PSA

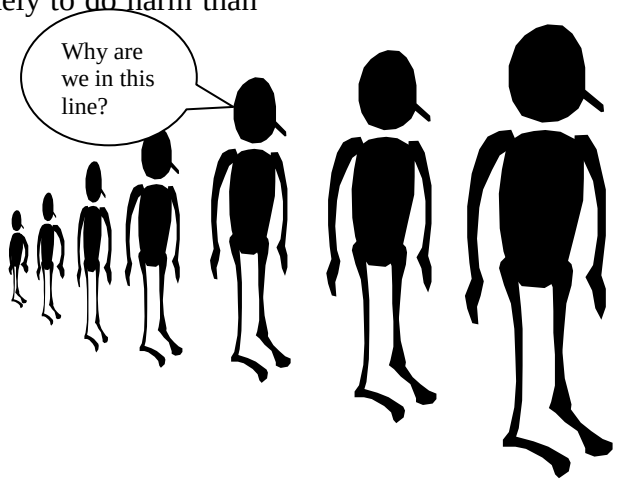
Patient Safety America Newsletter

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

***Question**: How many of the 50 states require public reporting of healthcare associated infections?*
a) 10 b) 20 c) 30 d) 40 e) 50

Misgivings about Direct-to-Consumer Screening

For most people the idea of non-invasive screening for potentially serious illness makes a lot of sense. However, if screening is made easily accessible, is endorsed by hospitals, and is cheap, then uninformed people may be wandering into a minefield they never expected to find. Three MDs expressed their viewpoint in *JAMA* on Public Citizen's criticism of HealthFair's cardiovascular screening.[1] The criticism from Public Citizen was in blunt language: "heavily promoted, community-wide cardiovascular health screening programs are unethical and are much more likely to do harm than good."[2]



The MDs seem critical of some respected hospitals "cobranding" with direct-to-consumer screening programs. Obviously the screening service has an interest in attracting as many people as possible and the hospitals are likely to benefit when new patients come into their systems as a result of screening. Direct-to-consumer screening companies are very likely not to disclose potential harms of screening because it is not in their financial interest. The authors point out that over its 20-year lifespan, HealthFair has likely grossed several hundred million dollars.

I thought I would look at the HealthFair's website (http://healthfair.com/) to discern the way they approach people who might be considering cardiovascular screening. The picture under the "Health Screening Packages" shows a woman who could not be more than 30 with what is probably an ultrasound device on her neck. The basic package, which costs only $179, has six screening tests, including a carotid artery ultrasound. To the right on the web page is a series of changing pictures showing boxy-looking buses with various advertisements painted all over them. At the bottom a scroll passes by with medical institutions that presumably endorse the screening.

I am all for *targeted* screening of folks in the community, but I could not find anything on the HealthFair website suggesting who should, and who should not, be screened. It was easy to find testimonials and even a TV announcement from Toledo, Ohio in which an unidentified woman outside the bus said "no matter what your age" you should get your numbers.

Should all adults have a carotid artery ultrasound? The purpose of such a test is to assess the risk of stroke caused by narrowing (stenosis) of the carotid arteries (a pair in the neck). The recommendation from the U.S. Preventive Task Force, the gold standard for medical guidelines, is clear: "Do not screen for asymptomatic carotid artery stenosis in the general adult population."[3] It seems that such screening in the general population is associated with far too many false positives. The author of the recommendation concluded his article with a lengthy compilation of the organizations since 2011 that have recommend *against* carotid artery screening in asymptomatic persons or those without specific risk factors.

I thought it was interesting to discover a statement of HealthFair's goals in forming partnerships:

-Improving the Continuum of Care for Participants
-Improve Hospital Market Presence
-Support Physician Partnerships
-Provide Substantial Advertising Value
-Generate Significant Public Relations
-Enhance Corporate Relationships

Please judge for yourself whether these goals are patient centered. I would be much more enthusiastic if the first goal were to discover serious health problems *in people at risk* for such problems, preceded by identification of precisely who it is that *is* at risk. In my opinion, any partnering with a hospital system must be predicated on a clear statement up front of who should and who should not be screened. The risk of false positives must also be made clear as part of informed consent.

