PSA

Patient Safety America Newsletter

October 2023 http://PatientSafetyAmerica.com John T. James, Ph.D.

Question: What agency controls your Medicare access to drugs? A) CDC B) FDA C) NIH D) CMS

988 Lifeline and Mental Health

The U.S. is in a suicide crisis with approximately 50,000 Americans committing suicide each year. A News & Analysis reporter wrote a perspective in *JAMA* about the value of the new 988 call number to use when someone is in a mental health crisis.[1] In July 2020 this number replaced the 1-800 number used for the original crisis hotline, but many people are unaware of this change or unfamiliar with the breadth of services, including support during an emotional distress or a case of suspected substance abuse. In the first year of its operation, the service fielded nearly 5 million calls, on-line chats, or text messages. The federal government has invested $1 billion to improve and expand access to the hotline, however, some shortcomings remain. For example, the calls are routed by the location of the caller's area code rather than her actual location. This means that sometimes the ability to locate services local to the caller is misguided. More languages have been added for the service, including Spanish. There is a widespread need for additional people to staff the hotlines.

Mental health crises in the U.S have increased in recent years and show no evidence of leveling off. Ideally, one would hope to manage the root causes of mental health crises, but short of that, a nation-wide, well-staffed, and well-known crisis hotline seems to be a good investment. *So, now you know that 988 is there to help you or someone you love. Do not hesitate to use it.*

Consumers Can Purchase a Blood Test to Estimate Alzheimer Disease Risk

A 'Medical News' article in the *JAMA* described Quest Diagnostic's new test for Alzheimer Disease (AD) risk called 'AD Detect Test.'[2] The test costs $399 and is available to selected consumers who are willing to part with a bit of blood and have certain risk factors for the development of AD. The test uses sophisticated chemical analytical procedures to calculate the ratio of 40/42 beta amyloid. Previously, the only way to detect brain amyloid was via a PET scan, which is much more expensive and requires a physician's orders.

The key question for patients considering buying the test is, 'How good is it?' Tests like this are not subject to FDA approval, so one cannot rely on any opinion from that agency. Perhaps you feel that you are experiencing mild cognitive impairments and just want to know your risk. Keep in mind that patients are poor judges of their level of cognitive impairment. A neurologist at Quest suggests that the test could be applied to folks with normal cognition. One physician has noted that the test has a high false positive rate. Another physician noted that because the test is marketed directly to patients, they may not have an opportunity to discuss the pros and cons of taking the test.

[1] https://pubmed.ncbi.nlm.nih.gov/37647060/

[2] https://pubmed.ncbi.nlm.nih.gov/37702998/

Shared Decision Making and Alzheimer Drugs

A couple of MDs wrote their opinion of the value of Alzheimer Drugs for treatment of that disease in *JAMA Internal Medicine*.[3] They noted that the old way of treating Alzheimer disease centered on the cholinergic hypothesis, whereas the more recent drugs target reduction in brain amyloids. Drugs in both categories have been FDA approved. While each type elicits statistically significant improvements in the progression of the disease, neither type has been shown to be 'clinically' significant. The authors admit that there is not a clear definition of clinical significance. Moreover, some of the side effects are substantial. The cost of the recently approved drugs is astonishing and could cost Medicare billions of dollars if they become widely used. I must wonder what would happen if both kinds of drugs, the cholinergic and amyloids, were tested together, perhaps at a lower dosage. Could there be synergy without serious side effects?

Interestingly, the authors posit that we should use more of the clinically proven drugs that treat the conditions associated with a higher risk of dementia. These include drugs to treat diabetes, hypertension, and depressions. These are known to have a clinically significant impact on the risk of Alzheimer Disease and other dementias. They opine that we would be wiser to spend money on treating the diseases that increase the risk of dementia rather than on unproven drugs that specifically target Alzheimer Disease. In my opinion, there is a call here to engage patients in shared decision-making about any fears they have of dementia or Alzheimer disease. I would not want to be the clinician explaining the risks and benefits of the best pathway. Patients must do their homework before taking any of the drugs specifically targeting Alzheimer Disease.

Who Controls your Access to Drugs under Medicare Part B?

