November 2023

http://PatientSafetyAmerica.com

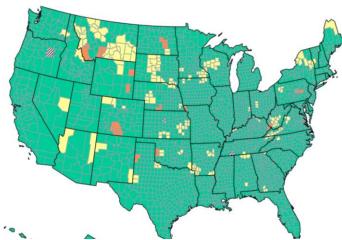
John T. James, Ph.D.

Question: How much money are states expected to get from legal settlements involving the opioid epidemic that has plagued and will continue to plague the US?

A) \$25 billion B) \$50 billion C) \$100 billion D) \$ 200 billion E) \$ 250 billion

Updated COVID-19 Vaccine Now Available

Just in case you are a fan of vaccines, the latest version of the COVID-19 vaccine is now available. Last month the CDC recommended that everyone 6 months or older get the new monovalent vaccine against the Omicron variant XBB.1.5.1 The FDA approved the vaccines, available from Pfizer or Moderna, for everyone 12 years of age or older and for emergency use in children 6 months to 11 years of age. All folks aged 65 or older, pregnant, or immunocompromised are considered most at risk for a severe case of the infection. It's not a bad idea to ask your primary physician if you may be at risk of more serious infections because of the health conditions already present in vour body.



COVID-19 hospitalizations/100,000 population in counties in the past week. Green (<10), yellow (10-20), orange (>20). Downloaded from CDC website on 10/29/2023.

The federal government is picking up the tab for this round of vaccines through its *Bridge Access Program* and *Vaccines for Children Program*. The spike proteins in the XBB subvariants are similar and those proteins are present on 90% of the circulating variants. Hence, a vaccine targeting one subvariant of XBB should be somewhat effective against the current subvariants. The virus is an everchanging target with a time constant of a few months. Hitting it with optimal vaccines is a challenge.

Subtle Effects of Poor Indoor Air Quality (IAQ)

During my tenure at NASA, my team was responsible for setting spacecraft air quality standards in cooperation with the National Research Council and monitoring compliance with those standards. Separately, microbial standards were set. The standards had to be set against the backdrop that spacecraft are small spaces and air scrubbers eat power, are heavy, and take up precious room. This situation is analogous to the situation on earth where buildings may have unsafe air quality, but the resources to rectify the situation are not easily built and maintained.

Unless we are hermits, we have all been in buildings that make us uneasy because of air stagnation. In my experience these have included crowded restaurants, old schools, and 'ancient' office buildings. A group of experts has called for the states to step up to improve IAQ in the absence

¹ https://pubmed.ncbi.nlm.nih.gov/37721745/

of federal regulation.² Apparently, it will take an act of Congress to allow federal agencies to implement new regulations. In the current political climate, that is unlikely to happen. Their proposal is called the Model State Indoor Air Quality Act. There is already ample data that IAQ needs improvement.

The proposed state law calls for regulatory structures, surveillance, transparency, interventions, and incentives. This would be up to each state to develop. Perhaps the action plan for my readers is to note times when IAQ seems poor and report this to your state health officials. Especially in a time when infectious spread is commonplace in buildings, better air flow and filtration is needed.

Heat Exposure and Severe Maternal Morbidity (SMM)

As a male, I can only indirectly experience the effects of hot conditions on a pregnant woman's hot wellbeing. My observation: conditions. especially in the third trimester, may elicit misery in a pregnant person. A team of investigators used Kaiser Permanente Data (2008 through 2018) from southern California to discern if there was an association between diagnosis of SMM and short or long-term exposures to high temperatures among singleton pregnancies.³ There were roughly 3450 SMM diagnoses among the 404,000 pregnancies (mean age 30 years). Long-term exposure to hot conditions was associated with a 28% increase in SMM risk, and hot conditions during the third trimester was associated with a 27% increase in SMM risk.

As my readers know, maternal mortality in the U.S. is an ongoing problem that seems to refuse a solution. There are many factors that seem to contribute to this problem. Perhaps, special cautions by pregnant women during heat surges could reduce the risk of SMM, although this may not be available to women who must work or live in hot conditions while pregnant.

Opioid Settlements and Money for States

A couple of experts wrote in *JAMA Forum* about the settlement of a multidistrict litigation lawsuit, the largest of its kind.⁴ The settlement was for \$26 billion, with a chance for \$6 billion more depending on the bankruptcy settlement with Purdue Pharma. In the end, something more than \$50 billion is going to be available for the states to spend. The question is how it will be spent considering the reality that 100,000 Americans per year are dying from opioid overdoses. Historically, a similar settlement with the tobacco industry in the 1990s resulted in states spending only 3% of their take on cessation programs. Much of that settlement money ended up in the state general funds.

The hope is that with the opioid settlement, more resources will be put toward mitigation of opioid deaths. Who decides that will vary from state to state and the transparency of that spending may be poor at best. Teams of experts have formulated plans for how states *should* wisely spend their take, but this could be ignored because of political expediency.

Gut Microbiome and Melanoma

It is no secret that certain antibiotics can disrupt the bacteria content of your gut microbiome. A couple of experts wrote about the findings of a recent study that associated the content of the gut microbiome with different stages of melanoma.⁵ There is something called the gut-skin axis. It is known that loss of microbial diversity in the gut is associated with atopic dermatitis, psoriasis, rosacea, and acne vulgaris. In the study described, Fusobacterium, which is associated with colorectal cancer, increased inflammation, and decreased antitumor activity, was more prevalent in patients with melanoma. The gut microbiome may also enhance the effectiveness of treatments in some individuals. The authors note that the study they reviewed adds a piece to the complex puzzle that comprises the causes and therapeutic responses to

² https://jamanetwork.com/journals/jama/fullarticle/2810395

³ https://pubmed.ncbi.nlm.nih.gov/37676659/

⁴ https://jamanetwork.com/journals/jama-health-forum/fullarticle/2810247

⁵ https://pubmed.ncbi.nlm.nih.gov/37647035/

treatments for melanoma. The picture is far from complete.

