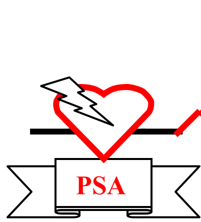


Patient Safety America Newsletter

August 2013 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: Which of the following illnesses has not been associated with over diagnosis? a) prostate cancer b) breast cancer c) lung cancer d) melanoma e) diabetes f) high blood pressure*

Questionable Drug Prescribers

One of the difficult questions in a free society is how much intrusion the government should exercise into the activities of individuals and corporations in order to protect citizens from unwitting harm. Most recently we have seen this in the debate between those who would increase government snooping to protect against terrorists and those who want freedom from this snooping. How much should the government intrude into the physician-patient relationship to protect the patient from harmful, overused procedures and harmful drugs? The Centers for Disease Control has called the abuse of prescription drugs an epidemic. The Inspector General of the Department of Health and Human Services has just proposed that the government needs more oversight into the prescribing of drugs to Medicare patients to curtail this epidemic (http://oig.hhs.gov/oei/reports/oei-02-09-00603.pdf).

The basis of the government's proposal is the finding, which was published in June 2013 using data from 2009, that more than 700 general-care physicians across the country had "questionable prescribing practices." The investigators used 5 criteria to discern questionable practices: 1) the average number of prescriptions per patient, 2) the total number of pharmacies associated with each prescriber, 3) the percentage of prescribed drugs with ***high*** potential for abuse (schedule II), 4) the percentage of prescribed drugs with potential for abuse (schedule III), and 5) the percentage of prescriptions that were for brand-name drugs. The investigators reviewed more than 1 billion prescription records created by more than 1.1 million prescribers.

As an example, to be designated a "high prescriber" in category 1 the prescriber had to prescribe an average of more than 71 prescriptions per patient, recognizing that the average for all prescribers was only 13 prescriptions per patient. In category 3, which constituted almost half of the total number of questionable prescribers, a prescriber had to have more than 14% of his prescriptions for schedule II drugs, whereas the average for all prescribers was only 2%. In other words the questionable prescribers were far out of the normal realm of prescribing practice.

As a person who most likely relies on at least one prescription drug, what should you do with this information? First, be aware that highly questionable prescribing is rare at less than 0.1% of all prescribers. Second, if your doctor seems eager to prescribe stimulants and narcotics (schedule II drugs) too freely, then ask about the risks of these and if there are not substitutes. If you are getting anything like 71 prescriptions per year from a single prescriber, then you need to ask about drug reconciliation, a process by which patients can be taken off of unnecessary drugs. You can find more detailed information and an informative video on drugs that are abused at the following link: http://www.pbs.org/newshour/rundown/2013/05/prescription-drug-abuse-cdc-answers-your-questions.html.

Fight over Salt and High Blood Pressure

In the pages of this newsletter I have advocated for less use of salt and for thoughtful control of high blood pressure, which can occur from ingestion of too much salt. Articles in 3 of the journals I read seem to make the situation more complex than I had supposed. For reference, the average amount of sodium consumed by Americans is about 3400 mg/day.[1]

To start with, the Institute of Medicine (IOM) just released a report declaring that there is no evidence that drastic reductions in salt to below 2300 mg/day reduce the risk of heart attacks, stroke or death in anyone (http://www.nlm.nih.gov/medlineplus/podcast/transcript062413.html). The Centers for Disease Control (CDC), which sponsored the study and the American Heart Association (AHA) have a different opinion, recommending consumption of no more than 1500 mg/day for those over 50 years old, blacks, and people with certain illnesses. AHA officials call the IOM report a potential disservice to the American public. An unnamed official from the CDC said it is ***not*** going to change its recommendations because of the IOM findings.

The IOM is accused of ignoring key studies, and the IOM in turn accuses the other major parties to this controversy as not looking objectively at the evidence. Other experts have weighed in with their arguments on how to interpret studies and what physiological mechanisms make too little sodium a health risk.[2]

In the meantime, the use of drugs to reduce blood pressure, if it is in the range of 140-159 mm Hg (systolic)/90-99 mm Hg (diastolic) or below in otherwise healthy persons, is ***not*** supported by randomized clinical trials. This finding was reported in a Cochrane Review (http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006742.pub2/abstract) and summarized in the "Less is More" section of the *JAMA Internal Medicine* journal.[3] The author of the article notes that treatment with blood-pressure lowering drugs has associated harms and seems to be more in the interest of the pharmaceutical industry than patients.

