Complementary and Alternative Medicine

- National Institutes of Health "Oregon Center for Complementary and Alternative Medicine": Value to Permanente Medical Groups and to Kaiser Foundation Health Plan and Hospitals

- The Herbal Medicine Pharmacy Update

- Jimson Weed Poisoning—A Case Report

- The Macrobiotic Diet as Treatment for Cancer: Review of the Evidence

- Symposium on Complementary and Alternative Medicine: In the Era of Evidence-Based Medicine, What's a Physician to Do?
Mission: The Permanente Journal is written and published by the clinicians of the Permanente Medical Groups and KFHP to promote the delivery of superior health care through the principles and benefits of Permanente Medicine.

On the cover: “Teardrop Arch” by Ahmad Abdalla, MD, is a photograph of this beautiful arch tucked deep in Monument Valley, Utah, far from the eyes of the casual passerby. It required a long desert drive and a short hike for Dr Abdalla to arrive when the light was perfect for this mid-morning shot.

Dr Abdalla has been a Head and Neck Surgeon with SCPMG since 1978. He is a graduate of the New York Institute of Photography and has been designated a “Master Photographer.” More art by Dr Abdalla can be seen on pages 6, 38, and 77.

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The rapid development of reproductive technologies has given birth to formidable ethical questions. A case study of the biologic construction of a child is presented with commentary addressing the physician’s, the patients’, and the unborn’s positions as well as society’s.
National Institutes of Health “Oregon Center for Complementary and Alternative Medicine”: Value to Permanente Medical Groups and to Kaiser Foundation Health Plan and Hospitals

In 1999, the National Center for Complementary and Alternative Medicine (NCCAM), one of the institutes and centers that make up the National Institutes of Health (NIH), approved a proposal from the Kaiser Permanente Northwest (KPNW) Center for Health Research to be one of 12 national Complementary and Alternative Medicine (CAM) research centers. This center would primarily focus on craniofacial disorders. Because of a growing interest in and use of alternative therapies by consumers to meet their health care needs, evidence of safety and efficacy was necessary to ensure the public health. In 1994, the Office of Alternative Medicine (OAM), the first NIH research and funding arm for alternative therapies, created a taxonomy to define these therapeutic practices, created research centers, and funded research projects. When OAM was expanded into NCCAM the budget grew from 19.5 million to 50 million dollars, with a projected budget for 2003 of 113.2 million. Research centers grew in number and scope. From their inception, the centers were charged with not only conducting rigorous research, but also developing the capabilities and capacity of a center, such as infrastructure support, laboratories, biometric functionality, and a critical mass of researchers, which requires attention to development of CAM investigators.

When the KPNW Center for Health Research won one of the 12 center grants they established The Oregon Center for CAM (OCCAM). The center was of interest to NIH because of its location in a metropolitan area with four CAM colleges—Oregon College of Oriental Medicine, National College of Naturopathic Medicine, Western States Chiropractic College, and the Oregon School of Massage—in addition to its association with the Kaiser Permanente (KP) medical care delivery system, the KP Dental Care Program, and the Oregon Health Sciences University School of Dentistry. The Oregon Center for CAM compounded this value by creating an executive committee composed of research and clinical representatives from all seven entities. This group’s expertise would ensure importing the best scientific thinking and experience in these disciplines. This in turn would instruct the development of rigorous research in CAM approaches to prevention, treatment, and mechanisms of action in craniofacial disorders. Alex White, DDS, DrPH, as the principal investigator, brought experience as a research scientist directly from previous work at NIH. Cheryl Ritenbaugh, PhD, MPH, co-investigator and medical anthropologist, brought 20 years of clinical trials experience and multi-institutional collaborative research and training experience at the University of Arizona College of Medicine. As an associate medical director for Northwest Permanente, I was working with the KP Regional Benefits Committee (RBC) designing member benefits in the area of alternative therapies in response to consumer and employer demand for these types of health care products and services. Because of this work and my professional interest in innovative approaches to medical care, I agreed to be a co-investigator on the grant and to sit on the OCCAM Executive Committee as the NW Permanente Medical Group representative.

To coincide with this special issue on CAM, I present a perspective on the value to the medical group, to the RBC, and to the KP health care delivery system of having an association with a CAM research center. I would like to address the following areas: why all Permanente physicians and clinicians will benefit; physician and clinician research opportunities; development of CAM services; continuing medical education opportunities for CAM; patient benefit; benefit to medical practice; and bridging between health care researchers and clinical care delivery operations.

**Why All Permanente Physicians and Clinicians Will Benefit**

Regardless of the region of the country in which they practice, KP physicians and clinicians have always benefited from sharing practice information. In the last ten
years, this cooperation has been enhanced with the proliferation of interregional groups, national KP education and learning conferences, and the work of the Care Management Institute. It is heartening for all to know that one of only 12 CAM research centers in the country is within our program. In the next year, center researchers will begin to publish findings from their studies conducted here, which will become part of a KP evidence base to instruct clinical practice. Already CAM center researchers, physicians, and clinicians have been teaching others about their research experience and findings. Finally, grant opportunities are available for those from all regions interested in pursuing CAM research.

Research Opportunities
An essential research center activity is to develop the research interest and investigator ability of clinical practitioners. OCCAM, in addition to its three major CAM projects, developed a research fellowship program. Two KP clinicians were selected as research fellows: Charles projects, developed a research fellowship program. Two KP clinicians were selected as research fellows: Charles

Research Opportunities
An essential research center activity is to develop the research interest and investigator ability of clinical practitioners. OCCAM, in addition to its three major CAM projects, developed a research fellowship program. Two KP clinicians were selected as research fellows: Charles Elder, MD, a NWP internist, and Jeff Weih, PA, LAc, an affiliated clinician in Physiatry. Dr. Elder studied meditation and Ayurvedic Medicine (an ancient Hindu medical system) in “Mind Body Techniques for Temporomandibular Disorder (TMD),” and Mr. Weih studied acupuncture in “Measurement of Nerve Activity and Blood Flow During Acupuncture Treatment.” Other KP clinicians who have worked on, or are currently working on, research projects supported by OCCAM include: Mark Rarick, MD, oncologist, studied an ancient Japanese acupuncture system in “Jin Shin Jyutsu for Mucositis of Chemotherapy”; Joe Leben, DDS, Director of the KP TMD Clinic, a co-investigator in the Phase II TMD trials; Susan Kiley, MSW, a member of the Vohs Award-winning KPNW Multidisciplinary Chronic Pain Clinic, for “Evaluation of Healing Touch for Headache Patients in the KPNW Pain Clinic”; and myself for “Assessing Communication and Relations Skills of Traditional Chinese Medicine Practitioners with Patients.” This communication study specifically focuses on using the Art of Medicine patient evaluation survey for acupuncturists working in the KP CAM network providing services to our members by referral and self-referral.

Having the assistance and advice of research experts so close at hand is extremely valuable for supporting physicians who are new at clinical research and at writing grant proposals. This assistance is necessary to ensure that their work formulating critical clinical questions and study design goes forward.

Development of CAM Services
Having an associated research center can be highly beneficial for people designing and developing clinical services. One new program is an example. Several years ago, John Scott, MD, a Colorado Permanente physician, developed the Cooperative Health Care Clinic concept, in which several patients with similar medical conditions gathered to have a group visit with their doctor and a multidisciplinary team. In the NW, Dr. Elder adapted this model to meet patients’ needs for information and guidance in the area of CAM. In part because Dr. Elder had developed credibility as a serious researcher of CAM through his fellowship with OCCAM, and because of demand for services by patients and physician colleagues alike, his pilot group clinic was recently expanded to better serve the region. Patient satisfaction with the clinic and with the supplemental information and treatment he offered demonstrated their need for alternatives to traditional medical care when there wasn’t a conventional alternative.

When an innovative clinical physician has experimental data, based on rigorous research design and methodology, and has presented that data at a peer-reviewed national conference, that physician has a credible place to start when discussing new alternatives with physician peers. It is no longer opinion or personal anecdote. This increases the legitimacy of the innovative effort and infuses the innovator with energy to work the research question harder and longer. Concomitantly, the visibility and credibility of the CAM research center is enhanced.

As a result of my personal involvement on the OCCAM Executive Committee, and as an OCCAM researcher, I improved my understanding of both CAM practitioners and their therapies, which in turn informed my evaluation of and decisions about CAM benefits design and implementation for KP members. Specifically, the improved working relationship built with Complementary Health Plans (CHP)—KPNW’s contracted CAM network—through collaboration on study design, has improved my understanding of the quality of care that CHP and its practitioners are committed to deliver to our members. The KP Art of
Medicine survey tool, used for several years across the Permanente Medical Groups, is now being used by acupuncturists at CHP. What will be the effect of this feedback for these practitioners? Our planned follow-up project will study its use in evaluation of patient and practitioner satisfaction for chiropractors, naturopaths, and massage therapists. To supplement this anticipated perspective, having an opportunity to bring the voice of KPNW physicians and KPNW patients to the executive committee’s discussion of CAM has been another benefit for the medical group.

As an initial response to consumer interest and demand for CAM, NWP formed an Alternative Medicine Journal Club (AMJC) to create a network of interested physicians and health care practitioners at KP, and to provide a discussion forum for both clinical and patient questions, and to review recent CAM literature. With the establishment of OCCAM the journal club was infused with CAM practitioners from the colleges and investigators in the study projects. Instead of a forum of uninformed clinicians seeking understanding from each other and from interpretation of the CAM literature, a new level of interaction and understanding occurred when this diverse group of people sat together with a common interest and talked about what they knew, didn’t know, and wondered about.

The Oregon College of Oriental Medicine (OCOM) is developing a doctoral program (one of the first in the country). Because of OCOM discussions with NWP physicians in the multidisciplinary chronic pain clinic, the College plans to have clinical preceptor rotations on medical services to enhance the integration of western medicine into the practice of traditional Chinese medicine. This association will enhance the education of NWP physicians, the integration of acupuncture into the pain clinic, and the use of NIH evidence-based indications for acupuncture in medical practice.

**Patient Benefit**

Ultimately, the most important benefit of OCCAM clinical studies is for KP patients. Patients who seek treatment for chronic pain often require a multidisciplinary approach utilizing multiple interventions simultaneously or in parallel. These patients become frustrated when conventional medical treatments fail to bring desired relief, and there are no other options for them. Across the country, they seek alternative therapies. TMD patients are one such subgroup. They are commonly referred to the TMD Clinic, directed by Dr Joe Leben. Here they may enter one of two OCCAM Phase II trials, and then be randomized to either usual care or...
Benefit to Clinical Practice

Physicians have expressed that they too look for alternatives and supplements to conventional western medical treatment for their patients, especially for chronic conditions, some of which are difficult to treat, such as fibromyalgia, headaches, irritable bowel syndrome, low back pain, dysmenorrhea, and chronic fatigue syndrome. Physicians can now refer these patients—or those seeking information, exercise, lifestyle changes, or herbal supplements—to Dr Elder’s CAM group clinic. The collaborative work between CAM practitioners and physicians can be viewed as foundational preparation for future creation of an integrated medicine clinic. This clinic will likely grow out of our multidisciplinary pain clinic. Several other physicians and clinicians with an interest in CAM are encouraged by having a CAM research center in our system. In conjunction with this, my participation in the research center has aided my development of other physician leaders in innovative clinical areas. Having a center developing investigational projects allows examination, comparison, and reevaluation of traditional medical care. This invigorates clinical practice.

Bridging Research and Clinical Practice

Researchers at the KPNW Center for Health Research, who have historically focused on population-based health care studies, have for several years looked for opportunities to work with physicians in clinical research addressing health care issues in the care delivery system. A new group of KPNW physician and research leaders meet together in a group called the “Bridge Advisory Committee” to learn from each other’s perspective and to encourage and support collaboration between research and clinical practice. Their focus is to conduct rigorous research on the most important clinical issues facing primary and specialty care physicians. OCCAM has exemplified how traditional medical researchers and practitioners from four alternative health disciplines can design and carry out research in the clinical setting, benefiting both groups and patients. The Bridge Group’s work is an expression of that model.

Because medical anthropologist, Nancy Vuckovic, PhD, collaborated with me as co-investigator on my OCCAM developmental study evaluating communication between acupuncturists and patients, she was introduced to, and then became a member of, the KP Interregional Clinician-Patient Communication Leadership Group. This bridging activity brought Dr Vuckovic’s professional research and anthropologic perspective to this clinical group, and she found value in participating in and learning from the clinical application of our communications research.

Conclusion

Having a CAM research center associated with a Permanente Medical Group and the Kaiser Foundation Health Plan and Hospitals has positively impacted several areas: research opportunities, development of CAM services, continuing medical education opportunities for CAM, clinical practice, patient care, and bridging research and clinical practice. Rigorous research, especially multidisciplinary, multihlth system collaboration has created the foundation for a high-quality evidence base for CAM in clinical practice. This continues the integration of conventional medicine and the best of complementary and alternative medicine for the benefit of patients. Implementing research findings improves the delivery of health care to meet patients needs, and to produce patient, practitioner, and physician satisfaction and improved health.

References:
soul of the healer

Impressed by a photograph in a magazine three years earlier, Dr Abdalla's imagination materialized into reality when, on a cold fall morning, he found himself standing in the middle of this beautiful West Virginia setting. Images that had been formulated in his mind over the years had finally been captured on film.

More of Dr Abdalla's work can be seen on pages 38 and 77.
Dr Janisse,

Having published an article in your very first edition of *The Permanente Journal*, I have watched it grow and mature into a fabulous journal. The content of your Summer 2002 issue was simply stunning. Great clinical content, human interest, art, quotations, and book reviews. This is absolutely world-class, and it fills me with pride to be part of a group that can produce this work. Please, if you have a spare minute, forward my compliments to all who work on this wonderful journal.

Thanks so much,
John Davenport, MD, JD
Physician Director, Primary Care Service Line
Chief, Department of Family Medicine,
Orange County Market Service Area, SCPMG

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**The Permanente Journal,**

I just read your article on physician retention. It is terrific! I have been a health care recruiter for 25 years. The article is one of the best I’ve seen.

Sue Cejka
Senior Client Partner
Healthcare Services

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**The Permanente Journal,**

As I was perusing the latest issue of the *Journal*, I looked at the photos of the authors and noted a wide range of ages, including one retired physician. It reminded me of Hawaii Permanente Medical Group (HPMG) and the range of ages of its physicians. I joined HPMG in 1968, when the group was nine years old, and worked with many of the original members. I learned just how difficult it was to start the group in a very hostile environment. Years later, after I had retired, I met with the Executive Committee of the group and learned that the present physicians had no idea of the history of HPMG—they had never heard of Phil Chu, who was the first president of the group and who held it together during the first troubled years—and just assumed that history began with their arrival! We then began to interview the early pioneers and put this all together in a 37-minute history of the group—not the Health Plan but only of the group. We had about 4 1/2 hours of tape to edit and now have a permanent record of the first five years of HPMG. The video was completed by a professional video production company about ten months ago and is (I hope) on file in the HPMG president’s office and (again, I hope) is being used in orientation of physicians who are new to HPMG.

The point is: How many young physicians of the other Permanente groups have any idea of the early history of their group? It is a shame if they don’t.

Thank you,
Arg Bacon, MD
Honolulu, HI

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**—Reply**

Thank you for your letter. Speaking for the Northwest, I want to tell you about a history project to accomplish just what you suggest Permanente physicians should do about their history. Six months ago, the NWP Emeritus Physician Group undertook writing a book about the history of the NW medical group, led by emeritus physicians Ian MacMillan and Harvey Klevitt. This July several of us toured the original Permanente Foundation Hospital built by Dr Ernie Sayward, the first NW Regional Medical Director, and Henry Kaiser in Vancouver, Washington, near the shipyards. The emeritus group will capture from the earliest NWP history up through the eighties for all current and future physicians to learn from.

Editor
Views and Use of Complementary and Alternative Medicine by Mid-Atlantic Permanente Medical Group Health Care Providers

Abstract

Context: Knowledge of Kaiser Permanente (KP) health care provider views about and use of many forms of complementary and alternative medicine (CAM) therapy may help KP develop appropriate services for patients and continuing medical education (CME) courses for providers.

Objective: To assess provider views and use of CAM therapy in their KP practice.

Design: Retrospective survey.

Main Outcomes Measure: Responses to one questionnaire administered to Mid-Atlantic providers in 2000.

Results: Of those surveyed, 26% responded (N = 141). In the 12 months before the survey, 48% of respondents used some form of CAM to treat patients. Respondents expressed strong interest in KP providing (or increasing) CAM services to patients, mainly for acupuncture, acupressure, and biofeedback. Respondents also expressed greatest interest in CME courses about these three types of CAM.

Conclusions: Providers appear interested in using and learning more about CAM therapy, particularly those forms having the strongest scientific evidence to support them.

Introduction

The increased use of complementary and alternative medicine (CAM) for medical problems\(^1\) means that clinicians may need a better understanding of CAM therapy. The knowledge base of practicing health care providers can be assumed to vary because the field of alternative medicine is so broad, new, and ever-changing and because so many clinicians are referring patients to alternative practitioners.\(^2\) Alternative medicine patient services and continuing medical education (CME) programs for providers need to be tailored to that varied knowledge base.

We did a pilot study to assess our region’s providers’ opinions about and use of alternative medicine. This study was funded by Kaiser Foundation Health Plan and approved by both the local Mid-Atlantic Permanente Medical Group (MAPMG) and national Kaiser Permanente (KP) Institutional Review Boards. The pilot study used an abbreviated form of a survey developed by Drs Nancy Gordon and Diane Sobel at KP Northern California.\(^3\)

Defining unconventional therapy, also known as CAM therapy, as that neither widely taught in US medical schools nor generally available in US hospitals was first popularized in a landmark study by Eisenberg at Harvard.\(^1\) His 1993 *New England Journal of Medicine* article showed that, in 1990, Americans made more visits to providers of CAM than to providers of traditional medicine and spent about $13.7 billion (out of pocket) on CAM therapy compared with $12.8 billion (out of pocket) for all hospitalization that year. Although some researchers define CAM therapy more narrowly, many use the broad definition which Eisenberg used and which we too used for this study.

CAM is generally used for chronic medical conditions such as cancer, arthritis, and HIV/AIDS, as well as for many types of chronic pain, including musculoskeletal and headache.\(^4\) Patients with these conditions tend to use medical facilities frequently, thus increasing total utilization of medical services.

Providers’ willingness to acknowledge that patients are seeking CAM is often based on their own professional and personal experience with CAM.\(^5\) Gordon et al reported that clinicians are unaware that patients are using CAM, because they do not ask patients about it. Patients report hesitancy to disclose use of CAM to their clinician because they feel the clinician will be critical of their nonmainstream choices.\(^3\)

When alternative modes of care are neutral\(^6\) or potentially beneficial, broadening the scope of that...
care benefits the patient and the clinician. However, some alternative forms of therapy can harm patients; therefore clinicians need to know when patients are seeking alternative care.

**Survey Methods**

The questionnaire developed by Drs Gordon and Sobel was adapted and shortened for this study. The questions were in Likert format, each offering a range of one to three or one to five answer choices (e.g., “not at all,” “somewhat,” or “great deal”). Several questions had space for comments.

The survey was sent out to all MAPMG primary care and specialty care physicians, nurse practitioners, and physician assistants whose patients might use CAM (e.g., obstetrics/gynecology, orthopedics, or neurology). As an incentive, 20 bookstore gift certificates each worth $50 were awarded from a random drawing of completed and returned questionnaires. Twenty-six percent of the surveys (N = 141) were returned within four weeks after an interoffice mailing; operational issues prohibited a second mailing to increase the return rate. Survey results were tabulated.

**Survey Questions**

**Use of alternative medicine**

Providers were asked if in the preceding 12 months they had used, had considered using, or had recommended use of any of 12 different modes of CAM therapy for prevention or treatment of any health problem.

**Interest in alternative medicine**

Providers were asked about their general level of interest in alternative medicine.

**Motivation to use alternative medicine**

Providers were asked about what motivated them to use CAM therapy. Providers often rely on personal and professional experience combined with updated scientific information to establish their practice styles. The majority of medical school curricula do not include substantial information about CAM, so it is unclear where providers get their motivation and interest to use CAM.

**Concerns about alternative medicine**

The basis of provider concerns about using each of seven individual types of CAM therapy was asked, and answer choices were the following: “not effective,” “harmful,” “not covered (by insurance),” “malpractice,” or “unknown.”

**Future opportunities for offering CAM at KP**

Providers were asked whether they felt that KP should increase CAM services, either through internal or external offerings. This question sought to reveal if providers were receptive to additional CAM services. A follow-up question asked providers which forms of therapy they would like to see introduced or increased at KP.

**Interest in attending CME courses in alternative medicine**

Providers were asked what CAM courses they would like to attend for CME credit. This information would help KP target and design CME courses that busy providers would find time to attend.

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**Table 1. Providers’ use of CAM therapy in practice during preceding 12 months**

<table>
<thead>
<tr>
<th>Mode of CAM therapy</th>
<th>Used</th>
<th>Considered using</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiropractic</td>
<td>30</td>
<td>23</td>
<td>32</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>15</td>
<td>20</td>
<td>31</td>
</tr>
<tr>
<td>Biofeedback</td>
<td>3</td>
<td>26</td>
<td>29</td>
</tr>
<tr>
<td>Massage therapy *</td>
<td>8</td>
<td>14</td>
<td>40</td>
</tr>
<tr>
<td>Meditation</td>
<td>16</td>
<td>14</td>
<td>51</td>
</tr>
<tr>
<td>Hypnosis *</td>
<td>3</td>
<td>24</td>
<td>11</td>
</tr>
<tr>
<td>Counseling</td>
<td>30</td>
<td>6</td>
<td>66</td>
</tr>
<tr>
<td>Diet</td>
<td>36</td>
<td>4</td>
<td>56</td>
</tr>
<tr>
<td>Herbal *</td>
<td>20</td>
<td>13</td>
<td>34</td>
</tr>
<tr>
<td>Yoga *</td>
<td>6</td>
<td>12</td>
<td>15</td>
</tr>
<tr>
<td>Prayer *</td>
<td>8</td>
<td>14</td>
<td>31</td>
</tr>
<tr>
<td>Homeopathy *</td>
<td>6</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

*Although these therapies were neither offered nor covered by KP, providers reported having used them according to their own definition of “used.”

**Results**

Of those providers responding, 48% had used or had recommended use of some form of CAM therapy in their practice during the preceding 12 months. The most common modes of therapy used were chiropractic, counseling, diet, and herbal. The most frequently recommended modes of therapy were counseling, diet, meditation, and massage therapy. When asked which modes they had considered using but did not actually use or recommend to their patients, providers most frequently listed biofeedback, hypnosis, chiropractic, and acupuncture.

At the time of the survey, the KP system offered chiropractic and acupuncture services on a limited basis. Biofeedback, although part of the base benefit, is used by fewer than .01% of members. Counseling was offered as part of the standard mental health coverage, and diet recommendations were offered by a KP nutrition department. Meditation training was part of a...
number of programs and classes available at KP, and the fee (although not directly covered) was about equal to an office visit copayment. Massage therapy, hypnosis, herbs, yoga, prayer, and homeopathy were not offered in the KP system; nor could providers directly refer a patient for therapy outside the system. However, some providers reported having used these modes with patients, perhaps according to their own definition of “used.”

Eighteen percent of respondents stated that they were extremely interested in alternative therapy, and 64% stated that they were moderately or quite a bit interested. Only two respondents stated that they were not interested at all.

Most of the providers who used CAM therapy did so because they doubted that patients were being adequately treated with traditional medicine (Table 2). The next strongest motivator was the belief that health problems are more effectively treated by using CAM therapy and traditional medicine together. The belief that CAM therapy had fewer adverse effects than traditional therapy was a common motivator. Motivation to use or to consider using CAM therapy also came from the lay and professional media and from KP and national professional journals.

A provider’s own experience was not the motivator for using CAM therapy for 59% of the respondents. The driving forces may instead be a combination of belief in the effectiveness of CAM and knowledge about CAM gained from medical journals, coupled with desire to keep KP competitive.

Table 3 shows that providers’ general concerns about using CAM therapy in practice stem from lack of knowledge about CAM therapy, belief that CAM therapy is not effective or can do harm, and lack of insurance coverage for alternative therapy. Fear of malpractice lawsuits does not appear to be a major concern of providers.

Providers’ concerns about lack of information focused mainly on chiropractic, acupuncture, biofeedback, and herbal therapy. Lack of insurance benefits was the driving concern about using massage therapy and meditation. Concerns about using diet as CAM therapy focused equally on lack of knowledge about this use of diet and on its perceived ineffectiveness.

Most providers (85%) responded that at least one or more forms of CAM therapy should be increased or incorporated into the organization (Table 4). About 60% of providers believed that use of chiropractic, acupuncture, biofeedback, herbs, meditation, or diet and supplement therapy should be increased or incorporated into the KP system.

Interest was strongest for CME courses about acupuncture, acupressure, or herbal therapy. Providers were least interested in massage, yoga, and homeopathy CME courses.

**Discussion**

The study had a number of limitations, but most important was the low return rate. Because of the small sample size, we do not know how valid it is to compare our results with those of similar studies. A logical expectation that the providers who were most interested in and amenable to using CAM therapy would take the time to return the questionnaire was supported by the fact that only a few respondents were clearly negative toward CAM therapy. Ardently opposed re-

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**Table 2. Providers’ motivations for using CAM**

<table>
<thead>
<tr>
<th>Motivator</th>
<th>Not at all</th>
<th>Somewhat</th>
<th>Great Deal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Own experience</td>
<td>79</td>
<td>34</td>
<td>20</td>
</tr>
<tr>
<td>Experience of others</td>
<td>46</td>
<td>62</td>
<td>26</td>
</tr>
<tr>
<td>Patient not adequately treated</td>
<td>11</td>
<td>65</td>
<td>56</td>
</tr>
<tr>
<td>Belief of effectiveness</td>
<td>30</td>
<td>75</td>
<td>39</td>
</tr>
<tr>
<td>Fewer side effects</td>
<td>41</td>
<td>70</td>
<td>21</td>
</tr>
<tr>
<td>Media influence</td>
<td>50</td>
<td>70</td>
<td>11</td>
</tr>
<tr>
<td>Medical journal articles</td>
<td>34</td>
<td>88</td>
<td>11</td>
</tr>
<tr>
<td>Keep KP competitive</td>
<td>30</td>
<td>69</td>
<td>33</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

**Table 3. Providers’ concerns about using CAM**

<table>
<thead>
<tr>
<th>Mode of CAM therapy</th>
<th>Unknown</th>
<th>Not effective</th>
<th>Harmful</th>
<th>Not covered by insurance</th>
<th>Malpractice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiropractic</td>
<td>29</td>
<td>23</td>
<td>25</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>33</td>
<td>10</td>
<td>1</td>
<td>22</td>
<td>2</td>
</tr>
<tr>
<td>Biofeedback</td>
<td>28</td>
<td>6</td>
<td>0</td>
<td>23</td>
<td>1</td>
</tr>
<tr>
<td>Massage therapy</td>
<td>23</td>
<td>16</td>
<td>1</td>
<td>27</td>
<td>1</td>
</tr>
<tr>
<td>Meditation</td>
<td>15</td>
<td>5</td>
<td>0</td>
<td>24</td>
<td>1</td>
</tr>
<tr>
<td>Diet and supplements</td>
<td>18</td>
<td>18</td>
<td>15</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Herbals</td>
<td>30</td>
<td>23</td>
<td>25</td>
<td>8</td>
<td>6</td>
</tr>
</tbody>
</table>
spondents used the comment space on the survey to express their opinions.

Lack of analysis by provider specialty is another study limitation. Such analysis could have enabled us to design separate CME sessions for each provider’s specialty. The definition of CAM therapy varies, as previously mentioned. Some providers clearly would not consider biofeedback, counseling, or meditation as alternative therapy. In this study, no definition was supplied for “diet.” For some providers, diet means nothing more exotic than the healthy heart diet—clearly not an alternative therapy—for others, diet may mean macrobiotics, which some providers feel has a “fringe” quality.

For some providers, their lack of basic CAM therapy knowledge may have affected their viewpoint. For example, if they did not know what homeopathy is, they probably could not express a view about its effects.

On the basis of comments written by the respondents, we sensed a “mainstreaming” of CAM therapy. In general, when a new paradigm is introduced into medicine, physicians are greatly reluctant to accept the idea without substantial proof of its efficacy. Fifteen years ago, for example, using antibiotics for ulcers would be considered voodoo medicine, yet is standard care today. And for some providers in our survey, acupuncture or meditation were hardly considered alternative at all.

What constitutes efficacy in evidence-based medicine is itself under close scrutiny. For example, the belief that hormone replacement therapy for postmenopausal women prevents some forms of cardiovascular disease was medical dogma until recently. From our study, having scientific evidence about the efficacy of CAM instead of direct experience (personal or professional), appears to allow providers to feel some level of comfort in recommending CAM therapy to patients.

On the basis of a pilot study done (as part of a marketing survey) for the KP Northwest Region’s member population, we believe that patient use of, and views about CAM in the Mid-Atlantic States Region are similar among the Northwest region members. Because of the similar demographics of CAM users in the two regions, patient demand for CAM information and referrals is probably similar, and will probably drive providers’ interest in offering and learning about CAM. In our study, providers’ interest was strongest for CME courses about acupuncture, acupressure, or herbal therapy, probably because patients are using and asking questions about these forms of CAM therapy most often. Tailoring future CAM patient services and provider CME courses may in part be based on patient demands instead of strictly on provider interest. Matching patient and provider interests may be important for future implementation of new services.