Screening for Abdominal Aortic Aneurysms (AAA)

While thinking about screening for "silent killers," it seems appropriate to discuss new recommendations from the US Preventive Services Task Force when looking for AAAs, which are bulges in the aorta, the major artery carrying blood from the heart to the lower body.[4] The journal *Annals of Internal Medicine* offers a "Summary for Patients" that explains in plain language who should and who should not be screened. The best way to search for AAAs is ultrasound.

AAAs generally are silent until they are on the verge of or have ruptured. Such ruptures are an immediate, life-threatening event. The recommendation is to offer one-time screening to men aged 65 or older who have ever smoked. In general, aneurysms larger than 5.5 cm (about 2 inches) should be repaired with surgery. There was no evidence for such screening in women, and women who have never smoked should not be screened. A more complete patient summary can be found at: AAAscreening. "Patient Summaries" for a variety of other medical conditions can be found at: PatientSummaries.

My Aching Joints…and Wallet

Joint replacements are big business around the world. There is little doubt that replacement devices have enabled many Americans to live active lives until they are disabled by systemic disease. The cost of knee replacements varies 8-fold in hospitals in the same area according to a Newsweek article ($ForKnees). Some are finding that medical tourism is the answer to the high cost of joint replacements in the US (MedicalTour). My observation is that as the amount of money made from a medical procedure increases, so does the tendency to take advantage of the patient.

There has been a flurry of technology applied to improving conventional joint replacement devices; however, a comprehensive new study published in the *British Medical Journal* suggests that despite "good" intentions, newer devices are no better than the old ones, and in some cases are clearly worse.[5] The team of investigators studied publications on 3 hip-replacement innovations and 2 knee-replacement innovations. They found 118 studies involving more than 15,000 implants that fit their criteria for inclusion in their analysis.

Going into more detail about the results is probably too much for most readers. The lesson is that new devices are not necessarily better than old ones (and could be worse) and the FDA regulation of devices can leave patients at unacceptable risk of harm. You must do your homework if you are going to have a knee or hip replacement, and then when you talk to your surgeon, make sure you receive complete information about the replacement he intends to implant in you, why he selected the one he did, and how he excluded other choices. You should also make sure you understand the total cost of your replacement so you do not need a cardiologist when you get your share of the bills.

Pain Management

Almost all of us will require serious pain management during our lifetimes. So called Pill-Mills have sprung up in many areas because reckless, unregulated prescribing of addictive pain killers brings nice profits and too many deaths, for example in Florida (PainKillers). An article in the *JAMA* struck me as a well-structured approach to managing pain. The four authors of the study identified 92 suitable studies of which 35 involved drug interventions and 57 involved non-drug interventions, such as physical rehabilitation.[6] They came up with a tiered algorithm for pain management, which they applied primarily to management of older patients. Such patients may present pain-management challenges such as comorbidities (other diseases), slow metabolism, cognitive impairment, and past bad experiences with various pain medications.

For many patients a combination of less potent drugs that use different mechanisms of action may be appropriate. For others, a combination of drug therapy and physical rehabilitation may work the best. Success will ultimately depend on establishing mutual treatment goals between physician and patient. As a patient using pain medication, do not blindly allow your pain medication to be increased in dose without asking for alternatives. Apply Newton's first law along with your medication: "A body in motion tends to stay in motion…unless it spots a soft easy chair."

My Mother's Horrible Death…Written by a Physician

Stories matter when thinking about misshapen medical care. Many of us have our stories, but the stories of physicians seem to get the most attention because they have authority in the healthcare enterprise. A physician specializing in palliative medicine (end of life care), reported the various stories of his mother's death in *JAMA Internal Medicine*.[7] He gave the stories of the end of her life as reported in a local newspaper, by the police report, and by his mother's discharge summary. These stories belied the reality that the woman, aged 84, experienced a horrible death at the hands of the healthcare system.

