency Medicine Casebook. Emergency Medicine has evolved from a place in the hospital covered by part-time specialists from other fields and moonlighting residents to one of the most popular and sought-after residency programs in medicine. Patients arrive with a myriad of symptoms, day or night, seven days a week, and emergency physicians must sort through the problems and piece together a diagnosis in time to prevent permanent damage in evolving heart attacks or strokes, irreversible shock in certain infections, or life-threatening blood loss in trauma patients. The Clinical Emergency Medicine Casebook attempts to replicate the experience of caring for a real patient by providing presenting signs and symptoms, vital signs, physical examination findings, and pertinent initial laboratory electrocardiogram (EKG) or radiologic studies. After this, the reader is asked for a diagnosis and must turn the page of the book to find the answer.

The answer describes the diagnosis and an explanation of the clinical problem as well as further radiologic studies and reviews the literature about the disease and its treatment. Following this explanation are key teaching points that distill the discussion down to an essential four or five sentences with references for a student who might like to go into further depth.

The book contains 111 cases and each case is about three pages in length.

The fast-paced, case-based approach because it tracked with how I like to think about and to solve problems. Like many emergency physicians, I often have a short attention span and limited time, and I could cover the three pages per case in five to ten minutes, which never allowed me to get bored or to have my mind wander.

The book breaks down the cases into traditional core content areas, which is probably helpful for students or residents, but I found a bit too much of a clue if you truly wanted the case to be a diagnostic challenge. However, some of the cases were actually also management questions and the grouping may be helpful for students who wish to concentrate on treatment and management.

For future editions of this book, I might suggest more atypical presentations of commonly occurring emergencies, and even some atypical presentations of uncommon problems. Even experienced clinicians may not have extensive experience with atypical presentations, and failure to recognize them can lead to serious medical errors. This book mostly focuses on more typical presentations, which is helpful for beginning students and residents, but less challenging for the more experienced clinician. The discussions of the cases however always provide good, up-to-date and helpful information for physicians and students at all levels.

This book will be an excellent adjunct for medical students on an emergency medicine rotation, and a great review for residents and practicing clinicians. It will also be interesting to physicians in other specialties who would like to experience the analysis and treatment of acute presentations and management, which they may not see commonly in their practices except as consultants.

The radiographs, photographs, and EKGs are all of excellent quality, and add depth and detail to the cases. Both authors are teaching faculty at the Stanford/Kaiser Emergency Medicine Residency Program and work clinically at Kaiser Permanente Santa Clara Medical Center. Their cases have been previously presented to the residents and faculty at their program. Their love of teaching and their enthusiasm for using cases to illustrate important educational points permeates all of the cases in this charming book, and I am glad they decided to share these cases and their teaching approach with the broad emergency medicine student and clinician community.

David Sklar, MD, is Associate Dean of Graduate Medical Education and Professor of Emergency Medicine at the University of New Mexico School of Medicine in Albuquerque, NM. E-mail: dsklar@salud.unm.edu.

Health Care Reform

Readers of these two books will find them to be very informative and very timely during the current, contentious, national discussion on how to treat some major problems with the delivery of medical care in this country. Both books have been written by well-respected, experienced, national, health care leaders. Although both of these books are relatively easy to read, and are small-sized publications with about 150 pages, they will require thoughtful study to fully appreciate the extremely complex medical, social, political, and economic issues involved in trying to achieve President Obama’s goal, which both authors strongly support, of having an affordable, high-quality, health care delivery system that will provide an acceptable level of patient satisfaction to every individual in the very diversified population of this nation.

In the Preface of Howard Dean’s Prescription for Real Health Care Reform, Howard Dean, MD, describes his early experience of working on Wall Street, then graduating from Yale with a degree in political science, and later graduating from medical school at the University of Vermont with an MD degree. He writes that in 1980, while still practicing medicine, he was persuaded to go into politics. He was an elected member of the Vermont House of Representatives from 1982 to 1986. He was elected and served from 1987 to 1991 as the Lieutenant Governor; and from 1991 to 2003 as the Governor of the state of Vermont, where he instituted several reforms in health care programs. Dr Dean’s unusual broad experience is the basis for his recommendations on health care reform.

George Halvorson has been a leader in health care delivery systems for more than 30 years. He was President and Chief Executive Officer of HealthPartners, headquartered in Minneapolis, before he became the current President and Chief Executive Officer of the Kaiser Foundation Health Plan and Hospitals, headquartered in Oakland, CA. He has served on several national health care committees; he has received prestigious awards for his leadership and achievements in advancing health care quality; and he has served as an advisor to several foreign governments on matters of health policy and financing. On the basis of his long and successful career in managing health care delivery systems, his fourth book describes his experiences and his recommendations for health care reform.

