

# Complementary and Alternative Medicine: Panel Discussion

Lee Jacobs, MD, Moderator

**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 our-

selves 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 I believe about \$15.00 a year and you can see where they list all the companies that have passed and failed testing. You will find that the same companies nearly always pass or always fail the tests. I will say that some of the companies that always pass 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:** *A quick follow-up: After you pay your \$15.00, do they give bibliographic references to your patients, or do you send the patients to the Web site?*

**Dr Low Dog:** We tell them about the Web site and give them a handout that clearly states problems with certain medications and the fact that a lot of quality issues exist. We also give them a list of six companies that have repeatedly met GMP standards as well as a list of the herbs that have been clinically tested in clinical trials.

**Question from the Audience:** *Dr Elder, I noticed that you are doing research on temporoman-*

*dibular disease (TMD). Being in an otolaryngology practice, I see this problem regularly. Our guidelines recommend a prosthesis and maybe physical therapy, but I have patients who come back to me very frustrated with our approach and not noting improvement. I know of a dentist in the community who sounded as though he was into biofeedback and other alternative approaches, and his patients have told me that their problems have improved. Are you finding that the mind-body approach is much more important for a large number of these patients?*

**Dr Elder:** 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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cally significant. So the short answer is yes. There are two other larger CAM TMD trials at our Center for Health Research that are still ongoing. In these trials, TMD patients are being randomized to treatment with a range of CAM interventions, including acupuncture, massage, chiropractic care, and naturopathy. I think the relevant question for clinicians is, "Can we identify subsets of these patients who will be most likely to benefit from particular CAM interventions?"

**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 allhucema [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 qual-

ity, 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<sup>1</sup> 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 who take 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 Pharmacopeia [Homœopathic Pharmacopœia of the United States<sup>2</sup>] 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 7587 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<sup>3</sup> 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.

**... you need to use methodology appropriate for the effect you are evaluating.**

**Dr Low Dog:** Well, just to conclude that thought, let me emphasize that the 1997 study was a meta-analysis for which the investigators lumped together all homeopathic trials, gathering everything on which a homeopathic trial could be done. Apples weren't compared with apples; the researchers rejected many studies but included ones that compared different doses and different dilutions for different conditions. The conclusion was that the test substances marginally edged out the placebo when the results were considered as a whole. But how can this result mean anything? How can you compare a 6x dilution with a 100x dilution? So, the meta-analysis has been heavily hammered, and the conclusions were correctly challenged.

**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 herbals—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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*necessary medical care to patients. Has 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,<sup>4</sup> 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 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.<sup>5</sup> 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 unclear 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<sup>6</sup> suggesting improvements in serum lipid values, lipid peroxide levels, and other cardiovascular risk factors in patients who have undergone this multimodality procedure.<sup>6</sup> 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

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