Patient Safety America Newsletter

> *Question:* **As of the end of 2020, how many American deaths are associated with COVID-19?**
> **a) 275,000   b) 300,000   c) 325,000   d) 350,000   e) 375,000**

Poorly Monitored Medical Devices

Two patient safety champions, Madris Kinard and Lisa McGiffert, scored a substantial win last month by having a 'viewpoint' article accepted by for publication in *JAMA Internal Medicine*. The title of their article was 'Medical device tracking- how it is and how it should be.' I was further excited to find that the journal editors released the article immediately, stating as follows: '*This article is being released Online First for its public health importance.*'

The focus of the article is how unique device identifiers (UDIs) are used by the healthcare industry and regulators and how they ***should*** be used to better protect patients from having a potentially dangerous device implanted in their body without their knowledge. The story of UDIs for medical devices began in 2007 when Congress mandated that those who make medical devices employ an identifier system like the vehicle identification number (VIN). The industry and regulators were slow to act. In 2012 Congress set an action deadline. In 2013 the FDA adopted a final rule for UDIs.

Presently manufactures must use a UDI on critical devices that support life and by 2022 less critical devices will be added to those required to have a UDI. If fully implemented, the system could protect patients from devices that have been recalled, expired, or contain potentially allergenic materials. Presently, electronic health records (EHRs) are required to provide a field for UDIs, but these are often not used. The authors opine that the Centers for Medicare and Medicaid Services (CMS) must mandate use of this field by physicians and hospitals.

The authors note that in 2019 the FDA received 1.2 million adverse event reports on devices, but that only 1.6 % of these contained a UDI. This is a serious impediment to discovery of *specific*, harmful medical devices. Of the 1.6% of reports that contain a UDI, the UDI is redacted as a trade secret in 85% of those. Some device manufacturers have argued that revealing the composition of their devices (e. g. cobalt or chromium in hip replacements) must not be required. The authors opine that the rights of patients to know what is being placed in their body is more important than trade secrets.

Moreover, hospitals are not using the UDI as effectively as they could. For example, if a multi-use device has been found to be difficult to disinfect, that should be easily discoverable by hospitals that can, in turn, determine which patients may be at risk for infection. The authors call on Congress to 'authorize the infrastructure' to create a national, readily accessible registry for medical devices. This, and responsible actions by CMS and the FDA to make UDIs always used in EHRs, will improve the post-market surveillance of medical devices.

What can patients do when a medical device is proposed for placement in their body? Ask what the UDI of that device is and whether there are reports of adverse events associated with it. Ask that the device's UDI be recorded in your EHR, and then verify that this has been done. If you experience an adverse event associated with that device, ensure that this has been reported into the appropriate FDA database (Access Global Unique Device Identification Database). Let's work together.

Patient-Centered Care & Fee for Service

A woman primary care physician wrote her perspective about the 'incompatibility' of patient-centered care and fee for service care in the context of the care a woman in her late 90s. She was receiving primary-care from the author's team as her end of life approached while living at home. The elderly lady did not want a lot of testing for which Medicare would reimburse; she needed her care team to ensure that her medications were managed and that she had nutritious food in her house. Moreover, the team ensured that her goals were managed through frequent home visits and a formal declaration from her about sustaining a 'peaceful' death when the time came. Reimbursement from Medicare for such things is challenging.

Citing other research, the author notes that only 5% of Medicare fee-for-service payments are spent on primary care. She opined that primary care teams are adept at doing what the patient wants rather than procedures for which Medicare will readily reimburse. This may cause substantial monetary losses to the physicians in the care team. She proposes a 'predictable, progressive budget' that enables more of physician time listening to the patient, leading to fewer procedures that garner reimbursement. The basic idea is payment for a connection between patient and primary-care physician that endures over time until the patient's wishes for a peaceful death are acknowledged.

I remember many years ago, as part of a graduate course, reading a book for a class on dying. The book, published in 1969, was by Elizabeth Kubler- Ross, then a medical director in Illinois. It was called *On Death and Dying – What the dying have to teach doctors, nurses, clergy and their own families*. Since then, I have experienced the deaths of 3 people I deeply love. I think we are all called as we age to think about the kind of death we want and to have the courage to express our wishes to our families, doctors, and other caregivers. My point in all this is that 50 years ago the plea was on the table to listen to patients. It is only in the last 15 years that the idea of patient-centered care through shared decision-making has begun to take hold.

