PSA

Patient Safety America Newsletter

February 2022 http://PatientSafetyAmerica.com John T. James, Ph.D.

Question: Biogen reduced the annual cost of its Alzheimer's drug to A) $50,000 B) $25,000 C)$10,000

Peripheral Artery Disease and Smoking

Most of us are aware of the harm to our lungs and heart when smoking tobacco. Studies have accumulated showing that smoking also increases the risk of peripheral artery disease (PAD) and has an adverse impact on outcomes when treatment is necessary. A couple of MDs wrote an editorial that surveyed the problem.[1] PAD is defined as obstruction of the arteries that supply blood to our limbs. About 8 ½ million U.S. adults have the disease. Cigarette smoking increases the chances of having PAD by about 3-fold. A new study examined the effects of smoking on people being treated in the Veterans Administration Health System for PAD.

The investigators surveyed more than 14,000 records and matched non-smoking patients to those who were smokers. The chances of dying within 30 days after a PAD procedure was 0.6% in smokers and 0.1 % in non-smokers. The chances of post-procedural complications were about 13% in smokers and 9% in non-smokers. One of the complications of PAD is the need to amputate a limb. This happens less often in non-smokers. The editorialists note that smokers with PAD are seldom referred for smoking cessation. There are effective ways to quit smoking that include behavioral and drug therapy. The editorialists opine that intense smoking cessation should be implemented before revascularization is attempted in patients with PAD.

The action here is obvious for my readers who smoke. Their primary care physician should be implored to get engaged in a smoking cessation program. If you have a friend or family member who smokes, you might tell them about PAD and smoking. The CDC has estimated that smoking cessation can add up to 10 years to your life. Start with the American Heart Association.[2]

Drivers of Overuse of Healthcare

Given the fact that Americans spend far more on healthcare than any other large, developed country might suggest that we are healthier. Nope. A lot of the cost is attributable to overuse of healthcare that is unwarranted. A small team of investigators asked what factors in healthcare systems are associated with more overuse of procedures.[3] They looked at records from Medicare beneficiaries (average age 76 years) in 3745 hospitals in 676 systems. They had developed a 17-point template of low-value care to search records. This formed what they called their overuse index (OI).

Higher values of the OI were associated with a higher number of hospitals in the system, more acute care hospitals in the system, and higher number of beds. Higher overuse was associated with investor ownership and fewer primary care physicians. Less overuse was associated with teaching hospitals. The approach they used to make these associations is of potential use to researchers hoping to identify sources of overuse.

Patients have a role in reducing overuse, which may cause unnecessary costs and harm to patients. Always ask why a procedure is being performed and how the result will be used. Ask for a shared decision-making session.

[1] https://pubmed.ncbi.nlm.nih.gov/34613351/

[2] https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco/help-i-want-to-quit-smoking

[3] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2788097

Medicare Beneficiaries May Struggle with Drug Costs

Despite several attempts to reduce the out-of-pocket costs of drugs for Medicare beneficiaries with multiple health conditions, attempts have fallen short. In an invited commentary, a couple of experts wrote about the situation of drug affordability for seniors.[4] To begin with, half of Medicare beneficiaries in 2016 had annual incomes of $26,500 or less. For such folks, a cost burden for drugs of a few thousand dollars could impact their ability to buy the drugs they need, causing lost treatment opportunities. The Affordable Care Act helped some with keeping drug prices down, but for three chronic conditions, that was not the case.

The main cause of increase costs in those groups (atrial fibrillation, heart failure, and type II diabetes) were the entry of branded drugs that were recommended by guidelines for treatment. The costs may also be influenced by the type of Medicare plan – advantage vs. stand-alone. The writers note that Medicare has implemented a Senior Savings Model demonstration for diabetic patients. The goal is to limit patient cost to $35 per month. Various proposals in Congress have attempted a limit on drug costs in the range of $2,000 to $3,000 per year.

The authors suggest that physicians pay more attention to drug costs for specific patients that my struggle with out-of-pocket costs. If you are such a patient, do not be shy about communicating your concerns about cost. On the other hand, if you are taking 5 or more drugs, you might ask for medication reconciliation to see if all the medications you are taking are necessary.

