

Question: *What is the median cost of a course of anti-cancer drug treatment in the US?*
A) \$50,000 B) \$100,000 C) \$150,000 D) \$200,000 E) \$250,000

Improving Surgery Outcomes Needs Improving

Three surgeons, one from the US and two from the UK, wrote their opinion of how the means of improving surgical outcomes need to improve.¹ Specifically, they recognized the importance of data gathering but they opine that plenty of data exist that have not been acted on for improvements. The latter is where more emphasis is needed without neglecting data gathering. Moreover, improvement efforts must be well executed and inclusive. In that regard, patients may play an important role. They emphasize the importance of small-scale efforts toward improvement with the ultimate goal of sharing successes with others in the healthcare industry.

I would have argued for more transparency when an unexpected outcome occurs. In this regard, the patient has a key role. If the results of your surgery are not as expected from a thorough shared decision-making process, then complain to the surgeon and medical facility managers. I know this is not easy, but it may lead to safer surgery for those coming behind you as a patient.

FDA Struggles to Withdraw Ineffective Maternal Drug

Three experts, two lawyers and an MD, wrote their viewpoint about the FDA's current struggle to remove Makena, a drug used to prevent pre-term births, from marketing.² The drug was approved in 2011, over the objections of some

agency experts, through the accelerated approval pathway. If this drug worked, it would be important because about 1/10 infants are born prematurely (before 37 weeks gestation). About ¾ of infant mortality is associated with preterm birth.

A confirmatory study was FDA-mandated to be completed by 2016 to support the scanty evidence offered at accelerated approval. Difficulty recruiting pregnant women delayed the results until 2019. Those results were 'disappointing.' The experts that reviewed the data unanimously voted to withdraw approval of the drug. The manufacturer vigorously complained. In October of this year a hearing was held, and experts voted 14 to 1 to remove the drug from the market. This



action is 'vigorously contested' by the current manufacturer. It is no wonder; from 2018-2021 the CMS spent \$700 million on the drug. The drug appears to increase the risk of cancer in the children born to moms who used the drug. The authors propose a smart solution to deal with this sort of problem with accelerated-approval drugs. Make the approval automatically expire some number of years after initial approval.

A wise patient will ask if a drug they have been prescribed is off label or has a black-box warning. Perhaps there is a third question to ask, 'Was this drug FDA approved though the accelerated approval process?' Has a confirming study been published?

¹ <https://pubmed.ncbi.nlm.nih.gov/36069864/>

² <https://pubmed.ncbi.nlm.nih.gov/36480209/>

Statin Induced Muscle Symptoms and Vitamin D

Those I know who have started taking statins to reduce cholesterol and hopefully their risk of cardiovascular disease often tell me that the side effects of the drug were not pleasant.³ A team of investigators asked if supplementation with vitamin D would mitigate the symptoms and thereby encourage more patients to continue use of the prescribed drug. Symptoms were deemed positive if muscle pain or discomfort lasted for several days. Roughly 2,000 patients newly prescribed a statin were divided into two groups, one group given vitamin D and the other group a placebo. The study lasted almost 5 years. The results were clear: 31% of the vitamin D group and 31% of the placebo group experienced muscle symptoms. Similarly, 13% of those in each group discontinued the use of statins. This was the first randomized controlled study to assess the effects of vitamin D on statin-induced muscle pain.

An article that surveys the value of statins in specific groups of people and the potential side effects is available from the Mayo Clinic.⁴ Apparently, dietary changes are just as effective at lowering ‘bad’ cholesterol as statins for many patients.⁵ No more pizza!

Prevalence, Diagnosis, and Treatment of Anxiety Disorders (ADs)

An excellent review on the topic above appeared in *JAMA Clinical Review and Education*. It was written by a PhD and MD and contained many details.⁶ I’ll try to hit the high points that are appropriate for patients and their advocates to digest. The prevalence of ADs is second only to depression among mental health ailments. ADs are associated with a variety of physical symptoms including cardiovascular disease, GI problems, pulmonary symptoms, chronic pain, and migraine headaches. There are three general kinds of AD with the lifetime prevalence in parenthesis as follows: generalized anxiety (6%), social anxiety (13%), and panic disorder (5%). My point is that ADs are common, and you probably know someone who may have some level of AD.

A screening tool such as Anxiety Disorder-7 can be used by primary care physicians to help in diagnosis

of AD. The sensitivity and specificity for diagnosis by this tool is not especially awe inspiring (my opinion). The authors suggest that screening of young women with Patient Health Questionnaire - 4 may also aid diagnosis. ADs are more prevalent in young women. The median age of onset is 11 years. The authors cite a study showing that a large majority of AD diagnoses are missed and 40% of those with the disorder are not treated.

