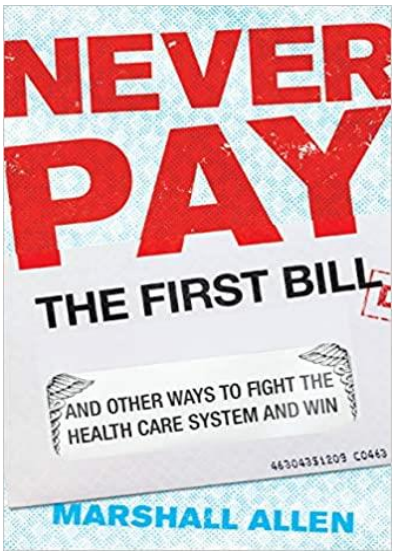
Patient Safety America Newsletter

July 2021 http://PatientSafetyAmerica.com *John T. James, Ph.D.*

***Question:** What percentage of kidney cancer patients are overtreated in the United States?*
A) 5%** **B) 10%** **C) 15%** **D) 20%** **E) 25%** **F) 30%** **G) 35%

Book Review: **Never Pay the First Bill and Other Ways to Fight the Health Care System and Win**
By: Marshall Allen



In the interest of full disclosure, I know Marshall Allen and recall that it was his journalism skills that propelled my 2013 article on medical errors in hospitals into the public arena. Marshall's new book has filled a void that has existed for decades – what can the individual do to fight back against a health care industry that often focuses on profits and not patients. He methodically captures the steps necessary to do battle with your provider who may have overbilled you or your insurance company that refuses to pay its share of your medical bill. How does one handle medical-bill, debt collectors? I especially like his first chapter because it explains why we should not pay unwarranted medical bills even when we can. We, the patients of America, are *TOGETHER* in our collective fight against bogus medical bills.

In part II he mentions the consent process, although he does not explicitly call it that. He provides a set of 'key questions' the patient should ask of his clinician, including, 'What does the United Services Preventive Services Task Force recommend? This is all with the goal of not having to fight back against unfair billing once you are overtreated. He basically describes a process of shared decision making. In Part III of the book, he gives advice to employers seeking to provide safe medical care for employees without breaking the financial back of the company.

The lesson for all patients who have been 'pushed around' by the American health care industry is to be fearless and patient with your pushbacks. We Americans pay far more *per capita* for our healthcare, yet our life expectancies are among the worst among developed countries. Yes, you can make this injustice shrink. 5 stars. $14 to $16 online.

Second Opinions and Correct Diagnosis of Pigmented Skin lesions

You have gone to your dermatologist to ask about a suspicious, new pigmented 'mole' on your body. Dermatologists call these things 'cutaneous melanocytic lesions.' A large group of scientists (https://pubmed.ncbi.nlm.nih.gov/34076664) investigated the value of getting a second opinion after one pathologist has looked at the cells from a biopsy of that lesion. Does a second opinion improve the accuracy of diagnosis? In this study, 240 lesions were examined by 187 pathologists. Their diagnosis was compared to the 'gold standard' reference diagnosis made by experts. With a single opinion, diagnoses were 83 % accurate with 8% over-diagnosed and 9% underdiagnosed. With a second opinion, the concordance with the standard diagnosis was over 87%.

My take-home message for readers is that second opinions can improve diagnostic accuracy, but if you are a patient with a presumed-benign skin lesion, you may want to carefully watch for changes in it and have it monitored annually. Melanoma is increasing worldwide and may be a challenging cancer to overcome if not caught early. Although there are many pictures of various skin lesions online, I would caution against self-diagnosis.

Your Annual Wellness Examination

Many of us value a yearly examination by a primary care physician to help find any medical problems that may be lurking in our bodies. In my younger years, I thought these were generally a waste of time, but NASA gave these freely to employees, so I got mine. Nothing important was ever found, although my hearing test (not a usual part of an annual physical) found gradual loss, and my kidney function declined as expected with age. As I aged into my 8th decade, I found that the annual physical was more important. An editorial stemming from a recent attempt to resolve the question of the value of annual physical examinations noted that the value of a physical exam depends on patient preferences and it being limiting it to targeted measurements. Interestingly, the writer opined that one unspoken value of this exam is to over-time build the physician-patient relationship (https://jamanetwork.com/journals/jama/article-abstract/2780635). This may lead to the patient being more forthcoming with medical concerns and better work-satisfaction for the physician.

