



February 2023

<http://PatientSafetyAmerica.com>

John T. James, Ph.D.

Question: How many Americans currently have medical debt?

A) 50 million

B) 100 million

C) 150 million

D) 200 million

Drugs Ads on TV and Therapeutic Value

Any American who watches television is certainly exposed to drug advertisements. Most come with clever-sounding names that may be suggestive of its therapeutic purpose. Typically, the long list of side effects is presented in a muted voice as people are depicted partying or playing in a park. Never forget that advertising executives know how to sell almost anything to an uninformed buyer. You are about to be better informed about drug ads.

A small group of investigators asked about the therapeutic value of drugs that were advertised from 2015 to 2021, including their indications for prescribing.¹ Therapeutic ratings for these drugs were extracted from German, French, and Canadian databases. There were three therapeutic levels – low, moderate, and high. The ratings depended on added benefit over existing drugs, safety, and strength of evidence. The investigators used the most favorable rating if more than one was available.

They found that of the 73 advertised drugs that they evaluated, 20 were rated of high or moderate value and 53 were rated as low value. In the 6-year study interval, the amount spent on advertising of high-value drugs was \$6.4 billion, and the amount spent on advertising low value drugs was \$15.9 billion. The authors note that their findings are consistent with the advertising approach to physicians. The authors propose a possible solution – allow only drugs with high therapeutic value to be advertised on television. I might propose that manufacturer’s advertising on television include

a huge, boxed warning at the end of the ad stating that ‘*This drug is of low therapeutic value.*’

A smart consumer must ask the prescribing clinician about any newly prescribed drug. Just because he saw it in a medical journal ad or you saw it advertised on television does not mean it is good.

Overlapping Surgeries

Three experts wrote about the situation with overlapping surgeries performed by surgeons on hospitalized patients.² Medicare and Medicaid forbid this practice and Mass General Hospital just got slapped with a \$14.6 million fine for doing this. The settlement also stipulates that surgeons must inform patients ‘when the attending surgeon has an overlapping surgical obligation.’ The American College of Surgeons has declared that overlapping surgeries are ‘inappropriate.’ So, what is the risk to patients from overlapping surgeries?

The authors cite a 2019 study of more than 8,000 surgeries in which it was found that overlapping surgery was not generally associated with increased in-hospital mortality or complications. However, in some subgroups, overlapping surgery was associated with increased risk of complications and mortality. For example, coronary bypass graft surgery had twice the mortality when overlapping surgeries were performed when compared to solo surgeries. A survey of 1,400 patients found that less than a third approved of overlapping surgeries. Apparently, many hospitals forbid this as it tends to erode the

¹ <https://pubmed.ncbi.nlm.nih.gov/36637824/>

² <https://jamanetwork.com/journals/jamasurgery/article-abstract/2797356>

patient's expectation of a 1 on 1 relationship with her surgeon. The patient has a right to know if overlapping surgeries are planned and precisely who will be involved and their level of training.

Serious Harm Still Common in Hospitals

A huge team of investigators used a sample of 2,809 medical records randomly sought from 11 Massachusetts hospitals taken in 2018 to discern the frequency of adverse events, including those that were preventable.³ Serious, preventable adverse events were evident in 1 % of the patient records. One death was deemed preventable. Medication errors were the most common adverse event (39%). The authors admit that the Global Trigger Tool they used to identify preventable adverse events may overlook a substantial portion of such events. The example they pointed to in this regard was the challenge of detecting errors in diagnosis.

This study was noteworthy in that it was published in the *New England Journal of Medicine*, arguably the top medical journal published in the US. I'll try to place this finding in perspective. Would you fly on a commercial US jet if your chances of serious harm were 1 %? For comparison, there is a 1 in 20 million chance of being on a commercial airline flight experiencing a fatal accident from 2012-2016.⁴ Go figure.

Motorcycle Rallies and Organ Donations

A modest team of investigators asked an interesting question: does the number of organ donors increase in areas where a large motorcycle rally is happening?⁵ They compared the frequency of donors one month before a rally and one month after the rally to the frequency during the rally. During the days of the rally, there were 21 % more donors per day and 26% more transplant recipients per day than at other times. Maybe the lesson here is to think twice before riding a motorcycle in a congested area. You do not want to become an organ donor.