CME sessions have been targeted to match providers’ interests (acupuncture, biofeedback, chiropractic,

<p>| Table 4. Providers’ opinions about increasing or incorporating CAM into KP organization |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>No</th>
<th>Probably not</th>
<th>Not sure</th>
<th>Probably yes</th>
<th>Definitely yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Should KP offer alternative medicine therapy?</td>
<td>5</td>
<td>6</td>
<td>15</td>
<td>58</td>
<td>57</td>
</tr>
<tr>
<td>Should the following CAM therapy be increased or instituted at KP?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chiropractic</td>
<td>10</td>
<td>8</td>
<td>23</td>
<td>37</td>
<td>41</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>4</td>
<td>3</td>
<td>26</td>
<td>48</td>
<td>40</td>
</tr>
<tr>
<td>Biofeedback</td>
<td>1</td>
<td>5</td>
<td>28</td>
<td>43</td>
<td>44</td>
</tr>
<tr>
<td>Herbs</td>
<td>12</td>
<td>13</td>
<td>30</td>
<td>33</td>
<td>32</td>
</tr>
<tr>
<td>Meditation</td>
<td>6</td>
<td>6</td>
<td>24</td>
<td>39</td>
<td>28</td>
</tr>
<tr>
<td>Diet and supplements</td>
<td>8</td>
<td>13</td>
<td>22</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>8</td>
</tr>
</tbody>
</table>

<p>| Table 5. Likelihood of providers to attend CME course about modes of CAM therapy |
|---------------------------------|-----------------|</p>
<table>
<thead>
<tr>
<th>CME subject</th>
<th>Likely to attend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiropractic</td>
<td>55</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>81</td>
</tr>
<tr>
<td>Acupressure</td>
<td>74</td>
</tr>
<tr>
<td>Biofeedback</td>
<td>68</td>
</tr>
<tr>
<td>Meditation</td>
<td>51</td>
</tr>
<tr>
<td>Massage therapy</td>
<td>48</td>
</tr>
<tr>
<td>Diet and supplements</td>
<td>62</td>
</tr>
<tr>
<td>Herbs</td>
<td>71</td>
</tr>
<tr>
<td>Homeopathy</td>
<td>49</td>
</tr>
<tr>
<td>Yoga</td>
<td>46</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
</tr>
</tbody>
</table>

In general, when a new paradigm is introduced into medicine, physicians are greatly reluctant to accept the idea without substantial proof of its efficacy.
and herbal) at KP’s local and regional centers.

Addressing which therapy providers believed would be most suitable for KP would help marketing and program development. In other managed care organizations, the driver for new services has been marketing. The services most likely to be expanded include acupuncture, biofeedback, chiropractic, diet and supplements, herbal, and meditation.

This study, although limited by its low return rate (and other problems), confirms that providers in the MAPMG are using or recommending the use of CAM therapy, most commonly acupuncture, biofeedback, chiropractic, counseling, massage therapy, and meditation. The study also suggests that CAM therapy modes with the strongest scientific evidence of safety and efficacy stand the greatest chance of acceptance by providers and, thus, increase in delivery.

Acknowledgements

Bob Dill, MEd, LPC, and Nancy Gordon, PhD, ScD, assisted with application of the project.

The Mid-Atlantic Permanente Medical Group funded the project.

References

Abstracts of Articles Authored or Coauthored by Permanente Clinicians

From Colorado: Treatment decisions about lumbar herniated disk in a shared decision-making program

BACKGROUND: An explicit process of collaborative (shared) decision making involving the patient and physician has been recommended for discretionary surgical procedures in which small-area analysis demonstrates high variation not attributable to differences in the patient population in the area. One such example is laminectomy for lumbar herniated disk (HD). An observational study was undertaken to evaluate the impact of an HD videodisk program on patient satisfaction, decision making, and treatment preferences.

METHODS: Enrollment occurred in the outpatient offices of surgeons treating Kaiser Permanente (Colorado Region) patients with HD who had indications for surgery. Enrollment took place from May 1993 to December 1995, and follow-up surveys of patients were completed by January 1997.

RESULTS: A 6.0% decrease in the undecided group and a 1.3% decrease in the group preferring nonsurgical treatment drove a shift of patients toward laminectomy, from 26.7% to 35.8% (Wilcoxon signed rank test = 349.5, p = .017). Postviewing preference (74.0%) was a better aggregate predictor of the ultimate treatment than previewing preference (70.0%) for laminectomy.

DISCUSSION: Viewing the videodisk increased the preference for laminectomy. However, limitations in the data prevented us from determining whether this change in preference was actually reflected in patients’ ultimate decisions. The fact that the strongest predictor of choosing surgery was the patient’s valuation of his or her condition supports shared decision making, with its emphasis on patient’s values. Participation in other videodisk programs has been low; perhaps physicians should ask patients to view these videodisks before their visits.

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From Northern California: Quality assurance and risk management in online medical discussion groups

There are thousands of sites on the Internet and World Wide Web where health care professionals and lay people interact to share medical information and health concerns. The majority of these sites do not have procedures in place to assess the quality of the information supplied by the providers or lay people, nor do they have any formal risk management policies to respond to posted material that may reveal a potential risk situation. This paper describes the quality assurance and risk management procedures that have been developed for KP Online—the Web site for members of the Kaiser Foundation Health Plan, Inc—and shares some preliminary findings based on these procedures.

From Southern California: A preliminary psychometric analysis of a computer-assisted administration of the Telephone Interview of Cognitive Status-modified
Buckwalter JG, Crooks VC, Petitti DB. J Clin Exp Neuropsychol 2002 Apr;24(2):168-75

Most screening tests of cognitive functioning require face-to-face administration by trained examiners. This limits their utility in epidemiology and in primary care settings. Further, existing screening tests have not been developed using established psychometric principles. We adapted the Telephone Interview of Cognitive Status-modified (TICSm) for administration as a computer-assisted telephone interview (CATI). We screened 3681 elderly women with the CATI version of the TICSm, using lay staff as part of a longitudinal study. A preliminary analysis of the psychometric properties of the TICSm indicated good internal consistency. Test-retest reliability is needed to confirm reliability. Further work remains to adequately judge the validity of the TICSm including comparisons with well-standardized tests and assessment of its predictive properties in identifying dementia. However, the CATI version of the TICSm appears to have potential as a cost-effective means of testing cognitive performance.

CLINICAL IMPLICATIONS: The evaluation of cognitive performance is increasingly recognized as a crucial part of effective diagnosis and treatment planning. Given the likelihood that cognitive testing will expand in medical practice, cost effective, yet psychometrically sound, means of assessing cognitive performance are needed. We suggest computer-assisted telephone interviews warrant further development for this purpose. — JB
From the Northwest:  
**Group cognitive-behavioral treatment for depressed adolescent offspring of depressed parents in a health maintenance organization**  

**OBJECTIVE:** A randomized, controlled effectiveness trial of group cognitive-behavioral therapy (CBT) for depressed adolescent offspring of depressed parents in a health maintenance organization (HMO) was conducted.

**METHOD:** Potential adult cases were found by reviewing antidepressant medication prescriptions, mental health appointments, and medical charts. Introductory study letters signed by each parent’s treating physician were mailed to the appropriate adults. Eligible offspring aged 13 to 18 who met current DSM-III-R criteria for major depression and/or dysthymia were randomly assigned to either usual HMO care (n = 47) or usual care plus a 16-session group CBT program (n = 41). Assessments were conducted at baseline, after treatment, and at 12- and 24-month follow-up.

**RESULTS:** Using intent-to-treat analyses, the authors were unable to detect any significant advantage of the CBT program over usual care, either for depression diagnoses, continuous depression measures, nonaffective measures, or functioning outcomes. Individuals in the usual care group (n = 47) were more likely to drop out in the first 12 months of the study. No clinical significant differences were identified between groups at any follow-up assessment. The authors were unable to detect any significant advantage of the CBT program over usual care, either for depression diagnoses, continuous depression measures, nonaffective measures, or functioning outcomes.

**CONCLUSIONS:** Group CBT does not appear to be incrementally beneficial for depressed offspring of depressed parents who are receiving other mental health care. However, given that many other studies have found positive effects of CBT for youth depression, this single study should not be viewed as evidence that CBT is ineffective overall.

**CLINICAL IMPLICATIONS:** The similar outcomes observed in the usual care and CBT group conditions indicate that universal care was as effective as state of the art, research-tested programs. However, both conditions resulted in unsatisfactorily low recovery rates.

From Northern California:  
**Race, epithelial ovarian cancer survival, and membership in a large health maintenance organization**  
McGuire V, Herrington L, Whitlemore AS. Epidemiology 2002 Mar;13(2):231-4

**BACKGROUND:** African-American ovarian cancer patients present with more advanced disease and have poorer survival than do white patients.

**METHODS:** To determine whether these differences occur among African-American and white patients who have equal access to medical care, we analyzed ovarian cancer patient characteristics separately for 1587 members of the Kaiser Permanente Medical Plan of Northern California and 5757 non-members.

**RESULTS:** The distributions of disease stage at diagnosis were similar among African-American and white patients, both in the Kaiser plan and elsewhere. However, ovarian cancer death rates, adjusted for disease stage and age at diagnosis and for histology, were higher for African-American patients compared with white patients, regardless of Kaiser membership status. The death rate ratios for African-Americans compared with whites were 1.32 (95% CI = 1.02-1.70) for Kaiser members and 1.20 (95% CI = 1.04-1.40) for Kaiser non-members.

**CONCLUSIONS:** Venlafaxine has greater efficacy than SSRIs although there is uncertainty in comparison with other antidepressants. Further studies are required to determine the clinical importance of this finding.

**www.rcpsych.ac.uk**

**From the Northwest:**  
**Efficacy and tolerability of venlafaxine compared with selective serotonin reuptake inhibitors and other antidepressants: a meta-analysis**  

**BACKGROUND:** In individual studies and limited meta-analyses venlafaxine has been reported to be more effective than comparator antidepressants, particularly selective serotonin reuptake inhibitors (SSRIs).

**AIMS:** To perform a systematic review of all such studies.

**METHOD:** We conducted a systematic review of double-blind, randomised trials comparing venlafaxine with alternative antidepressants in the treatment of depression. The primary outcome was the difference in final depression rating scale value, expressed as a standardised effect size. Secondary outcomes were response rate, remission rate and tolerability.

**RESULTS:** A total of 32 randomised trials were included. Venlafaxine was more effective than other antidepressants (standardised effect size was -0.14, 95% CI -0.07 to -0.22). A similar significant advantage was found against SSRIs (20 studies) but not tricyclic antidepressants (7 studies).

**CONCLUSIONS:** Venlafaxine has greater efficacy than SSRIs although there is uncertainty in comparison with other antidepressants. Further studies are required to determine the clinical importance of this finding.
From the Northwest:
Evaluating primary care behavioral counseling interventions: an evidence-based approach

Risky behaviors are a leading cause of preventable morbidity and mortality, yet behavioral counseling interventions to address them are underutilized in health care settings. Research on such interventions has grown steadily, but the systematic review of this research is complicated by wide variations in the organization, content, and delivery of behavioral interventions and the lack of a consistent language and framework to describe these differences. The Counseling and Behavioral Interventions Work Group of the United States Preventive Services Task Force (USPSTF) was convened to address adapting existing USPSTF methods to issues and challenges raised by behavioral counseling intervention topical reviews. The systematic review of behavioral counseling interventions seeks to establish whether such interventions addressing individual behaviors improve health outcomes. Few studies directly address this question, so evidence addressing whether changing individual behavior improves health outcomes and whether behavioral counseling interventions in clinical settings help people change those behaviors must be linked. To illustrate this process, we present two separate analytic frameworks derived from screening topic tools that we developed to guide USPSTF behavioral topic reviews. No simple empirically validated model captures the broad range of intervention components across risk behaviors, but the Five As construct—assess, advise, agree, assist, and arrange—adapted from tobacco cessation interventions in clinical care provides a workable framework to report behavioral counseling intervention review findings. We illustrate the use of this framework with general findings from recent behavioral counseling intervention studies. Readers are referred to the USPSTF (www.ahrq.gov/clinic/prevenix.htm or 1-800-358-9295) for systematic evidence reviews and USPSTF recommendations based on these reviews for specific behaviors.


From Southern California:
Relationship of body iron stores to levels of serum ferritin, serum iron, unsaturated iron binding capacity and transferrin saturation in patients with iron storage disease

None of the methods for assessing total body iron burden in patients with hemochromatosis is satisfactory. Although it is commonly believed that a relationship exists between serum ferritin levels and total iron burden, the extent of this relationship has not previously been documented. In the present investigation we measured the total body iron burden of 88 patients with putative hemochromatosis, 54 of whom were homozygotes for the 845G→A (C282Y) mutation. The total body iron stores were estimated from the volume of red cells removed during therapeutic phlebotomy corrected for an estimated 2 mg/day dietary iron absorbed during the phlebotomy period; the amount of storage iron was compared to the serum ferritin, serum iron, unsaturated iron binding capacity, and transferrin saturation before the beginning of phlebotomy. The serum ferritin proved to be the best predictor of body iron stores. The correlation between all of the analytes and the body iron burden was greater in patients homozygous for the C282Y mutation than in those who were not, including the compound heterozygotes for C282Y and H63D. The body iron burden tended to be greater in patients homozygous for the C282Y mutation than the other patients at any other given ferritin level. We conclude that the serum ferritin level does provide some information regarding total iron burden but even in the case of C282Y homozygotes, the correlation is not very strong.

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From the Southeast and Southern California:
Exposure to abuse, neglect, and household dysfunction among adults who witnessed intimate partner violence as children: implications for health and social services

Intimate partner violence (IPV) damages a woman’s physical and mental well-being, and indicates that her children are likely to experience abuse, neglect and other traumatic experiences. Adult HMO members completed a questionnaire about adverse childhood experiences (ACEs) including childhood abuse, neglect, and household dysfunction. We used their responses to retrospectively assess the relationship between witnessing intimate partner violence and experiencing any of the nine ACEs and multiple ACEs (ACE score). Compared to persons who grew up with no domestic violence, the adjusted odds ratio for any individual ACE was approximately two to six times higher if IPV occurred (p < 0.05). There was a powerful graded increase in the prevalence of every category of ACE as the frequency of witnessing IPV increased. In addition, the total number of ACEs was increased dramatically for persons who had witnessed IPV during childhood. There was a positive graded risk for self-reported alco-
holism, illicit drug use, iv drug use and depressed affect as the frequency of witnessing IPV increased. Identification of victims of IPV must include screening of their children for abuse, neglect and other types of adverse exposures, as well as recognition that substance abuse and depressed affect are likely consequences of witnessing IPV. Finally, this data strongly suggest that future studies, which focus on the effect of witnessing IPV on long-term health outcomes, may need to take into consideration the co-occurrence of multiple ACEs, which can also affect these outcomes.

From Northern California:
Severity of premenstrual symptoms in a health maintenance organization population

OBJECTIVE: To describe severity of emotional and physical symptoms in a large diverse sample; to examine demographic, health status, and behavioral correlates of symptom severity; and to describe use of medications and alternative remedies for premenstrual symptoms. METHODS: A total of 1194 women, ages 21-45, selected from members of a large northern California health maintenance organization, completed daily ratings of symptom severity for two menstrual cycles. An empirically derived algorithm defined symptom severity groups as minimal (n = 186), moderate (n = 801), severe (n = 151), or premenstrual dysphoric disorder (n = 56). Symptom severity as a continuous variable was defined by the two-cycle mean symptom ratings in the luteal phase. Demographic, health status, and behavioral factors and use of treatments for premenstrual symptoms were assessed by self-report. RESULTS: Luteal phase symptom-specific ratings were generally significantly greater in the premenstrual dysphoric disorder group than in the other groups (p < .001). Symptom severity score increased with each comorbidity and decreased with each year of age. Symptom severity was also inversely associated with oral contraceptive use (emotional symptoms) and better perceived health (physical symptoms). Hispanics reported greater severity of symptoms, and Asians less, relative to whites. Use of herbal and nutritional supplements for premenstrual symptoms steadily increased from 10.8% in the minimal group to 30.4% in the premenstrual dysphoric disorder group (p < .01).

CONCLUSION: The degree of premenstrual symptom severity varies in the population, is relatively constant within each woman over two consecutive cycles, particularly for emotional symptoms, and is influenced by age, race/ethnicity, and health status. Reprinted with permission from the American College of Obstetricians and Gynecologists (Obstetrics and Gynecology 2002 Jun;99(6):1014-24).

CLINICAL IMPLICATIONS: This study suggests that gynecologists should assess the degree of premenstrual symptom severity in their patients since a sizeable proportion of women suffer from moderate to severe symptoms and are at risk for overall poorer health and more comorbidity. Because symptom severity is relatively consistent from one cycle to the next, providers may not need to use prospective symptom reporting over two menstrual cycles for accurate diagnosis. — BS ✤

Learning

Learning is holy, an indispensable form of purification as well as ennoblement.
Rabbi Abraham Heschel, 1907-72, activist and Professor of Jewish Ethics and Mysticism
Immediate Hypersensitivity to Methylparaben Causing False-Positive Results of Local Anesthetic Skin Testing or Provocative Dose Testing

By Eric Macy, MD
Michael Schatz, MD, MS
Robert S Zeiger, MD, PhD

Abstract

Background: Parabens are widely used preservatives in food, cosmetics, and drugs, including many amide-type local anesthetic (LA) agents. Although parabens have been associated with delayed contact sensitivity, immediate hypersensitivity reactions rarely result from parenteral exposure to parabens and even less commonly result from mucosal or cutaneous exposure. In addition, immediate hypersensitivity rarely results from use of amide-based LA agents administered in pure form (ie, prepared without preservatives).

Objective: Analyze outcome data from LA skin testing (ST) and provocative dose testing (PDT) administered during a 16-year period; and present the history in three initially LA ST-positive cases, one of which proved to be related to methylparaben.

Methods: Results of all LA ST or PDT done in a large HMO allergy practice caring for 285,000 to 510,000 people in Southern California from August 13, 1985 through August 7, 2001 were reviewed.

Results: Of 287 patients who had amide-type LA ST or PDT done initially, 252 received the LA agent preserved with methylparaben. Three patients demonstrated a positive ST reaction to lidocaine preserved with methylparaben. All three had a negative ST or PDT reaction to pure LA agents. These agents included lidocaine. One patient, who had a history of immediate hypersensitivity reaction when exposed orally to parabens in foods, had a positive reaction to subsequent ST with pure methylparaben. No patient had a positive reaction to ST or PDT using amide-type LA agents.

Conclusions: Local anesthetic ST or PDT is a safe procedure, and immediate hypersensitivity to pure amide LA agents is extremely rare. Methylparaben was the only established cause for an immediate hypersensitivity reaction during LA ST identified in a large allergy practice during the past 16 years.

Introduction

Parabens are widely used as preservatives in cosmetics, foods, and drugs. Parabens have been extensively studied and are safe as currently used. They are commonly encountered as preservatives in multidose vials of amide local anesthetic (LA) agents. Parabens noncovalently denature proteins through their phenol moiety and haptinate proteins through their benzoic acid moiety. Rarely, patients can become immunologically sensitized to parabens. Methylparaben, one of the most commonly used parabens, is a well-documented cause of T-cell-mediated contact sensitivity.

One case report documented a urticarial maculopapular rash which resulted 36 hours after ingestion of a haloperidol solution containing methylparaben. Methylparaben has only rarely been reported to cause immediate hypersensitivity, even after parenteral exposure. Most of the documented cases of immediate hypersensitivity to methylparaben have been verified by a positive skin test (ST) result, but positive passive transfer (Prausnitz-Kustner) test reactions have been less frequently documented.
Immediate Hypersensitivity to Methylparaben Causing False-Positive Results of Local Anesthetic Skin Testing or Provocative Dose Testing

We reviewed the results of all LA agent PDT done ... 85,000 to 510,000 people in Southern California from August 7, 2001.

have also been reported.8

Reports are rare of well-documented positive ST or provocative dose testing (PDT) results to amide LA agents in patients evaluated for possible clinical reactions to LA agents. LA testing is routinely done using multidose vials of LA agents containing methylparaben as a preservative. Some reported (but poorly documented) positive ST or PDT reactions to amide LA may in fact be reactions to methylparaben and not to LA agents. The present report confirms that methylparaben is responsible for at least some of the positive ST or PDT results in patients tested with amide LA agents.

Methods

We reviewed the results of all LA agent ST and PDT done in a large HMO allergy practice providing all of the allergy consultative services for 285,000 to 510,000 people in Southern California from August 13, 1985 through August 7, 2001. This study was reviewed and approved by the Southern California Kaiser Permanente Institutional Review Board.

ST with LA agents was done on the forearm, and PDT was done on the upper lateral arm. A negative saline control, a positive 0.1%-histamine control, and an initial undiluted LA prick puncture (PP) test were placed and read at 20 minutes. A wheal 3 mm greater than the saline control was considered a positive test result. If the PP test result was negative, the histamine control positive, and the saline control negative, then an intradermal (ID) test using 0.04 mL of a 1:100 dilution of the LA agent was placed along with the saline and 0.01%-histamine controls. These tests were read at 20 minutes and, if negative, a single-blind placebo, 1-mL subcutaneous injection of saline was administered. If the placebo challenge was negative after 20 minutes, then a 1-mL subcutaneous injection of an undiluted LA agent was administered, and the patient was observed for 20 minutes.

The placebo or active-drug PDT was considered positive if the patient had a positive wheal-and-flare reaction at the site of undiluted LA administration, any acute-onset pruritic rash distant from this site, 15% decrease in blood pressure, wheezing, or 15% decrease in FEV1 of pulmonary function occurring during the 20-minute posttest observation period. Only objectively observed adverse reactions reported during the performance of the placebo or active-drug PDT were considered positive challenges.

A 1% or 2% solution of lidocaine with 0.1% methylparaben was the material most commonly used for ST or PDT. A 1% solution of mepivacaine with 0.1% methylparaben was the second most commonly used material containing methylparaben. A pure 1% or 2% solution of lidocaine was the most commonly used LA agent that did not contain methylparaben. Other LA agents with and without preservatives were selected for use on the basis of the patient’s clinical history or by request of the patient or referring physician. Some patients had ST or PDT with more than one LA agent or with the same preparation more than once. Some of the additional tests used to further characterize reactivity of the three initially ST-positive patients were limited to puncture and intradermal ST. Epinephrine-containing materials were not used for any testing.

Results

Of the 287 patients who had at least one LA ST or PDT, 253 patients were exposed to lidocaine. Mean age of patients at initial testing was 47.8 ± 19.1 years (range, 3.9 to 91.9 years). The cohort included 220 (76.7%) women and 67 (23.3%) men. Of subjects tested, 252 (87.8%) were also exposed to 0.1% methylparaben. Table 1 lists the amide LA agents used for routine ST or PDT and the results of the tests. Table 2 lists the 25 subjectively perceived adverse reactions reported. Of these reported adverse reactions, 22 (88%) occurred in women, and 3 (12%) occurred in men. Fourteen

<table>
<thead>
<tr>
<th>Preparation</th>
<th>No. of subjects tested</th>
<th>No. (%) of subjects with adverse reaction reported despite negative PDT result</th>
<th>No. of subjects with positive test result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1% or 2% lidocaine/0.1% methylparaben</td>
<td>232</td>
<td>19 (8.2)</td>
<td>3*</td>
</tr>
<tr>
<td>1% mepivacaine/0.1% methylparaben</td>
<td>18</td>
<td>3 (16.6)</td>
<td>0</td>
</tr>
<tr>
<td>1% bupivacaine/0.1% methylparaben</td>
<td>2</td>
<td>0 (0)</td>
<td>0</td>
</tr>
<tr>
<td>Totals for preparations containing methylparaben</td>
<td>252</td>
<td>22 (8.7)</td>
<td>3 (1.2)</td>
</tr>
<tr>
<td>1% or 2% lidocaine</td>
<td>22</td>
<td>1 (4.5)</td>
<td>0</td>
</tr>
<tr>
<td>4% prilocaine</td>
<td>6</td>
<td>0 (0)</td>
<td>0</td>
</tr>
<tr>
<td>2% mepivacaine</td>
<td>8</td>
<td>2 (25.0)</td>
<td>0</td>
</tr>
<tr>
<td>Totals for local anesthetic agents without preservatives</td>
<td>35</td>
<td>4 (8.6)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

*These patients had dose testing using anesthetic preparations without preservatives and include two patients with positive result of prick puncture and one patient with positive result of intradermal dose testing.
patients had ST or PDT more than once. All patients who had LA ST or PDT more than once had a negative result on all tests except as noted in one of the three initially ST-positive patients. All three initially ST-positive patients subsequently tolerated PDT with pure lidocaine. No objective clinical signs of adverse reaction—including pruritic rash at the site of injection, distant pruritic rash or urticaria, wheezing, or hypotension—occurred in any patient during PDT.

Table 3 presents the additional immediate hypersensitivity ST results for the three patients who initially tested positive to lidocaine with methylparaben. Clinical histories of these patients are presented.

Case Reports

The patient in Case 1 was a 39-year-old man initially seen in the allergy department in 1994 with the chief complaint of adult-onset “food allergy” to ice cream. He also had a four-year history of immediate-onset burning, itching, swelling, redness, and pain after topical exposure to many shampoos and lotions. The cutaneous symptoms would start clearing within ten minutes if he completely removed the offending materials from his skin. He had no clinical signs of delayed contact sensitivity and no fixed eruptions or blistering rashes. The most problematic food was a particular brand of “pralines and cream” ice cream. Eating the ice cream caused immediate-onset oropharyngeal swelling, change in tone of his voice, and mild shortness of breath. He could drink milk and eat the other protein-containing materials in the ice cream, such as eggs and nuts, without any problem. The patient had no history of physical or idiopathic urticaria. Cold urticaria was ruled out by negative results of an ice cube test administered at the initial visit, and plans were made to give the patient a skin test with the constituents of the implicated ice cream. The patient failed to follow up with the rest of the evaluation. The patient next came to the clinic 51 months later with a new complaint of severe oral and facial swelling with the use of an over-the-counter topical oral benzocaine preparation. This condition became more problematic when, during the course of dental work, he was exposed to both topical benzocaine and parenteral lidocaine and had severe immediate-onset oropharyngeal swelling but no shock or anaphylaxis. The dental work was postponed. The patient had managed his previous problems from ice cream and other materials by avoidance. He now needed dental work and needed to know what LA agent he could tolerate. The patient had tolerated LA agents before 1994 without any problem. He had no history of hay fever, asthma, or any other drug or food allergy or intolerance. He was not taking any medications.

The patient in Case 2 (initially seen in 2000) was a 37-year-old, gravida 2, para 1 woman, four months pregnant, who had a history of possible allergic reaction to either penicillin or lidocaine. Fifteen years previously, the patient was treated with oral amoxicillin or penicillin for one week and with lidocaine spray for a sore throat. Twenty minutes after receiving a dose of penicillin and an unspecified time after lidocaine was sprayed into her mouth, palmar itching developed, and she fainted. She was aroused with smelling salts and was brought to the emergency department. She had cyanotic hands but no rash or respiratory difficulty. She received therapy but could not recall specific details of the allergic episode. Her symptoms resolved within a couple of hours. She had no history of allergic rhinitis, asthma, or allergy to food or insects, and her family history did not include allergic disease. The patient was well and was not taking medication. The patient was referred to the allergy department for assessment of possible allergy to lidocaine. Physical examination results were normal except for evidence of pregnancy. The patient was ST-positive to lidocaine with methylparaben and was ST- and PDT-negative to pure lidocaine (Table 4). We recommended that

| Table 2. Subjectively reported adverse reactions occurring during or after administration of provocative dose tests in 249 patients who had a negative reaction to local anesthetics containing methylparaben* |
|-----------------------------------------------|------------------|
| Adverse reaction                           | No. (%) of patients |
| Anxiety                                     | 3                |
| Cough, sneeze, or both                      | 2                |
| Headache                                    | 2                |
| Itch, no rash                               | 3                |
| Lightheadedness                             | 4                |
| Pain at injection site(s)                   | 2                |
| Nausea                                      | 3                |
| Sleepiness                                  | 2                |
| Delayed onset of adverse reaction (>24 hours) maculopapular rash at site(s) of methylparaben injection | 1                |
| **Total**                                   | **22 (8.8%)**    |

* Lightheadedness occurred in three (8.6%) of 35 patients who had a negative reaction to pure local anesthetic agents administered in provocative dose tests.

Of these reported adverse reactions, 22 (88%) occurred in women, and 3 (12%) occurred in men.
the patient return postpartum for penicillin testing and for further testing with methylparaben, but she moved from San Diego and did not return for further evaluation.

The patient in Case 3 was a 55-year-old woman referred to the allergy clinic for evaluation of local anesthetic allergy. Fourteen months before evaluation in the allergy department, the patient did not react to dental injection of lidocaine or to latex glove exposure. Two months before evaluation in the allergy department, similar lidocaine and latex exposure was followed in the evening by an unusual sensation around her lips, followed the next day by lip swelling. One week later, latex gloves and lidocaine were again used and were again followed the next day by onset of lip swelling. The patient needed further dental work. She had a history of postpolio syndrome. She had also noticed nonpruritic skin erythema on certain occasions, such as with heat. She had no history of hay fever, asthma, or eczema. She was being treated with verapamil, estrogens, and nortriptyline. Results of an ELISA test to latex were negative.

Intradermal using a 1:100 dilution of lidocaine with methylparaben initially produced a positive reaction manifested by diffuse erythema on the arms and trunk without pruritus or any other signs of a systemic IgE-mediated reaction. She returned 2-1/2 weeks later to have the skin tests repeated, but nonpruritic erythema from sitting in a warm room was already apparent, and the test was deferred. Four weeks after the initial test, the patient had a negative reaction to ST with pure prilocaine and with pure lidocaine. She had a negative reaction to PDT with pure prilocaine. When the patient returned (ten weeks after the initial test), she had a negative reaction to ST with methylparaben. She next returned 17 weeks after the initial test and had negative reactions to ST/PDT with lidocaine combined with methylparaben—the same preparation to which she initially had a positive ST result (Table 3).

Discussion

Depending on their chemical structure, LA agents are grouped into two categories: the ester group, which includes benzocaine, cocaine, procaine, chloroprocaine, and tetracaine; and the much more widely used, amide group, which includes lidocaine, mepivacaine, prilocaine, etidocaine, and ropivacaine. The esters are derivatives of para-aminobenzoic acid and share chemical features with parabens. No epinephrine was used in the testing, because epinephrine can mask both vasodilatation and the vascular permeability associated with a positive, immediate-hypersensitivity ST result and may also cause anxiety in some patients.