Race and Kidney Function

The disparity in healthcare between black individuals and most of the other American races has been long known and has been magnified by the advent of the pandemic. Many news sources have reported the inordinate number of COVID-19 deaths of black Americans. They are 3.7 times more likely to need hospitalization and 2.8 times more likely to die than other races. The death rate for black folks is about 125/100,000, whereas for white folks it is about 75/100,000 (The Guardian). Is it time to look for race-bias in the technical side of U.S. healthcare? Three MDs writing in the *JAMA* think that it is.

Kidney function is typically estimated by the glomerular filtration rate (eGFR), which depends on a 'race' coefficient for final determination. The MDs wrote their opinion that this coefficient tends to exclude black persons from treatment for chronic kidney disease (CKD) because it inflates the eGFR based solely on race. They do not see any justification for this adjustment. Removing this modifier would increase the portion of black persons with CKD from 15 to 18%, which translates to roughly 1 million more blacks with a diagnosis of CKD. Removal of the race adjustment would potentially gain earlier treatment of CKD because it would be diagnosed earlier. This may lead to specialty care as the CKG progresses. Patients of African heritage may wish to ask their doctor about not using the race-modifier when estimating eGFR.

Trust between Patient and Physician

Three experts write about how transparency on the part of a physician may improve the physician-patient relationship. The goal of transparency, especially if patient trust is weak, is to improve a patient's trust of her physician. The writers advocate three ways to deliver transparency to improve trust. The first is to discuss external relationships, say with a device company, that may be related to the type of care involved. In the days of COVID-19, it is appropriate to discuss external relationships that involve virus-testing or vaccine development.

A second way is to report factors that reinforce trust in the physician's competence. This could involve specialty certification status or maintenance of certification. Revealing outcomes in appropriate situations may build trust. The third way is to reveal appropriate personal information (revealing humanity). This may open a door to patients feeling comfortable about revealing personal information, thereby improving care.

In another article on improving patient's trust of the healthcare industry, three experts express their viewpoint about the ways misinformation affects trust by patients in their healthcare industry. The authors provide a table listing five types of misinformation. Here I must be brief, but I would recommend viewing of this table in its original form. The types were as follows: 1) pseudoscience (appears to be science but is not), 2) junk science (poorly performed studies), 3) outdated science (science is not a static undertaking), 4) inappropriately applied science (general science that does not apply to specific cases), and 5) Conflicting interpretation of science (biased guidelines).

In the end, I might observe that people want to believe what makes them comfortable or offers hope. Many believe wearing facial masks to limit spread of COVID-19 has not been based on valid scientific studies, so they demonstrate their bravado and pseudo-liberty by refusing to wear a mask. Many will pursue an unproven cure for chronic disease to maintain hope of a cure. Others will be deceived by a trusted professional into taking a drug that is highly dangerous in long-term use. In that regard, you might want to watch *Medicating Normal* (Watch | Medicating Normal).

Safer Ambulatory Care

Much focus has been placed on unsafe care in hospitals, much less so on out-of-hospital care. Two experts, one an MD and the other a PhD engineer, expressed their view of how ambulatory care could be made safer. The authors begin by summarizing the situation. One study found that 2-3 errors per 100 visits results in an administrative error, diagnostic error, or a medication mistake.

Other studies estimate that 1 on 20 US adults experience an ambulatory diagnostic error each year. For those on medications, one estimate is that 4 ½ million visits each year may involve an adverse reaction to medication. A lot needs fixed.

Fragmented data systems impede longitudinal discovery of mistakes. The authors estimate that most errors are due to misdiagnosis, medication errors, and communication errors. Increased use of health information technology may offer a partial solution. Another improvement would involve a culture where physicians feel comfortable reporting mistakes they or other doctors make. Payment for patient volumes may limit the time a physician needs to assess a patient's problems and preferences. I was happy that 'patient advocates' were mentioned as a source of promotion of ways to make care safer. At the individual patient level, each of us has a key role in improving ambulatory care. Be honest about your health problems, do your homework so you can communicate intelligently with your doctor, ask questions until you understand all your options, and if something goes wrong, report the unexpected harm.

