PSA

Patient Safety America Newsletter

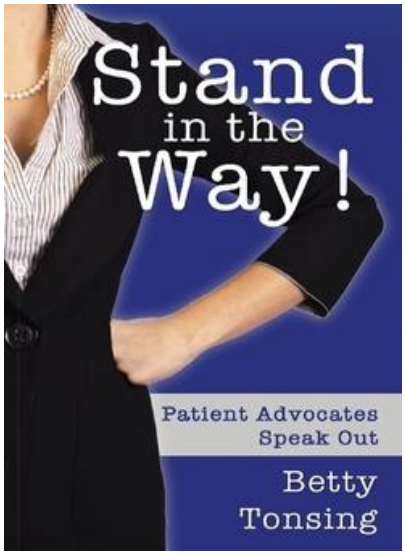
May 2014 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: If you were a 60 year old woman undergoing annual screening mammography for 10 years, what is the chance that you will receive needless surgery, radiation, and/or chemotherapy?*
a) 0.1% b) 0.7% c) 1.3% d) 2% e) 3%

Book Review:
Stand in the Way - Patient Advocates Speak Out

Betty Tonsing, Ph.D

I liked this book, but it gave me nightmares. I liked it because the stories Ms. Tonsing tells interested me - I think a lot about how one advocates for those in the throes of serious medical or nursing care. The nightmares came as I realized that I, and many other Americans like me, are going to walk in the shoes of those who tell their stories in Tonsing's book. My nightmare begins with exhaustive times spent taking care of another person in need of assertive advocacy in the face of inept caregivers. Later in my dark dream, I become the one who needs an advocate to survive callous and dangerous care. I wake up with a start as my advocate becomes exhausted and quits "standing in the way" of that care. I am all alone.



The first half of Tonsing's book tells the story of her advocacy for her husband, a retired history professor, over an 11-month period after he struggled to recover from a routine knee operation. In the form of a diary, the reader experiences the author's reactions of hope, despair, and anger as she shepherds her husband through care venues including hospital, rehabilitation facility, and nursing home. Only for a few days in the last months of his life is he ever home after his initial encounter with knee surgery in the hospital. Dr. Tonsing and her husband never expected this outcome from his "routine" surgery.

The scientist in Tonsing, she's a PhD after all, impelled her to systematically capture the stories of other advocates as they fight to prevent harm to a loved one unable to look after themselves. She developed a survey and was able to gather about 250 responses, from which she distilled the most poignant stories. The last half of her book is filled with these stories, bringing more nightmares to my mind. Battle does not ensue only at the place where your loved one is receiving care; it may be with Medicare or other insuring entities. Who is going to pay for all of this?

The most common reactions from those surveyed were that their presence was essential to the well-being of the patient and that the journey was frustrating and exhausting. About 10% of the advocates surveyed thought their experience was rewarding. According to those surveyed, there were allies along the way, including especially nurses, doctors and social workers, but there were also obstructionists as well – social workers, doctors, nurses and administrators. As an advocate you must know who is on your side and who thinks you are a pain in the donkey. Forty percent of advocates begin their role between the ages of 31 to 50, so do not assume that because you are relatively young, you will not soon be called upon to advocate.

Tonsing's stories are easy to read and convey a sobering message: if getting old in America is not for sissies, then advocating for someone in America is not for sissies either. 5 stars, Available at $8.99 as an e-book (Lulu) or $16 in paperback from Amazon.

Transfusion or Not

Many of you may have seen the recent report that transfusing new blood into old mice makes them mentally stronger. Now old folks, before you go to your doctor and ask for a transfusion, you might want to consider whether the infection risk associated with transfusions is worth the wisdom you might gain. A meta-analysis (combination of many studies) that included 18 randomized trials concluded that the hospital associated infection rate in those receiving liberal transfusions (hemoglobin below 10 g/dL) was 17%, whereas, in those with restrictive transfusion practices (hemoglobin below 7-8 g/dL) had only 12% infection rate.[1]

In an editorial on the subject, a physician notes that transfusions have been shown to reduce immune function in the recipient.[2] Given the potential for infection transmission within most hospitals, that is not where you want to be with reduced immune function. The editorialist notes that the best threshold for transfusions may actually be lower than the usual lowest of 7-8 g/dL. He notes that in Jehovah's Witness patients the mortality significantly increases when the hemoglobin is below 5 g/dL. As a patient that may receive blood while hospitalized, you should ask your doctor what the hospital's threshold is for giving a transfusion. If you feel empowered, then tell him you do not want blood until your hemoglobin reaches a level below 8 g/dL. However, in your specific case (e.g. serious cardiovascular disease), your doctor may have a compelling reason for a higher threshold, so listen to his reasoning. It is your body, not his.

