PSA

Patient Safety America Newsletter

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

Question: Among 11 developed countries, where does the US rank in health disparities?
A) fewest number of disparities B) average number of disparities C) highest number of disparities

Book Review

Stopped in My Tracks

By Christina Gomez, MD

Sometimes it seems that fate brings people together, but I believe it is more a gift of kindred spirits finding each other. Early in July, I had a meeting with Revered Edward Gomez, Vicar of St. Paul's Episcopal Church in Houston. I was at his church to work on food distribution, and he had asked me to meet him to receive a book his niece, an oncologist, had written. He handed me the small, white book entitled *Stopped in My Tracks – A Physician's Collection of Cancer Patients' Quotes*. The next day I read her book, enjoying both the words and drawings. At times I was astounded by Dr. Gomez's treasure chest filled with the words of her patients. It is a remarkable chronicle of her listening to her patients as they deal with cancer and the vagaries of treating it. I offer it as a chance for my readers to experience the compassion that stems from shared decision-making between patient and clinician. Each quote is worth slowly pondering to extract full insight. Do not rush your reading. Please visit her website: http://christinagomezmd.com/

Diagnostic Errors Common in USA

Investigators used a complex approach to estimate permanent disability and deaths due to diagnostic errors in 2014 in all healthcare settings in the USA.[1] Their estimate was published in *BMJ Quality and Safety* this July. They looked at the incidence of 15 types of harms including vascular events, cancer, and infection. They used literature data on the incidence of diagnostic errors in each category. Extrapolation to all diseases beyond the 'top three' types resulted in an estimate of 800,000 serious harms and deaths each year with an uncertainty range from 600,000 to 1,000,000. Using more conservative assumptions, the estimate was about 550,000.

To place this in perspective, the population of the USA in 2014 was about 3,200,000,000. Thus, the claim is that each year, based on 2014 data, about 0.025% of the population is seriously harmed by diagnostic errors. One individual has a small chance of being harmfully misdiagnosed each year, but over a lifetime of 80 years, one's chances increase to 2%. The message for patients is to be skeptical of any diagnosis that does not explain all your symptoms and clinical findings. Are the side

[1] https://qualitysafety.bmj.com/content/early/2023/07/16/bmjqs-2021-014130.full

effects of medication causing your symptoms? Could you have more than one disease process ongoing?

Reducing the Risk of Dementia

As we age into our 70s, 80s, and 90s, each of us is going to find that our mental capabilities decline slowly. Some of us will experience clinically diagnosed dementia. Is there anything we might do to mitigate our risk of dementia, not counting medications (see below). A team of investigators from Australia found an interesting association in adults over 70 between mental engagement and a 10% reduction in the risk of dementia when assessed over a 10-year period.[2] The reduced risk was not overwhelming but may be worth considering.

They looked at 10,300 participants whose average age was 74 years. Dementia was assessed by an expert panel applying international standards. The investigators found that 'more frequent participation in adult literacy activities (taking education classes, using a computer, and writing letters or journals) and in active mental activities (playing games, cards, or chess and doing crosswords or puzzles)' was associated with reduced dementia risk. Interestingly, increased social interaction was not associated with decreased risk of dementia.

The next time you are around an elderly person, encourage them to engage in literacy and mental activities that they enjoy. If you are 'elderly,' then push yourself to engage in mental activities. The gains may be small, but you may discover new interests.

The Slow Battle Against Alzheimer Disease

A huge team of multinational investigators evaluated the risks and effectiveness of donanemab, a drug approved for treating patients (60-85 years old) with mild dementia from Alzheimer disease.[3] It is an antibody targeting beta-amyloid found in brain tissue. The drug or placebo was given by infusion every four weeks for 72 weeks. They measured the destruction of the amyloid periodically through 76 weeks using MRI. Concomitantly, they assessed changes in dementia over a 76-week period with standardized tests (iARDS and CDR-SB).