Global Improvement of Patient Safety

The US is far from alone among countries needing serious improvements in patient safety. Two experts wrote their view about how improvements may be made on a global scale. For developed countries in the OECD, investigators reported in 2019 that adherence to medical guidelines and patient outcomes are highly variable among countries for 61 indicators. As an example of variability in avoidable hospital admissions, they cite the following: for chronic obstructive pulmonary disease, 15-fold variation; for congestive heart failure, 13-fold variation; and for diabetes, 5-fold variation. For developing countries, the problems are somewhat different. Children tend to receive far too little care as suggested by guidelines. At the bottom of the scale, in zones of conflict or refugee crisis, patient safety is minimal. In such regions, roughly 50% of deaths of children under 5 years are preventable.

The authors tabulate five categories they deem appropriate for improving patient care as follows: ensure access and infrastructure, strengthen accountability, reduce avoidable harm, improve basic clinical care, and finally, engage and empower patients, families, and communities. In my opinion, the last category is most important because it invites patient advocates to coproduce essential changes in the other four categories.

COVID LINKS

Healthwatch USA Newsletter, mostly on COVID: 20201201-HWUSA-Newsletter.pdf (healthwatchusa.org)

Republicans hold up COVID help bill, demanding protections for corporations that cause harm: AOC Says Republicans Holding Stimulus Check Hostage Over Demand for Corporate COVID Immunity (newsweek.com)

Long term effect of COVID on mental health: The Long-Term Impact of COVID-19 on Mental Health | Commonwealth Fund

Medical errors through the lens of our pandemic: Op-ed: The Invisible Pandemic - Hospital Watchdog

US is outlier in healthcare equity: Axios Vitals

Lawmakers intend to protect patients from surprise medical bills: Lawmakers strike deal to end 'surprise' medical bills - POLITICO

Extremists during pandemic attacking public health officials, raw example in Kansas: Pandemic backlash jeopardizes public health powers, leaders (apnews.com)

Why nursing homes struggled to contain COVID (report from Canada): Revera Pandemic Report – A Perfect Storm: The COVID-19 Experience for Revera and the Long Term Care Sector (reveraliving.com)

Nurse understaffing impedes response to virus: Chronic hospital nurse understaffing meets COVID-19: an observational study | BMJ Quality & Safety

Readmission and death after release from hospital with history of COVID-19: Readmission and Death After Initial Hospital Discharge Among Patients With COVID-19 in a Large Multihospital System | Critical Care Medicine | JAMA | JAMA Network

Great video on reporting COVID-19 adverse events (Randi Oster): COVID - 19 The Vaccination: Your experience matters - YouTube

(Kevin Kavanagh, MD) Viewpoint: Monitoring Systems Track COVID Vaccine Reactions | Infection Control Today

Discipline physicians spreading clearly false medical information, especially in a pandemic: What can Be Done about Doctors Who Spread Misinformation? | Physician's Weekly

NPR thoughts on vaccine distribution acceptance: Writer: Without Resources, COVID-19 Vaccine Rollout Could Fall At 'Last Hurdle' : Shots - Health News : NPR

Troubling insight into the FDA hearings on the Pfizer vaccine: Hearing Without Listening (pogo.org)

Excellent video by Fred Southwick, MD (from the RCA) on Covid-19 questions: COVID 19 testing, what test should you choose? - YouTube

Pandemic discloses hospitals' unpreparedness and greed: Hospital CEOs Have Gotten Rich Cutting Staff and Supplies (theintercept.com)

January 2021 Health Watch USA Newsletter with many excellent links to COVID information: http://www.healthwatchusa.org/HWUSA-Publications/Newsletters/20210101-HWUSA-Newsletter.pdf

NATIONAL QUALITY FORUM MEMBER

Answer to question: Will count 'c' or 'd' as correct. Using data from December 19 and adding the weekly death rate to that, I estimate 334,000. (US Coronavirus: CNN)