Treatment must be considered if the AD symptoms are persistent, lead to social and/or occupational impairment or impairment of functional living. Treatment may consist of drugs or psychotherapy. The side effects of some of the drugs may preclude their application to ADs. Before use of any prescription drug, the patient should know the associated benefits and risks. There are a variety of psychotherapy options, and these must be tailored to the nature of the AD and the patient’s preferences. Roughly half of untreated patients diagnosed with AD recover within a 12-year period. For those responding to treatment, relapses are common.

I think the key here is the extent to which a person’s anxieties impair their function. I think all of us must admit to having anxiety periodically. My sense is that anxieties may increase as we age. Our friends begin dying, our comorbidities accumulate, and we may become socially isolated. Ultimately, we anxiously ask, “Are we prepared for the final turn in life that ends in death?”

Association of Exercise with Breast Cancer Survival

A small group of researchers asked whether postmenopausal women, having survived breast cancer treatment, were more likely to live longer if they engaged in exercise.⁷ They studied 315 women (mean age 71 years) that had been diagnosed with early-stage breast cancer. They were followed over a 9-year period ending in 2022. A standardized test was used to sort the exercise levels into high, moderate, and inactive based on exercise sessions of at least 15 minutes duration. This was self-reported, leisure-time activity. After 9 years, the death rates were as follows: high exercise (12.9/1,000), moderate exercise (13.4/1,000) and inactive (32.9/1,000). The authors suggest that their findings indicate that a plan for exercise should be encouraged once a woman has received treatment for breast cancer.

³ <https://pubmed.ncbi.nlm.nih.gov/36416841/>

⁴ <https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statin-side-effects/art-20046013>

⁵ [Natural reduction in cholesterol](#)

⁶ <https://jamanetwork.com/journals/jama/article-abstract/2799904>

⁷ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2798622>

Overpriced Cancer Drugs in the US

Most of us who shop for high-dollar items acknowledge the reality that you often ‘get what you pay for.’ I have yet to buy a vehicle for which I did not bargain on the price. A couple of MDs wrote a short editorial in *JAMA Internal Medicine* entitled ‘Paying for cancer drugs-getting what we are (prohibited from) bargaining for.’⁸ They noted that the US spends roughly \$200 billion each year on cancer drugs, and the median cost for a course of anti-cancer drugs is \$200,000. They opine that we are not getting what we pay for. They cite a recent article showing that there is no relationship between the cost of a cancer drug and its clinical effectiveness.

There are several proposals to rectify the situation. One is to require indication-specific pricing. This means that the price of a cancer drug should be indexed to how well it is known to cure the specific cancer of the patient in question. Another approach would be to hold the line on pricing of drugs given accelerated approval by the FDA based on surrogate endpoints, and then allow a higher price when studies are completed that show the drug is effective against cancer. The idea of value-based pricing has been around for a long time, but the lack of political will on the part of federal officials has precluded patients (and their insurers, including Medicare) from getting what they pay for.

Over-the-Counter Hearing Aids

I have a close, personal relationship with my 4 ½ year-old hearing aids. They demand that I replace their tiny batteries far too often, they sometimes refuse to work, and I must store them in a drying jar to avoid Houston’s high humidity from degrading their performance. They are temperamental. I was asked by family members to get new ones this Christmas, so I have some expensive model on order through an audiologist. This is about to change for the public because the FDA has defined a new category of devices: over the counter (OTC) hearing aids. A couple of MDs described how this will help many patients who had been unable to afford hearing aids.⁹

Maintaining hearing capability is critical to overall health as we age. Previously, a small group of international companies (mine come from Germany) had

the market cornered and sold their products through audiologists. By the age of 70 years about half the people have significant hearing loss. Beginning with a workshop in 2009, there was a movement to provide inexpensive, quality hearing aids so more people could counteract their hearing loss. *Finally*, this past October, the FDA decided to create the new category of devices, knowing that there will be robust competition in the marketplace. People will no longer have to have a physician’s approval or work through an audiologist to buy the OTC devices.

Some advice. If a family member is experiencing hearing loss, do not be shy about asking them to purchase OTC hearing aids. My family ganged up on me. I think it is a good idea to ask an audiologist to evaluate your hearing periodically. Finally, use hearing protection whenever around loud noise. Here is one of the many sites that purport to rate OTC hearing aids.¹⁰

Sites and Links

Video from whistle blower on failures of the Medical Board of California to protect patients:

<https://www.youtube.com/watch?v=5pDQA3qQcZI>

Nursing hustle for big money; forget the residents:

https://www.propublica.org/article/hospice-healthcare-aseracare-medicare?utm_source=sailthru&utm_medium=email&utm_campaign=weekly-newsletter&utm_content=river