The summary surveys the international politics of redefining disease to include more "victims" at the level of the World Health Organization, and ultimately concludes that in the interest of wasting no more money and reducing patient harm, all countries need to return to the definition that high blood pressure is at the threshold of 160/100 mm Hg. The Cochrane Review noted that about 10% of those who start using blood-pressure-lowering drugs quit using them because of side effects.

If I were on a blood-pressure-lowering medication, I would ask my doctor what he makes of all of this controversy and whether I should remain on the drug. If I were having any side effects from that drug, and my blood pressure before medication was less than 160/100 mm Hg, I would ask my doctor for a withdrawal plan. In any case, exercise and prudent lowering of sodium in the diet are the best ways to lower blood pressure.

Speaking of Exercise…

OK all you couch potatoes, isn't it time you gave some thought to more exercise? Think in terms of aerobic exercise (walking, running, or swimming) and strength building (resistance band, weight lifting, or machine). About half of American adults get sufficient aerobic exercise and only a quarter get sufficient strength building exercise. To develop a personal plan for leaving your couch lonely, please check out reference 1 and others at this link: (http://tinyurl.com/bdzg7vv).

Medicare and Medicaid Fraud

A huge group of stakeholders have formulated ways to reduce waste and fraud in Medicare and Medicaid programs, and made recommendations to the Senate Finance Committee. If you want to have a look at the report summary go to: http://tinyurl.com/avjagpx.

Second-Hand Smoke

A couple of weeks ago I entered a house to make repairs to three doors. I immediately noted that the house reeked of smoke and that two adults were smoking cigarettes while watching TV in a back room. At least two young children were running around the smoke-filled house. Vehicles are also a common place for second-hand smoke exposure. One does not have to drive much to notice adults smoking in a car while young children are present. Estimates are that 11 million and 17 million non-smoking Americans are exposed to second-hand smoke in their homes and vehicles, respectively

(http://tinyurl.com/nvt4g7z). The manifold dangers associated with second hand smoke have been thoroughly spelled out by the American Cancer Society (http://www.cancer.org/cancer/cancercauses/tobaccocancer/secondhand-smoke).

Quitting smoking is daunting; however, if you cannot quit, then please consider non-smokers around you who do not deserve to have their risk of various diseases increased by your addiction to smoking. Especially, children should never be exposed to tobacco smoke – never.

Awaken My Patient

Sleep disorders affect up to 70 million Americans. The medical term for many of these disorders is obstructive sleep apnea (OSA), which means that airway blockages during sleep cause momentary cessation of breathing. Three experts write in the *New England Journal* that guidelines now call for surgical patients with OSA to receive respiratory support and be carefully watched post-operatively.[4] Such patients are at higher risk of respiratory failure because of "surgical insults" and the depressant drugs used to induce anesthesia. One study showed that only 20% of patients with OSA receive respiratory support, called positive airway pressure therapy**. If you have OSA and are about to undergo surgery, ask your doctor about respiratory support therapy.**

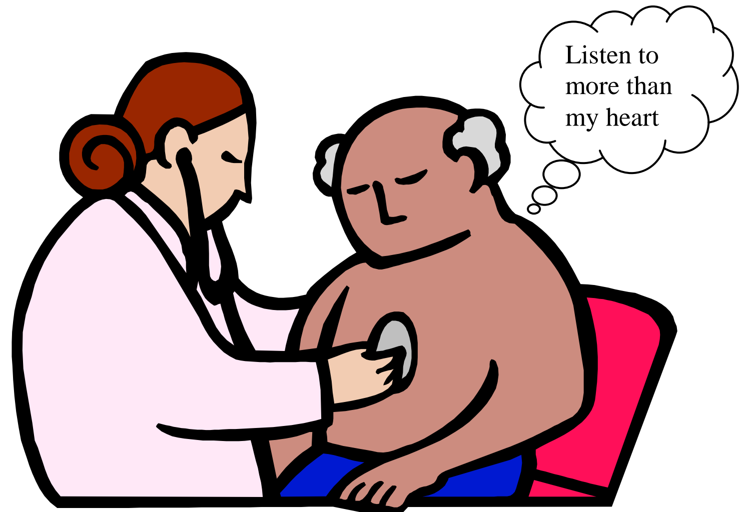
Doctor's Views of Patients

I have little doubt that most doctors could tell you how their ideal patient behaves. This past month a couple of articles in the *JAMA* have given some depth to that expectation. In the first article the writers ask what physicians must do to elicit more questions from their patients.[5]

What are the barriers to better communication from the patient's perspective? The first is strange surroundings – office, clinic or hospital. The second is fear of taking too much time from the doctor's busy schedule. This was termed "white-coat silence" by the writers.[5] From the physician's perspective, time with each patient is precious and the patient's questions may be difficult to answer. For example, physicians are often ill equipped to answer questions about how to reduce risk of harm.[5] In recent years several organizations have mounted campaigns to encourage patients to ask more questions of their doctors: (http://www.ahrq.gov/legacy/questions/).