Sensible Preoperative Testing

There are many points along the healthcare continuum where use of low-to-no value procedures are common. Preoperative testing was singled out in a recent 'Less is More' editorial by a couple of MDs.[5] Historically, it has not been easy to persuade physicians to discontinue common preoperative tests such as urinalysis. This is a cheap test, but cumulative overuse leads to millions in unnecessary costs and flies in the face of medical guidelines. Other low-cost, low-value tests include electrocardiograms and chest X-rays.

In 2010, eliminating insurance payments for low-value tests was clearly demonstrated by ceasing payment for vitamin D testing. The use of this test dropped 93% in the first year, and the drop was sustained in subsequent years. Another example: A multidisciplinary educational program was applied to train physicians to reduce unnecessary procedures before cataract surgery. Preoperative chest X-rays, electrocardiograms, and laboratory testing dropped from more than 90% in each category to 24-37% after education. This was sustained after the initial drop.

It is likely to be challenging for patients to have a role in reducing unnecessary testing. There is the ever-challenging question that patients may ask the clinician: 'Do clinical practice guidelines for the procedure I am about to have require this test?'

Unnecessary Spending on Ivermectin

Three experts tried to assess the amount of money misspent on the COVID drug ivermectin because it was not an effective treatment for COVID or its prevention.[6] The investigators compiled payments for prescriptions of this drug from December 2020 through March 2021. They eliminated patients with a parasitic infection, which is the intended use of this drug. The weekly total cost to Medicare and patients was $2.5 million per week. When extrapolated to the entire population for a year, this amounts to about $130 million. Even in the Medicare insurance exchange, this is not a trivial amount. The authors note that this is more than is spent on unnecessary imaging for low back pain for Medicare patients.

If a hyped drug is suggested for you that is off label, you must ask to see the evidence that the drug works and is safe. Be wary of anecdotal accounts and testimonials.

[4] https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2787784

[5] https://pubmed.ncbi.nlm.nih.gov/34338740/

[6] https://pubmed.ncbi.nlm.nih.gov/35024763/

New Guideline for Gout Treatment

The American College of Rheumatology recently released a new guideline on the treatment of gout. Three experts summarized the guideline and quality of evidence to support it.[7] Gout affects about 1 in 20 adults, and about 1 in 5 adults have elevated uric acid levels. The writers noted that gout, the most common form of inflammatory arthritis, despite having cheap and effective treatment, is *undertreated*. There is some indication that the acceptable level of uric acid in serum should be lowered to 6 mg/dl. If you suspect you may have elevated uric acid because of painful joints, then ask for a uric acid measurement. This is not generally performed on routine blood analysis. Ask your primary care doctor about the new guidelines.

In a *JAMA* News and Analysis article, the writer extols the benefits of walking for people with arthritis.[8] About 55 million U.S. adults have arthritis and only a third meet standards for exercise, including walking. The view is that exercise minimizes pain and the risk of falling. Walking seems to be ideal because it is low impact, cheap, and often readily available. My experience with walking and arthritis is that one must carefully choose how to walk. The goal is to get at least 30 minutes of moderately intense exercise 5 days per week. Alternative forms of exercise include cycling and swimming.

Surprise Medical Bills Gone?

According to a *JAMA Forum* article, surprise medical bills are common and can wreck anyone's budget.[9] About 1 in 5 emergency room visits involve a surprise bill and 1 in 6 hospital stays involve a surprise bill. Before the procedure, do not give written consent to pay for out-of-network bills or you may be stuck. There are many nuances to how to deal with surprise bills, but the first stop is the entity that issued the surprise bill. If one cannot settle with them or they with your insurance company, then an arbitration process may be initiated. Apparently, the American Medical Association and the American Hospital Association are suing the federal government, arguing that the way the dispute process works favors the insurance companies. If the situation is not resolved, the patient may complain within 120 days at: https://www.cms.gov/nosurprises, or call 1-800-985-3059.

Cannabis and Neonate Wellness

A couple of experts wrote an invited commentary about the effect of cannabis use during gestation on health outcomes of the newborn.[10] They pointed to a recent meta-analysis of data on the subject. Compared to babies born to moms who do not use cannabis, the in-utero exposures result in more likely low birth weight, pre-term deliveries, and more time in the neonatal intensive care unit. The writers caution that states that have already legalized recreational cannabis use should make it known that women who may become pregnant or who are pregnant should not use cannabis. It falls to the clinician to persuade the woman to avoid cannabis use during gestation.