Medical Board of California rejects an accountability act:

<https://www.nbclosangeles.com/investigations/medical-board-of-california-meeting-ends-in-frustration-for-patient-advocates/3047557/?fbclid=IwAR1Cu79d21dzRtSwR2hgFgOOG-B8MC-D0jIT3uEcgi5PctgwuPkB3TSnho>

Billions went to hospitals that did not need it (WSJ):

https://www.wsj.com/articles/billions-in-covid-aid-went-to-hospitals-that-didnt-need-it-11670164570?st=apkme6d55ypr1l5&reflink=desktopwebshare_permalink

Prenatal genetic testing is an unregulated industry (ProPublica):

https://www.propublica.org/article/how-prenatal-screenings-have-escaped-regulation?utm_campaign=socialflow&utm_medium=social&utm_source=twitter

Hospital acquired infections from dirty laundry:

<https://pubmed.ncbi.nlm.nih.gov/36345791/>

⁸<https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2798199>

⁹<https://jamanetwork.com/journals/jama/fullarticle/2799343>

¹⁰ [OTC Hearing Aids](#)

Abortion restrictions associated with worse maternal mortality (Commonwealth Fund): https://www.commonwealthfund.org/publications/issue-briefs/2022/dec/us-maternal-health-divide-limited-services-worse-outcomes?utm_source=alert&utm_medium=email&utm_campaign=Advancing+Health+Equity

Diagnostic errors in the emergency department (AHRQ): https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/cer-258-diagnostic-errors-summary.pdf

Decline in US life expectancy: <https://www.healthaffairs.org/content/forefront/decline-us-life-expectancy-nation-s-choice>

Drug overdoses in the US (CDC): <https://www.cdc.gov/drugoverdose/featured-topics/overdose-prevention-campaigns.html>

How to background check your doctor (Marshall Allen): https://marshallallen.substack.com/p/how-to-background-your-doctor-like?r=effbc&utm_campaign=post&utm_medium=email

COVID vaccines prevented millions of hospitalizations and deaths (Commonwealth Fund): <https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations>

US maternal mortality highest among developed countries (Commonwealth Fund): <https://www.commonwealthfund.org/blog/2022/us-maternal-mortality-crisis-continues-worsen-international-comparison>

Extending Medicaid postpartum health coverage to reduce maternal mortality (Commonwealth Fund): <https://www.commonwealthfund.org/blog/2022/improving-maternal-health-extending-medicare-postpartum-coverage>

CMS now requires hospitals to survey patients for pain before and after hip or knee replacement: <https://www.forcetherapeutics.com/how-updates-to-cms-fy2023-hospital-inpatient-quality-reporting-program-impact-orthopedic-providers/>

CNN's Jake Tapper's daughter nearly did a misdiagnosis: <https://www.yahoo.com/entertainment/cnn-anchor-jake-tappers-15-201606640.html?guccounter=1>

Hospitals suing patients: <https://khn.org/news/article/medical-debt-hospitals-sue-patients-threaten-credit-khn-investigation/>

High cost of ambulance service: <https://pirg.org/edfund/resources/emergency-the-high-cost-of-ambulance-surprise-bills/>

We need to learn from Germany to solve our medical debt crisis (NPR): https://www.npr.org/sections/health-shots/2022/12/14/1142601526/lessons-from-germany-to-help-solve-the-u-s-medical-debt-crisis?utm_campaign=npr&utm_source=facebook.com&utm_medium=social&utm_term=nprnews

How to look up your doctor's history (Marshall Allen): https://marshallallen.substack.com/p/how-to-background-your-doctor-like?r=effbc&utm_campaign=post&utm_medium=email

Patient engagement strategies by physicians are minimal: <https://pubmed.ncbi.nlm.nih.gov/35833416/>

Alice Tapper's story of being nearly killed by bad medical care: <https://www.cnn.com/2022/12/15/opinions/appendicitis-misdiagnosis-girls-tapper/index.html>

Medications associated with increased risk of dementia: <https://www.center4research.org/which-common-medications-are-linked-to-dementia/>

Hospital CEO's make too much money: <https://www.cleveland.com/letters/2022/12/no-hospital-system-ceo-should-make-more-than-twice-what-the-us-president-is-paid.html>

Interesting idea – The People's CDC: <https://peoplescdc.org/>

FDA broke its own rules in approving Aduhelm: <https://www.yahoo.com/news/congressional-report-u-fda-broke->

Answer to question: (D), approaching 200,000, reference #8

[180535003.html](https://www.commonwealthfund.org/publications/issue-briefs/2022/dec/us-maternal-health-divide-limited-services-worse-outcomes?utm_source=alert&utm_medium=email&utm_campaign=Advancing+Health+Equity)



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