In 1984, one patient who apparently had an immediate hypersensitivity reaction after mucosal exposure to methylparaben (delivered by barium enema) reportedly had a positive methylparaben ST result. Despite wide use of methylparaben as a preservative in foods, beverages, and drugs, no well-defined case of immediate hypersensitivity to methylparaben has been reported for patients who had index exposure to methylparaben. One report described an attempt to develop an in vitro test for IgE directed against methylparaben, but no positive sera were identified by the test. To date, no positive in vitro test for methylparaben or for amide LA-specific IgE has been reported. Little convincing information exists that amide LA agents as a class can induce clinically significant IgE production in humans.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Case 1</th>
<th>Case 2</th>
<th>Case 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1% lidocaine/0.1% methylparaben</td>
<td>10/35b</td>
<td>5/20b</td>
<td>0/0b</td>
</tr>
<tr>
<td>1% lidocaine/0.1% methylparaben</td>
<td>10/30b</td>
<td>10/25b</td>
<td>0/0b</td>
</tr>
<tr>
<td>1% lidocaine/0.1% methylparaben</td>
<td>22/50b</td>
<td>test not done</td>
<td>test not done</td>
</tr>
<tr>
<td>0.5% bupivacaine/0.1% methylparaben (ester)</td>
<td>test not done</td>
<td>test not done</td>
<td>test not done</td>
</tr>
<tr>
<td>1% procaine/0.09% metabisulfite*</td>
<td>0/0b</td>
<td>0/0c</td>
<td>0/0b</td>
</tr>
<tr>
<td>1% procaine/0.09% metabisulfite+</td>
<td>0/0b</td>
<td>test not done</td>
<td>test not done</td>
</tr>
<tr>
<td>0.1% methylparaben</td>
<td>3/40b</td>
<td>test not done</td>
<td>0/0b</td>
</tr>
<tr>
<td>0.1% methylparaben</td>
<td>0/0b</td>
<td>test not done</td>
<td>0/0b</td>
</tr>
<tr>
<td>0.1% methylparaben</td>
<td>test not done</td>
<td>test not done</td>
<td>0/0b</td>
</tr>
<tr>
<td>4% cocaine (ester)</td>
<td>0/0b</td>
<td>test not done</td>
<td>test not done</td>
</tr>
<tr>
<td>1% etidocaine</td>
<td>0/0b</td>
<td>test not done</td>
<td>test not done</td>
</tr>
<tr>
<td>4% prilocaine</td>
<td>0/0b</td>
<td>test not done</td>
<td>0/0b</td>
</tr>
<tr>
<td>1% lidocaine</td>
<td>0/0b</td>
<td>test not done</td>
<td>0/0b</td>
</tr>
<tr>
<td>1% lidocaine</td>
<td>negative reactiond</td>
<td>negative reactiond</td>
<td>negative reactiond</td>
</tr>
</tbody>
</table>

*Read at 20 minutes; †prick puncture; ‡intradermal test positive; §provocative dose test positive; †Metabisulfite is an alternative to methylparaben. All local anesthetic agents are amide unless noted otherwise.
Frequency of adverse reactions attributed to LA agents and actually caused by those agents has been reduced with widespread use of the amide type of LA agents throughout the past 30 years. The patient described in Case 1 had clinical symptoms of immediate hypersensitivity after oral and cutaneous exposure both to benzocaine and to methylparaben.

Fisher and coworkers presented data for 208 patients (referred during a 20-year period) who had a history of allergy to LA agents. Four of these patients had positive PDT test results, and another four patients had a delayed cutaneous reaction. Three of these eight patients were subsequently given LA agents and tolerated them well. The authors concluded that “a history of allergy to local anesthesia is unlikely to be genuine and local anesthetic allergy is rare. In most instances it can be excluded from the history and the safety of local anesthetic verified by progressive challenge.”

Gall and coworkers described 177 patients with a history of LA intolerance and found five who initially had a positive reaction to preservatives. Of 164 patients tested, the authors identified two (1.2%) who had a positive reaction to paraben PP and ST, virtually the same rate identified in the present study.

Of 252 patients, we identified only one (0.4%) who had a delayed-onset rash at the PDT site of exposure to the lidocaine combined with methylparaben. This result was compatible with contact sensitivty. This patient was told to avoid methylparaben.

This study documents the need to reconfirm initially positive test results, because transient dermographism may be missed by use of the saline control. We now recommend updating the previous recommendations from Schatz that lidocaine with methylparaben should be the initial material used for routine LA ST or PDT. Given the infrequency of positive test results, we would recommend repeating any positive tests not associated with clinically significant systemic reactions. If the test result remains positive, ST or PDT should be done using pure lidocaine. The person identified by this protocol as having a rare positive reaction to methylparaben can then actively avoid parabens and is unlikely to have a positive reaction to amide LA agents.

The present study confirms the rarity of positive ST or PDT results from exposure to pure amide LA agents. Our experience suggests that any positive reaction to ST or PDT using LA agents with methylparaben is likely either to result from exposure to methylparaben or to represent a false-positive result. Data from the present report add to the safety database of reactions to amide LA agents. Because today methylparaben is the preservative most commonly used in multidose vials, raising awareness that methylparaben is a potential cause for local reactions previously attributed to the anesthetic agent itself.

References
The Herbal Medicine Pharmacy Update

By Philip J Tuso, MD, FACP

Fifty-five percent of Alzheimer patient caregivers reported that they had tried at least one alternative therapy to improve the patient’s memory ...

Introduction
The continued use of herbal medicine in the United States and among members of Kaiser Permanente (KP) makes an updated review of this topic timely and important. Many pharmacies at KP facilities in Southern California now carry traditional herbal preparations. These “dietary supplements” are over-the-counter therapy that is not routinely screened for drug interaction by the pharmacy team.

This article discusses herbal medicine with the interests of the physician in mind by emphasizing the importance of understanding the risks and benefits of herbal treatment. We use the skills taught to us by Eddy1–4 to determine if selected herbal medicines pass the evidence-based-medicine test. We discuss selected examples of herbal medicine that have the potential to harm patients. The discussion is not intended to be a complete review of all aspects of herbal remedies.

Use of Herbal Therapy in the United States

Alternative forms of therapy are defined as intervention neither taught widely in US medical schools nor widely available in US hospitals.5–6 A 1997 national survey showed that 42% of Americans used some form of alternative medicine,5,6 but that figure may be higher for young, affluent, educated populations.7 Eisenberg5 reported that in the US general population, use of over-the-counter herbal medicine increased from 2.5% in 1990 to 12.1% in 1997, and consultation with alternative medicine providers increased from 10.2% in 1990 to 15.1% in 1997. The estimated total retail cost of herbal medicine in the United States is about $4 to $5 billion per year8 and is primarily paid by the people seeking herbal medicine treatment.5

Little was known about prevalence of the use of alternative and herbal medicine by older adults—the largest consumers of health care—until survey results were published by Foster in 2000.7 Thirty percent of the people surveyed who were aged 65 years or more reported using alternative medicine, usually chiropractic services and herbs. By extrapolation, about three million people aged 65 or more used herbal therapy in 1997, and two million used herbal therapy and prescription medication at the same time.9

Physicians are becoming aware of the potential benefit of some herbal medicines and are using them to treat conditions common in our elderly population. Fifty–five percent of Alzheimer patient caregivers reported that they had tried at least one alternative therapy to improve the patient’s memory,10 and 29% of older patients with arthritis reported seeing an alternative medicine provider for their arthritis.11 However, in 1997, Eisenberg reported that 57% of those aged 65 years or more did not disclose use of any alternative medicine to their physician.6 These data suggest that physicians should ask all patients, including high-risk patients such as the elderly, about their use of herbal medicine.

Adverse Effects and Drug-Herb Interaction

Patients taking prescription drugs and therapeutic herbs may be at risk for adverse drug-herb interactions, including interaction that alters bioavailability and efficacy of the prescription drugs.12 Drug interaction and adverse effects from herbal medicines are more likely to occur among patients who have chronic medical conditions, such as liver, heart, or kidney disease. Older patients have more comorbid illnesses and may be more susceptible to complications caused by herbal medicines.9,12–13 KP pharmacists routinely report potential drug interaction and adverse affects to patients and physicians. However, herbal medicine is not routinely included in these reports, because this information is not routinely programmed into our computer data systems.

Tenuous Position of Herbal Medicines in Evidence-Based Medicine

That we practice evidence-based medicine means that we base our decisions on evidence of benefit. If a therapy has sufficient evidence of benefit, we should recommend it to our members; if insufficient evidence of benefit exists or if evidence indicates that the therapy will harm patients, we should not recommend the
treatment. Our goals as physicians are to provide treatment that makes our patients better and to protect our patients from treatment that may cause harm. In addition, we do not want to waste members’ money.

Because herbal products in the United States are not approved by the US Food and Drug Administration (FDA) as drugs used to help treat diseases, these products do not undergo premarketing safety and efficacy studies and are not manufactured in a standard way. Herbal medicines are defined by the Dietary Health and Education Act of 1994 as dietary supplements, and they are presumed safe until new information shows otherwise. Companies manufacturing herbal medicine can make structure and function claims without support of scientific research, although the claims must be truthful and not misleading. Because herbs cannot be patented, no incentive exists for pharmaceutical companies to invest in research. The FDA would have to prove that an herb was harmful before taking it off the market; however, the FDA has no authority to test herbs.

From a quality control perspective, many are concerned about reported observations that herbal preparations are contaminated with pesticides, heavy metals, microorganisms, and conventional medication (acetaminophen, hydrochlorothiazide, indomethacin, phenobarbital, theophylline, and corticosteroids). This is just one of the reasons that pregnant women should not use herbal medicines. In addition, many herbal products do not contain what is written on the label.

The reference standard for testing efficacy of any therapy is the randomized clinical trial (RCT). Since The Permanente Journal last published a review of herbal medicine, more RCTs and meta-analyses of RCTs on herbal medicine have been published. We used these data to help determine whether or not selected categories of herbal medicine constitute evidence-based therapy.

Tables 1 and 2 show the results of RCTs, meta-analyses of RCTs, and case reports for a variety of herbal medicines. For a more complete review of this topic, please see the Ernst and Pittler article titled “Herbal Medicine.”

Table 1 lists herbal medicine that passes the evidence-based-medicine test. Systematic reviews and meta-analyses of RCTs show that some herbs may be efficacious for treating symptoms of certain diseases, such as ginkgo for dementia and intermittent claudication, horse chestnut extract for chronic venous insufficiency, kava for anxiety, and St John’s wort for depression. However, before starting these forms of herbal medicine, consumers and their physicians should review the consumer report on the herb posted on the Internet at consumerlab.com and other resources for information. For example, a recent study published in the Journal of the American Medical Association (JAMA) suggests that St John’s wort may lack efficacy for treatment of moderately severe depression.

Table 2 lists herbal medicine forms that do not have studies supporting their use as evidence-based medicine. These herbs should not be used or should be used only with extreme caution. For instance, licorice has mineralocorticoid properties and has been reported to cause hypokalemia in some patients. Hepatitis has been reported in patients taking comfrey, chaparral, or celandine and should not be used by patients with liver disease or who are taking medication that may affect liver function.

Other herbal medicine forms, such as ginger, ginseng, feverfew, devil’s claw, and dong quai, can interact with warfarin sodium and may affect platelet function and bleeding times. This type of herbal medication should not be taken by patients already taking anticoagulant medication such as aspirin, warfarin sodium, or nonsteroidal anti-inflammatory agents. Patients scheduled to receive any procedure that may cause bleeding should be asked if they are taking herbal medicine and should be instructed to stop taking herbs which have anticoagulant

| Table 1. Herbal medicine forms that have studies supporting their use as evidence-based medicine |
|-----------------|-----------------|-----------------|
| Herb            | Condition treated | Reference       |
| Ginkgo (Ginkgo biloba) | Dementia          | 20              |
| Horse chestnut seed extract | Chronic venous insufficiency | 22 |
| Kava (Piper methysticum) | Anxiety          | 23              |
| St John’s wort (Hypericum perforatum) | Depression       | 24              |

| Table 2. Herbal medicine forms that do not have studies supporting their use as evidence-based medicine |
|-----------------|-----------------|-----------------|
| Herb            | Condition treated | Reference       |
| Asian ginseng (Panax ginseng) | Decreased mental performance | 27 |
| Evening primrose (Oenothera biennis) | Premenstrual syndrome | 28 |
| Feverfew (Tanacetum parthenium) | Prevent migraine | 29, 30 |
| Garlic (Allium sativum) | High blood cholesterol levels | 31 |
| Ginkgo (Ginkgo biloba) | Tinnitus | 32 |
| Valerian (Valeriana officinalis) | Insomnia | 33 |

... these products do not undergo premarketing safety and efficacy studies and are not manufactured in a standard way.
properties for two weeks before receiving the procedure.38-43

Several recent publications report on renal failure caused by Chinese herbs.44-53 Other recent reports indicate that taking St John's wort can result in lower cyclosporin levels, which have been associated with transplant rejection.54-59 Both of these findings are explained in more detail in the following sections.

### Table 3. Herbal medicine forms that may harm patients34

<table>
<thead>
<tr>
<th>Adverse effect</th>
<th>Herb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal failure</td>
<td>Chinese herbs (Aristolochia sp)</td>
</tr>
<tr>
<td>Transplant rejection</td>
<td>St John's wort (Hypericum perforatum)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>Aconite (Aconitum napellus)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Ephedra sp</td>
</tr>
<tr>
<td>Hypertension and hypokalemia13</td>
<td>Licorice (Glycyrrhiza glabra)</td>
</tr>
<tr>
<td>Hyperthyroidism</td>
<td>Kelp (Fucus pyriferus)</td>
</tr>
<tr>
<td>Hepatitis39,53</td>
<td>Comfrey (Symphytum officinale), Chaparral (Larrea tridentata), Celadine (Chelidonium majus)</td>
</tr>
<tr>
<td>Bleeding disorders38-41</td>
<td>Ginger (Zingiber officinale), gingko (Ginkgo biloba), ginseng (Panax ginseng), feverfew (Tanacetum parthenium), devil's claw (Harpagophytum procumbens), dong quai (Angelica sinensis)</td>
</tr>
<tr>
<td>Seizures</td>
<td>Evening primrose oil (Oenothera biennis)</td>
</tr>
</tbody>
</table>

For a more complete list of herbs that may have serious adverse effects, please refer to the complete German Commission E Monographs, Therapeutic Guide to Herbal Medicines (English translation) published in 1998.34

### Chinese Herbs Nephropathy

Chinese herbs nephropathy is characterized by rapidly progressive fibrosing interstitial nephritis without glomerular lesions.54-55 Patients in whom this disease develops are seen initially for subacute renal failure that progresses rapidly to end-stage renal disease, even though the patient stops taking the herbs immediately upon diagnosis; ultimately, the patient requires dialysis and a renal transplant.46-47 Aristolochic acid contained in these Chinese herbal preparations is suspected to be the nephrotoxic agent.48-49 In other patients taking Chinese herbs, urinary tract carcinomas have developed.50-53

### St John's Wort and Acute Organ Transplant Rejection

St John's wort (Hypericum perforatum), an herb extract, is an over-the-counter remedy for treating depression.54-55 Moschella6 published a case study describing a renal transplant recipient who self-prescribed St John's wort, an action which resulted in marked reduction in cyclosporin levels. Acute transplant rejection after ingestion of St John's wort has been described in heart,57 kidney,58 and liver69 transplant recipients. Transplant rejection episodes did not recur when patients stopped taking St John's wort.

### Herb Information Resources

ConsumerLab.com, LLC (www.consumerlab.com) provides independent test results to help consumers and health care providers evaluate nutrition products.25 This resource should be reviewed by physicians as well as by consumers, although the Web site may not be free and may require subscription for some users. For example, a search of the ConsumerLab.com Web site in preparation for this article yielded a report on ginseng9 which showed that of the 21 ginseng products tested, seven contained less than the acceptable amounts of ginsenoside (active ingredient for ginseng), two had levels of pesticides 20 times more than allowed levels, and two contained more than the acceptable level of lead.

Physicians need to be aware of potential risks of using herbal medicine and are encouraged to visit www.consumerlab.com and review the information on herbal products before recommending any herbal medicine to patients.

To keep the FDA apprised of the real risks of using herbs, physicians can report adverse effects of any herbal medicine to FDA MedWatch on the Internet at www.fda.gov/medwatch.33

### Conclusions

This article describes selected forms of herbal medication that have some evidence that they help to treat certain disease conditions, some herbs that have no evidence of benefit, and some herbs that are known to cause harm. Most of these conditions can also be treated with conventional medication.

As a result of the Dietary Supplement Health and Education Act of 1994,44 manufacturing of herbal extracts is not submitted to the type of quality control used for manufacturing conventional medication; nor is premarketing safety and efficacy research required. Not all herbal preparations are safe, not all herbal products are standardized to particular levels of the active ingredient, and herbal products may contain contaminants such as pesticides and heavy metals.
nephropathy, and transplant rejection. The use of most herbal medicine is not evidence-based, and the risk clearly outweighs the benefit.

Consumers and clinicians need to become familiar with the potential risk and benefit of herbal medication, and one good information resource is on the Internet at www.consumerlab.com. As health care providers, we should be leaders in asking our patients about herbal medicine use and counseling patients about any interaction herbal medicine may have with prescribed medication. In addition, physicians are encouraged to report adverse reactions to herbal medicine to the FDA MedWatch on the Internet at www.fda.gov/medwatch.

Sponsoring legislation should be considered in order to require that herbal medicine be subjected to the same stringent premarketing scrutiny and controls as conventional drugs. Pharmacists should be aware of herb-drug interaction, and our pharmacy and clinical information systems should be programmed to include information about herbal medicine and interaction profile screening.

References

As health care providers, we should be leaders in asking our patients about herbal medicine use and counseling patients about any interaction herbal medicine may have with prescribed medication.
Abstract

Physical symptoms caused by psychosocial stress are responsible for most primary care office visits. Stress capable of producing illness may be in the patient’s life at the moment or may result from past trauma, depression, or childhood stress. Here is one patient’s story. For more information about stress-related illness, please log on to www.stressillness.com.

Emma was the sort of patient who drove her doctors to despair. She had been suffering from bowel problems for nearly eight decades. Just looking at her massive medical record was discouraging.

She was 87 years old with loosely curled, pearl-white hair. She answered questions thoughtfully and in great detail. Her eyes searched your face to see if you had the solution to her abdominal cramps and alternating diarrhea and constipation. These symptoms were not severe, and sometimes they even went away—but never for more than a week or two. No diagnostic test had ever revealed an abnormality. No treatment had ever worked for very long.

All appropriate studies had been done at least once: lower-GI series, sigmoidoscopy, upper-GI series, small-bowel series, ultrasound, CAT scan of the abdomen, colonoscopy, gastroduodenoscopy and numerous blood tests. Her chart also showed a number of different trials of medication: antispasmodic agents, antidepressants, and one prescription for a tranquilizer.

Was there a source of stress in her life? “Since my husband died, I get lonely at times,” she replied when asked. But he had passed away more than ten years before. For the most part, her days now were pleasant and productive. She wasn’t depressed or anxious.

Her symptoms had begun when she was a child. Had she experienced any difficulties during that time in her life? She had grown up on a farm in a valley in the Rocky Mountains. Her parents loved each other and their five children. There was no abuse, no alcoholism, and no pressure. In many ways, it was a storybook place. Emma was the oldest daughter. When she was six years old, a sister was born. With the large number of other children and the work of the farm, the mother relied on Emma to care for the baby. Emma took to this task as she would to a favorite doll. She held, fed, dressed, changed, played with, sang to, and slept with her sister. They were inseparable.

Two and a half years later fever developed in the infant. Medical resources in rural areas in 1918 were not abundant. By the time appendicitis was diagnosed, it was too late—the child died.

Emma went into shock. The emotional self-expression usual for a young girl temporarily shut down. At the funeral service, an uncle made a remark that remained with her the rest of her life. He pointed out that she was the only person in the church who wasn’t crying. His tone implied that she must not care about her sister’s death. Her guilt, already intense, went off the scale. While she related this story, her eyes watered.

Her rapidly flowing speech slowed to a trickle, and her lively face softened. She looked away from me toward the landscape painting on the exam room wall. Not surprisingly, her sister’s death affected her entire life. Within two months, she began caring for a newborn on a neighboring farm. Sometimes, though, she couldn’t make the walk to the neighbors because during that time, her stomach first began bothering her. The pains persisted during high school and college, where she supported herself by caring for children.

Her career choice: pediatric nursing. She married and had several children of her own. She raised them, with great care, to adulthood. Through all these years, her symptoms persisted.

She stopped talking and looked again at the landscape painting. After awhile, she turned back. “You know, you’re the first doctor that ever asked me about my sister,” she said. “What do you think I should do?”

I recommended that she visit an elementary school at recess so that she could see the children on the playground. She was then to pick out a girl who reminded her of herself at age eight. Emma was then to ask herself what such a girl could do to save a two-year-old with a ruptured appendix in the days before antibiotics. Once she had done that, I suggested that she return home and write a letter to her infant sister, asking forgiveness. She thanked me quietly and has not been to a physician about her illness since.
Jimson Weed Poisoning—A Case Report

By Kit Chan, MD

Abstract
Jimson weed, a plant best known among adolescents and young adults for its hallucinogenic properties, grows as a wild herb in the United States. Ingestion of jimson weed produces the toxidrome of anticholinergic intoxication. Understanding and recognizing the classic signs and symptoms of anticholinergic intoxication can help clinicians evaluate persons presenting with jimson weed poisoning.

Introduction
Ingestion of jimson weed (Datura stramonium) is fairly common and can lead to intoxication and to anticholinergic manifestations that are potentially dangerous. The plant is a wild herb that grows throughout the United States, usually matures between May and September, is accessible to almost anyone, and is particularly popular among adolescents curious about the plant's hallucinogenic effects. Understanding the signs and symptoms of jimson weed toxicity can lead to early diagnosis and proper case management. Anticipatory counseling for teenagers and parents may also prevent experimentation and resultant harm.

Case Report
The mother of a 15-year-old boy brought him to the emergency department (ED) because of his bizarre behavior, including hallucinating. The mother had been advised by a neighbor that several neighborhood youths had been taken to nearby hospitals after ingesting wild flowers and then hallucinating. The patient's mother had entered the patient's room and found him shaking, mumbling, and trying to pick at nonexistent items. She noted several white flowers in his room and brought them to the ED.

In the ED, the patient was restless, pacing incessantly, and shaking. He was awake, alert, and oriented to name but not to place or time. Vital signs included oral temperature 99.3°F (37.4°C), blood pressure 117/72 mmHg, heart rate 103 beats/min, and respiratory rate 24 breaths/min. Pupils were dilated to 8 mm, symmetric, and minimally reactive to light. Mucous membranes were dry, and bowel sounds were decreased. The extremities were warm to the touch but were not hot. Neurologic examination showed that the patient was confused and mumbling, cranial nerves were intact, and both motor strength and reflexes were within normal limits. During the examination, the patient reached into the air as if trying to catch a nonexistent object.

Results of an emergent fingerstick blood glucose test, complete blood count, chemistry panel, and urinalysis were normal. Results of a toxicology screen were negative for alcohol, benzodiazepines, amphetamines, marijuana, tricyclic antidepressant agents, opiate agents, and phencyclidine. An electrocardiogram showed sinus tachycardia without other abnormality. Granulal structures appeared normal on computed tomography scans administered without contrast medium.

On the basis of both the clinical presentation and a history of ingesting a wild plant, the ED physician suspected jimson weed intoxication, which was confirmed by comparing the mother's plant specimen with a picture of jimson weed (obtained from the Internet). The patient denied any drug use but stated that his friends had given him a blended drink consisting of strawberries, a wild plant, and a small amount of alcohol. In the ED, the patient received several doses of lorazepam intravenously as treatment for agitation. He was admitted to the hospital for observation and for monitoring. The patient remained stable, and his mental status improved. At a subsequent interview, the patient admitted that he and his friends had consumed jimson weed deliberately: They had tried it for the first time after hearing that it was hallucinogenic. After 36 hours of observation, the patient was discharged from the hospital.

Discussion
Jimson weed is a member of the nightshade family. An earlier name for the plant was Jamestown weed, coined after intoxication from the plant was first recorded in Jamestown, Virginia, in 1676; the name was subsequently shortened to jimsonweed. The same plant is known also as thorn apple, angel's trumpet, stinkweed, and green dragon. The plant has been used for centuries to treat asthma, diarrhea, intestinal cramps, and nocturia because of its anticholinergic effects, and its hallucinogenic effects were mentioned in Homer's tale, The Odyssey.

Jimson weed reaches a height of five feet and consists of large, jagged leaves and trumpet-shaped flowers, that may be white or purple. At maturity, the plant bears green fruit, each containing four compartments and holding as many as 100 seeds. Although all parts of the plant...
are poisonous, the leaves and seeds contain the highest concentration of atropine, hyoscyamine, and scopolamine. One hundred seeds contain approximately 6 mg of atropine. A dose of atropine exceeding 10 mg is regarded as potentially lethal.

Today, jimson weed poisoning is found primarily among adolescents who seek the hallucinogenic effects of the plant. In 1998, 152 cases of jimson weed poisoning were reported nationally to the American Association of Poison Control Centers, but the true number of cases is undoubtedly far higher.

The anticholinergic effects of jimson weed are attributed to the atropine, hyoscyamine, and scopolamine components. Symptoms of jimson weed toxicity usually occur within 30 to 60 minutes after ingestion. Initial symptoms include hallucinations, dry mucous membranes, thirst, dilated pupils, blurred vision, and difficulty speaking and swallowing. Subsequent effects may include tachycardia, urinary retention, and ileus. Rarely, late symptoms may include hyperthermia, respiratory arrest, and episodes of seizure. Slowing of gastrointestinal motility may prolong elimination of the toxin, thus causing symptoms to persist for 24 to 48 hours.

Classic anticholinergic symptoms include mydriasis; dry, flushed skin; hallucinations; agitation; hyperthermia; urinary retention; delayed intestinal motility; tachycardia; and episodes of seizure. The mnemonic for anticholinergic symptoms—blind as a bat, dry as a bone, red as a beet, mad as a hatter, and hot as a hare—thus applies well to jimson weed poisoning.

Effective treatment of jimson weed poisoning requires a primary survey, clinical evaluation and recognition, elimination of the poison, supportive treatment, and continuing observation. The primary survey includes assessment of the ABCs—ie, airway, breathing, and circulation. Although rare, some patients with jimson weed intoxication may be seen for episodes of seizure or coma. If compromise of the airway is suspected, prompt intubation and mechanical ventilation are indicated.

A detailed history and physical examination results obtained after the patient’s condition is initially stabilized can often give clues leading to a diagnosis of anticholinergic toxidrome, even if jimson weed poisoning is not immediately identified. A common presenting complaint is altered mental status. The patient may have visual hallucinations, auditory hallucinations, or both. Physical examination may show tachycardia and elevated blood pressure. Hyperpyrexia is seen in about 20% of the cases. Other manifestations include mydriasis, blurred vision, decreased bowel sounds, and dry mucous membranes.

A toxicology screen is useful to rule out concomitant use of other drugs. Most documented lethal cases of jimson weed ingestion occur in persons with polysubstance abuse, including use of jimson weed combined with alcohol, marijuana, or cocaine. Drug screens usually do not detect pure anticholinergic poisons, and other laboratory tests are usually not helpful for identifying jimson weed as the cause of symptoms.

Absorption of jimson weed may be minimized either by using an agent that binds to the toxins or through removal of gastric contents by inducing emesis or administering gastric lavage. Activated charcoal binds to the toxins in jimson weed and decreases overall absorption of these toxins. The usual oral dose of activated charcoal for adults is 1 g/kg. If medical attention is sought within several hours after ingestion or if the patient has been intubated, removal of the ingested plant by gastric lavage can be considered. Emesis may be induced by using syrup of ipecac if the patient is awake and relatively alert. The usual dose of ipecac is 30 ml for adults and 15 ml for children.

Among initial assessment and attempts to eliminate the toxin from the gastrointestinal tract, most cases of jimson weed poisoning can be managed simply with observation until symptoms resolve. However, cardiac monitoring, serial recording of vital signs, and serial neurologic assessment are important for detecting occasional occurrence of life-threatening events and for establishing resolution of symptoms. Serial examinations usually indicate improvement within 24 hours, and most patients need less than 48 hours of observation.

Patients with anticholinergic poisoning should be observed by using a cardiac monitor because of the risk for tachyarrhythmia from inhibition of vagal effect on the sinoatrial node. Propanolol may be used for treating symptomatic tachyarrhythmia; the dosage for adults is 1 mg given intravenously for one minute and repeated every five minutes (maximum dose, 5 mg); the dosage for children is 0.01 to 0.1 mg/kg, (maximum dose, 1 mg).

Patients also need close observation for hyperpyrexia and convulsions, because either condition can be fatal. Cooling measures (eg, sponging or a cooling blanket) may be used to treat hyperpyrexia, and intravenous fluid resuscitation may prevent this complication. Convulsions may be treated initially with benzodiazepine therapy. Hypertension is usually transient and usually does not necessitate pharmacologic intervention unless hypertensive crisis is suspected.

In severe cases in which patients have symptoms of anticholinergic crisis (eg, dysrhythmia, coma, seizures, clinically significant hypertension, or poorly controlled hyperpyrexia), the use of physostigmine is
antipsychotic and sedative drugs) can worsen symptoms of jimson weed poisoning.

The mnemonic for anticholinergic symptoms—“blind as a bat, dry as a bone, red as a beet, mad as a hatter, and hot as a hare.”

Benzodiazepine therapy is the main treatment for acute agitation, and use of restraints may be necessary to avoid injury to the patient or hospital staff. Clinicians must remember that drugs with anticholinergic properties (eg, some antipsychotic and sedative drugs) can worsen symptoms of jimson weed poisoning. Agents such as haloperidol or chlorpromazine can exacerbate agitation, and psychosis and should therefore be avoided.

**Conclusion**

Jimson weed poisoning produces classic anticholinergic symptoms, is usually self-limiting, and usually requires only supportive measures and observation. Recognizing the signs and symptoms of anticholinergic poisoning can help clinicians identify the toxidrome early and intervene appropriately in life-threatening cases, which occur rarely. High levels of jimson weed ingestion may produce dangerous medical conditions, such as cardiac arrhythmia, hyperpyrexia, seizures, coma, and respiratory arrest. Physostigmine is the preferred treatment for severe cases of jimson weed poisoning, and benzodiazepine therapy is the preferred treatment for agitation. Anticipatory counseling, especially around summer and early fall (when the jimson weed plant matures), may help deter adolescents from experimental use of this plant.