³ <https://pubmed.ncbi.nlm.nih.gov/36630622/>

⁴ [Plane Crash Statistics \(flyfright.com\)](http://flyfright.com)

⁵ <https://pubmed.ncbi.nlm.nih.gov/36441514/>

Dangerous Devices for Sale

A group of experts took an in-depth look at the ongoing relationship between devices subject to a Class 1 recall and similar devices under the FDA's 510(k) process.⁶ A Class 1 recall means that the FDA has discovered that there is a high probability that the device will cause adverse health effects or death. Devices are typically cleared by the FDA for marketing when the manufacturer demonstrates that the new device is similar to predicates (devices already cleared). The problem appears when the predicate device has already been subject to a Class 1 recall.

The investigators asked what are the chances that a newly cleared device gets a Class 1 recall because its predicate device has had a Class 1 recall? The answer they found was that a device cleared based on a predicate with a Class 1 recall is 6 times more likely to have a Class 1 recall than if the predicate device had not been recalled. The authors conclude "Safeguards for the 510(k) pathway are needed to prevent problematic predicate selection and ensure patient safety."

If a clinician is planning to place a device in your body, you may want to ask if it or any similar device has been subject to recall. My guess would be that he may not know the answer.

Informed Consent and Genetic Studies

A couple of MDs wrote a short editors' note pertaining to the information needed by those who agree to have a thorough genetic test.⁷ The case under consideration is dilated cardiomyopathy, which is more common in black Americans. The study was undertaken to determine the extent of genetic factors' contribution to the disease. Apparently, 20% of those participating in the study mistakenly understood that genetic testing could reveal a variant, and this could lead to a cure. The authors opine that patients must be aware of the risks, benefits, and implications of genetic testing. This requires a shared decision-making process. This process must include discussion of the

⁶ <https://pubmed.ncbi.nlm.nih.gov/36625810/>

⁷ <https://pubmed.ncbi.nlm.nih.gov/36383369/>

uncertainties of the test results and their implications for family members. A good question to ask before agreeing to a genetic test is, “How will the results of the test affect my prognosis and treatment?”

Anticoagulants Benefits vs. Cost

Three researchers explored the way physicians communicate information to patients facing a decision about which type of anticoagulant to take – either warfarin or a direct oral anticoagulant (DOAC).⁸ The former is an older medication that is dirt cheap, whereas the latter is relatively new and expensive. The investigators pulled 37 encounters between physician and patient from the Verilogue Point of Practice Database. The goal was to assess whether the physician’s shared decision-making encounter was balanced. The advantage of DOACs is that they have a reduced risk of bleeding, and they require much less attention to periodic blood draws to measure anticoagulant levels. The high cost of DOACs could be a factor in whether a patient can afford the drug, and this, in turn, may affect patient compliance.

The problems found with physician encounters centered on emotional information, discussion of TV ads, and limited knowledge of costs. For example, some patients were told that warfarin is used in rat poison. Ads on TV are intended to sell the DAOC in question, so are naturally biased and should have no place in a balanced discussion. Finally, physicians were unprepared in most cases to discuss differences in costs to the patient. In my opinion, this finding is another example in which the patient must take the initiative with questions. Treat your discussion like you were buying a car: How reliable is it, how will I like driving it, and how much will it cost me? You may want to ‘test drive’ a medication before you decide to take it for a long time.

Teen Suicide and Mental Health Support

Two experts provide comments on a newly published study showing that shortages of mental health facilities are correlated with higher rates of

suicide in children ages 5-19 years old.⁹ About 5,000 child suicides were completed in the 2015-6 timeframe. They found that living in an area with a shortage of mental health professionals correlated with a higher rate of suicide by firearm. The authors note that money alone cannot fix the problem because there is a serious lack of trained child mental health professionals. Telehealth could potentially help relieve some of the shortages. Parents could limit the duration of screen time, which has been shown to correlate with suicide risk. Addressing poverty and inequity in healthcare delivery could go a long way to relieving the deficit in mental health services for children. Lack of health insurance limits access to mental health services because of fear of costs.

Evidence-based Fall Prevention in Hospitals

Treatments after harmful falls in hospitals are a common cause of non-reimbursable expense. Hospitals have a strong economic incentive to avoid patient falls. A huge team of investigators sought to determine the effectiveness of an evidence-based fall prevention strategy on controlling the costs of falls.¹⁰ The approach of the study was to count the number of falls in a given period of time, implement the intervention, and then count the number of falls in the same length of time. The result was that before the fall-prevention protocol was implemented, there were 2503 falls and 900 injuries. After the protocol was in place, the number of falls in an identical period was only 2078 falls and 758 injuries.

