PSA

Patient Safety America Newsletter

August 2011 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: What percentage of physicians experience burnout in the United States?*
a) 5% b) 15% c) 25% d) 35% e) 45%

Food-borne Disease: A Slow Death

If we Americans are going to improve our health and control unsustainable costs, then we are going to have to look beyond traditional clinical medicine. Last month I summarized an article called "Comparative effectiveness – Looking under the Lamppost" in which two MDs declared that we spend 95% of our healthcare dollar on clinical care, yet only 20% of health outcomes depend on clinical care. The remaining 80% of determinants include behaviors and community wellness environments. Herein I will summarize an article from the *American Journal of Cardiology* last year and given to me by a physician colleague who knows my distaste for conventional clinical cardiology as a healthcare solution.[1]

The article specifically advocates and scientifically demonstrates our need to look elsewhere besides under the clinical lamppost for care of cardiovascular disease. The physician-author advocates preventing cardiovascular disease by consuming a plant-based diet. He rightly asserts that our Western diet of processed oils, white flour, and dairy and meat products progressively injures the lining of our blood vessels, leading to overt clinically-evident heart disease. Of course the healthcare industry is not especially sad about all this since $21 billion is spent each year on statins alone and $5 billion on stent placements.

One of the major problems with this "outside-the-box" approach is that few insurance companies pay for nutritional counseling needed to support a person as he transitions his diet. In addition, physicians fail to inform patients of this option because they assume patients lack the ability to change diets. To quote the author: "In the history of our [medical] profession, have we ever before developed an expensive, painful, non-therapeutic treatment of the leading killer of women and men while failing to inform them of the cause of their illness?" The keys to success are informing the patient about the mechanisms at work on his cardiovascular system when he consumes a Western diet, and follow-up sessions to reinforce compliance.

The author initiated a study in 1985 by placing patients with serious cardiovascular disease on a plant-based diet. He has followed those patients for more than 20 years and claims reversal of their disease through a series of publications in major medical journals. His patients lose weight, see a fall in blood pressure, and quit having chest pains (angina). They do not need statins or stents. Thus, you as a patient have to decide if you want to fall into the hands of cardiologists with their scalpels, probes, cauterizing machines, and drugs.

The author works at the Cleveland Clinic Wellness Institute and is credited by President Clinton for part of his recovery from cardiovascular disease: (http://www.vegsource.com/news/2010/09/president-clinton-credits-caldwell-esselstyn-md-for-decision-to-go-plant-based.html). Personally I'm going to work on transforming my diet to one based on plants. Here is a rather slow-moving, one-hour lecture that might encourage you: http://video.google.com/videoplay?docid=-5215695644951404318#, also Google 'Esselstyn.'

Book Review:

Doctors Ain't What They Used to Be

By Jack V. Kahn

I usually do not read books that fail to provide well referenced information about the need for improved patient safety and how to achieve those improvements. This small book was an exception to my usual reading and I am glad that I made that exception. Mr. Kahn, a syndicated radio show host and medical correspondent, begins his trek into the wilderness of medical error by retelling 50 experiences as described to him by victims of medical error. I thought I would be bored by reading the witness of 50 victims, but I was not bored at all.

As one reads these brief accounts, the human suffering comes clearly through. His survey is nicely balanced, hitting the high points of medical error: healthcare acquired infections, wrong medications, botched surgeries, wrong diagnoses, communication problems, and lack of accountability for errors. From the examples, which comprise fully half his book, he sets out in various directions.

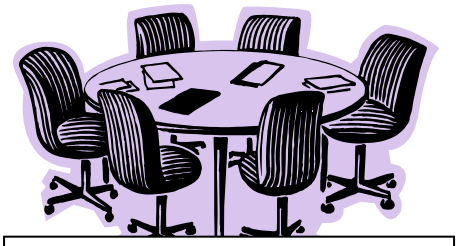
We are told how to find out information on doctor performance and how to write a letter to our doctors and nurses so that they will be aware of critical information about you as a patient. The next to last chapter was especially interesting to me because it addressed something I want to do one day: publically protest in front of the institutions responsible for the medical errors that made me into a patient safety activist. I found his mini-treatise on first amendment rights distracting, but I liked his advice on how to protest without getting arrested.

The last chapter encouraged us all to know about the drugs we are prescribed and be absolutely certain each one is needed. This advice is perhaps a little simplistic. There are few absolutes in medicine and a drug may be a balancing of risks that are not fully known. A prime example is when to take blood pressure lowering medications to head off damage to your cardiovascular system.