**Practice Tips**

Jimson weed is popular among adolescents curious about the plant’s hallucinogenic effects.

Anticipatory counseling for teenagers and parents may also prevent experimentation and resultant harm.

Jimson weed reaches a height of five feet and consists of large, jagged leaves and trumpet-shaped white or purple flowers.

Intoxication results in anticholinergic effects. Initial symptoms include restlessness, shaking, hallucinations, dry mucous membranes, thirst, dilated pupils, blurred vision, and difficulty speaking and swallowing.

The mnemonic for anticholinergic symptoms—“blind as a bat, dry as a bone, red as a beet, mad as a hatter, and hot as a hare.”

Treatment may include: activated charcoal, emesis, cardiac monitoring, propanolol, cooling measures, benzodiazepine and physostigmine.

**References**


**Acknowledgment**

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How Can We Integrate Alternative Approaches and Mainstream Medicine to Treat Chronic Low Back Pain?

Introduction
Our patients are using alternative approaches to medical problems—both common and rare—and are spending more money per year on alternative therapy than they do on traditional medicine. Unless we ask, we often are unaware that our patients are using alternative therapy. Alternative approaches, when integrated into mainstream medicine, often broaden our treatment options, an advantage which is especially true when treating chronic pain.

The Case
A 64-year-old man who received disc surgery eight years ago was seen recently for failed back syndrome (impairment and disability after back surgery). Pain, which had worsened six months before without an inciting event, limited him to light duty at work and prevented him from getting a sound night’s sleep. Initial diagnostic evaluation included evaluation by the departments of neurology, rheumatology, physical medicine, and rehabilitation and physical therapy. Examination results were normal, except for musculoskeletal strain and indefinite mild radicular symptoms. No bladder, bowel, or sexual dysfunction was noted. X-ray films showed no abnormalities except some age-related arthritis. The patient did not exercise, nor had he kept up with the back-strengthening program recommended to him by physical therapy after his disc surgery. The patient was moderately obese and smoked about half a pack of cigarettes a day.

Diagnostic Evaluation
This patient profile is familiar, as is the frustration of trying to help these patients. There is little left to add to the evaluation at this point. I always do a physical examination because there may be a new finding and because patients may expect an examination. Normal examination results reassure me that I am going in the right direction. For this patient, there are no additional findings from the physical examination.

Treatment
I spend most of my time with this patient discussing lifestyle issues—in this case, the issues are traditional, although handled slightly differently than in traditional practice—and I make suggestions about alternative therapy appropriate to integrate into his care.

My six-pronged approach to treatment:
1. Lifestyle issues: Recommend weight reduction, increasing exercise, and smoking cessation.
2. Biopsychosocial: Discuss job satisfaction and workplace ergonomics.
3. Cognitive and behavioral program: Address patient’s pain and decreased functional status (ability to work).
4. Supplements: Prescribe glucosamine HCl.
6. Devices: Consider using transcutaneous electrical nerve stimulation (TENS) unit.

Lifestyle issues
I spend time probing the patient’s motivation and readiness to change. I explain that patients who change lifestyle behaviors are most often motivated by:
1. fear (example: fear of poor health)
2. bargaining for rewards (example: If I exercise, I will hurt less.)
3. mentor factor (example: If I quit smoking, I will be a better role model for my kids.)
4. ego (example: If I lose weight, I will be more attractive.)
5. peer pressure

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6. relationship to a higher being
7. personal or other

In this case, I ask the patient if he has a sense of a previous successful style of change—big or small, fast or slow. For example, did he cut back on his smoking all at once or by one cigarette a day? I ask him to consider how ready he is to change now. At the end of the visit, I ask him to go home and spend some time thinking about previous motivators for change.

I will probably not persuade a patient to start doing back exercises unless the patient is ready to do them. I rely on the physical therapy department to teach exercises to the patient; I rely on my relationship with the patient to help identify barriers to exercising. My expectation is that the patient will make only limited progress on one lifestyle change after this visit. I schedule another visit three to six weeks later to discuss the patient’s progress. At that visit, I reassure the patient that limited progress is not failure and that we just need to figure out the next barrier to change. Often, just getting a patient to think about changing lifestyle behavior is the biggest step.

Biopsychosocial

We know from the literature that job satisfaction is directly related to improving back pain. Therefore, I spend a few minutes reviewing the patient’s work situation, including job satisfaction and autonomy. If the patient is clearly unhappy, we spend some time reviewing options.

We might also review workstation ergonomics: adjusting chair height, adding wrist rests (to computer keyboards) or lumbar supports, or making other ergonomic changes may improve low back pain.

Cognitive and behavioral education program

Most Kaiser Permanente (KP) regions have these programs, which may be called chronic pain or chronic disease self-management programs or may be known as mindful meditation or mindful movement programs. Programs consist of two- to three-hour weekly or biweekly sessions held during six to ten weeks and are led by a multidisciplinary group of trained patient leaders, behavioralists, physicians, or any combination. Members with a variety of ailments participate (mixed disease model). Programs provide education about chronic conditions and chronic pain and teach patients self-management and relaxation response techniques. Numerous studies show that the body’s response to stress and pain can be changed using the relaxation response, the medical term applied to nonreligious meditation.

Supplements

Glucosamine has clinical evidence to support its use for treating osteoarthritis. Glucosamine is available in a plain formulation or combined with chondroitin sulfate. Initially, I prescribe plain glucosamine for three months at the following dosage: 1000 mg three times daily (tid) for the first two weeks (loading dose) followed by 500 mg tid for ten weeks. Bone remodeling, determined on the basis of subjective improvement of symptoms (not x-ray examination), takes three months to occur. For some patients, the improvement will be 20%, for others 80%. I have yet to be able to predict who will respond and, if so, by how much.

Patients whose condition improves by taking glucosamine must realize that sustained improvement depends on taking glucosamine for the rest of their lives. Because the supplement costs about $30 a month and is not covered by insurance, I check to make sure that my patients are taking a brand of glucosamine containing the active ingredient and whose manufacturer guarantees certain standards of product cleanliness and purity.

Because the supplement and herbal product industry is not well regulated, I ask the patient to use either the brand we carry at KP or a brand that is adequately rated by an independent testing lab and reviewed in www.consumerlab.com. (See sidebar for other reliable Web sites for information on supplements and herbal products.)

Numerous studies show that the body’s response to stress and pain can be changed using the relaxation response ...
Manual therapy

If a patient has spine-related back pain but does not have a disc herniation, fracture, trauma, cancer, or other contraindication listed in the Mid-Atlantic Permanente Medical Chiropractic Referral Guidelines, I recommend a trial of manipulative or chiropractic care. If the patient has no improvement within four to six visits, I have the patient discontinue the trial therapy and reassess the choice of manual manipulation.

A variety of massage techniques may be beneficial for back pain. Massage therapy is not a member benefit in any KP region except for its Northwest Region, where state governments mandate that it be included in benefits. I recommend that patients receive deep-tissue or Swedish massage, and I instruct patients to communicate clearly with the massage therapist (before and during the massage) about the degree of pressure that is comfortable.

Acupuncture

A variety of different types of acupuncture exist, including Chinese traditional, Japanese, Korean, and French Energetics. For a trial of six to eight treatments, I have no preference as to the type of acupuncturist—physician or nonphysician. Some data suggest that electroacupuncture may provide more benefit than simple acupuncture; acupressure and shiatsu using the traditional acupuncture ashi points may also be beneficial. I do not believe that underlying structural abnormalities, such as spinal stenosis, can be changed with acupuncture, but the pain such conditions cause might be alleviated.

Devices

Two devices, a TENS unit and a magnet, have been found useful for a few patients. The evidence in the literature is not strong for efficacy of TENS units, but some people feel this form of electrotherapy helps.8 Magnets, on the other hand, have NOT proved to help alleviate mechanical back strain.9

Summary and Followup

For this patient, I recommend weight reduction, smoking cessation, exercise, taking supplements (glucosamine), and attending a cognitive-behavioral mindful meditation movement program. About halfway through a six- to ten-week program, I recommend starting either manual therapy or acupuncture. If the patient is resistant both to starting any lifestyle change and to attending a pain program, I recommend either acupuncture or manual therapy and schedule a follow-up appointment in a month. I use that appointment as a chance to reassess the patient’s barriers to changing lifestyle behavior that interferes with recovery.

References:

Tense Muscles

Holding onto anger only gives you tense muscles.

Joan Lunden, Television personality and author
The Macrobiotic Diet as Treatment for Cancer: Review of the Evidence

By Joellyn Horowitz, MD

More recently, macrobiotics has come to mean a dietary regimen used to prevent and treat many diseases; in this sense, its more philosophical aspects are somewhat de-emphasized. In addition to the dietary provisions of macrobiotics, however, other applications of macrobiotic principles—eg, increased emphasis on physical activity; minimized exposure to pesticides, other chemicals, and electromagnetic radiation; and stress reduction—may also be beneficial for cancer prevention.1,2

Because the philosophy of macrobiotics promotes the concept that phenomena are universal and interrelated, the practice of macrobiotics engenders respect for the spiritual nature of life—a view that bolsters the morale of cancer patients.1 Patients adhering to this lifestyle necessarily take an active role in their own treatment, ie, by making necessary lifestyle modifications. Actively participating in their own treatment restores a sense of power that is sometimes squelched by conventional treatment, much of which is inherently disempowering because it can cause overwhelming pain and debilitation. Emphasizing patient spirit and power may be important for cancer prevention and patient survival as well as for improving the quality of life for people with cancer.3,4

I found this patient to be a very pleasant gentleman whose wit and humor were evident from the moment I sat down to interview him. I could also see an intelligence behind his sparkling eyes, so it came as no surprise to find that he wished to actively participate in making decisions about his treatment. Immediately after learning of his diagnosis, he began researching his illness on the Internet, in the library, and in the medical section of his local bookstore. He had decided to try the macrobiotic diet after reading a 1982 book titled Recalled by Life: The Story of My Recovery from Cancer, Dr Anthony Sattilaro’s autobiographical account of overcoming metastatic prostate cancer.7

Macrobiotic Dietary Guidelines

The macrobiotic diet first introduced to the United States by George Ohsawa consisted of ten progres-
sively restrictive stages; in the final stage, only brown rice and water were permitted. Not surprisingly, this version of the diet was associated with reported cases of scurvy, anemia, low blood protein, low blood calcium levels, emaciation, renal failure, and death. Kushi reformulated and popularized macrobiotics in the United States by emphasizing a high-complex-carbohydrate, low-fat diet that is tailored to meet individual needs, depending on age, sex, activity level, personal needs, and environment.

The diet consists of five categories of foods (with recommended weight percentage of total food consumed):

- Whole cereal grains (40%-60%), including brown rice, barley, millet, oats, wheat, corn, rye, and buckwheat; and other less common grains and products made from them, such as noodles, bread, and pasta.
- Vegetables (20%-30%), including smaller amounts of raw or pickled vegetables—preferably locally grown and prepared in a variety of ways.
- Beans (5%-10%), such as azuki, chickpeas, or lentils; other bean products, such as tofu, tempah, or natto.
- Regular consumption of sea vegetables, such as nori, wakame, kombu, and hiziki—cooked either with beans or as separate dishes.
- Foods such as fruit, white fish, seeds, and nuts—to be consumed a few times per week or less often.1,2

The standard macrobiotic diet avoids foods that include meat and poultry, animal fats (eg, lard and butter), eggs, dairy products, refined sugar, and foods containing artificial sweeteners or other chemical additives. All recommended foods are preferably organically grown and minimally processed. Consumption of genetically modified foods is also discouraged. For people with cancer, these restrictions may be absolute for a period of time until some recovery has occurred. Several personal accounts describing individual applications of the diet detail the initial period of the diet—in which all animal foods and fruit are avoided—followed by periods in which these foods are reintroduced into the diet.

**Potential Risks of the Macrobiotic Diet**

Cases of infants with symptoms of malnutrition (including deficiency of vitamins B12 and D) have been reported in the medical literature. The possibility of such types of nutritional deficiency has been documented in systematic surveys of groups of infants and families who followed a macrobiotic lifestyle. These studies of nutritional status—primarily in infants or in growing children—have formed the basis for most warnings against use of macrobiotic diets to treat cancer. Assuming that any appropriate treatment minimizes nutritional deficiency, many physicians believe that imposition of the dietary restrictions is potentially dangerous for patients who are already losing alarming amounts of weight. In contrast, these nutritional restrictions have been proposed to help slow progression of cancer by starving the rapidly reproducing cells responsible for the disease.

Dr Sattilaro was a 49-year-old physician when he was diagnosed with prostate cancer, which had already metastasized to several bones. His prognosis was very poor—he had multiple metastases—so he decided to treat himself with the macrobiotic diet. After a year of adhering to the diet, results of Dr Sattilaro’s follow-up examination showed complete resolution of the bone metastases. He continued the diet and remained cancer-free at followup three years later.

Even before the patient related to me Dr Sattilaro’s story, I was familiar with it, having learned of it while researching the macrobiotic diet during my second year of medical school. At that time, I was taking an elective class in complementary/alternative medicine (CAM). The class exposed me to similar stories of patients who recovered from cancer after using macrobiotic dietary therapy. These stories appeared in such books as Dr J Kribler’s (1979) Healing Miracles from Macrobiotics; M Kushi’s (1983) The Cancer Prevention Diet; V Brown and S Stayman’s (1984) Macrobiotic Miracle: How a Vermont Family Overcame Cancer; H Faulkner’s (1993) Physician, Heal Thyself; E Nussbaum’s (1992) Recovery from Cancer; and Cancer-Free: 30 Who Triumphed Over Cancer Naturally (1991) by The East West Foundation with A Fawcett and C Smith.

**Does the Macrobiotic Diet Have Anticancer Properties?**

According to the 1997 report produced by the American Institute for Cancer Research and the World Cancer Research Fund, increasing daily consumption of vegetables and fruit from 250g to 400g may lead to 20% fewer cases of cancer worldwide. An increasing collection of evidence suggests that consumption of whole grains can reduce the risk of cancer at various anatomic sites. Studies of rats have suggested that consumption of sea vegetables (dietary seaweed) may decrease the risk of breast cancer. Given that macrobiotics endorses a diet high in consumption of vegetables and whole grains, a logical assumption is that the practice of macrobiotics should also reduce the risk for cancer. However, few studies specifically suggest macrobiotics as an effective cancer prevention...
method. A few studies comparing two populations of women—those who eat a vegetarian or a macrobiotic diet and those who eat a typical US diet—suggest differences in estrogen metabolism between these two populations and, that a vegetarian or macrobiotic diet may affect estrogen metabolism in ways that reduce the risk for hormone-dependent forms of cancer, including breast and prostate cancer.

The data are even more limited regarding macrobiotics as effective treatment for patients who already have cancer (ie, the focus of the present literature review). Much of the evidence is purely anecdotal, consisting of individual cases reported by those affected. Only one published study attempted to obtain more systematic information regarding efficacy of the macrobiotic approach to cancer, and that study was severely hampered by its retrospective design.33 No prospective or randomized controlled clinical trials on the subject have been published.

The only published study in the peer-reviewed medical literature was conducted by Gordon Saxe while a graduate student at Tulane University under the direction of James Carter.33 The study had two components: one that focused on primary pancreatic cancer and another that focused on advanced prostate cancer. All study subjects had sought advice about macrobiotics from a certified counselor. Records maintained by macrobiotics counselors were used to identify 101 people who had seen a counselor for pancreatic cancer during the period extending from 1980 through 1984. Attempts were made to recontact these people, and 28 of them (or their next of kin) were reached. Of these 28 respondents, 23 reported that a macrobiotic diet had been followed for at least three months. Median survival of the 23 persons who had followed a macrobiotic regimen was 13 months after diagnosis; in contrast, median survival was three months for pancreatic cancer patients enrolled in the National Cancer Institute’s Surveillance, Epidemiology, and End Results (SEER) program.33

Unfortunately, the Tulane report was flawed. Comparison of survival times was biased in favor of macrobiotics. Most important, the 23 persons in the macrobiotic series must have had to survive at least three months to be included. As noted in the SEER data, 50% of all people diagnosed with pancreatic cancer are dead at three months after diagnosis. Lack of information on other factors that may influence survival in both the macrobiotic and control groups also limits interpretability of the Tulane study.

The prostate cancer component of the Tulane study was similarly flawed: The nine patients with prostate cancer who adhered to a macrobiotic diet had a median survival of 228 months compared with a median survival of 72 months in matched control subjects. The study did not clearly identify the criteria by which control subjects were matched or how they were selected.33

I told the patient about the existing data and referred him to the available literature. A month later, the same patient opted to receive the prostatectomy surgery. The cancer had not yet spread to local lymph nodes at that time. Although not eating a strictly macrobiotic diet when I last saw him (four months after the surgery), he was continuing to eat a diet high in vegetables and low in animal fat because he believed that this regimen gave him more energy. His postoperative urinary incontinence was improving with use of Kegel exercises, and his oncologist was expecting the cancer to resolve completely.

Summary
Given the anecdotal and flawed nature of the few data currently available, the efficacy of the macrobiotic diet as a treatment for cancer is impossible to determine at this time. We should also keep in mind (in the case of the 63-year-old man described above, for example) that conventional screening tools for identifying prostate cancer have not been definitively shown either to enhance or to extend life. Moreover, screening for prostate cancer (ie, when and how often to screen, which tools to use) is a contentious topic among medical experts. On the basis of their individual preferences and experience, each physician with whom I have had the opportunity to work has offered different advice on the subject. Nonetheless, although the medical literature currently available does not show that macrobiotics extends the life of cancer patients, we must keep in mind that few data are available and that further investigation is warranted.

Practice Tips
Macrobiontcs has come to mean more than just a way of eating and includes increased emphasis on physical activity; minimized exposure to pesticides, other chemicals, and electromagnetic radiation; and stress reduction.

The diet consists: whole cereal grains, vegetables, beans, sea vegetables, fruit, white fish, seeds, and nuts.

According to the 1997 report produced by the American Institute for Cancer Research and the World Cancer Research Fund, increasing daily consumption of vegetables and fruit from 250g to 400g may lead to 20% fewer cases of cancer worldwide.

Acknowledgment
Beatrice Golomb, MD, Department of Geriatrics, University of California San Diego School of Medicine, reviewed the manuscript.
References


Walking through a fish market on the Potomac, in Washington, DC, Dr Abdalla was attracted by the orderly arrangement of these crabs. More of Dr Abdalla’s work can be seen on pages 6 and 77.
Successful Practices in the Physician Work Environment: We Work Together

Permanent physicians seek to provide patients with excellent clinical care and an excellent service experience during brief office visits. However, many patients have heightened expectations for service, and some have preformed beliefs about their diagnosis and treatment. There is great variability in how well departments, modules, and teams respond to this and other challenges to achieve high patient satisfaction while building a positive work environment. This research asks what practices distinguish “teams” (departments, modules, or teams) that both enjoy a positive work environment and excel at satisfying patient expectations.

Identification of Successful Practices

The Physician Work Environment Workgroup of the Interregional Care Experience Council conducted focus groups in three regions to identify successful practices in the physician work environment. The central focus was identification of practices that discriminate “highly rated” teams (those with high scores on patient visit satisfaction and physician satisfaction surveys) from “medium-rated” or “low-rated” teams (those with medium or low patient and physician satisfaction scores). Physician satisfaction was defined as the average team rating on five physician survey items previously shown to be correlated with satisfaction. Members of the Physician Work Environment Workgroup are listed in Table 1.

The Work Environment

The Care Experience Council is dedicated to identifying actions leaders can take to improve service. The work is grounded in the KP Results model. Similar models have been supported by research in service industries. The KP Results model hypothesizes causal linkages between leadership actions, the work environment, patient satisfaction, and outcomes:

<table>
<thead>
<tr>
<th>Leadership Actions</th>
<th>Work Environment</th>
<th>Patient Satisfaction</th>
<th>Clinical &amp; Business Outcomes</th>
</tr>
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</table>

This model implies that a positive physician work environment is essential for retaining and recruiting physicians, for patient satisfaction, and for promoting important outcomes. Kaiser Permanente (KP) research has identified evidence for a link between the work environment and patient satisfaction.

Methods

Physicians and researchers from the Physician Work Environment Workgroup conducted 20 focus groups in Georgia, Hawaii, and Colorado. The teams were asked questions related to what makes them feel supported to satisfy patients and the role of their local physician-leader in that support them. In Georgia and Hawaii, the participants were physicians, local physician-
leaders, associate providers, and staff in teams. In Colorado, physicians and local physician-leaders from departments participated.

**Findings**

Five categories of successful practices that distinguished between highly rated teams and medium- or low-rated teams emerged from a qualitative analysis of the transcripts. Physicians in the highly rated teams use these five successful practices (Table 2).

The highly rated teams use all five practice categories, whereas the medium and low-rated teams tended to use fewer practice categories or use them less consistently. Contrasting features of highly rated teams and medium- and low-rated teams are displayed in Table 3. Quotes from physician team members exemplified each category of successful practice (Table 4).

The following are descriptions of the five successful team practice categories.

### Table 2. Five successful practice categories

<table>
<thead>
<tr>
<th>Practice Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Connect guiding principles and values to daily work.</td>
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<tr>
<td>2. Demonstrate physician leadership by example.</td>
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</tr>
<tr>
<td>3. Emphasize team development to create support through interdependence.</td>
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<tr>
<td>4. Set goals within team's sphere of influence.</td>
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<tr>
<td>5. Provide recognition and constructive feedback.</td>
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</tbody>
</table>

1. **Connect principles and values of team and region to daily work**

   Highly rated teams use the guiding principles and values from the region and from the team to guide daily decision making, align goals, and motivate the team. The most effective principles and values are simple and easily applied to daily work (eg, “First in quality, first in service,” “Treat patients and team like family”). At decision points, members of the team deduce what

### Table 3. Contrasting practices of highly rated vs medium- or low-rated teams

<table>
<thead>
<tr>
<th>Team practices</th>
<th>Practices of highly rated Teams (high physician and patient satisfaction scores)</th>
<th>Medium- or low-rated teams (medium or low physician and patient satisfaction scores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connect principles and values of team and region to daily work</td>
<td>Use principles to solve problems, align goals, &amp; unify team (eg, “Treat patients &amp; team like family,” “First in quality, first in service”)</td>
<td>Lack connection of principles to daily work</td>
</tr>
<tr>
<td>Leverage principles and values</td>
<td>Value patients and team (spend time in team and individual development, eg, training, meetings, consultants, and facilitators)</td>
<td>Focus primarily on patient satisfaction</td>
</tr>
<tr>
<td>Service beliefs</td>
<td>Believe clinical and service quality are compatible goals</td>
<td>Believe quality and service are mutually exclusive</td>
</tr>
<tr>
<td>Model expected behavior</td>
<td>Physicians communicate high standards, exemplify (not just talk about) what is expected</td>
<td>Less conscious of effects of modeling on each other</td>
</tr>
<tr>
<td>Address complaints and translate into plans</td>
<td>Include staff and Associate Providers (APs) in decisions — “Everyone has a voice”</td>
<td>Lack staff and AP input in decision making</td>
</tr>
<tr>
<td>Physician-leader sets clear direction</td>
<td>Physic-ian-leader’s direction is less clear</td>
<td></td>
</tr>
<tr>
<td>Emphasize selection</td>
<td>Emphasize selection for team fit—they will wait for the right person</td>
<td>Less emphasis on team fit</td>
</tr>
<tr>
<td>Role clarity</td>
<td>Know roles of all team members (permit interdependency)</td>
<td>Have less clarity on roles of others</td>
</tr>
<tr>
<td>Inclusiveness</td>
<td>Be respectful—use input from all team members</td>
<td>Have a physician-centered hierarchy</td>
</tr>
<tr>
<td>Interdependence</td>
<td>Support each other so all can finish on time</td>
<td>Have individuals struggling alone in silos</td>
</tr>
<tr>
<td>• Feel they are “in this together,” so they can “give up the turf”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Track performance</td>
<td>Use team-level data to track performance, including team satisfaction</td>
<td>Tend to track patient satisfaction only</td>
</tr>
<tr>
<td>Team identity</td>
<td>Have meaningful, positive team identities</td>
<td>Lack a positive team identity</td>
</tr>
<tr>
<td>Set goals within team’s sphere of influence</td>
<td>• Clarify scope of team influence</td>
<td>Set sights too high (eg, regional decisions)</td>
</tr>
<tr>
<td>• Pursue goals within sphere of influence (start small)</td>
<td>Have more team influence</td>
<td></td>
</tr>
<tr>
<td>Source of improvement</td>
<td>Take responsibility for improvements, but use outside help (training, analytical support, consultants, leaders)</td>
<td>Look outside of team for improvement</td>
</tr>
<tr>
<td>Recognize</td>
<td>• Convey verbal, individualized, 1:1 recognition from members and patients</td>
<td>• Have insufficient recognition</td>
</tr>
<tr>
<td>• Make staff and associate provider recognition a priority</td>
<td>• Fail to convey patient comments to team</td>
<td></td>
</tr>
<tr>
<td>• Provide recognition at the team level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constructive feedback</td>
<td>• Address interpersonal concerns in a timely manner</td>
<td>Tolerate interpersonal problems</td>
</tr>
<tr>
<td>• Give learning feedback to all (even physicians)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
is required from the principles and own their decisions. An example of a concept that guides highly rated teams is the belief that service and quality are compatible, not mutually exclusive, goals.

2. Demonstrate leadership by example

Physicians in highly rated teams model expected behaviors. They demonstrate—rather than ask for—exemplary behavior. Physicians and physician-leaders set the tone and direction for the group. Physicians give everyone in the team a true voice in decisions and empower nurse-leaders to participate.

A proactive, positive attitude is present in these teams. The positive physician example reaches the team members, who then reflect the modeling in their interactions with patients. In turn, physicians are cheered by the good examples set by team members. Positive patient comments to the team complete the feedback cycle.

In highly rated teams, physicians make timely team alterations. They set expectations for performance and manage to meet them. The team addresses interpersonal challenges rather than permitting them to undermine the team’s functioning. The physicians anticipate and plan for upcoming changes instead of reacting to them.

This research was designed to identify practices that discriminate between the highly rated teams and the medium- and low rated teams. However, one identified leadership practice benefited all teams in one region: having open communication with the regional leadership team. The physicians appreciated this practice and were empowered both by board updates in the facilities and frequent, small group meetings with leadership. These meetings were especially valuable because the physicians felt free to ask direct questions about tough issues—the “elephants in the room.”

3. Emphasize team development to create supportive interdependence

Interdependence is working in a group as though you could not work without each other. These teams think as a system and distribute the workload across the team. Pervasive use of the word “we” is the most definitive sign of a highly rated team. Functioning in an interdependent manner is associated with reduced stress, a more predictable workday, and freedom from the feeling of having to carry the burden alone. Team members “jump in to help others.” They get up and walk around to determine who needs support. Everyone works together to provide an excellent experience for patients and have a more orderly workday than when they worked more autonomously. Team members jointly examine and deal with problems and improve processes together. In time, highly rated teams develop a positive team identity, consistent with the team’s principles and values. They are aware of the value and uniqueness of their team. Successful team development is associated with an emphasis on at least five foundational elements, which appear in Table 5.

4. Set goals within the team’s sphere of influence

Teams that aspire to change major policies and programs outside the team’s sphere of influence are vulnerable to becoming demoralized. Highly rated teams do not spend their energy trying to change the system; instead, they start with small, realistic goals. They get involved with making improvements instead of assigning blame and looking outside the team for a better work environment. By aspiring to achievable goals, team members increase their odds for success and build influence and control over their work environment. Success breeds more success.

5. Provide recognition and timely, constructive feedback

Feeding back information to all work group members is observed

Table 4. Physician quotes exemplifying the five successful practices

<table>
<thead>
<tr>
<th>Successful practices</th>
<th>Physician quotes from the teams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connect principles and values of team and region to daily work</td>
<td>“We have the perspective that if you’re delivering quality care, then your patient satisfaction should be up there too.”</td>
</tr>
<tr>
<td>Demonstrating physician leadership example</td>
<td>“Years ago, we decided to stop looking at what providers wanted, or what nurses or MAs wanted, and went back to the focus of ‘What is the best thing for the patient?’ ... How are we going to make the patient’s process smoother, more efficient, make them happier with the experience?”</td>
</tr>
<tr>
<td>Emphasizing team development</td>
<td>“(The physician lead) comes in happy to be here. He never complains about too much business.”</td>
</tr>
<tr>
<td></td>
<td>“He is fair ... He wouldn't ask me to do something he doesn't do himself.”</td>
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<tr>
<td></td>
<td>“Our team lead has a style you want to emulate. You want to be like him ... He praises us ... and he sets the tone with everybody on the team.”</td>
</tr>
<tr>
<td>Setting goals within the team’s sphere of influence</td>
<td>“I spend a lot of time telling people that we have to be clear about what our influence is, and about what we can expect, and what we can’t expect. I have no problem with telling people ‘that’s something we can’t control.’”</td>
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<tr>
<td></td>
<td>“We have discussions outside team meetings. We look at our [quality and service scorecard] and figure out how we can improve things ... to help the whole team improve quality.”</td>
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<tr>
<td></td>
<td>“We look for small successes. We look for things we can work on and fix.”</td>
</tr>
<tr>
<td>Providing recognition and constructive feedback</td>
<td>“At the end of the day, [the physician lead] says ‘thanks for your hard work. I appreciate it’ ... simple comments about the day several times a week.”</td>
</tr>
<tr>
<td></td>
<td>“When I first started, I had a reputation of reducing each nurse to tears at some point ... but I got through all that ... they were honest enough to tell me.”</td>
</tr>
<tr>
<td></td>
<td>“When a patient says ‘Thanks for saving my life,’ that makes my month. Patients who have the perspective that ‘I’m going to work on and fix’”</td>
</tr>
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</table>
in the highly rated teams. Simple, verbal recognition received from a patient or team member is the most valued recognition. The physicians want to know that their effort and time are noticed. Public recognition given at large events, while valued by some, is not as helpful as simple comments by leadership and colleagues. Financial rewards are not consistently motivating. When interpersonal discord disrupts the work, highly rated teams deal with the problem in a timely manner, even if a physician is the disruptive team member.