Now let's flip the coin over and ask what the responsibilities of patients are in making personal decisions and in medical-research participation.[6] Two MDs note that patients not only need to participate in decisions about their personal healthcare, they need to be willing to participate in research that could improve decisions for patients that come along after them. For example, a recently hospitalized member of my family who had surgery was invited to participate in research on a new pain management drug that was used under the tongue. The patient readily agreed to the research plan and found the protocol for use of the drug very helpful in managing the pain. Others in the study were not as happy, but they may have received a placebo.

At another level, patients can allow their medical records to be used for research purposes. Many of the studies I address in this newsletter were built around

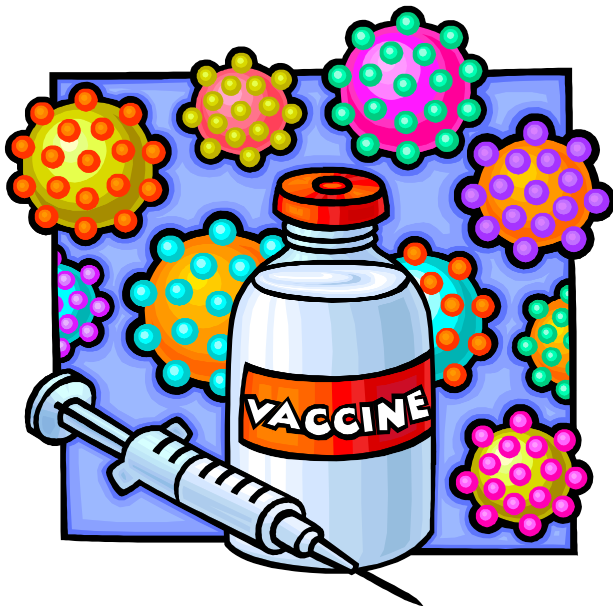


analyses of medical records. In the clinical setting, patients can uniquely address their willingness to comply with doctor's orders, which at times can be too complex or unrealistic. Furthermore, patients have an obligation to report drug side effects, whether the drug is one already FDA-approved or is part of a research protocol. I would add one more level of patient participation. Many institutes and government agencies are asking patients to participate in the design and selection of medical

research protocols (http://www.pcori.org/). In my opinion, retirees should think seriously about this last opportunity because they are more likely to have had medical "experiences," and they have the time to devote to making the care of subsequent generations better than the care they received.

Getting to Disease Prevention

In an article entitled "The paradox of disease prevention – Celebrated in principle, resisted in practice" an MD asks how we can identify the obstacles to preventive care and how those obstacles can be surmounted.[7] The idea is to prevent illnesses at the population level, say by vaccination, rather than treat each sick individual that has not been vaccinated. The writer sites many reasons that prevention is difficult to sell (I'll add my example using vaccination): 1) success is invisible (Did I really need that vaccination?), 2) lack



of drama (I went to work every day as usual), 3) delayed rewards (shingles did not get me for years after I was vaccinated), 4) population effects do not affect me (I'm supposed to get a shingles vaccination, but no one I know has gotten this illness) and 5) inconsistent preventive advice (Who says I need a vaccination at age 50, I thought it was 60?).

In my opinion, the most telling barrier to preventive care listed by the MD writer was "commercial conflicts of interest." The example given by the writer was the sworn belief from big tobacco that nicotine is not addictive. My examples of commercial conflicts of interest would include over-diagnosis of many conditions such as diabetes and high blood pressure with resulting expensive treatments when simple preventive strategies would be more patient centered. As H. Gilbert Welch, MD stated it, "There is the failure to distinguish between an epidemic of disease and an epidemic of diagnosis."[8] Or as the title of Rosemary Gibson's book suggests, we are the victims of "The Treatment Trap."[9]

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Answer to question this month: all are associated with over diagnosis[8]