In the first place, the last 15 days of her life cost $216,000 in medical bills for high-tech, futile interventions. The woman's initial hospitalization was caused by serious injuries from a car accident. The writer said he knew she would not survive, yet her medical team considered her advance directive against life support irrelevant to her care. The physician writer knew she was near death because her severe osteoporosis would never allow her to recover from her many bone fractures. His mother seemed to understand that she was near death, yet her son remained silent about his feeling that she could not recover. Perhaps fortunately, a massive stroke made it clear to all her caregivers that the end was near. Looking back, the writer observes that end-of-life-decisions place a huge and unfair burden on the patient and family. He feels that it is the physician's responsibility to step up and give a clear prognosis when death is near.

I think in many cases it is not easy for physicians to predict when death is near. A close relative's long-time friend is battling widespread, untreatable metastatic cancer, and has been for more than a year. In the past 3 weeks she has been in home-hospice care and in-and-out of the hospital twice. She has had fluid drained from her lungs twice and is seldom lucid. It is clear to everyone, but unspoken, that death is near…but how near is just not known? The ordeal is exhausting her husband who is her only caregiver at home.

National Patient Safety Monitoring Board?

A news article in the *JAMA* noted the testimony given by several of us to a Senate Subcommittee on July 17th, about the need for improved patient safety.[8] I was pleased that the writer mentioned my study in the *Journal of Patient Safety*, but the best came in a quote from Dr. Jha, "Until hospital CEOs are lying awake at night worrying about safety, it [improved patient safety] is not going to happen." My colleague Lisa McGiffert from Consumers Union suggested the creation of a board with the title above to regulate and improve patient safety.

Placebo and Nocebo

Most of us know that the placebo effect occurs when we take a pill that has no possible effect in improving our health, yet if we are told it will, then we think it has improved our health. This effect is particularly strong when antidepressants are assessed for efficacy. A viewpoint article by an MD neurologist in the *JAMA* points out the "nocebo" effect on treatment outcomes.[9] The nocebo effect unfolds when we are told what side effects to expect from a drug, and this makes us more likely to report side effects than if we were never told about the potential side effects.

This has important implications when evaluating the risk-benefit profile of a new drug. The author proposes a collection of strategies to mitigate the nocebo effect, to include the following: balance information on desired and adverse effects, teach coping strategies for adverse effects, be empathetic to the patient, and address the patient's concerns. You may have vicariously experienced the nocebo effect when listening to a TV advertisement for a drug and the side effects sound like a call to suffering.

Which Diet to Follow

I have friends that have tried perhaps a half dozen different diets, typically with mixed results. As for me I have been content to slowly gain weight as I try to manage with no structured diet. A new study compared the effectiveness of various well-known diets.[10] The investigators surveyed almost 60 articles that described the results of various diets at 6 and 12 months after starting them. The low carbohydrate diets yielded 8.7 and 7.2 kg weight loss at 6 and 12 months, respectively, whereas the low fat diets yielded 8.0 and 7.3 kg weight loss at 6 and 12 months, respectively. For you pound watchers, 8 kg is about 18 pounds. The article's authors emphasize that the dieter must adhere to the diet if they want to lose significant weight. Therein is the problem for most of us.

Communication in Hospitals

A research group asked how often mistakes were made in handoffs between the overnight staff in two Canadian academic hospitals and the morning staff.[11] They found that over a 26-day period the on-call, overnight trainee omitted 40 % of the clinically important issues and failed to document 86 % of these issues in the medical record. This study demonstrates the importance of competent communication during patient-care handoffs in hospitals and the potential for medical records to be quite incomplete. How this might apply to US hospitals is unknown.

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Answer to question this month: c) 31, from reference #8 and Lisa McGiffert of Consumers Union