

Reducing Fall Risk in the Elderly

Falls are one of the dark clouds that hang over us as we age. I've known older folks who have fallen, and after "treatment" for things broken, were never themselves again. In our world of curbs, steps and craggy sidewalks, falls are all too common. A team of [researchers](#) performed a meta-analysis by combining 40 studies to determine if exercise reduces the risk of falls. Their combined studies involved almost 23,000 people of mean age 73 years. Typical exercise was multicomponent, including aerobic, strength, and balance, and of moderate intensity. On average, this was accomplished in 3 sessions per week of about 50 minutes each. Controls were active older adults.

The investigators found that the risk of a fall decreased about 10% in those who engaged in formal exercise programs. There was also a tendency to reduce fractures by about that percentage. To me, the key is to find an exercise that you enjoy doing, find someone to do it with, and know that you are reducing your risk of a harmful fall. My choice of exercise is to walk, although I admit that once I fell over a 2-inch lip between a wheel-chair access ramp and the street that was covered with leaves. I caught my fall, ending up with only a few scrapes. My point is to exercise where the risk of *any* fall is minimal.

Risky Drugs and Lax FDA Oversight

As I write this, we are in the third day of grounding in the U.S. of all 737 Max commercial aircraft due to 2 recent crashes. This is because the risk of flying the aircraft is too high considering the lack of understanding of the causes of the crashes. Most feel that this is a responsible way to manage such risk. This is not the case when it comes to FDA's management of risks associated with potentially harmful drugs that it has approved. It is supposed to do that under a program called REMS (Risk Evaluation and Mitigation Strategies).

The idea of REMS is that when the FDA approves a drug for marketing that has substantial safety concerns, the manufacturer is required to devise and perform a REMS. This is something like Boeing proposing to be the only investigator in the crash of 2 of its 737 Max aircraft. Two [experts wrote](#) about their concerns with the way FDA is employing the REMS and how drug companies exploit it. A REMS may include a patient

information flyer, a physician information source or physician training and drug-use registration for the riskiest of drugs. According to a DHHS (Department of Health and Human Services) Inspector General Report, the FDA has little insight into the effectiveness of REMS. Manufacturers have abused the system in order to block generic manufacturers from entering the market.

The authors trace the role of REMS, especially in the use of Trans-mucosal, Immediate-Release Fentanyl (TIRF) drugs. An investigator pried information out of the FDA on the TIRF REMS, finding a litany of failures. Once available, these documents revealed widespread off-label prescribing. Moreover, many patients receiving prescriptions were opioid intolerant. Despite this information available to the FDA, it failed to act to improve the REMS.

The writers made 3 recommendations: 1) the FDA should write the REMS, not the manufacturer; 2) assessments submitted to the FDA should be publically available; and 3) the FDA should have more enforcement power over REMS. In my opinion, this situation is a prime example of failed regulatory practices, aggressive marketing, and lack of transparency. This is a recipe for patient harm. The only thing patients may do is to know, as best you can, all the risks and benefits of the drugs prescribed to you and do not take any of them until you do. Make sure your clinician has a good reason for prescribing a drug and ask if it is off-label.

Fighting Cancer Together

Cancer is often a frightening diagnosis to receive. The disease will likely be treated by an oncologist. One of these specialists, writing his [viewpoint](#) in the *JAMA* expressed the need for better clinical decision support because of the complexity of diagnosis and treatment of cancer. The writer opines that patients with cancer may have done much internet searching to understand what they are facing and what treatment options may be available. However, useful decision support for both patient and clinician is regarded as "rudimentary" in many situations.

This calls for a partnership between oncologist and patient. The oncologist may not be aware of the latest findings since these happen at an astonishing rate for many types of cancer. The patient may have well-founded concerns about costs of therapy; the oncologist should be sensitive to this concern. If treatments are not successful, then end-

of-life counseling may be necessary. Obviously, the writer is addressing oncologists, but there is a message here for patients. I'd present these as follows: if there is any uncertainty in your diagnosis, then get a second opinion. Know all you can about your specific cancer and the available treatments and where these may be obtained. Prepare to manage your out-of-pocket costs if the best drug for you is priced at hundreds of thousands of dollars. Know what to expect from side effects of drugs, radiation, and surgery. Above all, do not assume your oncologist knows everything. You must be partnered with him to fight your cancer.

Unfair Out-of-Pocket Billing

Three experts express their [perspective](#) on how to protect patients from the shock and distress of huge medical bills from care received out-of-network. Even though the Affordable Care Act limits patients' requirements for out-of-pocket spending, this applies only to in-network charges. Out-of-network charges remain unlimited, inviting unfair practices. There are two conditions that lead to unfair charges. These are when insurance plans have limited networks that may not include the specialists needed, and when the patient unknowingly uses out-of-network services, such as out-of-network physicians practicing in an in-network hospital.

The experts are of the opinion that fair and efficient arbitration between the provider of services and the insurance company would protect the patient from unfair billing practices. Such a process requires clear guidance on what amounts to a fair charge for services. They favor a federal regulation rather than piece-meal regulations at the state level. The State of Texas may be able to help patients handle surprise medical bills. This is the website: [Texas bills](#).

Rationing Healthcare in the U.S.