In my opinion, if you take an antibiotic that seems to change your gut microbiome, you may want to take a probiotic to restore your gut microbiome. If you have a melanoma, you may want to ask about therapies that restore your gut microbiome if it is not diverse. In any case, discuss this with your oncologist. I know of too many people who lost their lives to melanomas.

Promise and Pitfalls of Artificial Intelligence (AI) in Medicine

In a question-and-answer interview, the *JAMA* Editor in Chief interviewed an MD expert about AI.⁶ In the future, there will be a series of experts interviewed about use of AI. This reflects the importance being placed on the rising tide of AI in its various forms. The expert noted that November 30, 2022, is the day that ChatGPT came out, and it will be remembered in history. ChatGPT has evolved since then. The promise of ChatGPT is that its output is natural language and is likely to impact the doctor-patient relationship. It could be like a third 'person' present during a shared decision-making session (my view). The large language models take in everything on the web before 2021.

The expert spoke about three horizons as we develop AI. Horizon 1 could help doctors chart and code treatments. The second horizon could help doctors manage patients with multiple chronic diseases. The pitfall here could be that patients can have their own ideas about their preferences. Horizon 3 would be suggesting diagnoses based on the data available on a given patient. On this last horizon, the interviewee suggested that physicians need to think hard about what they want from AI. Moreover, the values of each patient must be factored into discussions about treatments. Finally, there are the bioethical questions that must be answered before we get too far down the road with AI at our side. Could AI steal away the reasons people went into medicine in the first place? Ideally, that is about serving the health needs of other human beings through personal interactions and mutual trust. In my opinion, spirituality plays a role in the doctor-patient relationship. I do not think a Chatbot has a role in this context.

My reason for including summaries on AI is that patients must be aware that this phenomenon is coming and may soon be a part of their routine interactions with their doctor. Patients should have at least a rudimentary understanding of the nature of AI and be unafraid to ask how it is involved in their care process decisions. For example, read on...

Chatbot Compared to Surgeon-Generated Informed Consent Documentation

It is well known that informed consent is often poorly delivered and poorly documented when patients face an invasive procedure. A large team of MD's tested how well the risks, benefits, and alternatives (RBAs) were delivered for six common surgical procedures (colectomy, coronary artery bypass graft, laparoscopic cholecystectomy, inguinal hernia repair, knee arthroplasty, and spinal fusion). They compared the RBA documentation generated by a large language model (LLM) ChatGPT-3.5 with documentation randomly found in signed informed consent documents in electronic health records.

The investigators found that the ChatGPT did better on the mean composite completeness and accuracy score, the description of the benefits of surgery, and the alternatives to surgery. The risks of surgery were comparable in ChatGPT vs. surgeon. The rubric for scoring the results was developed by three expert groups, including the American College of Surgeons. The authors concluded that in their testing the ChatGPT documentation was more readable, accurate and complete than those produced by surgeons for the six procedures studied. There is potential to relieve surgeons of documentation burden and provide patients with the information they should know before deciding to have an invasive procedure.

⁶ https://pubmed.ncbi.nlm.nih.gov/37755919/

⁷ https://pubmed.ncbi.nlm.nih.gov/37812419/

Interesting Links

Elephant in the California waiting room:

https://www.elephantinthewaitingroom.com/?utm_sour ce=twitter&utm_medium=static&utm_campaign=kaiser escalation&utm_content=mcgraphic&twclid=24ocmh1n 0xlir9bt2pg44prrfn&s=03

Harmless tumors over diagnosed in the U.S.:

https://fortune.com/2023/10/02/growing-case-for-doing-less-harmless-cancers-overdiagnosed-america-health-carolyn-barber/

Epidemic of chronic illness is killing us (WaPo):

https://www.washingtonpost.com/health/interactive/20 23/american-life-expectancy-dropping

How to keep patients from risky medical devices:

https://www.statnews.com/2023/10/02/fda-medical-device-safety-adverse-events-reporting/

We must restore maternal care to rural areas:

https://www.commonwealthfund.org/publications/2021/sep/restoring-access-maternity-care-rural-america?utm_campaignl

Flawed medical records: Why Duplicate and Mismatched Patient Records Are a Bigger Problem Than You Think (medicaleconomics.com)

Where is high healthcare spending going in the U.S.: High U.S. Health Care Spending: Where Is It All Going? | Commonwealth Fund

About 4.5 billion people world wide lack access to essential health services:

https://www.who.int/news/item/18-09-2023-billions-left-behind-on-the-path-to-universal-health-coverage

TX Medical Board Newsletter. Note portion on informed consent (weak!):

https://www.tmb.state.tx.us/dl/58879CA2-3FD7-9AA8-8C7B-17B947366AF8

Sick medicine in Oregon (it's their medical board): https://www.kgw.com/sickmedicine

Unnecessary stents harm many and waste billions of dollars (Lown Institute):

https://lowninstitute.org/register-unnecessary-stentshow-professional-inertia-endangers-patients-andwastes-billions-of-dollars/

American healthcare making us sicker and poorer (Commonwealth Fund):

https://www.commonwealthfund.org/publications/surveys/2023/oct/paying-for-it-costs-debt-americans-sicker-poorer-2023-affordability-survey



Answer to the Question: B) \$ 50 billion (ref. 4)

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In the face of global ageing and persistent social inequities, the Salzburg Statement on the Value of Care and Caregiving is a paramount call to action. The role of care and caregiving has long been underrecognized, but it is truly the foundation upon which societies are built.