The bottom line for the bean counters was that \$14,600 in patient care costs were avoided per 1000 patient days after the implementation of the protocol. This strikes me as a marginal reduction in costs given the potential burden of a new fall-prevention protocol. However, for me the message is that implementation of an evidence-based fall prevention protocol in a hospital can reduce the harm from patients falling.

⁸ <https://pubmed.ncbi.nlm.nih.gov/36315125/>

⁹ <https://pubmed.ncbi.nlm.nih.gov/36409471/>

¹⁰ <https://pubmed.ncbi.nlm.nih.gov/36662505/>

Greed Threatens US Healthcare

The venerable Don Berwick, MD wrote his views about unbridled greed in the US healthcare system.¹¹ His leading opinion is expressed as follows: “The grip of financial self-interest in US health care is becoming a stranglehold, with dangerous and pervasive consequences. No sector of US health care is immune from the immoderate pursuit of profit, neither drug companies, nor insurers, nor hospitals, nor investors, nor physician practices.” He goes on to characterize many details where greed is the hallmark of the healthcare industry. Then he describes the impact on Americans. Roughly 100 million Americans suffer from medical debt and 1 in 8 people owe more than \$10,000. Fear of medical debt is known to cause people to skip care they need. Healthcare is about twice as expensive in the US as in other developed countries, yet our health status is much worse. Dr. Berwick is not optimistic that this can be fixed: “The cycle is vicious: unchecked greed concentrates wealth, wealth concentrates political power, and political power blocks constraints on greed.”

In my opinion, patients like you may have a say on reducing greed in American healthcare. If you note something amiss in your medical bills, report the problem to appropriate authorities and insist on a response. Keep your state and federal legislators informed of your struggles with the cost of your medical care. Do all you can to resist becoming a pawn of the medical industry. Be a king or queen.

Links of Interest

Medical errors in the Emergency Department (AHRQ):
<https://effectivehealthcare.ahrq.gov/products/diagnostic-errors-emergency/research>

Thanks to Bob Leper: Hearing aid reviews (Consumers Reports):
<https://www.consumerreports.org/health/hearing-aids/>

Don Berwick on greed in US healthcare, speech at the IHI:
<https://www.fiercehealthcare.com/providers/ihf-forum-don-berwick-calls-out-healthcare-greed-calls-industry-protest>

¹¹<https://jamanetwork.com/journals/jama/fullarticle/2801097>

PP: Pulmonary embolism: [What Is Pulmonary Embolism? | Emergency Medicine | JAMA | JAMA Network](#)

Tragic case of botched care of a child in Iowa:
<https://dailyiowan.com/2022/05/02/iowa-city-surgeon-sued-after-child-dies-following-adenoid-surgery/>

Entertaining tour of the 2022 Shkreli Awards for healthcare exploitation and patient harm:
<https://lowinstitute.org/projects/2022-shkreli-awards/>

Medical malpractice briefing book:
<https://centerjd.org/content/briefing-book-medical-malpractice-numbers>

Pending collapse of the US healthcare delivery system (Time):
<https://time.com/6246045/collapse-us-health-care-system/>

Widespread loss of free access to preventive health services may be coming: <https://www.commonwealthfund.org/blog/2023/millions-could-lose-access-free-preventive-care-services>

Firearm trauma from a physician who tries to heal these (NEJM):
<https://www.nejm.org/doi/full/10.1056/NEJMp2214971>

Prices of seven drugs increased in 2021 so much that the US paid \$800 million more for them:
<https://www.statnews.com/pharmalot/2022/12/06/drug-prices-icexifaxan/>

Biden administration targets overuse of antipsychotic drugs in nursing homes:
<https://www.usatoday.com/story/news/health/2023/01/18/nursing-homes-have-long-overprescribed-patients-nursing-homes/11069221002/>

Americans are not that happy with the healthcare they receive (Gallup poll): <https://news.gallup.com/poll/468176/americans-sour-healthcare-quality.aspx>

Americans putting off healthcare due to high cost:
<https://news.gallup.com/poll/468053/record-high-put-off-medical-care-due-cost-2022.aspx>



NATIONAL
QUALITY FORUM
MEMBER

Find past newsletters:

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

Answer to question: (B) 100 million; see the last summary.