Mr Halvorson, in his Introduction, summarizes his harsh assessment that “Health care in America is badly organized, highly inconsistent, internally dysfunctional, sometimes brilliant, almost always compassionate, close to [being] data free, amazingly unaccountable in key areas, too often wasteful, too often dangerous, and extremely expensive.” He writes that to address these problems, “We need clear goals, a strategy to achieve each goal, and the tools necessary to achieve each strategy.” He provides data indicating that improving care for a few key, common, chronic conditions, and avoiding “avoidable [care] mistakes” could save “half a trillion dollars … and would have reduced the total cost of care in America by roughly 25%.” He calls for a “national commission on health care costs and quality” and admits “It will take quite a bit of political courage … [and some] targeted re-engineering of both care delivery and care financing” to get this job done.

Dr Dean, in his Introduction, vividly describes some of the problems he encountered during his former medical practice when some of his patients were unable to obtain suitable health insurance because they had a chronic disease, or because it was determined that they had a pre-existing disease, or for some other reason. He writes, “More than 14 million Americans receive their health coverage on the individual market, but although these patients pay hefty premiums, only a fraction of the dollars are spent on providing actual care.” Much has been made of the 47 million Americans who don’t have medical insurance. But the healthcare reform debate should also focus on the fact that an estimated 25 million working-aged Americans have health insurance but still can’t afford to see a doctor. … But our real challenge is dealing with the extraordinary damage that the private health insurance system has done to countless Americans who thought they had health insurance, faithfully paying huge amounts of money into the system over many years, only to find that their insurance company refused to stand behind them when they needed it most. … The real issue is [whether]
we should continue with an extraordinarily inefficient system that today features a private insurance industry that takes large amounts of money out of the healthcare system for shareholders, administrators, and executives while denying people the basic coverage that they think they have paid for. Dr Dean asks, “Should we give Americans under the age of sixty-five the same choice we give Americans over sixty-five? Should we give all Americans a choice of opting out of the private health insurance system and benefiting from a public health insurance plan?” In the first half of his book, Dean presents his analysis of some of the problems with current health care in America. He then describes in some detail the British health care program, and briefly reviews health care programs in some other countries. In the final section of his book he offers his recommendations.

Both authors agree with President Obama that everyone should have health insurance; and that the best way to eliminate cost-shifting, gross disparities between insurance practices, inefficient medical care and unnecessary procedures is to have a system that includes everyone. Mr Halvorson explicates the cost issue: “President Obama has called for us to reduce premium costs needed to insure an average American family by $2500 per family [or by about 21%] … Universal coverage is a first step … covering everyone in the country can significantly reduce the price of insurance premiums … [since] part of the money now charged to people in their private coverage insurance premiums really goes to offset the cost of providing unpaid care to uninsured people … That shifted amount now adds roughly $1200 to the premium costs of each family contract … eliminating that cost shift … solves roughly half the target [set by Obama] … To achieve the other $1300 in savings needed for family coverage, we will need to spend less money on care delivery … Do we have to ration care or deny services or care in some way to achieve these savings? No. We need to reduce the costs of care by improving care.”

Dr Dean agrees that universal health insurance is essential, and advocates eliminating the “so-called free-loaders,” those who do not buy health insurance, “either because they can’t afford it or because they choose not to.” On the basis of his experience in Vermont, he writes, “I suggest that rather than mandating coverage, we supply health insurance essentially for free to everybody under thirty years of age, while also ensuring that everybody else can afford to purchase adequate insurance … People over thirty will buy health insurance if they can afford it.” He also writes that “… the most important aspect of health care reform: Individual choice must not be merely preserved; it has to be expanded. … The federal insurance pool will include not just a number of private health care plans that … the individual … can choose from, but also has a so-called public entity … like Medicare … a government-run health care plan … [or a Medicare-like public option plan] … Without this option, I believe that health care will not be reformed.”

Dr Dean emphasizes that, “Portability is essential for fairness in our system … If you leave your job for a better one or one in a different state, an insurer shouldn’t be able to deny you coverage because you are too old or suffer from a preexisting medical condition.”

He also proposed, connecting the president’s solution to global warming with revenues for healthcare paying for healthcare reform by … creating a new, sustainable, revenue stream by reducing the output of carbon dioxide … and imposing a tax on carbon emissions plus a 10% tax on gasoline.2

Both authors agree on the importance of the electronic patient record for improving the quality of medical care by making the patient’s medical record universally available to all physicians who are taking care of a patient at the time of providing the care. Mr Halvorson urges that physicians have electronic access to “all of the information about all of their patients, all of the time.”

Dr Dean writes from the physician’s viewpoint, “… improved care will be a consequence of a system that has reduced duplication by means of a reasonable and universal technology for electronic medical records, hopefully put together by people who know as much about doctors and health care providers as they do about technology and software.”

Both authors emphasize preventive care, and cite data that indicates too few Americans receive all the preventive services recommended. Both authors recommend better management of chronic diseases that generate increasing costs especially for care of the elderly. Dr Dean also advocates expanding health research from its current focus on … “whether a particular medicine or treatment is safe and works”; to making “A greater federal investment in clinical effectiveness and cost effectiveness that compares different treatments and technologies.” He also recommends having universal health care formularies (lists of expensive drugs) that physicians can prescribe. He advocates that all health plans use Medicare’s policy of not paying medical care providers for “never events” when a patient suffers from a knowable and catastrophic mistake.