Three experts wrote in *JAMA* about the legal intrigues going on about how the Centers for Medicare and Medicaid Services (CMS) can decide against unfettered use of any drug approved by the FDA or device cleared by that agency.[4] The missions of the agencies are at the core of the tension. CMS is supposed to fund drugs that are 'reasonable and necessary' to the health of their beneficiaries,' whereas the FDA approves drugs that meet minimum standards of safety and efficacy. The difference became obvious lately when the CMS covered new FDA-approved Alzheimer drugs for use *only* in clinical trials. The idea is that such trials will demonstrate whether the drugs are 'reasonable and necessary.'

The problem is exacerbated by two proposed laws that seek to reduce CMS's discretion to decide what drugs to cover. The authors conclude: "The Medicare trust fund cannot become a blank check for any drug or device manufacturer granted authorization by the FDA. Medicare's survival and public health demand that officials distinguish between better and worse therapies when determining reimbursement. Bills like HR 1691 and HR 2408 are a step in the wrong direction." Does anyone smell money behind these bills?

Association between Sedentary Time and Risk of Dementia

While we are thinking about dementia, a good question to ask is whether certain behaviors may be associated with increased risk. A study of nearly 50,000 Brits looked for an association with one's sedentary time per day and the risk of dementia after a 4-year follow up.[5] The average age of the subjects was 60 years and the sedentary time per day was measured using a wrist accelerometer over a period of 1 week. Sedentary activities include watching TV, sitting at a computer, or driving a vehicle. The data were divided into quartiles of average daily awake sedentary time as follows: 9.3 hours, 10 hours, 12 hours, and 15 hours. The hazard ratios for developing dementia in the quartiles were as follows: 1.0, 1.1, 1.6 and 3.2, respectively. Please

[3] https://pubmed.ncbi.nlm.nih.gov/37523164/

[4] https://pubmed.ncbi.nlm.nih.gov/37682556/

[5] https://jamanetwork.com/journals/jama/article-abstract/2809418

note that these findings do not establish a cause-and-effect relationship, although they are consistent with other research using differing approaches to the relationship.

In my opinion, the data invites us to think about the amount of sedentary time we spend each day. Think of your favorite non-sedentary activities: walking, cooking, gardening, shopping, sporting activity, cycling, etc. Perhaps as we age, we should do a little more to naturally reduce our risk of dementia. Maybe there is a cause and effect – maybe.

International Cardiovascular Guidelines and Shared Decision-Making

Pharmacists sought an answer to the question, 'How often do cardiovascular pharmacotherapy guidelines specify the need for shared decision-making (SDM).' They examined guidelines from the U.S., Canada, and the European Union published from 2012 through 2022.[6] They found about 2,700 documents that addressed pharmacotherapy and only 170 (6%) addressed SDM. Of the documents that were general cardiology guidelines, only 10% described SDM, whereas more specific guidelines, say for heart failure, contained SDM recommendations only 3% of the time. There were no significant differences in SDM frequency between guideline sources, and there was no significant change during the decade in which the documents were issued.

The authors note that SDM was 'infrequently promoted and facilitated across cardiovascular guidelines.' To me, this finding clearly suggests that if you want SDM with your cardiologist, you may be the one to initiate the process, starting with asking for a decision aid before engaging in SDM. You will need to ask the risks (probability and severity) and benefits of any recommended medication. You must ask about alternatives medications or the consequences of doing nothing. You must ask about strategies that do not involve any medication and how to get support for those (e.g., weight loss).

Respiratory Syncytial Virus (RSV) in Older Adults

A patient page in *JAMA* addressed the need for older adults to be vaccinated against this common respiratory infection.[7] The virus elicits symptoms like the common cold and peaks in incidence in winter months. Its effects can be severe in alder adults with roughly 10,000 deaths per year in those over 60 years old. Many chronic conditions increase the risk of RSV infections, and these can be especially prevalent in nursing homes. The spread of RSV can be limited by frequent handwashing, covering coughs and sneezes, and limiting close contact with others. A new vaccine is available, and the CDC recommends that using this should be discussed with your primary care physician. There are various side effects of the vaccine.