Table 5. Elements associated with strong team functioning

<table>
<thead>
<tr>
<th>Selection for team fit and balance</th>
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</thead>
<tbody>
<tr>
<td>Role clarity (knowledge of the roles of self and others)</td>
</tr>
<tr>
<td>Inclusive decision making</td>
</tr>
<tr>
<td>Interdependency (knowing and working with each other)</td>
</tr>
<tr>
<td>Performance tracking using team-level data</td>
</tr>
</tbody>
</table>

Conclusions

Teams with the highest levels of physician and patient satisfaction are distinguished by rich interdependence, in which all team members actively support each other on a daily basis. Conceptually, they are guided by principles and values and have realistic, attainable aspirations. The activities of these team members are focused on strengthening the team and setting a positive example for each other while caring for patients. In addition, regular recognition and constructive feedback is provided to sustain day-to-day team functioning. Medium-rated and low-rated teams addressed some practice categories but did not consistently address all categories.

The highly rated teams were not identical to each other. Each highly rated team found its own unique way to use the five categories of successful practice. These teams discovered multiple routes to success.

Leaders and Bosses

People ask the difference between a leader and a boss …

The leader works in the open, and the boss in covert.

The leader leads, and the boss drives.

Theodore Roosevelt, 1858-1919, 26th President of the United States

References

Tools of the Trade
By John J Kuiper, MD, FACP

Dr Kuiper was an internist and nephrologist with SCPMG in Panorama City for 26 years; since retirement, he has continued teaching and research at the UCLA Medical Center. Upon completion of a drawing class, Dr Kuiper rendered this 16x20-inch graphite on paper drawing of medical equipment that, with the exception of the newer stethoscope, served him for 43 years.
Symposium on Complementary and Alternative Medicine: In the Era of Evidence-Based Medicine, What’s a Physician to Do?

Introduction

Dr Jacobs: I want to welcome you all to this landmark morning for our [The Southeast Permanente] Medical Group. This session is noteworthy because this is the first time The Southeast Permanente Medical Group (TSPMG) has made a concerted effort to understand Complementary and Alternative Medicine (CAM) so that a dialogue can begin among the members of our organization. Just what does CAM include? How do we relate to our patients about complementary medicine? How do we integrate CAM into our practices and maintain an evidenced-based focus? These are the questions that this symposium will address.

Why is this Discussion Important to Physicians?

Although there are many reasons why we might benefit from understanding CAM, in my mind, two reasons stand above the others.

First, we want to maintain an open communication channel with our patients. We want them to be very comfortable in telling us what medications they are taking, because what they are taking or doing may have real clinical ramifications. However, we must be open and listen without prejudice; otherwise, they won’t tell us! If patients don’t feel comfortable, they won’t tell us what they are taking and why, in turn, they might not be taking what we prescribed.

Second, we may not be offering patients all potentially beneficial therapeutic options. Both a fully informed physician and a fully informed patient are certainly essential if shared decision making is to exist.

Introducing Panel Experts

First, I would like to introduce Paul Wallace, MD, Executive Director of Kaiser Permanente’s Care Management Institute (CMI), located in Oakland, California. Dr Wallace and CMI are doing absolutely cutting-edge work in evidence-based medicine and in promoting shared decision making. I continue to be impressed with the quality of their work, which I believe is now starting to be acknowledged in the medical community throughout the country. Dr Wallace will help us discuss CAM in the framework of evidence-based medicine.

Next, I would like to introduce Tieraona Low Dog, MD—a nationally renowned expert in the field and no stranger to Kaiser Permanente, as she is frequently invited to lecture on CAM. Dr Low Dog is from New Mexico and has been appointed to the White House Commission on Complementary and Alternative Medicine Policy. Named by Time magazine as an Innovator of Alternative Medicine in 2001, she has spent the past 20 years working to integrate the use of botanical medicines into the current health care system. So we’re thrilled to have Dr Low Dog here this morning to help our dialogue. I think that her national perspective and her understanding of the quality and uses of CAM will be extremely helpful.

Next, I want to welcome and introduce Lee Ballance, MD, a Permanente physician from the Kaiser Permanente Vallejo Medical Center in Northern California and Chief of Alternative Medicine at that facility. Yes, you heard me right: Imagine a medical group taking this subject seriously enough to have a department dedicated to it! We are all eager to hear about how CAM has been integrated into the physicians’ practices in The Permanente Medical Group in Northern California.

Finally, moving from Northern California to the Northwest, I would like to introduce Charles Elder, MD, a physician from the Department of Internal Medicine in the Northwest Permanente Medical Group, where he is Director of Quality Assurance at Kaiser Permanente Sunnyside Medical Center. Dr Elder is a clinical investigator at Kaiser Permanente Center for Health Research, where he does research in mind-body techniques.

So, that is our panel of experts. Let’s get started. I will ask the panel members to present some opening comments, and then the panel will entertain questions from the audience. Let’s start with Dr Wallace.

Lee Jacobs, MD
Moderator
Using Evidence to Understand New Approaches

Background: Making the Right Thing Easier To Do

Dr Wallace: Good morning. During the next few minutes, I’d like to think with you about how we go about knowing what is “right” for our patients, particularly as we encounter new ideas and interventions. First, however, I’d like to provide some brief background so you can know where I’m coming from.

My clinical training is in internal medicine, hematology, and medical oncology, which I practiced over the better part of 20 years. I got involved in producing clinical practice guidelines for a broad range of conditions about a decade ago. Since then, much of my professional focus has moved to aspects of evidence-based medicine and to making it accessible and applicable both for clinicians and for health plan members. I have also had the opportunity to do what is best called “administrative work” around population-based care. In short, I get to participate with a lot of people throughout the [KP] Program to think about how we can take what we know about medicine and apply it more effectively.

The first slide features the mission statement for the place I now spend much of my time and energy, the Care Management Institute (CMI). The mission of CMI is at the core of today’s task: to make the right thing easier.

“How do we manage in a world where not everything can be clear, where not everything can be certain, and where there won’t always be high levels of agreement?”

The First Cautionary Tale: Lessons from the Metastatic Breast Cancer Debacle

I want to share with you a simple definition for evidence-based medicine: I think that evidence-based medicine is being clear and honest about: what you know; what you don’t know, and what you’re going to do about it.

It’s a terrible condition for which clinicians really wanted to offer meaningful treatment while tens of thousands of women were led to believe that they were getting something more effective than what they were actually receiving. This situation violated what we talked about before around evidence-based medicine: It is about being clear about what you know, what you don’t know, and what you’re going to do about it.

I’d like to begin my talk by sharing with you a couple of cautionary tales. The first is the story that was very close to me as an oncologist. It dealt with the role of high-dose chemotherapy and autologous bone marrow transplantation for women with metastatic breast cancer.

As you all recall, this has been quite a contentious topic over the past 15 years—even showing up on the cover of Time magazine—and has been the subject of innumerable lawsuits. Access to this intervention has actually been legislated in several states. The dilemma is that after 15 years of performing these transplants, people get around to actually doing the studies in a way that accounted for the biases inherent in investigating this approach—only to learn that it didn’t work! What a shame; it would have really been nice if the approach had worked, because metastatic breast cancer is a terrible condition for which clinicians really wanted to offer meaningful treatment while tens of thousands of women were led to believe that they were getting something more effective than what they were actually receiving. This situation violated what we talked about before around evidence-based medicine: It is about being clear about what you know, what you don’t know, and what you’re going to do about it.

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There is a major difference between making observations and actually conducting a controlled trial. An associated aspect to this sad story is that the major study cited as showing that this approach to metastatic breast cancer had benefit turned out to be research fraud. I think this fact reflects the pressures that people are under to give the public important new therapeutic options. The South African investigator who produced the study explained why he fudged the data: He thought it so important for people to have this therapeutic option that he made the data look as though the therapy had benefit. If anything violates basic scientific principles, I think that’s it.

So, the cautionary tale here is not that we assume research may be fraudulent but that approaches don’t always work—even when they look as though they should work and when they intuitively appeal to us as beneficial. As physicians, we have a responsibility not only to be clear about what we know but to be equally clear about what we don’t know absolutely. Where I think people “dropped the ball” on the tragic breast cancer story is that we were not mindful of how the data were collected in the early suggestive (but not definitive) studies.

In summary, this breast cancer story highlights a principle that we should consider for any new approach: There is a major difference between making observations and actually conducting a controlled trial. Be particularly cautious of conclusions when existing initial observational data reinforce what we want to happen.

### A Second Cautionary Tale: Hormone Replacement Therapy

The next tale deals with perhaps a more common issue that we deal with in everyday office practice: hormone replacement therapy (HRT). How many people ten years ago used to be cheerleaders for hormone replacement for most women in their 50s? I see most of you raising your hands. And how many of you remain cheerleaders that way today? I see fewer hands being raised.

What happened to make us question that approach? Well, I think that, first of all, the medical community wanted to have something that we could do for women who were having menopausal symptoms. This approach was further encouraged by strongly suggestive information that women who took HRT had a lower incidence of heart disease. However, this observation ended up not being true when the HERS Study, a randomized trial, was published several years ago. After about four years of rigorously looking at randomized groups of women, we recognized that women who had pre-existing heart disease were actually harmed by taking HRT.

What was important about the observational data? Well, one of the challenges is that when we look back at the initially promising observations made in the 1980s, it turns out that many of these observations came from groups of women, many of whom were nurses, who probably had a lower overall risk of heart disease to begin with than the average female population. The study subjects had been self-selected, and the observational design did not make allowances for that fact. A variety of traps weren’t fully controlled. Although, in all likelihood, some women can take HRT safely, I think we have refined our understanding of who might actually benefit from it and who would not benefit—or worse, who is most likely to be harmed from it. So, when you now have a discussion with a woman about the risks and benefits of HRT, you can be much clearer about what we know, what we don’t know, and what we should do.

I don’t mean to imply that we shouldn’t provide therapy when we don’t know all about its approach, but I do mean that we need to be mindful of the traps if we act as though we know more than we actually do. The same lesson applies here as for the breast cancer story: There is a major difference between making observations and actually conducting a controlled trial.

### The Physician’s Mindset and Observations that Don’t Make Sense: Keeping an Open Mind

For many approaches, we neither have randomized control trial data nor are likely to obtain it in the future. Many other approaches introduced go against our intuition. For example, for me it is still difficult to fully reconcile myself with the mental maps that I learned in medical school about the role of *H. pylori* in peptic acid disease. If, during my residency 25 years ago, I had heard that we were going to treat some gastric problems with antibiotics, it would have sounded kind of nuts. However, it wasn’t nuts; instead, somebody was a good scientist and didn’t deny an observation...
just because it didn’t fit a preconceived notion. That scientist pursued what was observed on some laboratory slides of ulcers, and, after subsequently conducting good, scientific studies, the scientist actually changed the way that we think about peptic ulcer disease.

**Interacting with Patients Taking CAM: Evidence-based Considerations**

As we approach CAM, we should be aware that some approaches just won’t fit our current mindset but will prove true and that other things seem to be consistent with our mindset but are wrong. How do we find our way through this maze when interacting with our patients?

First of all, I think that when we interact with our patients, we can actually be clear with them about what we know and what we don’t know from an evidence-based framework. Their mindset and observations may be quite different from ours, and so our challenge is to instill in our patients a degree of trust so that we can understand with them what we’re getting into with the CAM approaches. Instead of presenting ourselves in the Marcus Welby mode—the all-knowing oracle—we need to be clear and upfront with our patients about what we know, what we don’t know, and what are we going to do about it.

**Evaluating CAM with Evidence: Should We Integrate CAM Into Our Practice?**

In addition to these principles of observation, several areas should be considered when evaluating the efficacy and side effects of CAM modalities.

First, keep in mind the timeframe when data are collected. You may have to decide the effectiveness of an intervention within a timeframe too short to fully account for future events. Work was recently done on several drugs that looked safe initially; a variety of problems with these drugs were seen after years of use. So, the length of the assessment period is an important consideration. You might not expect complications years after taking a drug if the studies available were conducted for only six months.

Next, as studies are done and data are collected, is it clear what problem formulation the research addresses? A great deal of challenge and nuance exists in how you formulate the research problem. For example, to study cancer chemotherapy, you might create a problem formulation that includes only people aged under 65 years. If you then see a patient who is aged 75 years, you must be aware of the problem formulation that went into creating the data. Part of clinical judgment is to think: what is there about 75-year-old patients that may not be the same as for 65-year-old patients, and how should I either discount or transfer the observations made with the 65-year-old age group?

Third, consider whether robust evidence exists to support the approach. Individuals and groups commonly offer what are promoted as “evidence-based” recommendations when the actual support for the advocated position is based on somebody’s favorite article viewed in isolation from other work on the topic. It’s easy to find an article that basically supports almost anything you want to support; the dilemma, quite frankly, is that this approach is not good enough. Being evidence-based requires systematic review and examination of all the literature relevant to a problem and must include recognition and accounting for variation in study methodology as well as in problem formulation. It’s important for us to understand whether an evidence-based recommendation shared with us by someone is in fact fully informed by all available evidence and reflects that information. Does the advocate simply cite a reference to back up what they say, or has the advocate actually cited and systematically reviewed all that’s known about that particular topic area? Has the advocate integrated the known information rigorously and then made a recommendation that reflects the whole picture? This is an evidence-based approach.

Finally, we contemplate the analytic approaches and then put things through an additional sieve, our clinical expertise, before drawing a conclusion as to whether to use a given approach or not. Evidence-based medicine is not about minimizing the importance of clinical experience and judgment; instead, evidence-based medicine supports leveraging those unique dimensions of clinicians’ value.

**What is the Role of the US Food and Drug Administration (FDA) and Its CAM Determinations?**

Let’s look at what the FDA does, so that when you hear that a drug has been approved by the FDA, you’ll know what it means. Does it mean that the drug is effective for all patients? No! The FDA is charged with answering questions about the safety and efficacy of the drug. These two words are very important.

Some safety rules are limited both in time and in how the evidence is collected; so, although these rules do establish safety to the standards applied, the FDA does not have a “crystal ball.” The FDA is inappropriately
criticized for not being able to anticipate future side effects of a drug, even though the rules the FDA functions under do not require investigation into these side effects. The FDA is asked to use a particular timeframe, to examine data in a prescribed way, and to determine whether a drug is safe within those real constraints. The FDA does those tasks well.

The FDA is also asked to conclude if a drug is efficacious. Does it really work? Efficacy means that in a controlled setting, with limits placed on that setting, the drug has discernible benefit. The FDA does not demand that a drug be better than—or even equivalent to—other drugs that exist for treating a particular medical problem. I’m not sure that fact is always clear to people, but it is important to realize that a drug can be approved by the FDA as having efficacy even if the efficacy is substantially inferior to other drugs or interventions.

So, a dilemma may arise because you want to ensure that your patients get the right treatment for them; limitations of FDA approval are an important consideration when selecting a drug. That’s why FDA approval is an important first step—but not the final answer—to establishing the effectiveness of a drug for a large population: We rely on appropriately framed and conducted randomized trials to give us this information. Even if these trials are conducted, they may lag behind initial FDA approval.

Another issue is that FDA-approved drugs are available for any practice situation, not only those addressed in the approval documents. Basically, physicians can prescribe almost any FDA-approved drug without being restricted to using it for the approved purpose.

The FDA reviews drugs that have a variety of alternative roles—some of which are germane to what we will be talking about today. The issue is not that the FDA is doing a bad job; the issue here is to be mindful of what the FDA can contribute but also of what they can’t contribute. They can give you some help, but they can’t tell you everything. If a drug isn’t FDA-approved, you should really be cautious; but even if the drug is FDA-approved, you still don’t necessarily know everything that you need to know about the drug’s applicability to a specific patient.

Alternatives to Evidence-based Medicine

Some folks in New Zealand recently shared a tongue-in-cheek perspective on alternatives to evidence-based medicine. A few “optional” approaches given by the authors include:

- **Eminence-based medicine**—The ability to make the same mistake with increasing confidence over an impressive number of years.

- **Veblenence-based medicine**—The substitution of volume for evidence as an effective technique for browbeating your more timorous colleagues and for convincing relatives of your ability.

- **Nervousness-based medicine**—Fear of litigation is a powerful stimulus to overinvestigation and overtreatment. In an atmosphere of litigation phobia, the only bad test is the test you didn’t think of ordering.

As with most good humor, this work has its root some actual reality and truth. I point these alternatives out to you just so you can recognize that there are a variety of reasons why we do what we do. On a serious note, our patients and peers have assigned eminence to the work we do; we owe it to them to support that eminence by being truly evidence based.

Closing Comments

In assessing the integration of CAM into our practices, I have given you some thoughts that I hope blend the scientific approach with common sense. This approach is really about recognizing that, as physicians, we’re bringing to our dialogue with our patients a certain amount of eminence from our training and from our background as well as insight from our experience—but that all this must be combined with rigorous, complete consideration of the evidence. Only then will we really accomplish in our practices what we’ve set out to do.

I will stop here. We will have a chance later with the panel discussion to understand how and what aspects of CAM might integrate into our practices on the basis of available evidence. Thank you.

References


Dietary Supplements and Botanical Medicines: A Commonsense Approach

**Introduction**

Dr Low Dog: That was excellent, Dr Wallace. You provided a great lead-in, because I’m also going to discuss the FDA. However, I want to focus primarily on two areas that are growing in popularity: dietary supplements and my area of expertise, botanical medicines.

For some cultures in the United States, herbs never went out of style. They remained, especially in culturally intact communities. I am from New Mexico, where many people use herbal medicines, although they use them in the context of their own cultural background and history. We have done research in those groups and found that they learned about herbal medicines from their parents, their grandparents, their aunts and uncles; and that they use herbs such as chamomile, lavender, and spearmint—benign herbs that are quite safe.

My main concern today is not with these groups of people; instead, my concern is primarily directed toward the folks who do not have a culturally intact memory, if you will, for how to appropriately use herbs. They’ve read about it in a magazine or book, they’ve heard about it on the news, and, of course, many—like my mother, for example—think that if they read it, then it’s true, especially if it’s in *Prevention* magazine.

I will be covering just a couple of topics, including regulatory status; quality control issues; herb-drug interactions; our current state of science regarding several herbs; and the issue of selling these products in your office.

**The Saga of Regulatory Oversight**

Starting around 1991, a government movement—led in part by Dr David Kessler of the FDA—attempted to regulate dietary supplements more strictly. Well, as you know, the American public does not like being told that they’re not going to have access to things that they want. Driven in part by a lot of misinformation that instilled fear, people wrote letters to their representatives in Congress; and the only topic in the history of our country that prompted more letters from the public to the government was the Vietnam War. That was how upset the American public was about losing their potential right to freely buy herbs and vitamins! All of this led to enactment of the Dietary Supplement Health Education Act (DSHEA), which basically guaranteed Americans access to dietary supplements. In my opinion, however, the legislation did little to address the issue of public safety; what it did was maintain that dietary supplements will be regulated as food under food regulations.

The problem with this step is that we accept a certain level of safety regarding food as long as it is prepared and handled correctly. By regulating these substances as food, we took away the FDA’s ability to demand safety data before these substances are released into the marketplace. Because of this Act, manufacturers of products introduced into the marketplace after 1994 are not required to give the FDA any information about their safety. Now, as Dr Wallace stated, the FDA is asked only to prove that something is unsafe. That sounds easy, but it’s not: Chasing the horse after it has already left the barn is actually quite difficult and very inefficient.

**Foods and Plants are Not Always Safe!**

We are the only country in the world that has chosen to regulate botanicals and dietary supplements as food. Some herbs, such as garlic, oregano, and basil, are foods as well as spices; however, other plants—goldenseal root, poke root, and blood root, for example—are not foods. They were never consumed as foods but were used as medicine. These plants are pharmacologically active and really have no place in a “food” category. Categorizing dietary supplements as foods that do not require any safety data prior to release into the marketplace has led to problems such as encountered with combining ephedra and guarana for weight loss and potential liver toxicity associated with kava. In my opinion, these problems will continue until this issue has been addressed.

**What’s Really in the Packet? Problems of Mislabelling and Underlabelling**

Mislabelling and underlabelling are very real problems. I am currently the Chair for the United States Pharmacopoeia (USP) Dietary Supplements/Botanicals Information Expert Panel. The USP is a standard-setting body for drugs and is now also setting standards for dietary supplements. This situation is interesting because most entries in the old US pharmacopoeias from the 1850s and 1870s were botanicals. Why were pharmacopoeias
created in the first place, and what problems originally necessitated development of standards? Hundreds of years ago, our drugs were botanicals; but even then, consumers had to contend with problems such as adulteration, contamination, and substitution of cheaper herbs for more expensive herbs.

A number of products coming from Asia (especially products used in traditional Chinese medicine) have been noted to be contaminated or adulterated. A study in Taiwan found that of 2609 traditional Chinese medicine products collected from the pharmacies of eight hospitals, 23.7% were adulterated with undeclared pharmaceutical medication; and more than half of the adulterated products contained two or more adulterants. The most common additives included nonsteroidal anti-inflammatory drugs (NSAIDs), diazepam, corticosteroid agents, and anticonvulsant agents. This problem is real. In addition, concern is growing about presence of toxic heavy metals (such as arsenic, lead, and mercury) in traditional Chinese medicines.

Botanicals are not the only problem; other dietary supplements also have failed to meet their label claims. A University of California Los Angeles (UCLA) study assessed 12 products that were said to contain androstenedione and concluded that only one of these products contained what it claimed on the label. One product had twice the amount of androstenedione, one product didn’t contain any, and one product provided 10 mg per day of testosterone—a clinically significant amount, especially given that it was not declared on the label. The point I want to make here is that, of 12 products, only one contained what it said it contained!

The other area of concern in the marketplace is the widespread use and advertisement for products containing ephedra and guarana. Now, tell me how much sense it makes to market to athletes a product that increases heart rate, raises blood pressure, and is labeled for use after heavy exercise! We should not be surprised when adverse events are reported.

In addition to problems with manufacturing, some botanicals contain naturally occurring toxic constituents. Aristolochic acid poisoning received a great deal of attention after a tragic accident occurred at a Belgian weight loss clinic that had ordered the relatively safe herb Stephania tetrandra from an herbal supplier. Instead of this herb, the clinic received Aristolochia fangchi, a botanical which contains aristolochic acid, a known nephrotoxin. Seventy women treated with this substance at the clinic were later diagnosed with progressive interstitial fibrosis of the kidney; in 30 of these women, terminal renal failure developed. The FDA has banned products containing aristolochic acid; however, a number can still be found on the shelves.

PC-SPES was a popular botanical product that had undergone clinical research indicating that the product may be effective for reducing prostate-specific antigen (PSA) levels both in androgen-dependent and in androgen-independent prostate cancer. Preliminary data were encouraging; however, questions of safety surfaced about men taking PC-SPES who had pulmonary embolism and bleeding diathesis. The California Department of Health tested several batches of the product and found that it contained warfarin. The FDA then removed the product from the market because of adulteration with a pharmaceutical agent. Unfortunately, more investigation indicates that products sold between 1996 and 1999 were adulterated with indomethacin, diethylstilbestrol, or both.

The “bottom line” is that we have good reason to be cautious about the products available on our store shelves. You would have less of a problem if you lived in Europe, because these products are more tightly regulated there. In the United States, we do a good job of giving the public access to dietary supplements, but we have done little to ensure that what they’re buying is actually what they think they are getting.

**Kava-Related Liver Damage**

Kava is an herb with proven anxiolytic properties. This herb has been popular in the South Pacific as a mildly intoxicating beverage as well as a medicine. I always enjoyed it while traveling through the islands of Fiji and Samoa and found it useful for occasional neck and back pain, especially when traveling and not sleeping well. Kava is generally sold as a concentrated, standardized product, mostly from Germany.

In November 2000, German health authorities issued a warning alerting the scientific community that nine patients had been diagnosed with what seemed to be kava-related liver damage. The German authorities asked for feedback from the industry, requested manufacturers’ safety data, and began networking with the other European drug-regulating agencies. By November 2001, 29 cases of possible kava-related hepatotoxicity were reported in Europe, and the FDA had received reports of as many as 62 adverse events associated with kava.

Germany has removed kava from both the over-the-counter and prescription markets; France, Switzerland, and Canada have followed. The United Kingdom and
Ireland also will probably remove kava from the marketplace. The FDA is “investigating” the matter, and kava is still readily available in the United States; however, a number of lawsuits against the manufacturers of kava products are currently underway. Although people have argued that kava has been safely used for thousands of years, the substance was used in a very small, genetically isolated group of people who used a water-extracted preparation that was not concentrated to contain 70% kavalactones! Hepatotoxicity appears to be seen primarily when kava is taken in highly concentrated forms. In the United States, I will remind you, some adolescents use kava as an intoxicant at parties, sometimes taking as much as 20 times the recommended dose. People who take kava in concentrated form, take kava for a long period of time, combine kava with alcohol or acetaminophen, or choose more than one of these behaviors may just end up having liver failure.9

**Complexity of Botanicals, Attempts to Verify Quality**

I want to point out that botanicals are complex and are therefore somewhat difficult to study. We do not have standardized, validated analytic methods for evaluating most of these plants, and developing USP standards is a long, tedious process. Although typical medicines contain one isolated chemical, plants contain hundreds of constituents in varying amounts. Constituents vary from plant to plant, depending on such factors as when the plant was harvested, how it was dried, and how much rain it received. Some active constituents in the plant may vary thirtyfold. However, although standards are difficult to determine, we are not excused from solving the quality control problem that currently exists in the United States.

I want to tell you about two initiatives currently being conducted in the United States to address quality control issues by developing quality verification programs. Existing in addition to the USP is another group, the National Sanitation Foundation (NSF), which certifies water filtration systems. If a company is willing to submit to a Good Manufacturing Practice (GMP) audit by having its manufacturing facility inspected and then having their products randomly tested four times a year, then the company may place a certification seal on the front of their product’s label. This seal is not an endorsement of the efficacy of the product, but it does indicate that the bottle contains what is stated on the label. This certification will go a long way toward assuring American consumers that they are getting a quality product. For example, if one of the 20 ginkgo products on the market receives a certification seal for purity and quality—meaning that it contains what it claims to contain and nothing else—certainly that will be a step forward for the consumer. But although I think it will help, the number of companies coming forward to participate in this certification process are few.

**Herb-Drug Interactions**

Attending a talk yesterday, I listened to an acupuncturist describe the way in which practitioners learn the properties of an herb so that herb-drug interactions can be prevented. This description was his explanation for why we don’t see many herb-drug interactions. Understanding the pharmacologic actions of an herb will certainly yield some insight into its potential “class” interactions; however, without appropriate pharmacodynamic and pharmokinetic studies, we have no way to accurately predict which herbs might interact with a given drug. Nothing inherent in the known properties of St John’s wort would have allowed us to predict that it interacts with two metabolic processes within the body: the P450 CYP3A4 system and P2 glycoprotein.10

Whether or not St John’s wort interacts with oral contraceptives has not been explored until recently. A study presented in March 2002 found that more than half of the women receiving birth control pills (norethindrone) who then started taking St John’s wort had a decrease in estrogen levels and had breakthrough bleeding.11

What about herbal interactions with warfarin? I tell medical residents: If a question on an exam ever asks which of the following drugs herb X interacts with and warfarin is listed as an option, check that one. In general, patients taking any drug with a narrow therapeutic window (e.g., anticonvulsants, cardiac glycosides, warfarin) should be counseled to be cautious about using dietary supplements. My bottom line with patients in my own practice is that the more necessary that a drug is for life and the more narrow the therapeutic window; the fewer choices they have for exploring the use of dietary supplements and herbal medicines. We try to choose more noninvasive types of alternative therapy—including massage, meditation, biofeedback, and yoga—if that’s what the patient is looking for. That way, at least the patients are not ingesting problematic substances and may improve their health without using substances that may alter the mechanism of response to necessary medications.

**The Danger of Observation Alone in Evaluating Efficacy**

A growing body of research about plants supports what Dr Wallace said about the need to be very cautious about
observation. For instance, I love reading the stories about digitalis. A book written in the 1860s or 1870s presented 32 diseases that should be treated with foxglove, a plant containing cardiac glycosides (digitals). The list of diseases included typhoid, dysentery, and a range of other ailments. When viewed from a purely observational perspective, treating these ailments with foxglove made sense to early practitioners, as digitalis slows the heart rate. Because digitalis was observed to slow the rapid pulse that normally accompanies a high fever, digitalis was used commonly as a treatment for fever and infectious disease; however, it also killed people.

If you look back through history, you’ll find that many of these plants in fact had some effect on the vast array of conditions we treated but that we had no explanation for these effects. There were probably a few ailments for which an herb was truly efficacious, but it is unlikely that a single herb could treat the hundreds of problems that were sometimes claimed.

Dietary Supplements Proven Effective: Saw Palmetto and Glucosamine, but not Chondroitin

Because preparations of saw palmetto, glucosamine, or chondroitin cannot be patented, pharmaceutical companies have no incentive to produce them or to do the research needed to ensure their safety and efficacy. This lack of patent protection hinders research on botanicals and other dietary supplements in this country by preventing manufacturers from collecting a sufficient return on their research investment.

Despite this fact, some success stories have been reported. We are now able to state with some certainty that saw palmetto is more effective than placebo for treatment of mild benign prostatic hypertrophy (BPH). In addition to one meta-analysis that was done, the Cochrane Review also has issued a favorable position.13 Saw palmetto is indicated for patients who have mild symptoms, no sign of clinically significant obstruction, and normal creatinine level. I have to question why saw palmetto isn’t available on more hospital formularies. It’s not really an option for many patients because a $2.00 copayment is required for terazosin as compared with $28.00 for saw palmetto at the local health food store. However, if I have an elderly, normotensive man with very mild symptoms of BPH and don’t want to give him something that might make him orthostatic, recommending saw palmetto as initial therapy may be wiser.