The good news was that the drug decidedly reduced brain amyloid but the change in dementia progression was not as much as one might hope. At the end of the 76-week study, the patients treated with donanemab showed less decline in the two mental acuity rating scales than the those in the placebo group. For the iARDS scale the decline from baseline was about 10 points in the treated group and 13 points in the placebo group. Using the CDR-SB system the increase in score (showing increasing dementia) was 1.7 units in the donanemab and 2.5 units in the placebo group. Thus, the progression of the disease was somewhat slowed by the treatment.

The unfortunate news is that 3 patients in the treated group died and one in the control group died, and these 4 deaths were attributed to the treatment process. Serious adverse events were slightly more common in the drug vs. placebo group (17.4% vs. 15.8%). The adverse events caused 8% in the drug-treated group to drop out, whereas 4% of the placebo group dropped out. There was substantial variability in the dose of donaanemab given in the various centers where it was administered. I would not want to be a physician trying to explain the pros and cons of taking this drug. My sense is that the infusion process is no fun. The study remains ongoing as the participants are followed for a longer period.

The FDA's Oversight of Post-Marketing Studies

In *JAMA Health Forum* a team of MDs and JDs expressed their view that the FDA's flexibility in approval of drugs has not been matched by a stringent process for post-marketing studies.[4] The goal of post-marketing studies is to confirm that the drug in question is reasonably safe and effective. Ideally, lacking such confirmatory studies, the drug

[2] https://pubmed.ncbi.nlm.nih.gov/37450299/

[3] https://jamanetwork.com/journals/jama/fullarticle/2807533?guestAccessKey=b33a6468-53f7-46b0-a5d7-6f361432d323

[4] https://pubmed.ncbi.nlm.nih.gov/37294583/

should be removed from the market. The authors suggest that the FDA has the authority to enforce post-marketing studies on drugs with 'residual uncertainty' and react with swift removal from marketing approval when the studies are not forthcoming in a timely way.

Without going into many details of how the authors think this could happen, I might opine that there is no force I know that is going to impel the FDA to change its speedy pre-market approval processes and bolster its post-marketing confirmatory studies. Except you. After reading the original study, which has open access, you should write to the FDA asking for the agency to improve its drug-approval processes.[5] Your letter would gain great strength if you or someone you know has been harmed by an ineffective and harmful drug. In the meantime, always be wary of taking a drug that has been on the market for less than 3 years.

Health Inequities in 11 developed Countries

We Americans like to think we are good at everything, but many of us know that one of our greatest problems is the health disparities in our country. Just how bad is that disparity? A team of experts attempted to quantify geographic health disparities (urban vs rural) across 11 countries: Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the UK, and the US.[6] They surveyed 22,400 people in these countries using answers from randomly selected adults in three domains: health status and socioeconomic risk factors, affordability of care, and access to care. The average number of disparities among the nations was 1.9. The US had significant disparities in 5 measures, whereas the Netherlands, Canada, and Norway had no significant geographic disparities. The US was the top nation for disparities.

The US ranked highest among six disparities in the 11 countries as follows: multiple chronic conditions, experienced material hardship, skipped needed medical care, skipped dental care, serious problems with medical bills, and avoidable ER visit in the past 2 years. The authors suggest that the US should look at the way countries do healthcare that had no disparities – Canada, the Netherlands, and Norway. Clearly the US has room for vast improvements, but using models in much less populous countries may not be applicable in our large and diverse country.

In my opinion, several targets are suggested for change in the US: encourage (monetize?) healthy lifestyles to reduce chronic conditions, expand affordable access to health insurance by expanding Medicaid, and avoid polypharmacy that tends to send people to ERs.

Cognitive Impairment and Head Banging

Recently I enjoyed time with a grandson who was practicing football for the first time with his helmet on. His helmet was of heavy construction designed to thoroughly protect my grandson's head (I hope). A team of scientists asked if male UK soccer players (no helmet) with more headings of the ball per game or practice had a higher incidence of cognitive impairment later in life[7]. The number of headings per match were sorted into these categories: 0-5, 6-15, and more than 15. There were 459 retired players in the study. Heading and cognitive impairment were assessed via telephone interview; it was self-reported. The incidence of cognitive impairment was 9.8 in the low heading group, 14.8 in the middle group, and 15.2 in the high heading group. I am confident that none of my readers are professional soccer players, so what is the point of summarizing this study?