In principle, most of us are against formal rationing of healthcare, but according to an MD expressing his [opinion](#) in the *JAMA*, the reality of the way healthcare is delivered in the U.S. causes *de facto* healthcare rationing. Rationing happens in the following circumstances: limited healthcare insurance, high out-of-pocket charges, making medical services unavailable, and by prolonged waits for care. With the dawning of expensive genetic treatments, the writer asks if healthcare is going to be further rationed. He points to the

philosophical debate in the U.S.: Is healthcare a right or a privilege?

Many possible causes of our high healthcare costs have been suggested – overuse of procedures, defensive medicine against malpractice suits, and overpriced drugs, to name a few. The author points to his target - the U.S. needs to reduce its administrative costs for healthcare, which he views as about 10% of the overall cost (\$3.5 trillion per year). Cutting administrative costs in half would save about \$180 billion per year. I like a quote he offered at the end of his editorial: *“In the richest country in the world, in which many of the greatest scientific and medical advances are developed, it is a blight on the US soul that each of its residents does not fully benefit from available health care.”*

I am a fan of curtailing overuse, which follows from the “fee-for-service” model of U.S. healthcare. My MD associates believe fee-for-service is beginning to wane, but unless insurance companies and patients refuse to pay for low-value care, it will probably never stop. Curtailing hopeless, invasive procedures near the end of life would also save money. I'm of the opinion that improving informed consent through shared-decision making would also lead to dramatically lower costs.

Diet Improvement for Depression Relief

Depression seems to be the hallmark of our fast-paced, isolating culture. The usual practice is to throw medications at patients, often keeping fingers crossed in hopes of a favorable outcome. As I am writing this, the FDA has approved a drug for [post-partum depression](#) that has some nasty side effects such as passing out, requires 2 ½ days of infusion in a special facility, and costs \$34,000.

Two Australian experts [opined](#) in the *JAMA* that it is time to consider dietary adjustments to relieve depression. The authors point to meta-analysis of observational studies as a background for “dietary psychiatry.” But now these have been supplemented with 2 new randomized studies that somewhat support the application of dietary psychiatry. These involved over-weight and/or obese people with depression short of being classified as “major.” Diet was improved in one study by implementation of a Mediterranean style diet. Depression is difficult to measure since it depends on patient-reported perceptions.

Dietary improvement alone is not going to be a panacea for relieving depression. The authors conclude that treating serious depression is going to be multifactorial. This could include counseling, medications, physical fitness and dietary changes, especially those that relieve obesity. I would point out that the increases in depression may be due in part to the widespread use of medications that have depression as a side effect. It is complicated.

Colonoscopy in the Elderly

There are few benefits to growing old, but one of these is that the balance of value vs. risks for colonoscopy is tipped in favor of *no more colonoscopies*. Guidelines suggest that a colonoscopy after the age of 75 is of [low value](#). Three MDs describe a [teachable moment](#) that led to a colonoscopy in a 92-year old man.

It seems that the patient had rectal bleeding, so a colonoscopy was performed to determine the cause. It appeared to be sigmoid diverticulitis, but during the colonoscopy, two large polyps were discovered. These were left in place and the bleeding stopped spontaneously. Months later, against the recommendation of his primary care doctor, the family talked the old man into having a colonoscopy to remove the polyps. The polyps were removed, but this resulted in more bleeding, anemia, vomiting, aspiration pneumonia, bacteremia, urinary tract infection, and atrial fibrillation. This “domino effect” required a variety of treatments over 12 days of hospitalization. He needed 10 months to recover to his baseline before the harmful treatment to remove the polyps.

The writers discussed the need for the gastroenterologist to carefully discuss the pros and cons of colonoscopy in a man this age. Given his comorbidities, limited life expectancy, slow growth of such polyps, and risk of bleeding, the family should have opted for no removal of the polyps.

An [editorial](#) in the *Annals of Internal Medicine* laments the lack of evidence that colonoscopy is superior to Fecal Immunochemical Tests (FITs). The story is interesting. In 2000, there was evidence for the effectiveness of colonoscopy in screening for colon cancer, but little evidence comparing FIT to colonoscopy. Subsequently, Congress, in its usual infinitesimal wisdom, ordered

Medicare to cover colonoscopies with no evidence that colonoscopy is better than FIT. In the U.S. only about 2/3rds of adults aged 50 to 75 have ever been screened for colon cancer by any method. The authors believe that more information in the hands of patients about FIT would substantially increase the rate of screening. There are many types of FITs, so ask your doctor which one to use if you decide that colonoscopy is not your favorite screening tool. A positive FIT must be followed by a colonoscopy.

Losing Your Driver’s License

A [perspective](#) article in the *New England Journal of Medicine* entitled “Don’t ruin my life” gave guidance to the clinician in dealing with elderly people that should cease driving. I recall that when my father approached 90 years old and his doctor recommended that he give up his driver’s license, he was angry at that doctor until the end of his life. It may be a tense time in the patient-doctor relationship. The author advocates use of the patient’s history and physical exam as tools to discern the need to recommend loss of license. She does not recommend any clinical testing for driving skills. There are interventions that help the patient continue to drive, such as modification of the vehicle, but the medical opinion must be clearly stated to the patient.

Just because your license to drive has been taken, does not mean that you’ll never drive again. In some cases, rehabilitation can lead to a restored license. If you live long enough, you too will lose your license. Maybe by then there will be self-driving cars readily available. Think positive.



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Answer to question: b) Mississippi, see the figure on page 1