The only good study that compared saw palmetto with one of the alpha blockers was a three-week study—and, of course, you should know that saw palmetto doesn’t work in three weeks. If you’re looking for a rapid effect, you’re not going to find it in saw palmetto: it really doesn’t begin to take effect for six to eight weeks, and the effects are maximized at about three or four months—so a regimen of this substance must be started early. The USP has recognized the once-per-day (320 mg/day) and twice-per-day (160 mg twice daily) dose for saw palmetto.

Glucosamine is another dietary supplement that really prompts the question of whether it should be considered alternative or complementary medicine. I don’t really like either term, because every treatment modality, dietary supplement, and botanical gets included in it. It doesn’t matter if you’re talking about homeopathy, massage, energy medicine, iridology, or botanicals; we just throw everything under this umbrella of “CAM.”

Sixteen trials on glucosamine now exist; however, all but one have shown benefit.14 The Cochrane Review issued a positive recommendation, finding that glucosamine was more effective than placebo.14 Actually, several studies showed that glucosamine was as effective as NSAIDs,14 and the Lancet study15 may have actually shown joint preservation by glucosamine in osteoarthritic patients. Patients obtained tremendous relief with glucosamine compared with placebo, and radiographic imaging showed greater joint preservation (in the knee) in patients who received glucosamine;16 however, follow-up studies are needed to determine if glucosamine is actually our first disease-modifying agent for osteoarthritis. When I spoke recently to a group of rheumatologists, I asked how many of them would recommend glucosamine in an older patient who may not be a great candidate for treatment with NSAIDs. Most of them felt comfortable recommending glucosamine—a response very different from responses given three and four years ago. So, now I need to ask, why isn’t glucosamine more available on a formulary? You still have to buy it from Sam’s Club or Wal-Mart or the health food store, not with a copayment at the hospital pharmacy.

Although studies show that glucosamine is efficacious, studies on chondroitin are less impressive: The bioavailability of chondroitin taken orally is still unclear. Because chondroitin costs about twice as much as glucosamine and has unproven effectiveness, patients are probably better off in the long term to use glucosamine without chondroitin.

A Few Closing Comments

In conclusion, I just want to comment again that I think this terminology of “complementary” and “alternative” is
problematic. Medicine should really be about what works—the best choices that can be made from what we know at the time, and remedies and treatments that present the least harm. We need to be careful not to place something in the category of complementary and alternative and then add to it a lot of mysticism and pseudoscientific information and present it as something that it isn’t. We do want to offer people choices and options for therapy—but only for options that are proven or that offer some reasonable hope of benefit.

I believe that further research will help us learn a lot more about the potential benefits and pitfalls of botanicals and dietary supplements. The Natural Medicines Comprehensive Database (www.NaturalDatabase.com) is a good resource for health care professionals. People argue that it’s a little conservative, but I think we should err on the side of conservatism, especially when we are not familiar with the subject.

All right, I think I’ll stop there. I look forward to your questions during the panel question-and-answer session. Thank you.

References
Integrating CAM Into a Group Practice: The Experience of The Permanente Medical Group in Northern California

Introduction

Dr Ballance: One day, a patient came in and told me, “I don’t take medicine.” Before I moved on, I asked, “Do you take anything else?” She said, “Oh yeah,” and pulled out a large bag of supplements—to which I replied, “Well, so I see: If the FDA will approve it, you won’t take it; but if they don’t approve it, you will.” Then she laughed and said “Well yeah, something like that.” What I considered medicine, she didn’t.

Terminology has been a real challenge for our organization, just as it is for patients. Our CAM Advisory Group wanted to use the phrase “integrative medicine,” but we decided not to do that because it might confuse the issue with the principle of Kaiser Permanente (KP) being an integrated model of medicine. Because we didn’t think we would get the term “integrative medicine” accepted in our integrated medical group, we had to continue with “complementary and alternative medicine.”

I’m going to talk about complementary and alternative medicine within The Permanente Medical Group (TPMG) in Northern California. You should know that we have about three million patients and about 4000 physicians. A major challenge for us is to manage CAM in such a large patient population and with such a diverse practitioner population.

The History of CAM in TPMG

When I came to KP Vallejo in 1980, I found that an acupuncture service was already in place. I am told that in 1976, an emergency department doctor from Walnut Creek, Forrest Gioppa, returned from a two-year study in England with Felix Mann and taught 35 Permanente physicians how to do acupuncture. Two of them that I know of adopted the skill in their practices. One was Russ Erickson, a pediatrician at the KP Richmond facility, who is still very active in the American Academy of Medical Acupuncture. The other was Howard Liebgold, Director of the KP Vallejo Rehabilitation Unit, which is the KP rehabilitation unit for all of Northern California. When I arrived in 1980, it was mainly Dr Liebgold who was using acupuncture. A Chinese-trained radiologist also had a small acupuncture practice within the facility.

When Dr Liebgold retired, his successor expanded the acupuncture practice in the Rehabilitation Department and created an Alternative Medicine Clinic at KP Vallejo. This event created something of an uproar because it attracted publicity through the local press and at least one national magazine. We started to get letters from all over the country wanting to know if people could come and use the service; if we had housing facilities so they could stay with us; and if we treated all sorts of maladies. This was the reason we decided to create the position of KP Vallejo Chief of Alternative Medicine. Soon thereafter, the KP Northern California Region created the Regional Director of Alternative Medicine position and appointed Dr Harley Goldberg to it.

Early Alternative Medicine Activities of The Permanente Medical Group

We needed to respond to several problems developing regionally. First, we had to respond to the mandate for chiropractic coverage for Medicare patients. And how would we manage the issue of acupuncture, which was being provided for almost anybody with any diagnosis? Very important, if we did acupuncture at KP Vallejo, were we going to provide it also at KP Walnut Creek? At KP Redwood City? We knew that many patients and members were coming to us for advice about nutritional supplements and about other treatment modalities. How should we respond to that need?

A 1996 survey of Northern California Health Plan members and clinicians by Nancy Gordon of our Department of Research and David Sobel of Regional Health Education revealed that a large number of both members and clinicians were using alternative modalities and wanted their health care system to incorporate such modalities.1

The State of California Department of Managed Care required that if we provided a service at one location, we would have to provide this service consistently to our three million health plan members in Northern California. This was one of our earliest challenges. We developed method-
Integrating CAM Into a Group Practice: The Experience of The Permanente Medical Group in Northern California

Early Challenges as CAM is Extended Regionwide

For us, the major challenge was to provide CAM services in a consistent, high-quality way across all KP facilities. For example, after the herbal therapy workgroup approved six herbal and supplement products, the next question was how we should manage availability of the products: Should they be placed on the formulary? Where should they be made available? Most important—and this reflects the issue Dr Low Dog raised—how do we recommend something if we don’t know the quality of the product?

We asked the pharmacy services department to evaluate several manufacturers so that we could be assured that the products were of good quality. Pharmacy Services conducted site visits to review manufacturing quality and developed a short list of products from which we purchased specific products. The USP Verification Program (USP-VP) now is available and has been presented in Northern California. We have agreed to use the USP-VP standard in the future for products we purchase. However, USP standards did not exist for herbs and supplements when we began this project.

Framing the Clinical Discussion of Alternative Treatments

A recent series of articles in the *Annals of Internal Medicine* has been edited by Eisenberg and Kaptchuk and is well worth your attention. The articles address basic questions: What is alternative medicine? What are its major treatment modalities? How should we address the questions of malpractice and integration? Eisenberg has ingeniously defined three categories of use: To approve, to accept, and to discourage. Working in musculoskeletal medicine, I often accept—or even encourage people to consider—the use of glucosamine. It appears to be very safe and seems to be about as effective as NSAIDs. The quality issues have been addressed by our pharmacy and by national organizations such as Consumer Reports and ConsumerLab.com. Glucosamine is an over-the-counter product, so it’s not on our formulary. People are going to pay a dollar a day if they buy it from a warehouse store or a little more than that if they buy it from us (because we don’t stock the volume that the warehouse stores have). But to me, non-steroidal anti-inflammatories are inherently risky when used by older people, especially to treat chronic conditions; and even the safest NSAIDS carry a fairly high risk of gastrointestinal bleeding. So, I often find myself encouraging patients to give glucosamine a trial.

For intermediate categories, Eisenberg talks about condoning or accepting CAM use. Many CAM options seem pretty safe but do not show evidence of efficacy or quality—for example, use of valerian for sleep or chiropractic for “tennis elbow.” You might say to somebody who wants to try these, “I have no evidence that they will work, but I think it probably wouldn’t hurt, so it sounds reasonable to try it; come back and tell me what happens.” This approach assumes that you have evaluated the problem and have offered the patient the standard options that you have available.

An example of something that I would discourage today would be the use of kava for anxiety. Although this use has shown pretty good efficacy, recent European reports of liver failure make me hesitant to condone use of kava until more is known. Eisenberg talks about accepting, condoning, and
discouraging use, and I think that that is a very good framework for clinical discussion.

**Future CAM Research at TPMG**

We believe that anything we bring in must be evidence-based. We have to agree at some level that the substance is effective or safe, or else we have to make it a research project. If one of our staff comes to us believing that an alternative modality offers great benefit, we ask them to set up a clinical study to see if they can prove that to be the case. We are moving to create an infrastructure that will support reasonable pilot studies for research projects that people want to do. We believe that we have the population of patients and interested physicians to be in an excellent position to do cutting-edge research. We have a standing CAM Research Committee in association with our Division of Research and have a growing number of research projects underway. Our Research Committee coordinator is available to consult with clinicians interested in developing research trials.

**Education and CAM**

Another guiding principle has been the importance of educating ourselves and our fellow practitioners as well as our health plan members and patients about the safety, efficacy, and quality of CAM interventions. We have sponsored a series of regional teleconferences on various CAM issues. We have worked to make CAM resources available in the Clinical Library and in the Permanente Knowledge Connection (PKC) so that our clinicians can now access the most up-to-date information from the desktop. Patient tipsheets have been developed for the herbs and supplements that have been approved for use, and Frequently Asked Questions (FAQs) have been prepared for acupuncture and chiropractic. Where possible, CAM modalities have been included in patient educational material such as the menopause guidelines. Classes in such practices as yoga, tai chi, qigong, and Feldenkrais movement have been instituted at most of our facilities.

**Conclusions**

We believe that CAM options that have been proven safe and effective should not be distinguished from mainstream methods of care. I shouldn’t have my own practice where people come and talk about herbs while other physicians tell patients that they don’t know anything about those things and that they should go and talk to Dr Ballance! The solution to this problem is best stated in a quote from my Chief of Medicine, who recently retired after 25 years. He said, “What’s all the fuss about? If it works, everybody should do it; if it doesn’t, no one should.” The spirit of this quote probably best characterizes integration of CAM into the practices of TPMG physicians.

I will stop here and answer any questions during the panel discussion. Thank you.

**References**

Integrating CAM Into Practice: The KP Northwest Story

Introduction
As a general internist with an interest in CAM, I find it exciting to be at Kaiser Permanente (KP), because our group is at the cutting edge of integrating CAM with conventional care. We have a great story to tell! In this discussion, I will paint a broad picture for you of what we are doing in the KP Northwest Region (KPNW) in the area of complementary and alternative medicine (CAM). As we go along, you should be thinking, as an individual practitioner, about how you can begin to actively integrate evidence-based CAM into your practice. As we, both as individuals and as an organization, gain increasing proficiency at doing this, the care experience for patients as well as for practitioners will proportionally improve.

First, I will talk about why we are interested in CAM in the first place. Then, against that backdrop, we will look at what is happening in the Pacific Northwest. I will describe the networks of CAM providers to whom we refer our patients, how we make those referrals, and under what circumstances. Next, I will review several ongoing projects that introduce CAM practice within our own medical offices. Finally, we will talk about the Oregon Center for Complementary and Alternative Medicine Research, an NIH-funded CAM research center based at the KP Center for Health Research (in Portland, OR). When we have concluded, I think you will all clearly understand that we have a great story to tell. You should also gain at least a few practical ideas for integrating CAM that you can then take right back to your practice.

Background of the CAM Movement
What is behind the CAM movement? Why do we even care about CAM in the first place? I’ll describe four forces that are propelling this phenomenon forward: medical utilization, competitive pressures, physician practice patterns, and legislative mandates. Regarding medical utilization, I refer to a study published by Eisenberg and colleagues in the New England Journal of Medicine in 1993.1 The authors of that paper conducted a national telephone survey of 1539 adults to ask about details of their CAM use. Approximately one third of respondents reported use of at least one CAM modality during the preceding 12 months.1 When the survey was repeated four years later, in 1997 (with the data published in JAMA in 1998),2 the 34% figure had increased to 42%! The data suggest that CAM use is widely prevalent among patients and that, far from representing a fad, this use is increasing.

Another figure illustrates the competitive pressures which this use of CAM generates. In 1998, Landmark Health Care Corporation conducted a national telephone survey of consumers to ask them how much importance they attach to CAM coverage when selecting a health plan.3 Thirty-one percent of respondents answered that CAM coverage is very important, 36% responded that it is somewhat important, and 33% said that it is not important.3 We thus conclude that CAM use among patients is high and that for about two thirds of patients, CAM coverage is a consideration when purchasing health insurance. These two phenomena play an important role in propelling CAM onto the health care agenda.

Physician practice patterns represent another important consideration. In a study by Gordon and Sobel published in The Permanente Journal in 1999,4 the investigators mailed a survey to all primary care clinicians and a subset of the obstetrics and gynecology clinicians in the KP Northern California Region (KPNC) and received approximately 800 responses. Approximately 70% of clinicians who responded were somewhat or very interested in having better CAM availability for their practices. These clinicians were then asked to explain why they wanted this improved access to CAM. Although “growing patient demand” and the need for KP to “remain competitive” were cited as important reasons, these were not the most popular answers; the two main reasons given by KPNC clinicians for wanting improved CAM access were that 1) patients are seen for problems that cannot be adequately treated with more conventional methods and that 2) the clinicians believed that many health problems can be more effectively treated by using a mind/body or holistic approach than with a more conventional, Western approach.4

That most of the KP clinicians responding to the survey wanted better CAM access is important—but not
surprising. What is fascinating, however, is that the main reasons relate not to patient demand or to competitive pressures but to self-perceived shortcomings in our own conventional clinical paradigm. A pressing need to expand the armamentarium of the primary care clinician thus represents another major force driving the CAM phenomenon forward.

In addition to patient demand, competitive pressures, and physician practice patterns, legislative mandates represent a fourth important factor in the equation. In the state of Washington, the “any category of provider” statute was enacted in 1995. With approximately one third of our health plan membership residing in Washington state, efforts to comply with this law have had a substantial impact on operations in the KPNW. Succinctly stated, the law mandates that health insurance companies doing business in the state of Washington must provide coverage for clinically indicated health care services provided by any category of provider for which there is a licensing body in the state. In other words, because Washington awards licenses to acupuncturists, chiropractors, and naturopaths, KP’s health plan must cover those services when clinically indicated. Along with patient demand, competitive pressures, and physician practice patterns, the “any category of provider” statute has played a substantial role in shaping our approach to CAM at KPNW.

What KPNW is Doing to Meet the Challenges of CAM

Having a clear sense of why we are interested in CAM, we can now discuss efforts underway at KPNW to meet this challenge. First, we have established relationships with local networks of CAM providers to provide services on a referral basis for our patients when these services are clinically indicated. For acupuncture, referrals to an Acumed network provider can be approved only for Washington members in the setting of chronic pain or for nausea and vomiting associated with either cancer chemotherapy or pregnancy. These referral guidelines are based in large part on the NIH consensus statement on acupuncture, which, though released in 1997, nonetheless represents an excellent synopsis of the evidence base. Accepted indications for referral are acute nonradicular back or neck pain only, for which most patient referrals are approved for a total of approximately six visits. KPNW is using this Chironet referral mechanism with sufficient frequency that the possibility of providing limited chiropractic services as an internal service is being considered. For naturopathic services, we similarly contract with a network called Naturenet. Historically, referral has been indicated for women with perimenopausal symptoms in whom hormone replacement therapy has failed or is contraindicated; currently, these guidelines are under review. In practice, KPNW approves approximately two or three referrals per month for naturopathic care.

In addition to referral-generated consultations, some of our members’ employers purchase a product that allows the patient to self-refer to CAM providers. Substantial copayments and other limitations apply, and patients who select this plan are obligated to select from among the network providers.

Although most of the CAM care provided by KPNW to our members is delivered through these affiliated networks, several efforts through the KP primary care, pharmacy, health education, and other departments offer members access to CAM services at our own medical offices. As one example, KPNW offers an internal, referral-based group integrative medicine clinic. The rationale inspiring the clinic stems from well-known improvements in communication, quality, and cost, which can be achieved by maintaining an internal referral service (ie, versus an outside referral service). In addition, the clinic introduces further efficiency by using the cooperative health care clinic model. Staffed by a primary care physician and a nurse, the group clinic is open to any member who is interested in a holistic model of care and who is referred by another clinician for treatment of a subacute or chronic medical condition.

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educating members and clinicians about herbal supplements and with evaluating supplements for potential inclusion in the over-the-counter shelves of KP pharmacies. The committee conducts evidence reviews of popular herbal extracts and is responsible for identifying appropriate suppliers with good manufacturing practices. We expect that some supplements, such as glucosamine sulfate, saw palmetto, ginkgo, and St John’s wort may be available to members at KPNW pharmacies in the near future.

The KPNW Health Education Department has several CAM-related offerings for members. These offerings include a women’s health education series (with some lectures led by naturopathic physicians) and a class on managing stress and anxiety that teaches breathing, visualization, and relaxation techniques as well as a number of other stress management tools. In addition to these programs, numerous individual KPNW clinicians provide integrated care in a number of ways. For example, both hypnosis and healing touch are offered by trained clinicians at our regional pain clinic. Several osteopathic physicians in KPNW do spinal manipulation, and a dentist at our Temporomandibular Disorders (TMD) Clinic offers neurofeedback.

In addition to these clinical activities, KPNW is active in the areas of both CAM education and research. The KP Center for Health Research has been designated one of about 16 NIH-funded CAM research centers in the country. Known as the Oregon Center for Complementary and Alternative Medicine Research (OCCAM), the consortium includes investigators and clinicians from KP, from the Oregon Health & Science University, and from four CAM colleges located in the Portland metropolitan area. OCCAM is currently conducting three large phase II clinical trials and also provides funds for smaller developmental projects, all focusing on evaluating CAM interventions in the setting of craniofacial disease. In addition to these research projects, OCCAM offers research fellowships to help train clinicians as CAM clinical researchers. Several KPNW clinicians have been awarded funding by OCCAM, both for fellowship training and for developmental research.

In cooperation with OCCAM, KPNW sponsors a quarterly CAM journal club that provides a forum for continuing education in the area of CAM research as well as opportunities for discussion and networking among members of the KP community interested in CAM. These dinner meetings generally last about two hours and are attended by a broad range of health care professionals, including physicians, nurse practitioners, CAM providers, clinical investigators, pharmacists, nurses, and others.

Conclusions
This impressive array of activities shows that KP is in a leading position to support, at both practitioner and system levels, integration of evidence-based CAM into routine practice. The history of our group is one of bold and farsighted innovation, and it is incumbent upon us to provide strong leadership on this issue. Individual clinicians can educate themselves to provide accurate information about CAM to patients, to refer patients to CAM providers when this is indicated, and to recommend herbal extracts for appropriate purposes. In addition, some KP clinicians have received CME training in CAM systems and modalities. Both patient and clinician satisfaction with the care experience stand to dramatically improve as we move forward with this work.

References
8. Elder C. Application of group outpatient visit model for the delivery of integrative medicine at a health maintenance organization. Presented at the 2nd International Conference on Complementary, Alternative and Integrative Medicine, Boston, MA, April 12-14, 2002.
**Moderator:** I want to thank all four of our experts for their highly informative presentations. It is valuable to have experienced people addressing the issue from different perspectives. Now let me open it up for comments or questions for our expert panel.

**Question from the Audience:** Dr Ballance, do you have any data on the cost-effectiveness and utilization of your acupuncture service?

**Dr Ballance:** I am glad you asked that question. The short answer is no; we don’t yet have that data. We decided to implement the program on the basis of our review of the literature. We believe that offering acupuncture is a good care option for this population [patients with chronic pain] and that it may be more cost-effective than some of our traditional approaches. At the same time, we realize that the burden is on us over the next few years to prove that hypothesis with studies, and we are beginning to put the infrastructure in place to do those studies. We are now in the process of collecting data on cost and outcomes. The preliminary data are provocative, but, as I said, they are preliminary.

**Dr Wallace:** I just wanted to comment that whenever we raise the issue of cost, we need to discipline ourselves to think about value. If we recognize that value has two components—cost and quality—then we will clearly see that it is artificial to think about the cost of something without also thinking about its quality. Our obligation, both as clinicians and as decision-makers in administrative roles, is to maximize the value of the services that we provide to purchasers as well as to members. I think the way we should look at questions like this is to ask, “Does this actually improve the quality of what we are doing?” and “Is this the way that we can best manage costs for our patients while maximizing value?” So, my caution would be that whenever we start thinking, “What does this cost?” we should also ask how it actually works for our medical group and for our patients in terms of adding value.

**Dr Ballance:** I want to make one other point. You should be aware that acupuncture is a very protean field. Acupuncture is probably taught in several schools—some that use Chinese herbs and some that don’t. Our acupuncturists do not use these herbs, because we do not have an adequate understanding of all the issues of Chinese herbal preparations.

**Question from the Audience:** Dr Low Dog, you mentioned that you admonish us to be concerned about the safety of herbal preparations that people use. Patients ask me all the time if they should buy their herbs from any one company. Are there certain manufacturers that we can trust to produce safe preparations?

**Dr Low Dog:** You can go to Consumerlab.com for about $15.00 a year to find out whether the tests include Nature’s Way, Twinlab, and Solgar, and that a number of other large companies have good quality. Consumerlab.com is a great group to support, because this Web site provides information that will help you know where the problems are.

**Question from the Audience:** As you point out, TMD can be a difficult condition to treat using conventional modalities. A mind-body approach would seem like an appealing alternative. An interesting finding in our pilot study of mind-body techniques for TMD was that from a clinical standpoint, there was surprisingly good compliance with these interventions. We offered patients one of three mind-body interventions: transcendental meditation, qi gong, or neurofeedback and found that, of those who presented for initial treatment and instruction, about 70-80% of patients regularly practiced the techniques at home and stuck with the relatively demanding follow-up schedules. In addition, within-group improvement in pain intensity scores for the treatment group was statisti-
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51% of the population is aware of these herbal agents. At least 80% of my patients are taking some sort of botanicals.

Question from the Audience: I am a gastroenterologist, and I see a lot of patients who have symptoms of irritable bowel syndrome as well as abnormal liver test results. The patients typically have had a battery of tests (such as serologic testing or CT or MRI scans) before they even see me. The cause of these symptoms turns out to be that the patients were taking herbs. You just ask a simple question—basic communication—about what they have been taking, and they pull out their bag of herbs. At least 80% of my patients are taking some sort of botanical tea or other herbs.

Two questions: First, have you seen this side effect? I also was wondering whether, in your future studies of cost-effectiveness, you might consider measuring not only the cost impact of the pain or the disease process but also how awareness of these herbal agents might lower the cost of inappropriate referrals or the inappropriate use of imaging technology.

Dr Low Dog: I think that part of the communication with patients is about normalizing behavior and communicating so that the patient clearly understands the questions. I live in New Mexico, where 51% of the population is not “Anglo”; they are either Native American or Hispanic. Knowing the culture and how to ask questions is essential. In addition to asking the usual questions—“Do you take any prescription drugs prescribed by the doctor?” or “Do you take any over-the-counter remedies, like Tylenol or Pepto-Bismol?”—you should use specific language: “Do you use any herbal remedies? Do you use any ginkgo? Do you use any allucema [Spanish for lavender]?” Most of my patients will respond, “Oh, yes.” It is amazing. When we first started doing this in the emergency department, we just asked, “Are you taking any dietary supplements?” The answer was always, “No, no.” When you start asking, “Do you use any herbal products, such as ginkgo or echinacea?” people say, “Oh, yes.” My point is that you have to ask for specifics or else patients will not tell you that they are taking botanicals.

Remember, patients have their beliefs and the culture of their community, and our beliefs and our culture may be different. So, being aware of their community and what people are using is, I think, very important. To answer your question, I believe that this awareness will definitely decrease unnecessary tests. I do think that if primary care providers can be a little more diligent, we can reduce costs and decrease the number of referrals.

Regarding the abnormal liver test results and gastrointestinal upset, slimming teas and diet teas are loaded with diuretics, alkaloids, and glycosides that can cause blips in their liver function test results.

Dr Wallace: My response would be that to improve quality, we must reduce defects and errors. I would argue that a referral to a gastroenterologist is a defect if it is made without fully ascertaining that the person is taking a potentially liver-toxic substance. The best way to approach defects is often systematically. That way, we can better understand the defects in our system so that we can improve the quality of the service we offer. To do this, I think I would try to identify early opportunities to reduce defects and errors—for example, by educating patients and clinicians.

My own philosophy... is that if the substance is not something we would commonly consume in our diet... then they are really best avoided.

Dr Ballance: I just wanted to add that I heard a story in the hallway a month or two ago about someone who was admitted for nausea and loss of appetite. When the dust settled, the clinician found that the symptoms began when the patient started taking herbs and supplements. I agree with Dr Low Dog’s comments. We need to ask patients about their intake of herbs and supplements by using the most specific questions we can. A recent study by Nancy Gordon of our Division of Research showed that the yield is substantially increased when patients are asked about specific supplements as opposed to being asked more global questions about “herb” or “supplement” or “alternative medicine” use. There is no universal name out there for all these products.

Dr Low Dog: Just a quick comment: With the botanicals, gastrointestinal symptoms are some of the most common side effects because herbs can contain gastric irritants. Pharmacologically active plants are rich in these irritants—alkaloids in particular—and may contain substances that cause vomiting and that are toxic in larger doses. So, gastric upset is not uncommon.

Question from the Audience: Dr Low Dog, is there a registry of neonatal side effects and syndromes resulting from botanical products?

Dr Low Dog: That’s a good question. We don’t know the effects of many of these plants on organogenesis or the implications for fetal outcomes. Data on whole-animal reproductive toxicology exist for the top botanicals, such as echinacea and ginkgo. Many have been studied extensively in Germany. No major problems have been identified on the basis of this limited information. My own philosophy with patients is that if the substance is not something we would commonly consume in our diet—foods such as chamomile, peppermint, garlic, and oregano—then they are really best avoided.

Question from the Audience: Dr Low Dog, could you comment on the effectiveness of progesterone creams?

Dr Low Dog: Sure. As long as the cream contains USP progesterone (usually 3%), there is some evidence that it does help with hot flashes and other symptoms of menopause—especially perimenopause.

Obstetrics & Gynecology in 1999 published a year-long study of the effects of progesterone cream
on bone loss comparing progesterone cream against a placebo cream. Women in both groups were also given calcium and vitamin D. Both groups of women had exactly the same bone loss, and the authors concluded that progesterone cream does not protect bone. However, an interesting finding was that the women who received progesterone cream had a strongly statistically significant reduction in menopausal symptoms within the first six weeks after the study began. So, I think that if women want to use this cream, fine; but it should not be relied on when oral estrogen is being taken—it should not be used to complement the estrogen in protecting the uterine endometrium.

**Question from the Audience:** I have a question about patients taking little drops of some substance that they get in bottles from homeopaths. What are these patients taking?

**Dr Low Dog:** The founder of homeopathy was Christian [Friedrich Samuel] Hahnemann, an Austrian trained physician, who developed the system of homeopathy in the early 1800s, a time when physicians in the United States treated many diseases with bloodletting and administration of arsenic, mercury, and toxic botanicals.

Generally speaking, homeopathy is, in essence, the opposite of allopathic medicine. Let me use a case of a nauseated patient to demonstrate what homeopathy is. The approach is to take an herb which, if administered in a reasonable concentration, would actually trigger the symptoms. In our case, the herb would make the patient vomit. That substance is then diluted into minuscule concentrations, which are then given to the patient. The idea is that by administering the substance in vanishingly small concentrations, it will actually treat the patient’s symptoms. An American Homeopathic Pharmacopoeia [Homeopathic Pharmacopoeia of the United States] sets the standards for homeopathic medicines.

In a sense, that is what we do in allopathic medicine when we immunize our patients or when we give allergy immunotherapy.

There is no doubt that homeopathy is safe, but no evidence shows that it is effective. A person might have to consume 7567 gallons of an herbal preparation to get one molecule of the active substance, so I’m not surprised that the herbal preparation is safe. I am also not surprised at the lack of evidence showing that it works.

**Dr Elder:** A couple of comments: Hahnemann and his followers are said to have been pioneers in random controlled testing of drugs and medications. So, he did us a great service in that area, and you can see that his approach was probably in some ways more scientific than the observational and evidence-based approach in place in the 1800s.

Some limited evidence shows that homeopathic products are effective. Findings from a meta-analysis by Linde and colleagues published in the *Lancet* in 1997 were not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo. Given that the homeopathic product is certainly harmless—although not for the pocketbook—it is probably fine as long as patients don’t forego regular medical treatment for an important problem.

**Dr Wallace:** When we look at types of studies, we see sort of a hierarchy between observational studies and randomized controlled trials. I think meta-analysis is really one step further up that hierarchy: observational trials are at the bottom, then randomized controlled trials, and then meta-analyses at the top. You may also consider that the magnitude of the effect must be taken into account when you are deciding what kind of trial to use. For example, you don’t need to do a randomized controlled trial of the impact of anesthesia on surgery: Observation is absolutely adequate to make a valid conclusion in that context. But when you begin to work with smaller effect sizes—things such as the impact of hormone replacement therapy on women who have cardiovascular disease—the actual impact is really pretty modest compared with the whole population, so you need to use methodology appropriate for the effect you are evaluating. By the time you get to arguing whether the analysis shows a marginal effect, you have to take a step back and ask whether you are looking at something clinically and biologically significant and whether the only way to find the effect is to torture the data over centuries. And you have to remind yourself of the problem that you are trying to solve and consider whether it is really worth it. You have to consider whether there are better ways to focus your effort and whether to rely on other things.

I think that is how I would filter my skepticism about homeopathy; I would ask whether we have to look under that many rocks to find something that suggests benefit. If so, then we might want to look in other places—places where I think there might be more direct kinds of evidence.