Internal Medicine Residents vs. Chatbot

Three MDs compared the History of Present Illness (HPI) of patients as taken by senior internal medicine residents and a Large Language Model (LLM) Chatbot.[8] This sort of comparison is important because it could lead to reduced time burdens on clinicians. Four residents created the Chatbot using three patient interview scripts centered on types of chest pain. The LLM was incrementally engineered to reduce HPI mistakes. The final version was compared to the resident generated HPIs. Prompts from the LLM needed to 'evolve.' The Chatbot generated HPIs were only one point below the resident generated HPIs on a 15-point quality scale. The authors call for close collaboration between clinicians and AI developers before a clinically useful LLM tool is ready for use in the real world.

In my opinion, in a few years you will be able to 'talk' with a Chatbot to deliver your entire medical history. The Chatbot will be able to generate prompts and take the information given to it by real

[6] https://pubmed.ncbi.nlm.nih.gov/37676658/

[7] https://jamanetwork.com/journals/jama/fullarticle/2809541

[8] https://pubmed.ncbi.nlm.nih.gov/37459091/

patients and create flags for clinicians to consider. For example, if the history taken of my son who was dangerously potassium depleted had included a dietary summary, the lack of dietary potassium would have become apparent. No such history was taken by his clinicians, but a well-trained LLM Chatbot would not have overlooked this important facet of the patient's history. Patient advocates must also be involved in the development of clinical based Chatbots, not just clinicians. We patients are the ones who know our history.

Interesting Links

COVID-19 surges; we need better standards: COVID Risks increase

Female surgeons frustrated by male domination of field: https://www.theguardian.com/society/2019/jan/08/female-surgeons-frustrated-by-male-dominated-field-study-finds?CMP=share_btn_link

Martha's Rule – It is past time to listen more to patients: https://demos.co.uk/research/marthas-rule-a-new-policy-to-amplify-patient-voice-and-improve-safety-in-hospitals/

National Center for Health Research newsletter: https://www.center4research.org/wp-content/uploads/2023/08/August-2023-NCHR-Digest-1.pdf

Doctors billing for cancer patient portal messages: https://www.cancertherapyadvisor.com/home/cancer-topics/general-oncology/billing-for-patient-portal-messages-reduces-docs-workloads-but-may-increase-financial-toxicity-for-cancer-patients/

Whitehouse report on patient safety: https://www.whitehouse.gov/pcast/briefing-room/2023/09/07/pcast-releases-report-on-transforming-patient-safety/

Hospital in CA putting nurses in danger; they are striking: https://lapublicpress.org/2023/09/the-hospital-is-putting-nurses-in-danger-st-francis-nurses-strike-in-lynwood/

World Patient Safety Day, September 17th: https://www.jointcommission.org/resources/patient-safety/world-patient-safety-day/

AI is coming to the clinician-patient relationship. Are you ready: https://www.aafp.org/about/engage/sponsored-resources/intelligence-infused-solutions-help-clinicians-and-patients.html?cid=DM89540&bid=252901897

Columbia University sheltered a sexual predator doctor for many years: https://www.propublica.org/article/columbia-obgyn-sexually-assaulted-patients-for-20-years

Private equity companies and hospital operations = bad news: https://www.medpagetoday.com/opinion/second-opinions/106333?xid=nl_secondopinion_2023-09-17&eun=g1330759d0r

If you suspect fraud, report it at 1-800-MEDICARE (1-800-633-4227). Visit **Medicare.gov**, the official source for Medicare information, to learn more about preventing Medicare fraud.

Beware of pitches for Medicare plans: Private Plan Pitch: Seniors' Experiences Medicare Marketing | Commonwealth Fund

Arizona voids law protecting doctors from being sued for malpractice: https://www.yourvalley.net/stories/arizona-court-voids-law-aimed-at-protecting-doctors-business-from-covid-lawsuits,448041

Texas Medical Board criticized for slow patient safety response: https://www.kxan.com/investigations/excessive-disappointing-concerns-grow-over-texas-patient-safety-law-delay/

Washington Post – huge increase in patient harm during hospital care in Maryland: https://www.washingtonpost.com/dc-md-va/2023/09/24/maryland-hospital-safety-harm/

Medical misinformation research is cratering under GOP legal attacks: https://www.yahoo.com/news/misinformation-research-buckling-under-gop-185648947.html

NATIONAL QUALITY FORUM MEMBER

Answer to Question: D) CMS

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