Howard Dean writes his book primarily from the viewpoint of a medical practitioner. George Halvorson writes primarily from the viewpoint of a health care administrator. Their books complement each other, and reading both will provide to the reader a more comprehensive review of the very complex problems facing this nation in its attempt to develop an affordable and high-quality health care program that is accessible to every American.

References
CME Evaluation Program

Kaiser Permanente physicians may earn up to 4 AMA PRA Category 1 credits for reading and analyzing the four designated CME articles, by selecting the most appropriate answer to the questions below, and by successfully completing the evaluation form. Other clinicians for whom CME is acceptable in meeting educational requirements may report up to four hours of attendance. Please return (fax or mail to the address listed on the back of this form) to The Permanente Journal by April 30, 2010. Forms may also be completed and submitted online at: www.kp.org/permanentejournal. You must complete all sections to receive credit. (Completed forms will be accepted until April 2011. Acknowledgment will be mailed within two months after receipt of form.)

Section A.

<table>
<thead>
<tr>
<th>Article 1. (page 4)</th>
<th>Article 2. (page 11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients’ Perspectives on Nonadherence to Statin Therapy: A Focus-Group Study</td>
<td>Alcohol and Lung Airways Function</td>
</tr>
</tbody>
</table>

All of the following were identified as reasons for nonadherence by focus group participants except:
- a. concerns about liver and kidney damage
- b. difficulties obtaining a new prescription from physicians
- c. concerns about the depletion of coenzyme Q10
- d. uncertainty about their clinical need for statins

Which of the following was suggested by focus-group participants as a method to improve adherence:
- a. providing links to reliable Web sites with information on statins or high cholesterol
- b. receiving automated reminders from physicians or the health system about statin prescriptions
- c. starting with the lowest dose of the medication
- d. conducting more frequent laboratory testing to monitor for adverse effects

Which of the following statements is true about alcohol intake and lung airway function?
- a. persons reporting drinking two or fewer drinks per day had better airway function than abstainers
- b. persons reporting drinking three to five drinks per day had better airway function than abstainers
- c. persons reporting drinking six or more drinks per day had better airway function than abstainers
- d. a and b
- e. a, b, and c

Which of the following statements is false?
- a. heavy alcohol drinkers (six or more drinks per day), independent of a smoking history have more impaired lung airway function than light (two or fewer drinks per day) or moderate drinkers (three to five drinks per day)
- b. the FEV1/FVC ratio tends to decrease with age.
- c. patients who drink moderate amounts of alcohol and smoke have a reduced risk of developing abnormal airway function than those who smoke and do not drink alcohol
- d. there is no difference in the development of abnormal airway function in whites, African Americans, or Asians
- e. women who drink alcohol have a reduced risk of developing abnormal FEV1/FVC than abstainers

The Kaiser Permanente National Continuing Medical Education Program (KPNCMEP) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. The KPNCMEP designates this educational activity for 4 AMA PRA Category 1 credits. Each physician should claim only those hours of credit that s/he actually spent in the educational activity. All editors, reviewers, and authors have no conflicts of interest to disclose; where any possible conflict is indicated, it has been reviewed and found not to have any impact on the article content.
CME Evaluation Program

Section B. Referring to the CME articles and the stated objectives, please choose your level of agreement next to each statement as appropriate.

<table>
<thead>
<tr>
<th>Article 1</th>
<th>Article 2</th>
<th>Article 3</th>
<th>Article 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>The article covered the stated objectives.</td>
<td>strongly agree</td>
<td>strongly agree</td>
<td>strongly agree</td>
</tr>
<tr>
<td>I learned something new that was important.</td>
<td>strongly agree</td>
<td>strongly agree</td>
<td>strongly agree</td>
</tr>
<tr>
<td>I plan to use this information as appropriate.</td>
<td>strongly agree</td>
<td>strongly agree</td>
<td>strongly agree</td>
</tr>
<tr>
<td>I plan to seek more information on this topic.</td>
<td>strongly agree</td>
<td>strongly agree</td>
<td>strongly agree</td>
</tr>
<tr>
<td>I understood what the author was trying to say.</td>
<td>strongly agree</td>
<td>strongly agree</td>
<td>strongly agree</td>
</tr>
</tbody>
</table>

Objectives
1. To inculcate the use of evidence-based medicine as part of the science of medicine
2. To stress the art of medicine via enhanced patient-physician communication, improved care experience for patients, and more satisfying caregiving experience for physicians and staff through better teamwork
3. To review appropriate updates on the diagnosis and treatment of clinical conditions
4. To describe infrastructure and systems improvements that lead to improvements in outcomes and patient care experiences

Section C. What change(s) (if any) do you plan to make in your practice as a result of reading these articles?

Section D. (Please print)

Name ________________________________
Title ________________________________
NUID # ______________________________
E-mail ______________________________
Address ______________________________
Signature ____________________________
Date ________________________________

Mail or fax completed form to: The Permanente Journal
500 NE Multnomah Street
Suite 100
Portland, OR 97232
Phone: 503-813-2623
Fax: 503-813-2348

CME
The Permanente Journal/Spring 2010/Volume 14 No. 1