I liked this book and recommend it to patients and others who might be just getting into the patient safety movement. Its language is simple (i.e. non-medical) and its treatment of issues is balanced and digestible. It does seem somewhat incomplete, but then I remind myself that Mr. Kahn is planning more books to complement this first in his series, and those will presumably fill in the gaps that this "BOOK ONE" has not considered. **4 stars**, www.doctorsaintwhattheyusedtobe.com, $12.95.

Dangerous Medical Devices

The Food and Drug Administration (FDA) approves medical devices for use in and on the bodies of patients who may need them. A device presented to them for approval can take three routes to reach the market where it can be placed in or on you: 1) the slower, more rigorous premarket approval (PMA), 2) expedited approval of devices similar to ones already approved (510k process), or 3) exempted from regulation. At face value this seems reasonable since it attempts to balance the need for quick approval of improved devices against the need to protect patients from dangerous new devices. Unfortunately, it is not working out that way. In recent years only 1% of devices were reviewed by the more rigorous PMA process.



FDA Meeting on Devices

Three experts asked how many of the devices on the FDA's high-risk recalls were approved by each of the three processes between 2005 and 2009.[2] During that period 113 devices were recalled and only 19% of these had been through the most rigorous PMA process. Most of the remaining recalled devices (71%) had been through the expedited 510k process. The largest category of high-risk recalls (31%) was for cardiovascular devices.

The authors trace the regulatory "adjustments" that have led to this imbalance between rapid approval and exposing patients to "life threatening" problems from medical devices. Perhaps the last straw came in 2002 when Congress and President Bush approved the Medical Device User Fee and Modernization Act, and then the FDA interpreted it to mean an expedited approval whenever possible.

For perspective, during 2006 alone the FDA received reports of 2830 potential device related deaths and 200,000 adverse event reports. The largest single type of device recalled was the automated external defibrillator (AED). It seems that 20% of AEDs have been recalled for malfunctions

and hundreds of people have died due to AED malfunctions.

Two physicians wrote comments on the findings of this study.[3] They note that the FDA is taking steps to improve its approval processes, but these by no means ensure the protection of patients. In their opinion, devices that sustain life should not be placed in the 'low-risk' category for evaluation. But they note that there are deficiencies in the data used to support even high-risk devices approved through the most rigorous PMA process. The authors point out that for law makers and the FDA "Doing the right thing will require withstanding the pressure of [device] industry lobbyists." That should be no surprise.

If your doctor proposes to use a medical device on or in you, then ask many questions about it. When was it approved? How often has it been used and how often has it failed? Be careful of answers stating that *similar* devices have been used for years. This may mean that you have little assurance that you are not being exposed to unnecessary risk by the *specific* device being proposed to you.

Adverse Drug Events in Older Patients

I often wonder at the names used to describe a certain medical thing that places patients at increased risk of harm. Five experts published an article critical of the use of PIMs in older adults. What is a PIM, you might ask. PIM is the acronym for "potentially inappropriate medication." What does "inappropriate" mean in this context? It means that the medication prescribed to you places you at high risk of harm. For purposes of this summary, I'm going to call these "PIMs" what they actually are: high risk medications (HRMs), an acronym that comes close to spelling "harm."

Labels aside, the goal of the study was to determine if HRMs actually led to avoidable drug events that cause or contribute to urgent hospitalization.[4] The experts used a new screening tool called STOPP to identify HRMs in 600 patients aged 65 or older who were admitted a teaching hospital with acute illness. Using criteria from the World Health Organization and a "local expert panel," they identified 219 events that were caused or contributed to by the prescription of HRMs. When HRMs were prescribed that were inconsistent with the STOPP criteria, the patient had a nearly 2-fold risk of an avoidable adverse drug event actually occurring.

The message for you as a patient is that drugs are an invasion of your body just as surely as the scalpel and radiation. Do not accept drug prescriptions without understanding whether they may be HRMs. Ask the prescribing physician why you need the medication. Remember, physicians are seldom held accountable for prescribing HRMs, so no one is looking out for you except you.

Dirty Drug Company Marketing

Those of us who park themselves in front of the TV in the evenings know that drug companies pursue aggressive marketing approaches to patients. Physicians are the other target of drug-company marketing, and a recent investigation reveals how cleverly marketing strategies can be hidden behind seemingly legitimate scientific inquiry.