I might have added that a physical exam is a must if the individual is experiencing changes in health that are not associated with normal ageing. I could have added one additional benefit for me personally. As the date for my exam approaches, I make every effort to lose weight, so I do not embarrass myself when I hop on the scales.

Device Recalls by the FDA

Devices are cleared for marketing through the 510k process in which a device is deemed to be essentially like ones already marketed and by the Pre-Marketing Approval (PMA) process in which devices are subjected to more rigorous testing before marketing. A small team of investigators (https://pubmed.ncbi.nlm.nih.gov/33956132/) assessed the fraction of FDA recalls in each category from 2008 through 2017. The follow up time for an FDA recall to be issued varied from of 2 to 12 years. During the years of approval, 28,000 devices were cleared by the 510k process and 310 by the PMA process, the latter being much more expensive.

The portion of recalled 501k-cleared devices was only 11%, whereas the portion of recalled PMA-approved devices was 27%. Recalls are issued when post-marketing use reveals serious safety concerns. In my opinion, these high portions of recalls suggest the public may be guinea pigs. As a patient, you should ask any physician proposing to insert a device in your body if there is a recall of the proposed device, if the benefit-risk profile is favorable, if the clinician has received payments from the device maker, and how long the device has been on the market. You may not want to be among the first to get the thing after marketing approval.

Non-guideline Treatment for Kidney Cancer

Medical guidelines are the consensus standards for discovery and treatment of disease, ideally based on the best available information at the time of guideline creation or revision. The quality may vary depending on independent expert review and whether there is bias in those who created the guideline. None-the-less, these are the standard by which the quality of medical care should be judged unless there is a compelling reason to deviate from guidelines. A small group of researchers asked whether the demographics of gender and race affected the portion of kidney-cancer treatments that were non-guideline based in records from the National Cancer Database from 2010 through 2017 (https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780799). The subjects were from 30 to 70 years old and in otherwise good health. Investigators discovered 158,400 records, of which 48,500 showed non-guideline treatment.

In females, there was a lower probability of undertreatment, and higher odds of overtreatment compared to males. Black and Hispanic patients had higher odds of undertreatment. Uninsured patients had higher odds of undertreatment and lower odds of overtreatment. Regardless of the demographic differences, the finding that 31% of the patients received treatment that deviated from guidelines should be cause for concern. Of the care that deviated from guidelines, 92% involved overtreatment.

Guidelines are the purview of physicians. During a shared decision-making process, the patient should ask what guideline is being followed for her care, especially when something as serious as kidney cancer is present. If deviations are planned from guidelines, the clinician should be prepared to give the patient a sound reason for deviation.

Aspirin for Primary Prevention of Cardiovascular Events

Last week in a careless accident, I cut both of my hands on glass shards from a broken mug. Noting that I had had further bleeding in the waiting room, the first question the physician asked me in the emergency department was whether I was taking any anticoagulant, including aspirin. I had not been, but according to a recent commentary on the use of aspirin in older people that have never experienced a serious cardiovascular event, about 20 to 50%, depending on age, do take low-dose aspirin (https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781119). The question is whether the benefit of this outweighs the risk. The answer to that question is not well established. The bottom line, if you take a daily low dose of aspirin, is to keep track of any excess bleeding events you may have and discuss any concerns with your primary care doctor. I know some people that take a low dose aspirin *every other day*. Perhaps, not a bad idea.

Hospital Price Transparency

An eclectic team of researchers asked whether a sample of 100 of the largest US hospitals showed compliance with the federal government mandate to make prices available to the public (https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2781019). The law was finalized in 2019 and went into effect January 1, 2021. The researchers examined websites in early March 2021. The law requires hospitals to publish cash prices for services and payer-negotiated rates. It further requires hospitals to show out-of-pocket costs for 'shoppable services' that apply to services that can be scheduled in advance.

The investigators found that 75 of the 100 highest-revenue hospitals were not fully compliant with the law. They note that the fine for non-compliance is $300 per day, a pittance compared to the gross revenue of a large hospital, which is typically in the hundreds of millions of dollars. One does not have to be smart to deduce why compliance will be quite slow. I would have made the fines increase over time to the point where they cause economic pain for non-compliance within 6 months.