In my view, the growing evidence against prenatal cannabis use is not unlike the evidence that accumulated on alcohol use during pregnancy. This led to a 1977 public health warning that alcohol use during gestation should be avoided.[11] There is the fundamental truth in toxicology that 'dose makes the poison.' Perhaps there is some level of safe cannabis use, but that level remains unknown.

Placebo 'Induced' Adverse Events

One key to a credible study of a drug or vaccine is to sham expose a group of controls who are comparable to those receiving the drug or vaccine. A group of investigators looked at the effects of sham vaccination in the trials of COVID vaccines.[12] They found 12 articles with reports of

[7] https://jamanetwork.com/journals/jama/article-abstract/2787570
[8] https://pubmed.ncbi.nlm.nih.gov/34751710/
[9] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2788126
[10] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2788459
[11] https://pubmed.ncbi.nlm.nih.gov/26137906/
[12] https://pubmed.ncbi.nlm.nih.gov/35040967/

systemic adverse events for a total of about 45,000 subjects, split about 50/50 between those who received the vaccine and those who received a sham vaccination. About 35% of the placebo group reported adverse effects, which included mostly headache (19%) and fatigue (17%) after the first dose. After the second dose, 32% of the placebo group reported adverse effects. These are called 'nocebo' responses.

Nocebo effects accounted for 76% of the adverse events observed in the first-vaccinated group and 52 % of the adverse effects reported in after the second vaccine shot. The authors suggest that these high rates of nocebo effect should be considered when the rate of adverse events is reported to the public. In other words, if there is a high rate of systemic adverse effects reported by vaccinated people, then one must ask how many of the reports may be due to a nocebo effect caused by nothing more than the experience of an injection.

Interesting Links

Bad doctors not being held accountable by medical boards: https://www.dailykos.com/stories/2022/1/10/2072785/-Bad-doctors-big-problems-Part-I-When-do-no-harm-does-not-apply

Know the compensation of executives at non-profit hospitals: https://www.hospitalfinances.org/

Maine medical board stepping up to the problem of doctors giving misinformation about COVID: https://bangordailynews.com/2022/01/14/news/as-covid-misinformation-spreads-maine-medical-boards-investigate-doctors/

CMS Press release on Aduhelm coverage: CMS and Aduhelm analysis.

Advance care planning may need to be reconsidered: https://californiahealthline.org/news/article/advance-care-planning-palliative-care-experts-paradigm-shift/

Houston anti-vax doctor sues Houston Methodist for suspension: Houston anti-vaxx doctor suspended

Editorial/article on co-production of healthcare, which includes patients: https://academic.oup.com/intqhc/article/33/Supplement_2/ii6/6445900

WHO 5-minute video on Omicron concerns: https://www.youtube.com/watch?v=dXu9VZIJun8

FDA video on how to report problems with products they regulate: https://www.youtube.com/watch?app=desktop&feature=youtu.be&utm_medium=email&utm_source=govdelivery&v=6QGBHQfg52Y

What is wrong with the FDA (Shannon Brownlee): https://washingtonmonthly.com/2022/01/20/whats-wrong-with-the-fda/

Build Back Better legislation would greatly improve healthcare: https://www.commonwealthfund.org/blog/2022/how-build-back-better-bill-would-improve-affordable-care-act-coverage

Leapfrog on choosing a hospital wisely: https://www.leapfroggroup.org/patients-families

Florida hospital traps patient for months, gives toxic drugs, sends bill for $1.2 million to family: https://www.abcactionnews.com/news/local-news/i-team-investigates/the-price-of-protection/local-hospital-uses-court-to-keep-patient-for-a-year-charges-1-2-million-in-medical-bills

CMS's decision summary on Aduhelm: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=305

Aduhelm and Medicare's decision: https://www.science.org/content/blog-post/aduhelm-and-medicare

Past FDA chief criticizes CMS's decision on Aduhelm: https://endpts.com/scott-gottlieb-criticizes-cms-in-feud-over-aduhelm-coverage-calls-out-their-lack-of-expertise/

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http://patientsafetyamerica.com/e-newsletter/

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Answer to question: (B). Biogen reduced the annual cost from $56,000 to $28,000 per year.