Patient Safety America Newsletter

December 2017 http://PatientSafetyAmerica.com John T. James, Ph.D.

Question: *According to the CIA's World Fact Book, which of these countries had worse maternal mortality in 2015 than the United States?*
a) Spain b) Estonia c) S. Korea d) Cyprus e) Greece f) New Zealand

A Dream Come True – Inpatient Portal

One of my proposed patient rights requires that while hospitalized, patients are offered full access to their medical records. Based on experience with an early system that is capable of accomplishing this goal and more, three experts describe the surprises and successes of their project at the Ohio State Wexner Medical Center. Their teams implemented a patient portal using a tablet that offered the following features: daily care plan, roster of their care team, secure messaging with the care team, ability to add patient notes, and to readily access health information. Initially, test results were withheld for 48 hours, but patients' demands for immediate access caused the care teams to relent and give immediate access, except for a few sensitive measures such as HIV test results. Photos of the care teams were updated with each shift change. Patients that were readmitted to the hospital after having used the tablet, demanded that they have it again. The results were so promising that the tablet-portal system has been put in place in all 7 hospitals in the OSU system.

"If we spend enough time dreaming, then the dream might eventually become real."
– **Fennel Hudson, A Meaningful Life - Fennel's Journal - No. 1**

To me this is exciting news of the first order. This sort of access should be provided in every hospital in the U.S. Of course, there will be some issues with full implementation – who is allowed to use the portal, what languages are available, what questions can be asked and which are off limits. For example, can I ask if anyone on my care team has a malpractice judgement against them or medical board sanction?

American Patient Bill of Rights

Patients shall know if an off-label drug or device is to be placed into their body

Patients shall know exactly who will do their invasive surgery

Patients shall know if their care is evidence based, and if not, then why not

Patients shall know their out-of-pocket cost before any procedure

Patients shall be offered their medical record each day while hospitalized

Patient Control of Their Health Data

Many Americans have experienced problems getting their health information transferred from one clinician to another. The pathway to patient data ownership was recently described in a viewpoint in the *JAMA*. The authors view 3 components as

essential before patients own their data. First, data elements must allow sharing of information among different medical record-systems; second, a record of each patient encounter with a clinician must be automatically delivered to the patient's record; and third, data use agreements must exist with those associated with compiling data for the patient's record. The authors rightly observe that patient control of their health information is an essential component of patient-centered care. Of course, there are going to be details to work out because patient preferences are going to vary. Another issue it seems to me is how much detail should be in the record. If I had 3 stents stuck in my coronary arteries, do I want a series of angiogram images in my record showing the placement of each stent? Do I want a video of my exercise stress test, or simply the findings? According to *Forbes*, it seems that changes in the law in most states will be necessary to establish that patients own their medical records.

Public Reporting of PCI Results

Cardiologists refer to sticking a catheter into a major coronary artery as Percutaneous Coronary Intervention (PCI). It seems that PCI is performed about a half million times each year in the U.S. Five states require public reporting of the outcomes of PCI, 3 of which have required it for a long time (Massachusetts, New York, and Pennsylvania). Two MDs survey the impact of public reporting of PCI. It is clear that PCI rates decrease when public reporting is required, especially in critically ill patients that present a higher risk of an adverse outcome. This clearly places such patients at risk of not receiving the treatment they need to live. The authors suggest that this unwanted effect could be mitigated by keeping the reporting out of the public eye – just exchange it between clinicians and institutions. Another suggestion would be to report outcomes based on disease state – how ill is the patient undergoing PCI. The authors point out that the public is not using PCI outcome data to select hospitals and cardiologists in any case. The reasons for this may be complex, but I'll bet most patients do not even know such data are available. The bottom line for the authors is that public reporting of clinical outcomes may be valuable for some procedures, but may have unwanted effects for others. I think keeping the data from the public is a non-starter. Clinicians know how to "adjust" data for variations in the severity of illness of the patients they serve. It becomes simply a matter of doing this in a way that patients can understand. We are not stupid.

Public Reporting of Surgical Outcomes

New York State has required reporting of surgical outcomes for many years after officials noticed that there was a wide variation in outcomes from hospital to hospital and from surgeon to surgeon. Ashish Jha, MD wrote a forum article about whether public reporting should be at the hospital level or the individual surgeon level. It's no surprise that some surgeons are not in favor of surgeon-level reporting. In fact, some surgeons left New York State because of the law. Dr. Jha notes that when we look at surgeon outcomes, we are actually looking at the performance of his or her team. He also notes that a recent study showed that there is a wide variety in the skill with which surgeons perform dissection and suturing, and those with better basic technique have much better outcomes.

In the end, Dr. Jha argues that reporting at the hospital *and* surgeon level is necessary. Caution is necessary to ensure that surgeons do not avoid especially difficult cases that could erode their publicly reported outcomes. Surgeons can *voluntarily* report their outcomes to a public database available from the Society of Thoracic Surgeons or Consumers Reports. That has obvious limitations.