Three investigators asked whether the 1995 "clinical trial" of Neurontin, an anticonvulsant drug, was a legitimate investigation or a seeding trial.[6] A seeding trial is a study whose main purpose is to promote use of new drugs that have just been approved or are under review by the FDA. Such trials are characterized by marketing involvement in study design, in data collection and analysis, and in keeping the true purpose of the study from boards designed to protect patients. To quote a commentary on such trials: "These trials deceive investigators, clinicians, and patients, subverting the scientific process and violate ethical norms."[7]

During the seeding trials, which involved 2800 patients, 11 patients died, 73 experienced serious adverse effects and 1000 experienced less serious adverse effects. In many cases physicians were given 'promotional' rewards, such as a free

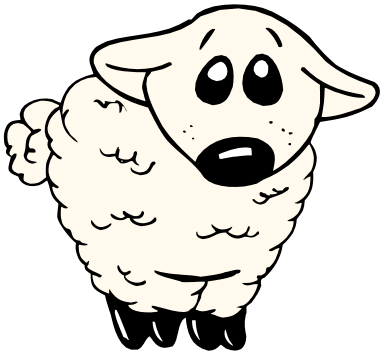
> Despite over 2 decades of research into medication safety, preventable adverse events continue to be a problem of epidemic proportions in the outpatient setting.
> Jeffrey L. Schnipper, MD[5]

dinner, for recruiting patients to the study. Situational analysis by the drug company indicated that another purpose of the trial was to block neurologists from prescribing a competing anticonvulsant.

Many other disclosures point to the fact that the Neurontin trial was designed to increase market share, which it did, and not provide new scientific evidence of efficacy. The authors are highly critical of the Institutional Review Boards comprised of experts who are supposed to protect patients from unscrupulous treatments. In this case the boards involved were duped. Of course there are many legitimate trials of new drugs. **If you are asked to participate in a drug trial, you must ask many questions before saying yes. Patients in this seeding trial were denied sufficient information to give informed consent.**

A Wolf in Sheep's Clothing

Most of us have been solicited by Health Advocacy Organizations such as the American Cancer Society, March of Dimes or Autism Speaks. Many of these organizations provide a valuable service to patients with specific illnesses or the potential for being at higher risk of an illness. A commentary in the *JAMA* by an expert from Columbia University points out that too often the recommendations from such advocacy groups can be inconsistent with evidence-based medicine and can needlessly increase healthcare costs.[8] One example the author decries is that the American Cancer Society insists that "annual mammograms for women over 40 years are essential." This declaration tends to ignore the balance between risk of disease and harms of over diagnosis when screening a population with a low risk of the targeted illness. Using scientific evidence, a panel of experts recommended against "routine screening mammography in women aged 40-49 years."[9]



Before you contribute to a Health Advocacy Organization ask its proponents how the organization supports the use of evidence-based medicine in their recommendations. Certainly, before you *follow* the recommendations of such a group, ask whether their policies reflect evidence-based medicine or are there to hype the advocacy agenda of the group.

References

1) Esselstyn, CB. Is the parent therapy for coronary artery disease the radical mastectomy of the twenty-first century? *Am J Cardiol* (www.ajconline.org), 2010
2) Zuckerman, DM, P Brown, and SE Nissen. Medical device recalls and the FDA approval process. *Arch Intern Med* 171:1006-1011, 2011
3) Redberg, RF and SS Dhruva. Medical device recalls. *Arch Intern Med* 171:1011-1012, 2011
4) Hamilton, H, P Gallagher, C Ryan, et al. Potentially inappropriate medications defined by STOPP criteria and risk of adverse drug events in older hospitalized patients. *Arch Intern Med* 171:1013-1019, 2011
5) Schnipper, JL. Medication Safety…Are we there yet? *Arch Intern Med* 171:1019-1010, 2011
6) Krumholz, SD, DS Egilman, and JS Ross. Study of Neurontin: Titrate to effect profile of safety (STEPS) trial. *Arch Intern Med* 171:1100-1107, 2011
7) Alexander, GC. Seeding trials and the subordination of science. *Arch Intern Med* 171:1107-1108, 2011
8) Rothman, SM. Health advocacy organizations and evidence-based medicine. *JAMA* 305:2569-2570, 2011
9) US Preventive Services Task Force. Screening for breast cancer: recommendation statement. *Ann Intern Med* 151:716-726, 2009

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Answer to question this month: d) 30-40%, Dyrbye and Shanafelt. *JAMA* 305:2009, 2011