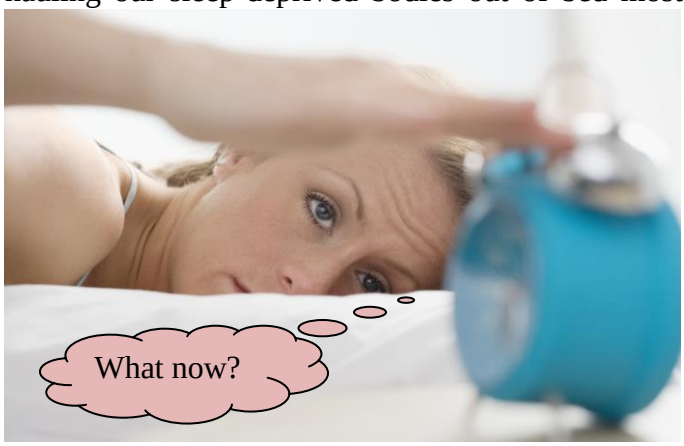
Watchful-Waiting or Surgery?

If you are diagnosed with prostate cancer, one of the difficult decisions is whether to accept the risk of side effects from prostate removal or just engage in watchful-waiting to determine if your cancer invades other tissue. A Swedish study has just reported that radical prostatectomy substantially reduces the risk of death from prostate cancer when compared to watchful-waiting.[3] The investigators randomly assigned about 700 men with prostate cancer to a group receiving surgery or a group without any surgery. The follow up time was just over 23 years, during which time 63 men in the surgery group and 99 in the watchful-waiting group died of prostate cancer. The benefit of surgery over watchful-waiting was largest in men under 65 at the time of diagnosis.

So, if you have been diagnosed with prostate cancer, what should you do with this new information? I'd have an in-depth discussion with my surgeon and get a second opinion from an informed doctor that is not a surgeon. The choice is not easy.

Alarming!

Many of us respond to an alarm clock by hauling our sleep-deprived bodies out of bed most mornings. Rarely, we may experience another type of alarm that means our lives are at risk if we do not immediately take steps to avoid a disaster. Many lives have been saved by such alarms. Unbeknown to me, and presumably you also, is the expert opinion that alarms in hospitals can actually place patients at additional risk of harm. According to a viewpoint article in the JAMA by 2 MDs, two major institutes that monitor hospital safety have made hazards from alarms the target for change in 2014.[4]



According to the writers there are three conditions necessary for an effective alarm: 1) it activates only because of a *serious* problem, 2) the clinician or nurse recognizes that the alarm is associated with the problem, and 3) the clinician or nurse knows what to do about the problem. The

writers describe two examples where alarms were set to off or mute, and this resulted in the death of a man and a teenage girl, respectively. They point out that alarms are omnipresent in most hospital wards and finding a quiet place to actually think can be a challenge.

One interesting comment was the need for artificial intelligence to help identify the "problem" when several alarms are reporting off-nominal conditions. In the opinion of the MDs, alarms are no longer an "Umbrella of Safety" for patients. They call for "a biologically valid, clinically relevant, and patient-centered model" for alarms. I would suggest that as an informed patient or a patient advocate, you should know what alarms could occur and what the appropriate response time should be. You don't want to be an "alarmist," but you need to know what is supposed to happen when a hospital alarm signals trouble.

Over-Prescribing of Antibiotics

There is no doubt that antibiotics have saved millions of lives since penicillin was first identified by Alexander Fleming 85 years ago, but too much of

any good thing can be bad. And so it is these days in medicine that antibiotics are overused to the point that patients are placed at additional risk of harm because of it. A large team of investigators ask if overprescribing by primary-care clinicians could be curtailed by a simple intervention.[5] The intervention was to get clinicians to sign a "commitment letter," written to be understandable by the patient, requiring judicious use of antibiotics in patients with acute respiratory infection. Poster-size copies of the letter along with the physician's photograph were hung in each examination room for 12 weeks. Control clinicians received no offer to commit to improving antibiotic prescribing.

