PSA

Patient Safety America Newsletter

December 2012 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: If you are 50 years old, what are your chances of dying of colon cancer over the next 10 years?*
a) 10% b) 5% c) 2% d) 0.5% e) 0.2% f) 0.1%

Book Review: **Beat Your a-Fib**
By Steve S. Ryan, PhD

Generally, I identify the books I want to review, but this one found me. I do not have A-Fib, an irregular beating of the small chambers of the heart, but many older people do (about 10% at 80 years of age). You may have heard the Pradaxa® advertisements on TV for treatment of A-Fib not caused by valve problems. If your cardiologist diagnoses you with A-fib, you have a myriad of choices to deal with your illness. The thesis of Dr. Ryan's book is that a cure is better than management with drugs. He earned a PhD in educational communications and backs up his opinions by support from at least two MDs. He has recovered from A-Fib, a diagnosis he received in 1997. He knows firsthand what he is talking about. I'm certainly no cardiologist, but in my opinion this book is an excellent place for those with A-Fib to learn more about their illness and the treatments available. The text is easy to read and Dr. Ryan elaborates with clear diagrams, relevant examples, lessons learned, and snippets of "wisdom."

You may find a simple solution to your a-Fib problem, or you may need to consider invasive procedures or drugs. There are serious risks in not treating the disease. Dr. Ryan's book is an excellent place to build your knowledge of this disease so that you can be a full partner with your cardiologist in deciding your best course of treatment. Obviously, a cure is better than a lifetime of management with drugs, but you must understand the risks of either choice. You must also be wary of bias in your cardiologist's opinions. For example, Dr. Ryan offers a fine explanation of electrolytes (magnesium, calcium [too much], and potassium) in managing heart arrhythmias, but too many cardiologists overlook this potentially simple solution to A-Fib. Five-stars for those with A-Fib. Amazon, $28.

Chemotherapy and Advanced Cancer

As we age, we think more about our personal risk of cancer. By the time most people are 60 years old they can name friends who have died from this insidious and dreaded disease. Many years ago when I was working at the National Cancer Institute on a model of colon cancer, I remember President Nixon declaring a "war on cancer," and then budgeting much funding to win that war. Decades later we are still fighting that war. We may have won a few battles, but the war continues to favor the disease. Just like the combat wars our country has fought, the way we battle cancer has unintended consequences because people are harmed by collateral damage.

Last month four MDs wrote an article entitled "Cancer screening campaigns – getting past the uninformative persuasion" in the *New England Journal of Medicine*. It describes the widespread overuse and misuse of cancer screening.[1] They opine that patients need to be told the absolute risk of death with and without screening instead of being frightened by advertisements. An old ad they depicted from the 1970s shows a stern looking woman below a caption reading "If you haven't had a mammogram, you need more than your breasts examined." Unfortunately, these days cancer screening ads, although more gentle, have become marketing tools for parts of the medical industry.

The authors suggest that physicians and patients need to have better data on the efficacy of a screening test before they make a shared decision that one is needed. There are serious risks of too

much screening. The authors describe a screening guide for lung cancer that they have just developed with the National Cancer Institute. The guide points to absolute risks with and without low-dose CT scans to detect lung cancer in high risk people (30 pack-years of smoking). Of course, the guide advocates smoking cessation as the best remedy for fear of lung cancer.

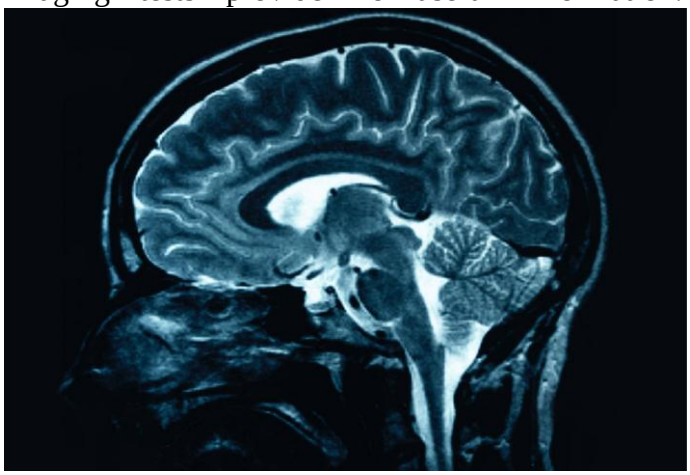
On another battle front, when an advanced cancer is stealing the life of a patient, does that patient understand that chemotherapy is not going to win the battle for their life?[2] A team of medical experts asked if patients with incurable cancer understood that the chemotherapy they were receiving was for palliative purposes and offered no hope for a cure. Their findings surprised me.