Active Surveillance for Basal Cell Cancer

Active surveillance entails close monitoring without any initial treatment. The rational for this is that the potential harm from an initial treatment may be worse than living with a cancer that may never cause harm to the patient. Two MDs from dermatology departments provided a rationale for active surveillance of basal cell carcinomas that are less than 1 cm across, not in the facial area (i.e. on limbs and torso), and in immunocompetent people (https://pubmed.ncbi.nlm.nih.gov/34125141/).

They wrote an informative summary of the importance of basal cell carcinoma that I will summarize here. Each year about 3 million Americans are diagnosed with basal cell carcinoma at a median age of 67 years. Only about 1 in a million persons with this diagnosis will die from this cancer. Typical surgical treatment is to remove tissue until the margins show no cancer cells. Adverse effects of surgery are common and include bleeding, infection, and the surgical wound breaking open. About 100,000 Americans receive treatment for basal cell carcinomas in the last year of their lives. The authors point out that surveillance could

be conducted by telemedicine under some conditions. A wise patient will ask about active surveillance if diagnosed with basal call carcinoma.

Make Shared Decision-Making a U.S. Law

German law requires that all possible treatment options be considered by the patient and clinician during a process of shared decision-making (SDM). A large group of investigators in a German healthcare system described the implementation, in a neurology department, of the SHARE TO CARE program that complied with this SDM law (https://www.aerzteblatt.de/int/archive/article/218777). They developed a 4-point approach to implementing SDM as follows: training physicians using video recordings, showing video and print media to encourage patients to actively participate, creating evidence-based decision aids, and training nurses as patient coaches.

Patients reported an increase in their level of SDM and better preparation for their decision making. The percentage of physician-patient encounters that went above a SDM threshold increased from 57% to 77%. A similar law has been passed in the UK. Implementation of SDM has been shown repeatedly to reduce overtreatment, undertreatment, and inappropriate treatment. In my opinion, it is time for a similar law in the U.S. This may interfere with the 'business model' of American medicine by putting patient needs ahead of profits.

COVID and General Links

Case made to FDA asking it to wait until 2022 to approve COVID vaccines: Why we petitioned the FDA to refrain from fully approving any covid-19 vaccine this year - The BMJ

CDC's COVID data tracker: https://covid.cdc.gov/covid-data-tracker/#variant-proportions

Antivaxxers use CDC VAERS database to attack vaccination: https://www.npr.org/sections/health-shots/2021/06/14/1004757554/anti-vaccine-activists-use-a-federal-database-to-spread-fear-about-covid-vaccine

When patients feel like hostages (Mayo Clinic Proceedings, 2017): https://www.mayoclinicproceedings.org/article/S0025-6196(17)30394-4/fulltext

Pharma donations to congress persons: Two-thirds of Congress cashed a pharma campaign check in 2020 (statnews.com)

FDA should never have approved new Alzheimer drug (Center 4 Health Research): Statement of Dr. Diana Zuckerman on FDA's Approval of Alzheimer's Drug Aduhelm | National Center for Health Research (center4research.org)

Third FDA expert resigns over approval of Alzheimer drug: Third member of U.S. FDA advisory panel resigns over Alzheimer's drug approval | Reuters

States with growing population, such as Texas, have the worst health care: The Fastest-Growing U.S. States Have the Worst Health Care (hbr.org)

Marty Makary MD on the US health care system (great video): https://www.prageru.com/video/overmedicated-america/?utm_source=Iterable&utm_medium=email&utm_campaign=campaign_2438143

Trailer for Doctor Death: https://www.youtube.com/watch?app=desktop&fbclid=IwAR0_xXWPz5ng_J75CF6RkC4ZL-agg1Dopv7B7LhC4Z5BROWpg0UHaiElcoA&v=WUydwrPAY-M&feature=youtu.be

Device makers pay huge sums to orthopedic surgeons that use their products: https://khn.org/news/article/spine-surgery-implants-device-makers-orthopedic-surgeons-kickbacks/

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Answer to question: (F) 29% (92% of 31% as reported on page 2 of this newsletter)