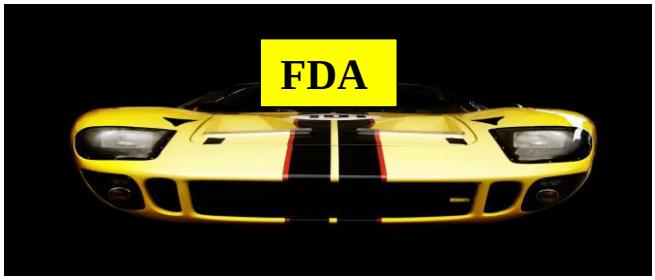
Inappropriate prescribing before any intervention was at 43% for the future-intervention group and for the control group. After the intervention period, the inappropriate prescribing rate went to 53% for the controls and to 34% for the intervention group. The investigators deduced that commitment posters were a cheap and effective means to reduce inappropriate antibiotic prescribing. Patients obviously have a role here. No doubt some read the posted letters and asked their clinician if they really did need an antibiotic. You have to read something while waiting for the doctor to appear in the examining room – it might as well be a poster that intelligently engages you as an agent of safer antibiotic stewardship.

No to a Stent

My patient safety work has enabled me to make many valued new friendships, and one of my most valued is that with Yanling Yu from Washington State. In a recent *JAMA Internal Medicine* "Less is More" perspective, she wrote about her mother's decision 9 years ago not to have an angioplasty and possible stent placement.[6] After a long discussion with the doctor who had recommended angioplasty, her mother decided to go with a much more conservative treatment – optimal medications and lifestyle changes. These served her well over the intervening years. Of course Yanling's story is just that; it is not a scientific study, but it brings home an essential point to those considering allowing invasion of their body by a cardiologist – you had better ask many questions and get informed. Many people have had unnecessary stents placed in coronary arteries. I salute Yanling for her informative perspective and her mother for the courage to intelligently say NO!

Fast Track Drug Approval – Your Chance to be a Guinea Pig

Just in case you have not noticed, everything these days happens faster than it did 5 or 10 years ago. And so it is with the speed at which the Food



and Drug Administration (FDA) approves certain categories of drugs. Under the moniker of "Health Law, Ethics, and Human Rights" in the *New England Journal of Medicine*, three experts discuss the pros and cons of faster approval of certain drugs by the FDA.[7] Here are the pros and cons expressed by the writers:

- Rapid approval based on less data means a higher chance that drugs that are ineffective or unsafe (or both) could be approved.
- Rapid approval of breakthrough drugs means certain patients may get the drugs they need to live.
- FDA's post-marketing strategies to determine safety and effectiveness are weak.
- Once a drug is placed in use, it is difficult to reverse its use.
- Patients may not want to participate in a clinical trial once a drug has been approved to treat their illness.
- There are weak barriers in the US to use of marginal therapies when compared to barriers in European countries.
- There are no restrictions on off-label use antibiotic and antifungal "breakthrough" drugs.

In my opinion, a cautious patient should know if the FDA has approved, within the last 3 years, any drug prescribed to them. If that is the case, then the patient must ask if the prescription is off label and how and for what conditions the drug was approved by the FDA. The cautious patient needs to know if it came through on a fast track and whether she is a guinea pig. Patients must also report any adverse effects of the drug experienced while taking it.

Mammography Pros and Cons

A couple of experts that are not especially keen on too much mammography screening calculated the risks associated with annual screening for 10 years in a woman starting at age 50.[8] If 1000 women in this age group undergo this screening regimen, then 0.3 to 3 will avoid dying of breast cancer, 500-700 will experience a false alarm (repeat of screening), 70-100 will undergo a biopsy, and 3-14 will be treated needlessly with surgery, radiation, or chemotherapy. Each woman has to decide how often she needs screened and how to react if she receives "suspicious" results. Biennial screening is worth considering.

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Answer to question this month: c) 0.6 to 2% with 1.3% mean, in reference #8