The investigation included 1200 patients with incurable, metastatic lung or colon cancer that were receiving chemotherapy. Of the patients with lung cancer 70% did not understand that their chemotherapy was not at all likely to cure their cancer. Of the colon cancer patients, 80% had the same misunderstanding. When the patients were broken into three groups according to how well they felt their doctor was communicating with them, the investigators found that the chances of misunderstanding was twice as high in the bottom "communication" group as in the top "communication" group. The authors note that many patients receiving chemotherapy for incurable cancers may not be making informed decisions about their treatment.

In my opinion, the problem lies squarely on the doorstep of the oncologists who do not communicate well. It is unethical not to communicate clearly to patients that their chemotherapy is not going to give them a cure. There is often a perverse incentive present because oncologists get a commission for "selling" chemotherapy to patients.[3] Frankly, I know of several people who suffered extreme nausea and profound fatigue during chemotherapy, and then died in a few months anyway. Lack of informed consent from patients is too often one of the tragedies of American medical care.

Imagine Less Imaging

Two MDs writing in the *Annals of Internal Medicine* describe the "Choosing Wisely Initiative" to limit the use of medical tests that are of no value.[4] Nine professional medical organizations were each asked to identify 5 tests or treatments that were often being overused. Of the 45 practices identified, 24 involved overuse of diagnostic imaging. The authors cite a study from America's Health Insurance Plans [likely to be biased in my opinion] from 2008 that claims 20% to 50% of "high tech" imaging tests provide no useful information.



Given that these auspicious groups have identified overused tests, how does the industry respond to this finding? The authors suggest that tort reform is needed to allay physicians' fear that they will get sued for not performing some "useless" test. I disagree with this conclusion. It is the physician's job to know when a test is useful and when it is not – this is often given in evidence-based guidelines. If a physician follows such guidelines, then he should be protected from any law suit. On the other hand, if the physician does not know the applicable guidelines, which often seems to be the case,[5] then he is placing himself at additional risk by not "shot-gunning" the imaging tests. Any suggestion of tort reform, as it has been styled in Texas, will do exactly what it has done there – leave patients unprotected from uninformed and impaired physicians.

Other suggestions from these MDs are more reasonable in my opinion. Self-referral by MDs and patient demands for advanced imaging lead to overuse of imaging. Radiologists, they suggest, should be more diligent in deflecting unnecessary testing when ordered by other physicians. This has the drawback that radiologists make money reading images, so there is an incentive *not* to tell other physicians that they do not need an imaging test for their patient.

In my opinion there are four important things that can be done here. Make all patients pay some

reasonable portion of any imaging test so there is not the patient demand for "free" imaging tests. Secondly, I'd withhold payment for any imaging test that is inconsistent with guidelines unless there is a clearly written reason for this deviation by the physician. Thirdly, I'd require all physicians in my hospital that order or read imaging tests to demonstrate familiarity with the guidelines from the American College of Radiology. Finally, I'd give doctors protection from lawsuits when they follow guidelines for imaging that preclude some imaging procedure. Tort reform, Texas style, is nothing more than a rancid swamp in which harmed patients have been drowned.

A Call to Help the Littlest Babies

Anyone who has had a premature birth knows that the medical bills associated with that can be catastrophic. There are many expenses associated with attempts to keep tiny babies alive and much of that expense involves the use of drugs. Three experts writing in the *JAMA* express the need to quit using each preterm newborn as if he or she were part of an "uncontrolled and unapproved clinical trial that will not yield data of any substantial value."[6]

The fact is, 90% of the drugs used on preterm babies have never been approved for use in such little ones, and as many as 60 different drugs have been used on one baby. The authors point out that no new medications have substantially improved outcomes for premature babies since the introduction of corticosteroids and lung surfactant almost 2 decades ago. The National Institute of Child Health and Human Development has prioritized and sponsored research to address this problem, but there seems to be no funding for this work. The risk to the baby is two-fold in the sense that there can be immediate harm or there can be delayed harm that is not evident for years as the child develops.