**Question from the Audience:** I am discouraged by some of the information today about the herbs—especially the large amount of money patients spend on these products, the poor quality standards for the ingredients, and the lack of evidence of their efficacy. It seems to me it is the lucrative business that drives the marketing, not an honest attempt to provide...
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Is the medical community failed? If the FDA can’t fix it, can the medical community?

**Dr Low Dog:** First, let’s talk about just how widespread CAM is. I think it is important to recognize that the growth of CAM is true in some respects, but the statistics are actually inflated, and involvement in CAM may not be as widespread as you think. If you look at David Eisenberg’s study, the largest percentage of what folks were doing that we call “CAM” consisted of exercise, prayer, and weight management programs, such as Weight Watchers.

There certainly is a concern over the marketing of CAM. At the White House Commission, we heard extensive testimony from Hispanic physicians who are very concerned about the growing use of CAM among exclusively Spanish-speaking people because they are being specifically targeted.

With regard to the quality of CAM promotions, the Federal Trade Commission (FTC) told the White House Commission that in one afternoon—four hours—of going through Web sites looking for fraudulent medical information, they found 400 such sites. These sites were blatantly fraudulent, misleading, and misrepresentative, especially about conditions such as HIV and cancer. This is the kind of misinformation the public is exposed to. We have to figure out a way to balance public access with public safety. Consumers want to know that what they are buying is safe and that it is actually what the label says it is. We have an obligation as a medical community to provide them with this assurance.

In terms of taking action, the White House Commission’s report recommended to Congress that an organization such as the Institute of Medicine should implement a review on the subject.

**Dr Ballance:** I think Kaiser Permanente can assume some of these tasks ourselves. For example, today we have heard that efforts on the West Coast are being taken to identify evidence-based activities and then to identify suppliers which achieve good manufacturing standards.

**Dr Elder:** I agree. Kaiser Permanente can have a major impact as the organization leverages its size and generates interest on the part of manufacturers to become involved in standardization initiatives so that our members can be assured of product purity and accurate label claims.

**Question from the Audience:** My question is for Dr Low Dog: Have you found any particular botanicals efficacious for treating premenstrual syndrome (PMS)?

**Dr Low Dog:** With regard to botanicals for PMS, the Shellenberg trial on Vitex, or chaste tree berry, was published in the British Journal of Obstetrics and Gynaecology in 2001. The study showed good efficacy for all parameters of PMS, so I will often recommend chaste tree berry along with calcium. Vitex is its botanical name, chaste tree berry is its common name. It usually takes a couple of cycles, but most women do quite well on it, so I think is a reasonable approach for PMS.

**Question from the Audience:** We have talked a lot about ingesting things and about using topical medications. Practically speaking, what do you tell the healthy young lady who comes to your office and wants your opinion about colon cleansing?

**Dr Low Dog:** This comes up a lot. A strong marketing effort for colonic therapy is aimed at people who feel like they are unclean if their bowels are not regularly moving. This marketing approach capitalizes on a long-standing belief existing throughout the history of medicine that if the colon is not cleansed, people become ill. So I listen to patients and then try to steer them toward foods that are actually healthy additions to their diet, and I tell them to avoid things such as colonic therapy or laxatives.

**Dr Elder:** I would agree. When the patient asks me about colonics, I generally discourage their use. It is true that in some CAM systems, such as western naturopathy and ayurveda, there is a strong emphasis on maintaining strong digestion and keeping the body free of toxins. As Dr Low Dog points out, however, the best way to achieve this goal is simply through a healthy diet. In the ayurvedic system, there is a procedure called “Pancha Karma,” which is a seasonally administered multimodality intervention, including therapeutic massage, inhalation of herbalized steam, application of heat, and administration of herbalized enema preparations. There is clinical trial data suggesting improvements in serum lipid values, lipid peroxide levels, and other cardiovascular risk factors in patients who have undergone this multimodality procedure. So, although the concept of detoxification is something that I think we should not completely dismiss intellectually, as a practical matter—with the problems related to quality control and the many unorthodox issues here—I suggest that we advise our Kaiser Permanente patients to avoid colonic therapy.

**Moderator:** Well, I think we should stop here. I do want to thank the panel for their involvement. You four have presented a wonderful symposium that will help our medical group here in Georgia as we begin the journey to better understand the opportunities and challenges presented by these alternative approaches. I suspect that the readers of these proceedings in The Permanente Journal will also derive real benefit from this dialogue regardless of where they are in the integration of complementary and alternative medicine.

**References**


soul of the healer

Spider Web
By Suzanne Ackley, MD

Dr Suzanne Ackley is an orthopedic hand surgeon with SCPMG in Orange County, California since 1986. She lives in Newport Beach, CA.
Clinical Information System (CIS)
Baselets Help Standardize Evaluation of ADHD in the KP Colorado Region

By Mark Groshek, MD

Introduction
For more than three years, nearly all patient charting in the Kaiser Permanente (KP) Colorado Region (KP Colorado) has been done in an electronic medical record called the Clinical Information System (CIS), a national version of which is currently being introduced to several KP Regions. One powerful tool in CIS is the baselet, a module containing a set of prewritten items that can be inserted into a clinical progress note. The purpose of this article is to describe a baselet instituted in KP Colorado to help streamline telephone intake of pediatric health plan members whose parents call to schedule an evaluation for attention deficit and hyperactivity disorder (ADHD), often because the child is having problems at school.

Organizational Context for Creating an ADHD Baselet
In KP Colorado during the past two years, the departments of pediatrics, family practice, mental health, health education, and pharmacy have formed the ADHD Task Force (Table 1) to develop tools for standardizing the telephone intake, clinical evaluation, and treatment of health plan members with ADHD. In developing its approach, the ADHD Task Force has drawn from recent guidelines published by the American Academy of Pediatrics (AAP),1,2 the Agency for Health Care Policy and Research (AHCPR),3 the National Institutes of Mental Health (NIMH),4 and national experts5 as well as from Best Practices guidelines developed in the KP Northern California Region.6

To improve the quality of care to our members, the task force has developed seven major goals:
- Assure that information needed to assist in this evaluation is obtained by clinical staff and practitioners before the initial visit.
- Assure that adequate time is allotted to complete the evaluation.
- Provide tools that allow health care practitioners to adequately assess patients both for signs of ADHD and for signs of other disorders that may coexist with or masquerade as ADHD.
- Provide suggestions for appropriate treatment of ADHD when the condition is diagnosed.
- Provide tools to support close follow-up of patients diagnosed with ADHD.
- Ensure a cooperative relationship between participating departments so that patients can make a smooth transition between them when interdepartmental referral is needed to provide proper care.

Description of the ADHD Baselet: Structure and Processes
Baselets are among the most powerful tools in CIS and are conceptually similar to the macro feature of word processing programs. Both tools are designed to allow users to insert prewritten items into a document by using only a few keystrokes instead of typing the item completely, letter by letter. In CIS baselets, prewritten items may include medical history, results of physical examination, other types of assessment, physician orders, and other plans. Items can be inserted as full text or as coded terms. Any of these items may be selected (“turned on”) or deselected (“turned off”) by the person who is charting. Selecting an item causes the item to become part of the patient’s permanent medical record; deselected items do not be-

Table 1. Attention Deficit and Hyperactivity Disorder (ADHD) Task Force members—KP Colorado

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Mark Groshek, MD, practices Pediatrics at the Arapahoe Medical Office in the Colorado Region, and is the Lead Physician for KP Online in Colorado. He is also an avid rower. Email: Mark.R.Groshek@kp.org.
These features enable clinicians to edit items so that charting is done accurately for each patient. Because the clinician need not type everything by hand, a baselet can increase the speed and completeness of charting. In addition, blocks of text can be added to a baselet to provide instruction and guidance to users of the baselet. In the baselet for ADHD, such blocks include information about diagnostic criteria and treatment approaches for ADHD and for other related disorders. As long as these blocks remain deselected, they do not become part of the patient's permanent chart.

After the clinician has edited the information to accurately reflect the patient's medical history and results of physical examination, this information is committed to the chart. At this point, the information becomes a permanent part of the medical record, and blocks that were not selected are deleted from the chart.

Every clinician and other staff member who provides patient care using CIS has an in-basket. In addition, each department has one or more departmental in-baskets. When a clinician or other staff member electronically signs a note in CIS, a copy of the note can be sent electronically to another person's in-basket. All clinical staff may look at any in-basket, thus helping to assure that needed actions remaining to be taken will be taken. Each department specifically assigns persons to manage the departmental in-baskets.

Most appointments in the primary care departments in KP Colorado are made by appointment clerks in the KP Colorado call center. Because these clerks do not provide direct

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**Quotes From Nurses Using the ADHD Baselet**

Caroline Koehler, RN, from the KP Colorado Region's East Medical Facility, says, “The ADHD baselet is clear, concise, and easy to use. It's an effective tool to accurately telephone triage these children. It gives the RNs a clear baselet to direct the patient to the appropriate department for continued care. Overall, it's a very helpful telephone triage tool.”

“This has really streamlined the triage process for complicated behavioral concerns,” said one nurse of the KP Colorado Region’s Westminster Medical Facility. Another said, “It is a great prompting tool for guiding our phone interview for behavioral and emotional issues.” A third added “It really has helped me make appropriate triage decisions about whether to send the member to mental health or to pediatrics” for initial evaluation. “It’s very thorough and quite user-friendly,” said a fourth nurse.

In addition, each department has one or more departmental in-baskets. When a clinician or other staff member electronically signs a note in CIS, a copy of the note can be sent electronically to another person's in-basket. All clinical staff may look at any in-basket, thus helping to assure that needed actions remaining to be taken will be taken. Each department specifically assigns persons to manage the departmental in-baskets.

Most appointments in the primary care departments in KP Colorado are made by appointment clerks in the KP Colorado call center. Because these clerks do not provide direct...
health systems

The nurse who responds to the phone call opens the ADHD Triage Baselet (Figures 1 and 2). This baselet includes some explanatory text for the nurse in addition to a series of questions designed to assist in screening patients for clinically significant mental health problems. These questions are followed by a series of questions designed to assist in screening patients for signs of ADHD. The baselet includes instructions for the nurse in how to proceed on the basis of information provided by the health plan member. If the screen suggests presence of a clinically significant mental health problem, the nurse informs the caller that his or her needs are most likely to be served by scheduling an appointment with the mental health department. The completed note is routinely sent to the appropriate mental health facility, which then contacts the patient to schedule an evaluation. If the screen suggests that ADHD is the primary issue of concern, the nurse mails a packet of evaluation questionnaires to the patient’s family. An appointment is scheduled only after the completed forms are received; this procedure ensures that full information will be available to the clinician at the time of evaluation. If the problem seems to be neither ADHD nor a clinically significant mental health problem, the nurse schedules a general appointment for the patient.

The baselet is designed so that the nurse making the telephone call can complete the baselet either while making the call or immediately afterward. Each yes/no screening ques-
Conclusion

Feedback from nursing staff that use the ADHD baselet has been positive. These staff members have found that the baselet helps to explain the process of the evaluation thoroughly to health plan members, helps ensure completeness of intake screening, and simplifies charting of the intake encounter. The ADHD Task Force developed three additional baselet groups in CIS to help streamline and standardize the approach to ADHD at KP Colorado. We plan to introduce those baselets in future *Permanente Journal* articles.

Acknowledgments

Marcia E Howard-Odnert, RN, produced the CIS baselet screen shots.

References

They say you can’t go home. Well, I tried. To be precise, I went back to what was my home for the first 16 years of my life to see what was there. I suppose I was somewhat shocked—but then, perhaps I shouldn’t have been. When I grew up in Kingston/Edwardsville, in Pennsylvania, my neighborhood was decidedly the wrong side of the tracks. I never thought anything of it, because my street was home. The people seemed to be right out of Damon Runyon or Jack London. There was Pidgy, Donald Duck, Gunshi, and a host of characters that would have spiced up "Guys and Dolls."

Our grocery store was set between two beer gardens. Across the street were several pool halls, gambling establishments, and a bowling alley. While the coal mines were still in operation, people had worked and lived there. Schools were full of children; the standard small business establishments for a neighborhood were operating. When I left home at 16 or 17 to return few times until medical school and then not after, I carried a pleasant image in my mind. That was 40 years ago and the pleasant image remained in my engrams. Somehow I knew the area had gone downhill with the demise of anthracite coal mining. While I was in medical school, our store/home burned down, and my mother moved away from the street. I never returned to the area after the late 1960s. My first recent view of the street came on the detour through it that I took following my mother’s funeral. The image was so fleeting that nothing really stuck in my mind. But last May, I returned to the street for the first time in all those years to see what had become of my old neighborhood. After I got over the initial shock of being there, all kinds of impressions flooded in. First was the impression of size. The Main Street I grew up on would be an alley in Santa Monica. The block I grew up on was really short. The property I grew up on was tiny. Where home was now sits a low-slung bar populated by denizens straight out of "Deliverance."

The dirt I played in is still there, the dirt where I fell learning to ride a bike is still there. I don’t know about any of the people. The business establishments are gone; most of the storefronts are empty. The schools are closed. The streets throng with memories but few people are visible. Those who eyed the stranger with a camera, a sport coat and tie and stood next to a nondescript white Oldsmobile probably thought he was a federal agent photographing the bar/pharmaceutical establishment. Well, I suppose home is gone, home has changed; or perhaps it’s me who has changed. Perhaps the essence of the place has remained, and my reference points have changed so much that I no longer can appreciate what is there. If there are children in that neighborhood, it still is home to them. It probably still seems like a significant part of their world and not the depressed area it seems to me. Instead of gray dirt and dingy buildings in disrepair, Santa Monica is now my reference point. To my children, now adults, a wide tree-lined street with well-manicured lawns and a thriving city around them is their “home” memory. What will their home look like in 40 years? Will they be able to return and see the same neighborhood, or will degeneration strike their roots? We all carry a component of where we came from in our personalities. We all have behavior that is shaped by our early life experiences. Wherever we come from, whatever our home is like, we carry it with us. As we carry fond memories of beloved people, we can carry fond memories of home, whatever it has become. Perhaps in the end, home is not so much a place as an idea. Mine is still there—its corporeal reality just belies its spiritual existence. ❖

Calvin Weisberger, MD, is Regional Coordinating Chief of Cardiology for Southern California. He is co-author of the book "Practical Nuclear Cardiology." He has written other pieces in various venues.
How to Say No

Introduction
When patients demand medication, tests, or something not medically indicated, several things may go through your mind:
- Why is this happening to me?
- Until now, I thought I was having a good day.
- Who does the patient think I am, their medical waiter?
- No. No. No!

The usual scenario might find you repeating phrases such as the following:
- “No, you don’t really need this, because …”
- “There is no reason to order this [test, procedure] or to either prescribe or take this [medication].”

As most clinicians know, taking this approach does not always work. Well trained as we are in the medical sciences, practiced as we are in the art of healing, and wanting as we do to please our patients, we are often unready to say no to patients when they want a particular prescription or test, even if it is unwarranted.

What strategies can we use to address these frequently uncomfortable situations?

Establishing Rapport
Before a patient listens to your advice, a good clinician-patient relationship must be established. The trust placed by patients in their clinicians must be established up front. Often, however, this relationship must be established in unfamiliar surroundings, such as the emergency department or urgent care department. In these busy areas, where each patient-clinician interaction is very brief, establishing rapport—the first of the Four Habits of Highly Effective Clinicians—is particularly important because it sets the tone of the interaction, during which the patient must develop the trust essential for hearing (and accepting) medical information and adhering to therapeutic regimens. To establish rapport with the patient, the clinician may say something personal or use “small talk” upon entering the examination room. For example, if the clinician knows that the patient has been waiting in the examination room, the clinician may say to the patient, “I am sorry about the wait.”

Elicit the Patient’s Perspective
A patient’s own explanation of his or her illness is called the Explanatory Model and is an important consideration in delivering effective medical care. The ability to discover the patient’s perspective regarding his or her medical condition is a crucial skill for clinicians because it may prevent or defuse potential conflict with the patient, who usually has a personal reason for requesting a particular drug or medical procedure. The reason may seem illogical to the clinician, but it always deserves to be heard. A patient may, for example, be afraid of catching pneumonia or being diagnosed with incurable cancer if a symptom is left unattended for too long. A patient may be reluctant or unable to express his or her theory and fear about the symptom. Most of the time, the patient wants (and expects) the clinician to relieve symptoms or address the patient’s fear. This expectation must be met before the patient can obtain satisfaction; indeed, the emotional needs of the patient must be addressed before any treatment is given. You must listen carefully for the psychological reason why the patient has come to see you. Only then can effective reassurance be given. Questions such as “What do you think is going on?” or “Are you afraid of anything in particular?” may allow the patient to reflect and express his or her own perspective.

Empathy
Empathy is a skill that allows a clinician not only to understand patients (ie, by identifying their emotions) but to effectively reassure them (ie, by verbalizing this understanding). By expressing this understanding verbally, clinicians can show that they care for their patients’ well-being and thus promote patients’ trust. For example, a clinician may say, “This cold must have been terrible for you!” or “Your headaches must have scared...
health systems

Acknowledging Difficulties, Being Flexible, and Setting Boundaries

When disagreement or dissatisfaction—expressed verbally or nonverbally—develops while interviewing the patient or while administering treatment, clinicians sense this difficulty but often do not address it. A clinician may have many reasons for refusing to acknowledge conflicts. “I don’t have enough time” or “I don’t want to get into an argument” are examples of these reasons. However, the conflicts will probably resurface later. The patient may initiate another office visit or develop distrust of the clinician or medical care system. Often, if you acknowledge the difficulty internally to yourself and verbally to the patient, that patient will take the first step toward negotiating a helpful compromise.

One such statement acknowledging a difficult situation could be, “I can see that we are having some difficulty here in agreeing on the treatment plan.”

In saying no, your flexibility is at issue. Therefore, when a conflict occurs, be conscious of whether you want more flexibility or whether you must set firm boundaries.

Invest in the End

Clinicians are generally more able to identify problems than to communicate findings. Patients who request antibiotic drugs or diagnostic tests are usually asking for symptom relief. They may request medication to cure a cold or may seek reassurance in the form of negative test results (eg, requesting magnetic resonance imaging [MRI] to prove that a headache is not being caused by a brain tumor). These initial reasons should be addressed, and the treatment goals formulated by the end of the visit should be consistent with the reason that initially prompted the patient to visit the clinic. Technical language should be used only sparingly, if at all, and words should be chosen to address directly the patient’s initial concerns. For example, the clinician might say, “You don’t have a brain tumor” instead of saying, “There is only a 2% chance that the MRI result would be positive.” Other important tasks are to involve the patient in making the final decision about treatment and to check for adherence to prescribed therapeutic regimens.

Conclusion

The Four Habits Model serves as a useful communication template for enabling clinicians to say no to patients who demand inappropriate drugs or medical procedures. Clinician-patient conflict—and the nonadherence that frequently results from this conflict—can often be avoided if the clinician uses empathetic, clear communication; negotiation based on acknowledgment; the ability to set boundaries; and flexibility.

References


Understanding

One should aim not at being possible to understand, but at being impossible to misunderstand.

Quintilian, 35-96 AD, Roman teacher of Rhetoric
In Memory of Carol Abramowski, RN, NP, MS
December 14, 1945—April 26, 2002

Carol Abramowski (left) and Winnie Star (right).

IT WAKES YOU UP TO LIFE
WHEN SOMEONE CLOSE TO YOU DIES
MOMENTS IN SMALL ELEVATORS
IN UNION WITH PERFECT STRANGERS
BECOME SIMPLE RAPTURE

CLIMBING EIGHT FLIGHTS OF STAIRS
ON ANY GIVEN DAY A STRUGGLE
BECOMES EFFORTLESS
WHEN YOU THINK OF WHAT YOUR FRIEND WENT THROUGH
TO LOSE HER LIFE

MORNING COFFEE AT THE LOCAL LINE
TRANSFORMS INTO GESTURES
RICH WITH KNOWING
THAT YESTERDAY WAS ALL IT WAS
AND TODAY IS ALL THERE IS

WHEN YOUR FRIEND DIES
THE WORLD CHANGES
AND THE SIGNS WITH ARROWS
POINTING RIGHT OR LEFT
DIRECT YOU TO THE NEXT STOP
AND AS YOU LOOK TO FIND THE TRUE DIRECTION
YOU ALREADY KNOW WHERE TO TURN

WHEN THEY DIE, THESE FRIENDS
YOU STOP LOOKING FOR A TREND
AND THE SIMPLE MOMENT
THAT LASTS A LIFETIME IN SILENCE
WITH GLAZED FACE
CONVEYS WHAT LOVE AND LIFE REALLY MEAN

By Winnie Star
May 10, 2002

Carol Abramowski was a women’s health nurse practitioner in the Department of OB/GYN at Kaiser Permanente Medical Center, San Francisco for nearly 20 years. She fought bravely after her diagnosis of cancer and was a source of inspiration for her family, friends, colleagues, and patients in the ways in which she coped with, prepared for, and accepted the inevitability of her untimely death. She will be dearly missed.

Winnie Star, RNP, has been a nurse practitioner in OB/GYN for 20 years at Kaiser Permanente Medical Center in San Francisco, CA. She has coauthored and edited several textbooks in women’s health. Her hobbies include writing poetry and short stories, and playing drums.
Roundtable Discussion –

Human Resource Leaders from

the Permanente Medical Groups

In support of the belief that all Permanente physicians are leaders, The Permanente Journal, in the Summer 2002 issue, created the new column: Physicians as Leaders. Sharon Levine, MD, from The Permanente Medical Group wrote a commentary introducing this new section, and Debra Mipos from The Permanente Federation presented the findings of a focus group on the subject.¹ Both authors supported the premise that whether or not a physician has an administrative title, he or she is viewed by the surrounding health care team staff as a leader for the work group.

The following conversations have been edited from a recent roundtable discussion. The participants included: Lee Jacobs, MD, Associate Medical Director for Professional Development, TSPMG, as Moderator; Mike McCabe, Manager, Permanente Human Resources, SCPMG; Craig Green, MD, Physician In Chief, Administration, SCPMG; Jill Steinbruegge, MD, Associate Executive Director for Physician Development, The Permanente Federation; Patty Fahy, MD, Associate Medical Director of Human Resources, CPMG; Marci K Clark, Director of Professional Resources, NWP; Tom Janisse, MD, Assistant Regional Medical Director, NWP; and Karen Tallman, Senior Analyst, The Permanente Federation.

Are Physicians Really Viewed by Staff to be Leaders?

Moderator: Probably the best way to open this discussion is to make certain that all of us are on the same page. So let me start by asking: Do you all support the premise that regardless of whether or not they have a formal leadership position, all physicians are viewed by the staff as leaders?

Marci Clark: I definitely support the premise. Certainly from the work group perspective, physicians are seen as leaders. They are leaders whether they want to be or not.

Dr Craig Green: It is important to acknowledge that in our society, there is a hierarchy of people, and like it or not, physicians occupy a place that is fairly high up in this hierarchy. For that reason, people tend to defer to us. I believe that physicians should accept that they are on stage and should act accordingly. Emmanuel Chabrier wrote an opera entitled The King in Spite of Himself, and I think that is the way it is with physicians as leaders. Physicians are leaders whether they believe they are leaders or not.

Dr Jill Steinbruegge: In addition to the hierarchical piece, there are some other very practical issues that put the physician into a leadership position. For example, it is the physician who determines the pace of the workflow. That then causes the staff who support that physician to act or react in certain ways. It is by default a leadership function. Because medical decision making is clearly in the physician’s realm, that drives what the rest of the team does and again, by default puts the physician in the leadership position.

Dr Green: When I raised this topic with our human resource leaders, they were very pleased to hear that this discussion was occurring, because they have seen the fallout from physicians who are unaware of the influence that they exert every day. What comes to the attention of human resource leaders are examples of how problems are compounded when a physician leads poorly and the people around him or her emulate that behavior.

Ms Clark: That all physicians are leaders is important because it places medical leadership at the forefront of the patient’s Kaiser Permanente medical care experience, right where it belongs.

Dr Patty Fahy: I agree. It is positional authority by nature of the fact that the physicians’ credentials put them into that leadership role. The contract between the Health Plan and the Medical Group also puts the physician in the position of authority and makes physicians responsible for the delivery of medical services. So, it is not only...
... in successful teams, physicians take responsibility for constructively addressing problems and engaging others to help solve them.”
—Dr Jill Steinbruegge

through informal leadership and positional authority but also by our medical services agreement with the Health Plan that the physician has authority for making decisions. 

Dr Green: The problem for many physicians is that they feel powerless—that what they do doesn’t make any difference and that nobody listens to them anyway. They don’t realize that people are watching and are going to change how they do business on the basis of what they see the physician do.

Moderator: In our team development activities in KP Georgia, we are starting to appreciate the importance of all the physicians on the teams understanding and demonstrating good leadership. In our model for team development, we have learned over the years that certain states of readiness must be addressed before embarking on the journey of developing strong, interdependent teams. In addition to having adequate staffing and a strong physician team leader (the formal leader), getting the other physicians on board as informal leaders is a critical step in having a successful team.

Considerations During Physician Recruitment

Moderator: Do any of your medical groups have a strategy to select physicians who demonstrate leadership competency skills during the recruitment process?

Mr McCabe: In Southern California, I would have to say that we have not had such a strategy as part of the overall interview process. However, in the forefront of the process for some area associate medical directors is the search for physicians who buy into the values and ethics of the partnership of Southern California. Although these characteristics may not always be obvious during the interview process, in our experience, these are the physicians who make good leaders.

Ms Clark: Although we haven’t had a specific recruitment strategy to address leadership skills, we do screen for quality of communication and interaction skills—both very important considerations regardless of the level of leadership we are talking about. In our recruiting process, we are now beginning to focus more overtly on fit with organizational and medical group goals.

What Does Informal Physician Leadership Look Like?

Moderator: It might be helpful for our readers to hear your description of what it looks like when a physician is a good informal leader in a workgroup.

Mr McCabe: Two things come to mind: First, a significant reflection of the level of leadership is the way a physician approaches the care and the service level given to members. The manner in which they treat members demonstrates the essence of Permanente Medicine. Second, the way physicians treat their peers and staff is important. If they treat people with respect and dignity, it is infectious.

Dr Green: I agree with Mike and would add another aspect: self-awareness. Physicians who are strong informal leaders know as they go through their day—and as they go through life—they are not in a vacuum. They realize that what they do has an effect on people, either positively or negatively, and so they take steps to channel each hour in a way that has a positive effect on others throughout the organization.

Dr Fahy: An article published in the Annals of Internal Medicine mentions that the best physician leaders behave as if they have a patient at their elbow. Although the authors are talking about formal physician-leaders, it is also true of informal leaders. They bring the patient’s perspective into every conversation. Excellent physicians are strong patient advocates, and they bring this perspective into their department or clinic and balance the needs of their staff and the patient.

Dr Steinbruegge: In addition, our recent research suggests that in successful teams, physicians take responsibility for constructively addressing problems and for engaging others to help solve them. As they say in the KP Colorado Medical Group, these physicians lead by initiating courageous conversations. They give both recognition for good work and constructive feedback about what can be improved. That’s strong leadership.

Informal Physician Leadership in Action

Moderator: Can any of you give some examples of when a physician, without a formal leadership title, demonstrated leadership skills?

Dr Tom Janisse: Recently, I presented worklife survey data at our All-Physicians meeting. Afterward, one of the physicians and I were talking about interactions with staff and about expectations and roles. He said, “You know, I actually have a clear statement of my expectations for my medical assistant posted right on my door.” I said, “That’s terrific; at least you are being explicit about it. Most people don’t do that. If people would share their expectations, that would be great.” He looked up in the air, thinking, and
then back at me and said, “You know what, I never asked my medical assistant her expectations of me.” That is an example of a physician “taking the lead.”

**Dr Green:** Although I don’t have a specific example, there is a situation that happens hundreds of times a day: how a physician deals with patients who are late. The physician can set an example by dealing with the late patient in a low-key, understanding, and positive way, instead of grousing or “flying off the handle.” It’s amazing how quickly the staff picks up on the behavior the physician models and affects the tenor in the clinic, their reaction to the physician’s response. Other team members observe the physician’s reaction to the late patient is one that really jumps out at me.

**Moderator:** Craig, that’s an excellent example, because every Permanente physician reading this discussion can identify with the late patient and with the various emotional responses the situation provokes. Team members observe the physician’s response. Other thoughts?

**Dr Steinbruegge:** Craig’s example brings to mind another situation—namely, how the physician handles adding another patient to an already very busy schedule. Although medically the problem could be handled on the phone, the advice nurse may be caught in the middle between the patient who wants to come in and the physician who says “they don’t need to come in. Find some way to take care of them.” How a physician supports the nurse and other team members in these situations is a reflection of their personal values, which strongly influence the team’s culture.

**Moderator:** Let’s say I’m a physician reading this dialogue, and you have convinced me that how I respond to situations will strongly influence how the team responds in the future. Can you help this physician? Are there leadership skills that a physician can learn?

**Ms Clark:** In KP Northwest, we have consultants from our CME and Professional Development groups who will work one-on-one with physicians to provide feedback on how their communication style and body language is coming across to others. Effective communication, both verbal and nonverbal, is critical to successful leadership modeling.

**Mr McCabe:** Although in Southern California we may not do as good a job at identifying the role of the physician in the medical group, we are now looking at our orientation program to make certain it is clear to new physicians that they are leaders with certain expected behavior. This is something that is on our radar screen in Southern California.

**Dr Fahy:** In Colorado, we are encouraging our informal physician leaders to attend our *Introduction to Management* training class. It is a two-and-a-half-day class with about 20 physicians in attendance. The physicians’ leadership experience falls into three groups: those with new administrative roles, experienced physician-managers, and physicians who have no administrative role. They have an opportunity to talk about things like recruiting, performance management, and working in the union environment. That dialogue goes quite a long way toward helping somebody improve his or her informal leadership skills.

**The Influential Physician People Want to Follow**

**Moderator:** It is important to emphasize for our readers that we are talking about physicians having influence over the staff, not heavy-handed control over them. We probably need to clarify that we are not talking about creating authoritarian “little Napoleons” on our teams. We are talking about encouraging Permanente physicians to be strong leaders so people want to follow them. Any thoughts to add?