The answer to this question is that as we ordinary people go through life, we should be vigilant about activities and locations that may lead to hard impacts on our heads. Older adults are more likely to fall and hit their head (my dad did this several times in his 90s). Some risks that come to mind are showers with no handholds, steep,

[5] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-contact-information There a variety of ways to contact the proper FDA office with your message.
[6] https://pubmed.ncbi.nlm.nih.gov/37418259/

[7] https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2807337

uncarpeted steps, uneven sidewalks, crinkled throw rugs, and poorly secured ladders.

Maternal Opioid Use and Infant Mortality

Opioid use disorder is far too common in the US. That illness has a profound effect on women who are pregnant and give birth. A team of investigators asked about the effect on the babies born to addicted moms.[8] The team looked at the records of 390,000 babies born to Medicaid moms between 2007 and 2018 in Tennessee. There were 1317 postnatal baby deaths. The investigation included infants whose mothers had opioid use disorder (OUD) or were born with neonatal opioid withdrawal syndrome (NOWS).

Per 1,000 person years, the death rate in babies that were in the OUD-/NOWS- group was 3.5. It was 8.4 in the OUD+/NOWS- group, and 9.2 in the OUD-/NOWS+ group. Obviously, babies born to mothers with OUD or that exhibit NOWS have a much higher mortality rate. The authors called for improved support for OUD moms and the babies born to them.

Interesting Links

Millions know someone who died for lack of medical care because of cost (2019): https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx?s=03

Vagaries of lung cancer screening: https://sensiblemed.substack.com/p/i-just-want-to-work-on-my-car

ENRAGING! Trying to kill Florida's free-kill malpractice law: https://www.wftv.com/news/local/lawmakers-again-try-finish-off-floridas-free-kill-legal-loophole/FHNZKS4S7VG3VHNGGXHRVV3DGA/

Health effects of climate change: Commonwealth Fund on Climate Change

Office of the Inspector General has a new tool kit for detecting adverse events: https://oig.hhs.gov/oei/reports/ae-toolkits.asp?stakeholder=adverse-events-toolkits

Pennsylvania hospitals do not have to report details of injury and death they caused to babies: https://www.pennlive.com/health/2023/07/pa-agency-rejects-mandate-gives-hospitals-option-to-report-details-on-baby-injuries-deaths.html

Severe maternal mortality doubled in Massachusetts from 2011 to 2020: https://www.mass.gov/doc/an-assessment-of-severe-maternal-morbidity-in-massachusetts-2011-2020/download

Massachusetts' healthcare is tops, yet still a mess: https://www.mhqp.org/2023/07/13/unsustainable-an-honest-assessment-of-massachusetts-healthcare-performance/?fbclid=IwAR2-pU8PGzwZwg35AN99AgMFbx0SUgsY5T28SaVDMxGRvjXbC755Hh_EEOs

Medical debt is eroding Americans' trust in doctors & hospitals: https://www.latimes.com/opinion/story/2023-07-16/medical-debt-healthcare-doctors

Reinventing the ER for mental health emergencies: The New Yorker

Medicine is plagued by untrustworthy clinical trials (UK, Nature): https://www.nature.com/articles/d41586-023-02299-w

People's Pharmacy on the high number of diagnostic mistakes that cause serious harm: https://www.peoplespharmacy.com/articles/you-have-likely-been-the-victim-of-diagnostic-mistakes

Female doctors sued far less often than male doctors: Medpage

Malpractice insurer manipulated for a huge settlement that fostered tort reform in Iowa: https://iowacapitaldispatch.com/2023/07/19/clinic-malpractice-award-was-engineered-to-win-iowa-lawmakers-support-for-tort-reform/

Answer to Question: (C), see reference #6

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

[8] https://pubmed.ncbi.nlm.nih.gov/37155175/