The solution to this obvious problem seems to be held in a number of hands. Randomized, controlled studies are needed, and the FDA should take a lead in this effort, using international collaboration as necessary to control costs. Drug companies need protection from putative harms caused by drug testing, which is reasonable, but only so long as the trial is sanctioned by an independent expert group. It seemed to me that one potentially productive effort was overlooked. It should be possible to do data mining on the drugs used on premature babies in the past to detect favorable outcomes and to identify harms, either from individual drugs or combinations of drugs. While these retrospective studies may not be definitive, they could certainly guide the choices of which formal clinical studies should follow.

Now for the Biggest among Us

In this story I'd like to make the leap from the smallest Americans born too early to those who suffer from obesity. The rate of American obesity in this country is on track to exceed 44% in all 50 states by 2030.[7] As of 2011 obesity rates vary from a low of 21% in Colorado to 35% in Mississippi. I fight being overweight myself, and I know many good people who struggle to avoid falling further into the illness of obesity.

The consequences of obesity are devastating to individuals and to the society in which they live. Type 2 diabetes, heart disease, stroke, cancer and arthritis are all associated with obesity. It is heartbreaking for me to see those I care about struggle with these secondary diseases that result from obesity. At the society level, it is estimated that excess, preventable obesity will cost us about $55 billion per year in medical care by 2030, and the cost in lost productivity will be roughly $500 billion per year.

A possible solution to the obesity epidemic is on the horizon. The FDA has just found that two new drugs to combat obesity have a favorable risk-benefit ratio. The history of previous drugs to limit obesity is not pretty – giving a portrait of many toxic effects. Both of the new drugs curb appetite and in a 1-year clinical trial in which they were combined with lifestyle modification, the drugs showed a much higher portion of persons loosing at least 5% of their body mass. For example, the drug Qsymia®, depending on dose, elicited 62-70% of the

participants to lose more than 5% of their body weight, whereas only 21% of those taking a placebo lost more than 5% of their body weight.

Clearly, a 1-year study does not reveal all the risks that might be associated with these drugs. Furthermore, these drugs are contraindicated for folks who are not obese because the risk of side effects outweighs the limited benefit of trivial weight losses in non-obese persons. These are not "magic bullets" that melt off the pounds. They are double-edged swords that could harm more than heal if not used carefully.

Now, I'm feeling really guilty about the two large cookies I ate after lunch. Frankly, I find that *avoiding* the temptation to overeat works best for me. Too often I find myself placed in proximity to temptation with only my weak will power between me and the cookies.

Virus Associated with Mortality in Nursing Homes

Like the youngest among us, the oldest represent a highly vulnerable population. Many older Americans live out their last days in a nursing home where infectious outbreaks are not uncommon. A new report has shown that an outbreak of norovirus is associated with increases in hospitalizations and mortality.[9] This highly contagious virus inflames one's stomach or intestines or both, leading to abdominal pain, nausea, and diarrhea. Nursing homes with fewer hours spent by registered nurses per patient had a higher mortality rate during the outbreaks. In choosing a nursing home, ask about the infection rate – this could be a lifesaver.

Your Chance to Read Doctor's Notes

A huge team of medical investigators decided to find out how patients and their primary-care doctors reacted to the patients having open access to the doctor's notes.[10] The study group consisted of 13,600 patients seen on an outpatient basis at three medical centers. About 40% of the patients opened their medical record at least once and were willing to complete a survey. The vast majority of patients reported feeling more in control of their care and adhered to medication schedules better. About 60% felt that they should be able to add to the notes and one third believed they should be able to correct the notes, but 90% of the doctors disagreed with this. By the end of the study almost all the patients completing the survey wanted their access to medical records to continue, and none of the doctors refused to allow continued access. About 1/3rd of the patients were concerned about privacy of their records.

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Answer to question this month: e) 0.2% or 1 in 500 (National Cancer Institute estimate in reference 1)