**Dr Fahy:** It is a baseline understanding that the physicians we are recruiting are collegial and collaborative. We hope that would immunize us against giving the impression that we are encouraging a dictatorial style when we emphasize the importance of physician leadership.

> “Effective communication, both verbal and nonverbal, is critical to successful leadership modeling.”
> —Marci Clark

**Dr Steinbruegge:** Leadership means different things to different people, and the most common idea about leadership is a general who tells everyone to “go up that hill.” That isn’t the kind of leadership we are talking about. In the Advanced Leadership Program, we ask the question, “What does every leader need?” The answer is: “followers.” So how does a physician without a formal title get followers? You don’t get them by bossing them around and telling them what to do.

**Dr Janisse:** Some of what we are talking about might be titled *The Subtle Leaders.*
Dr Steinbruegge: Or leadership by influence, rather than by fiat or by formal titles.

Dr Fahy: You might also consider it “the new leader.” It is evidence-based leadership that really works. It is not coercive leadership or Napoleonic leadership, but leadership by influence.

Dr Green: There is one other thing that leaders need besides followers: They need a clear goal where both the leader and followers are heading. One of the things all physicians can do is to set a goal for their local unit to do X, Y, and Z for all our patients. This activity is very powerful.

Moderator: Karen, I know that you interviewed physicians on adult medicine teams all around the country, and I think some of these comments on being an influential leader are consistent with key observations of your work.

Karen Tallman: Yes. The discussion today reaffirms our findings. The Care Experience Project looked at work units with high ratings on patient satisfaction surveys and physician surveys (the People Pulse) in contrast with work units with medium or low ratings on these measures. We observed the importance of physician modeling. Providers and staff form an interdependent system. In strong groups, the physicians set a positive tone for the group. They give recognition and corrective feedback. In high-scoring work units, physicians are inclusive in the decision-making process. By bringing all members of the team into the process, these physicians use the experience of the entire group to gain cooperation. Most importantly, we learned that when there are rich, positive interdependencies, there is less stress in the team and the workday is more predictable.

Moderator: Any areas that you identified in your team research that we did not cover in this discussion?

Karen Tallman: We found that a physician’s management of aspirations affected morale. In some of the teams with low patient and physician satisfaction ratings, people aspired to change things that were outside of their control. This had a demoralizing effect on the work unit. In contrast, the physicians in strong work units were focused on things they realistically could change—issues within their sphere of influence. They started with smaller projects. They succeeded with most of these projects and were able to expand their control over the work environment.

Moderator: Thanks, Karen. I would encourage our readers to review your research on page 39 of this edition of The Journal. I agree with you: Today’s discussion on the importance of all physicians as leaders mirrors the major findings of your work.

I do want to thank the panel for contributing to this dialogue. In many ways, this is just the beginning as we all continue to learn about this subject. Along with our readers, I look forward to your contributions to this topic in future editions of The Permanente Journal. Thanks again.

References

The Greatest Good

The greatest good you can do for another is not just to share your riches but to reveal to him his own.

Benjamin Disraeli, 1804-81, British statesman and Prime Minister
Born and raised in Alexandria, the city that housed the Pharos lighthouse, Dr Abdalla says that he has always been attached to lighthouse photography. He has traveled extensively to add to his lighthouse photographic collection. Portland Head lighthouse is one of the most beautiful settings he has come across.

More of Dr Abdalla's work can be seen on pages 6 and 38.
To Be or Not to Be—
Preimplantation Genetic Diagnosis

The case and commentary are reprinted from Ethics Rounds, 10(4), 2001. KPHP Inc. and TPMG Inc.

The development of reproductive technologies throughout the last four decades has given birth at a daunting pace to a host of formidable questions for ethical reflection. The 60s ushered in the birth control pill and prenatal testing for some genetic defects by amniocentesis. During the next decade, abortion was legalized and the first test-tube baby was born. The abortion drug, RU-486, became available in the 80s. In the last decade, Dolly the sheep was cloned, and a child was birthed by a 63-year-old postmenopausal woman and another conceived from sperm that had been harvested from a dead man.

With each major developmental milestone, we encountered fresh dilemmas unique to the new innovation while simultaneously revisiting older, fundamental arguments about the definition of life itself. New reproductive technologies aiming to foster the creation of life always brought with them additional ethical transgressions than does abortion, since a number of embryos are created and discarded in the process.

But the ethical complexity of PGD goes well beyond right-to-life issues for embryos. The complexity arises from this ability to perform positive selections. We can imagine a day in the not-too-distant future in which a woman would undergo an ovarian biopsy via endoscopy to provide tissue with hundreds of immature eggs. Maturation of the eggs in the lab would be performed, followed by fertilization from her partner and then PGD. Emerging technology will permit the analysis of hundreds or thousands of genetic loci. The couple then would have, say, 75 genetic profiles of potential children from which to choose. They might choose #32 for this first pregnancy and #59, along with some other contenders, could be frozen for their next pregnancy. Perfect babies and a family of their dreams.

If something seems less than perfect in this scenario, then we need to unpack our sense of unease. Are we just queasy about new things, or is there a coherent logic to these concerns?

The Patterson case offers the opportunity to think through some of these issues. A similar case received wide publicity last year in which parents used PGD to select an embryo that

Commentary
Preimplantation Genetic Diagnosis and the Biologic Selection of Children

By Jeffrey R Botkin, MD, MPH, Professor of Pediatrics and Medical Ethics, University of Utah

This case is by no means science fiction, as the ability to select future children for their genetic traits is now available. For the past 30 years, prenatal diagnostic technology has offered the ability to perform a negative selection—that is, the ability to detect an abnormal fetus and terminate the pregnancy prior to fetal viability. Now, as this case illustrates, preimplantation genetic diagnosis (PGD) offers the ability to perform positive selections—that is, the ability to select an embryo for desirable traits, as well as to discard those embryos with genetic flaws.

PGD is offered in over 50 centers around the world, and it is estimated that more than 500 children have been born following this procedure. PGD has been used primarily by couples who are at increased risk of bearing a child with a genetic disease or chromosome abnormality. The obvious advantage of PGD for some couples is the ability to initiate pregnancy with what is considered a healthy embryo rather than take a chance with traditional reproductive means and face the prospects of a termination decision four to five months into the pregnancy. Of course, for those who believe human life should be afforded full moral status at the moment of fertilization, PGD involves greater ethical transgressions than does abortion, since a number of embryos are created and discarded in the process.

By Kate Scannell, MD, is an internist, rheumatologist, and geriatrician at Kaiser Permanente Oakland, CA. She is author of the book, “Death of the Good Doctor” and a columnist for the Oakland Tribune/ANG Newspapers. She also edits Ethics Rounds for Kaiser Permanente. Email: kate.scannell@kp.org.

Jeffrey R Botkin, MD, MPH, Professor of Pediatrics and Medical Ethics, University of Utah. Co-Editor, Genetics and Criminality: The Potential Misuse of Scientific Information in Court; American Psychological Association 1999.
To Be or Not to Be—Preimplantation Genetic Diagnosis

In this article, we will explore fundamental ethical issues raised by reproductively focused technologies through a specific focus on preimplantation genetic diagnosis (PGD), a new technology that allows biologic selection of children according to their genetic profiles. Bioethicist Dr. Jeffrey R. Botkin, Professor of Pediatrics and Medical Ethics at the University of Utah, provides the commentary.

The theme for this article resonates with the recent first anniversary of the September 11 terrorist attacks on New York and Washington, DC. Since that violence, it has been difficult to reflect on matters of life and death without some degree of reflection through the lens of war. Speaking to this, one could remark about broad conceptual similarities between them; of using value judgments—about a particular nationalism, religion, genetic makeup—to determine the appropriateness of another’s continued potential to live; of attempting to control or minimize the native biologic and socioethnic diversity of the human population; or even of asking in each circumstance by what agency and authority each of us decides how life begins and how it should end.

CASE: The Biologic Construction of a Child

Oscar and Nadine Patterson present Nadine’s gynecologist, Dr. Quatrain, with their request for preimplantation genetic diagnosis (PGD) in order to create a healthy baby harboring the exact type of cells needed by their desperately ill five-year-old daughter, Randy, for an organ transplant. The procedure involves hormonal stimulation and egg harvest from Nadine, followed by in-vitro fertilization of the eggs with Oscar’s sperm. The subsequently formed test-tube embryos would then undergo genetic screening tests, and those embryos not was both free of a mutation for Fanconi anemia and a tissue match for their six-year-old daughter who suffered with the disease. Stem cells from her new brother’s umbilical cord were transfused into the little girl and, remarkably, the procedure worked. In that case, a new life was created to save a life in jeopardy.

If we accept the use of PGD for, say, Tay-Sachs disease or cystic fibrosis or muscular dystrophy, must we accept its use for gender selection or for the right HLA type, or, some day, intelligence or perfect musical pitch? While professional societies discourage the use of PGD for gender selection (other than for sex-linked genetic conditions), there are no articulated standards for the use of PGD that delineate its ethical applications. To work through these issues, we must start with the most basic question: What justifies preimplantation genetic diagnosis or any form of prenatal diagnosis? Potential justifications focus on the welfare of the fetus/child through preventing a burdensome existence—the parents through preventing the burdens of an impaired child, or on social welfare by avoiding the social costs of ill or disabled individuals. While these issues deserve more exploration than can be provided here, it strains logic and common experience to claim that the vast majority of individuals with heritable conditions do not benefit from their lives. Similarly, the investment society makes in the health of individuals with heritable or congenital conditions affords them great benefit with many secondary benefits extending through society. It is difficult to claim that these investments do not produce a substantial net benefit to society. Therefore, of the potential justifications for prenatal diagnosis, the most compelling, if not the only real justification, is to assist prospective parents in their desire to avoid the difficulties of an impaired child.

Note that this justification is not founded on a simple philosophy of parental autonomy. Prospective parents have strong negative rights to be left alone with their reproductive decisions, but they do not have positive rights to obtain any or all prenatal diagnostic services for any purpose they wish. This is simply because these diagnostic services are provided by moral agents—such as doctors, nurses, and counselors. As moral agents, professionals have the prerogative of deciding the scope of their services based on personal and professional values. As providers undertake an ethical analysis of the issues, they must balance the potential welfare of the prospective parents with the potential harms to others. In the case at hand, Dr. Quatrain has every right to analyze the Pattersons’ request in terms of his personal values and in terms of values that he would promote for his profession.

Continued on next page.
matching Randy’s cell type or those carrying the gene for her immunologic disease would be discarded. Embryos passing the tests would be implanted in Nadine’s womb. Once a baby was born, some of his or her bone marrow would be removed and transplanted to Randy in hopes of establishing a healthy immune system for her.

The Pattersons had not planned to have another child. The work of raising Randy through multiple infectious complications had stressed their relationship, and the family finances suffered after Nadine quit her job to provide for Randy’s care. But the Pattersons stumbled across a newspaper account of a “test tube baby” engineered by PGD in order to save his sick sister’s life. They also read that the involved procedures cost approximately $30,000 and were not covered benefits of insurance policies. Instantly, they envisioned a potential for their daughter to be made well and survive her otherwise fatal illness.

Dr Quatrain is uncomfortable with the Pattersons’ request. A devout Catholic, he views embryo discard as a form of abortion. Even when he tries to separate out a medical decision from his religious beliefs, he still concludes that it is wrong to create “designer babies” and to generate one life in order to sustain another’s.

Mr Patterson is annoyed by Dr Quatrain’s hesitation. He even suggests that the $30,000 fee should be paid by the health plan because Randy is a plan member and entitled to treatment to save her life.

What should be done? What ethical issues are raised by this case?

So what should Dr Quatrain decide in this situation? If, as a devout Catholic, he is opposed to the whole enterprise of PGD, then the discussion need not go any further. However, if he is willing to consider assisting with PGD for this purpose, he will need to think through the pros and cons more carefully. Beyond the harm of embryo destruction with PGD, the other potential harm with positive selections is to the children who would be created. Selection of children by parents for their purposes in life poses a threat to the child’s autonomy as s/he grows to chart his/her own course in life. Selection for traits that normally would be beneficial could be seen as a curse by the child, as parents bear down to achieve their goals and to make their investment worthwhile. Uninhibited selection of children may threaten the very foundation of the parent-child relationship that must embody a strong element of unconditional love.

But note that this risk to the future child hinges on the parents’ desire to use the child as the instrument for their goals. In this case, the Pattersons want to select a child, not for the qualities s/he would have as a person, but simply for his/her HLA matched cells. Once the cells were harvested from [the infant], any special expectations for him/her would cease. Certainly the child is being used for his/her cells; but, presumably, s/he would not be used only for cells, but would become a loved and welcomed member of the family. The Pattersons’ need for this help is compelling, and no harm to others is apparent (the discarded embryos aside).

So the deep problems inherent in the positive selection of children do not pertain to this case. PGD for the Pattersons looks like a win-win scenario—a new life is created and a threatened life can be saved. Would this selection place our society on a “slippery slope” to other kinds of unacceptable selections? Possibly, but only if we continue to use this powerful technology without a thorough analysis of its ethical justification and without a professional standard that clearly articulates a strong set of moral values.

References

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**THE HUMERUS ZONE**

Cartoon submitted by Don Wissusik, MA, MS, a Clinical Supervisor in the Department of Addiction Medicine at Cascade Park Medical Center, Vancouver, WA.
book reviews

Ophelia Speaks: Adolescent Girls Write About Their Search for Self
by Sara Shandler

The editor of this book is a teenaged girl who conceived the idea of publishing a book of brief essays written by adolescent girls. She asked hundreds of girls from around the country and from a wide range of backgrounds to write about the most important of their life experiences. The result is an impressive piece of psychosocial journalism that will be important and useful to anyone wanting firsthand descriptions of the life-shaping experiences faced by teenage girls. Some of those experiences reflect contemporary issues; some go back to biblical times. Ophelia Speaks is thus relevant for physicians, both in their practices and in their homes; for parents who cannot understand what is happening to their daughters; and for adolescents themselves.

The book is divided into five sections: The Body Under Assault; Family Matters; The Best and Worst of Friends; Touched by Desire; and Overcoming Obstacles and Coming Into Our Own. Each section begins with a few pages of the author's remarkably frank descriptions of her own feelings and experiences in that area, followed by those of her contributors. Of the process of creating the book, she writes, “... most girls, but not all, opened the door on dark and disturbing times. Still others allowed light, instead of darkness, to glitter in their contributions.”

Section One discusses sexual abuse, something we all tend to deny but which current news articles force us to acknowledge. The editor writes, “... I was asked, ‘Would you use the [Wesleyan College] escort service?’ I sighed, ‘I don’t want to recognize the possibility of my being raped at my new home. If I call the escort service, I’m admitting to myself I can’t be safe here walking alone.’... Yet the mere existence of sexual violence shapes me.”

Family Matters addresses loss, especially the ongoing effects of divorce, but also death. “I can remember nights that I would yell and scream at my mother—but only in my head. Why did you abandon us? Do you know what you did when you left us?”

Eating disorders are common, although we generally do not recognize them in our medical practice. These disorders are described clearly in the book, sometimes along with other distressing techniques, such as self-cutting: “When blood starts to gush out of the newly opened veins, all the bad feelings fly out with it and I find release. I find my heaven. If only they would ever let me bleed long enough. They believe they are saving me, but only I know how to save myself.”

The remarkable editor observes, “Sadly, tragically, three abusive themes—incest, violence, and alcoholism—were mentioned more often than all others when girls wrote about their fathers.”

Touched by Desire contains details, often counterintuitive, of adolescent love and affection. Some of the stories may induce personal remembrance of anguish and confusion or perhaps memories of emotional support and understanding. “No one wrote about feeling satisfied by first-time sexual relationships. Instead of feeling love and commitment, girls consistently reported disappointment and disillusionment.”

One girl writes, “I thought by having sex together we would become closer; instead it tore us apart.” The book contains meaningful descriptions of manipulative and destructive relationships.

Its concept and firsthand descriptions make this a remarkable book. Its thematic material makes it an important book because it affects us all: as humans, as parents, and as physicians. We might wonder how these girls’ emotions will later manifest in our offices decades later. Adolescence is not an easy time; we will remember that Shakespeare’s Ophelia escapes into madness. Some of these girls will escape into illness. Will we be aware of its causality? Or will we merely respond to its physical symptoms while knowing nothing of our patients’ unexpressed feelings?

Reference
**Helping Your Child Lose Weight the Healthy Way: A Family Approach to Weight Control**
by Judith Levine, RD, MS, and Linda Bine

The goal of *Helping Your Child Lose Weight the Healthy Way: A Family Approach to Weight Control* is particularly well suited for women who want to know all they can about pregnancy. The book will be a wonderful resource for mothers who have at least a high school education and an interest in learning. A full range of topics is covered, ranging from prenatal visits and genetics to laboratory tests and the reasons for them. Probably of greatest interest to mothers will be the section that discusses common problems in pregnancy, how to choose a healthy diet, and how to care for a baby. Useful information is provided about special situations and complications so that if problems do occur, readers are equipped in advance with the knowledge provided by this book.

*Helping Your Child Lose Weight the Healthy Way* is a helpful resource containing valuable information that most mothers will read, appreciate, and understand. The multiple editions of this book speak to its success in accomplishing its goal.

Luz Garcia, PA, is with the Department of Preventive Medicine in San Diego, CA. She also works in community clinics providing prenatal care.

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**Pregnancy, Birth, and the Early Months: The Thinking Woman’s Guide**
by Richard I Feinbloom, MD

The goal of *Pregnancy, Birth, and the Early Months: The Thinking Woman’s Guide* is written to educate pregnant women, and I, as a woman, certainly did feel very well informed after reading this book.

Now in its third edition, the book is written clearly, concisely, and comprehensively. The author, an experienced physician, starts with an unusual, interesting discussion of the decision-making process and provides information that people can use throughout their lives when facing complex choices. The first piece of advice given is for women to become widely informed about all aspects of pregnancy and reproduction so that they can evaluate the pros and cons of any pregnancy-related choices to be made. The book takes an intellectual approach to its subject (appropriate for most—but perhaps not all—of the intended audience), and relevant supporting data are provided freely. The book will be of interest not only to mothers but also to fathers.

*Pregnancy, Birth, and the Early Months* is particularly well suited for women who want to know all they can about pregnancy. The book will be a wonderful resource for mothers who have at least a high school education and an interest in learning. A full range of topics is covered, ranging from prenatal visits and genetics to laboratory tests and the reasons for them. Probably of greatest interest to mothers will be the section that discusses common problems in pregnancy, how to choose a healthy diet, and how to care for a baby. Useful information is provided about special situations and complications so that if problems do occur, readers are equipped in advance with the knowledge provided by this book.

*Pregnancy, Birth, and the Early Months* is a helpful resource containing valuable information that most mothers will read, appreciate, and understand. The multiple editions of this book speak to its success in accomplishing its goal.

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Review by Luz Garcia, PA

Review by Kathleen H Jones, MD

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do not address weight loss as the goal but rather describe ways to make slow, incremental changes in food choice and activity. Developing a healthy lifestyle is the goal: “Positive changes in food and fitness should be your goal—not changes on the bathroom scale.”

This book is not about putting your child “on a diet.”

The authors present a stepwise plan. First, assess the child: Does the child think he (or she) is overweight? Are you the only one who detects a problem? You should select an approach on the basis of answers to these questions.

Next they guide us gently through the process of gathering data. Growth charts for height and weight and calculation of body mass index (BMI) are presented clearly and simply, as are instructions in how to complete a food diary and eating behavior survey as well as how to assess your child’s (and your family’s) exercise attitudes and behaviors. Having acquired assessment tools, readers are presented with eight substantial chapters on basic principles of nutrition. Among the topics discussed are the food pyramid, how to understand nutrition labels, savvy grocery shopping and planning, how to eat healthfully away from home, and calorie-lowering strategies designed especially for kids. This section of the book serves as great reference material.

The third major section of the book, “Focus on Fitness,” starts appropriately with a chapter titled “Off the Couch!”: “The widespread use of two modern inventions—the television and the automobile—have contributed significantly to the decrease in physical activity among adults and children.” In terms of causing epidemic obesity, this decrease in activity is at least as important as overeating. As in the section on making healthy food choices, the “Off the Couch!” section emphasizes ways to make slow, incremental changes in family activity lifestyle. Emphasis is placed on the family being active together—not on the child joining organized sports or exercise regimens. All of the recommendations given in the book meticulously and sensibly avoid singling out one child as needing to lose weight or be more active. This approach not only respects the self-esteem of the child but also recognizes that long-term success can be achieved only if the whole family is involved and if changes are gradual, small, and ongoing. The authors also recognize that children learn best by example.

The last section teaches parents how to facilitate change and how to recognize their own attitudes that might hinder change. The book also contains a section of “kid-friendly” recipes, followed by excellent bibliographic references. The book’s recommendations closely follow recommendations of the Expert Committee on Pediatric Obesity convened by the Maternal and Child Health Bureau, Health Resources and Services Administration, US Department of Health and Human Services.

As a parent and as a pediatrician who is truly frustrated by inadequate skills in treating obesity, I see this book as a ray of light in a dark room. The book uses an excellent stepwise approach that treats obesity simply and logically as a chronic problem and warns against short-term, quick weight loss. The book is helpful not only for parents but also for any clinician who provides medical care to overweight children.

References

Kathleen H Jones, MD
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The World of Letters
The world of letters is the true world of bliss.

Abraham Abulafia (1240 - 1292), Jewish mystic
Why Our Drug Laws Have Failed and What We Can Do About It: A Judicial Indictment of the War on Drugs
by Judge James P Gray

Review by Jill Waalen, MD, MPH

If there’s any doubt that the country is awash in illegal drugs, Americans need look no further than their wallets: 79% of US paper currency circulating in this country carries detectable amounts of cocaine. And headlines heralding seizure of tons of marijuana, heroin, cocaine, or other drugs are not signs of successfully fighting the “War on Drugs”; instead, such drug seizure is a sign of failure—proof that illegal drugs are being found in ever-increasing amounts within our borders.

A lively narrative filled with similarly provocative insight, Judge James P Gray’s book details how current US drug laws have created a wonderland of unintended consequences. The book also pleads for acute change in the direction of these laws. As a 20-year veteran of the Superior Court in Orange County, CA, Judge Gray writes from the front line in the War on Drugs—a futile battle, which, he maintains, has to date mostly been prosecuted against drug users instead of suppliers. As a result, the laws have successfully filled ever-growing numbers of prisons across the country with nonviolent drug offenders while both availability of drugs and the criminal activity surrounding them continue to escalate.

Gray’s account of the endless stream of drug offenders into the nation’s prisons yields some astounding statistics. For example, the incarceration rate in the United States is higher than in any other country except Russia. This statistic is largely a result of jailing drug users: 58% of federal prisoners are serving time for drug offenses. One of every 150 Americans is in jail at any one time—and this number is growing. As a result, one in 20 white Americans and one in four black Americans will be jailed sometime during their lifetime.

One of Judge Gray’s examples of unintended consequences is that our main method of getting tough on drugs—trying to “incarcerate ourselves out of the problem”—has resulted in leniency for more violent criminals: The combination of overcrowded prisons and laws that specifically require drug offenders to serve full sentences has allowed criminals serving time for violent offenses to be granted early release to make room for more drug offenders. This result occurs because, unlike the rule governing drug offenses in many jurisdictions, serving a full sentence is not mandatory for many violent crimes (eg, bank robbery and kidnapping).

In fact, according to Judge Gray, one of the only laws that has functioned as expected in the War on Drugs is the law of supply and demand: Largely due to drug prohibition, the driving force in the increasing drug problem is the huge profit which accompanies drug trafficking.

Why Our Drug Laws Have Failed is intellectually stimulating and rivals the 2000 film Traffic in illustrating the pervasiveness of the drug problem in America. After reading the book, one finds it difficult to identify any aspect of American life that has not been corrupted by both our country’s drug problem and our chosen method of combating it. The enormous profits to be reaped from drug trafficking have encouraged creation of youth gangs, corruption of law enforcement officials, and a dramatic increase in crime rates. At the same time, the ever-escalating War on Drugs also has had negative effects: Channeling resources away from prosecution of other crimes; threatening the environmental health of developing countries by using toxic herbicides to eradicate drug-producing plants; and, in the name of drug interdiction, stripping civil rights from many US citizens in a way unlike any other pre-September 11 law enforcement initiative.

Judge Gray’s book presents an insider’s view backed by quotes from many other judges across the country who echo his desperation in the fight against illegal drugs. The book goes beyond the standard call for blanket legalization of all drugs, a call based solely on comparison with the failed prohibition on alcohol. The author digs deeper, tracing historical idiosyncrasies that have created the current situation. According to Judge Gray, original drug laws were “… fundamentally racist laws aimed at perceived threats to white women … [from the use of cocaine, marijuana, and opium] by black, Mexican, and Chinese men, respectively;” and in the decades since, US Presidents and the US Congress have continued to pass stringent laws—and when these laws fail, to pass more of the same—so as to gain the political benefits of “getting tough on drugs.” Judge Gray also
describes “the Prison-Industrial complex”—prison-building industries combined with the bureaucracies running the prisons—as a self-interested force that practices political opportunism in perpetuating the status quo.

Dividing the book into two roughly equal parts (as suggested by the title), Gray performs best in the first part: How the War on Drugs is failing. Probably because it lacks concrete examples of success, the second half of the book—the part that discusses what we can do about drug abuse—is less satisfying. Judge Gray outlines specific strategies for education, mandatory drug treatment, needle exchange, and drug decriminalization as steps toward a solution. In particular, he emphasizes education—but not the “Just Say No” variety. Instead, he argues for a more realistic, truthful approach that recognizes drug use as part of the culture and that portrays drug use as risky, harmful, and unattractive—an educational approach similar to that taken in current antitobacco campaigns.

For Judge Gray, drug decriminalization—a big step toward removing the profit from drug trafficking—would restrict and regulate drug sales instead of prohibiting them outright. Here his argument is buttressed by the apparently arbitrary line between some legally prescribed drugs (eg, tranquilizers) and illicit, “street” drugs. Although Judge Gray cites some successful examples of these approaches in other countries, no currently successful comprehensive model exists; and, as the second section of the book makes clear, changing our approach to the drug problem will ultimately require “a leap of faith,” ie, a willingness to try creative new strategies.

Although included in Judge Gray’s list of options, continuing to escalate the current War on Drugs is one option that, as the book clearly shows, is not viable. If the book attracts enough readers, its well-reasoned and convincing arguments may help increase the ranks of drug antiprohibitionists beyond the libertarian fringe and could draw a coalition of drug law reformists from all political quarters. Judging from the wide spectrum of support for the book—represented on the jacket by endorsements—from people ranging from political commentator Arianna Huffington to broadcast journalist Walter Cronkite to economist Milton Friedman—Judge Gray’s effort to assemble such a coalition is off to a good start.

Two Freedoms

There are two freedoms—the false, where a man is free to do what he likes; the true, where a man is free to do what he ought.

Charles Kingsley, 1819-75, English clergyman and novelist

References


CME Evaluation Form

All PMG physicians and those clinicians eligible to do so may earn up to two hours of Category 1 credit 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. This form must be returned (fax or mail to the address listed on the back of this form) to The Permanente Journal by December 20, 2002 in order to receive credit. You will receive an acknowledgment by January 6, 2002. You must complete all sections to receive credit.

The Permanente Journal has been approved by the American Academy of Family Physicians as having educational content acceptable for prescribed credit hours. Term of approval covers issues published within one year from the distribution date of November 2002. This Fall 2002 issue has been reviewed and is acceptable for one prescribed credit hour and one elective credit hour. Credit may be claimed for one year from the date of this issue.

Section A.

Article 1. Views and Use of Complementary and Alternative Medicine by Mid-Atlantic Permanente Medical Group Health Care Providers

Physicians are most likely to use an alternative form of therapy when:
- They use it personally with success
- Patients demand it
- Evidence-based information supports its use
- They believe that alternative medication has fewer side effects

Providers’ concerns about alternative therapies focus mainly on:
- Their lack of knowledge about complementary and alternative medicine therapy
- Their lack of personal experience with these forms of therapy
- Malpractice issues
- What their patients will think if they suggest alternative therapy

Article 2. Jimson Weed Poisoning—a Case Report

The following statements are true EXCEPT:
- The leaves and seeds of jimson weed contain the highest concentrations of potent chemicals
- Symptoms of jimson weed toxicity take longer than two hours after ingestion to occur
- Hallucinations, dry mucus membranes, thirst, blurred vision, and difficulty speaking and swallowing are presenting symptoms
- Elimination of toxin and symptoms persist for up to two days

Treatment of jimson weed poisoning is limited to:
- Activated charcoal and observation
- Gastric lavage and induced vomiting
- Cardiac monitoring and serial neurological measurements
- Use of physostigmine in severe cases
- All of the above
- A and b

(Continued on next page)
Article 3. How Can We Integrate Alternative Approaches and Mainstream Medicine to Treat Chronic Low Back Pain?

Which of the following is NOT an appropriate choice for the treatment of chronic mechanical back pain:
   a. Cognitive-behavioral mindful meditation movement program
   b. Acupuncture
   c. Lifestyle changes: weight reduction, smoking cessation
   d. Magnets

The biopsychosocial predictor most likely to be related to improved outcome for back pain is:
   a. Well-balanced family life
   b. Job satisfaction
   c. Status in the community
   d. Number of children


Practice teams which have high physician satisfaction show the following characteristics EXCEPT:
   a. Physicians and support staff are all included in decision making
   b. Physicians set the tone for the team by modeling expected behavior, rather than asking for exemplary behavior from others
   c. Physicians and support staff give each other recognition and constructive feedback
   d. Members of the team handle interpersonal discord in a timely manner
   e. Teams try to solve problems outside their sphere of influence to improve the work environment

Which of the following statements are true:
   a. Use of values and guiding principles to guide daily decision making characterizes work units with a positive physician work environment
   b. A strong team environment where everyone works together to provide an excellent experience for patients which creates high physician satisfaction ratings
   c. Research has demonstrated a link between the work environment at KP and patient satisfaction
   d. B only
   e. A and b only
   f. A, b, and c