Which Doctors Order Low-value Imaging?

It's no secret that perverse incentives persist in delivery of health care in the U.S. Obviously, if I were a physician faced with patients on whom I could recommend low-value imaging and I owned an imaging service, then I may be more likely to recommend imaging. A team of investigators examined the magnitude of self referrals for imaging in patients with uncomplicated headache or uncomplicated back pain. In either case, if a physician was an owner of an imaging service, then

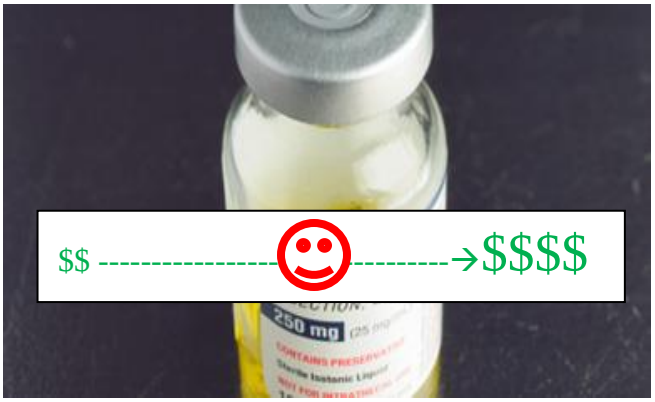
the chances of low-value use of imaging, primarily CT scanning or magnetic resonance imaging, was doubled compared to those that did not own an imaging service. Despite regulations against self-referrals, it seems that such practices have been able to persist. The message for patients, especially those who must share a large financial burden of their health-care cost, is to determine if guidelines are being followed for imaging when they have uncomplicated headache or low-back pain. It seems to me that if researchers can determine when overuse of imaging happens, then insurers can do the same and simply deny payment, noting that the patient will not be billed either.

When Clinical Practice Guidelines are in Conflict

There are areas of uncertainty when clinicians attempt to apply clinical practice guidelines to a specific patient. For example, they must ask if that patient fits the population or sub-population for which a guideline was intended. Does the patient have ancillary conditions that complicate use of the guideline? Is the patient too young or too old to apply the guideline? Finally, the clinician may have to decide among guidelines that are in conflict with each other. Two experts address the last question – what should be done in the face of conflicting guidelines? The authors mention two important conflicts: (1) should women have mammograms in the ages of 40 to 50 years? and (2) should glycemic control reflected in A1c tests be to 6.5% or be tailored to the patient's sub-population from 6.5% to 8.5%? The experts highlight the importance of identifying patient sub-groups that should have different targets for disease management. A consensus is needed, they write. I would have added to this editorial that patient preferences should guide the choice when guidelines conflict. Also, some of the guidelines I have seen characterize the strength of the recommendation. For example, the use of prostate specific antigen measurement in men to detect early prostate cancer may be classified as A, B, C, or D. The 2012 USPTF guideline assigned a "D" rating - do not screen - drawing heavy criticism. This resulted in flexible recommendations from the American Cancer Society to solicit patient preferences in the decision on whether to screen. An empowered patient will ask about how guidelines are being applied to their care.

How Much Money Is Made on Cancer Drugs?

I know a relatively young woman with metastatic breast cancer who must pay $2000 per month for her share of a cancer drug that holds marginal promise of slowing the metastases, let alone offering a cure. The total cost is $20,000 per month. Big Pharma justifies the high cost of cancer drugs based on the huge amount it alleges must be spent to develop a new cancer drug. Is this true? Two experts set out to answer this question by comparing the research and development costs with revenue after marketing approval by the FDA.



The investigators used Securities and Exchange data to estimate the development costs and revenue of 10 cancer drugs that were approved for marketing from 2006 through 2015. The average development costs were $650 million and the average revenue was $1,658 million. The authors acknowledge that their sample is a small subset of cancer drugs that have been developed. Other studies by quite different methods have varied considerably from the present estimates; however, the authors make a good case for generalizability of their findings. I would point out that laws against Medicare negotiating drug costs allow such large apparent profit margins – about $1 billion per drug. The Pharma lobbying expenses for 2016 were about $250 million, supporting almost 1,400 lobbyists. I would suggest that the large profit margins result from Congressional lobbying.

Shocking Price Increases on Old Drugs

To compliment evidence that the cost of new drugs seems inordinate based on R&D costs, one might ask how it is that the cost of old drugs, even ones with marginal benefit, can suddenly skyrocket. Two MDs wrote a brief editorial using the example of respiratory corticotropin, which was approved by the FDA in 1952. Apparently, the stuff is approved for a variety of odd conditions, including infantile spasms, multiple sclerosis exacerbations, and a bizarre list of other things. Questor acquired the drug in 2001 and the price immediately went from $1650 to $24,000 per 5 ml vial. Mallinckrodt acquired the stuff in 2014 and jacked the price to $34,000 per 5 ml. Medicare paid out $1.3 billion between 2011 and 2015 for this drug. While the drug may be of some use in infants, rheumatologists, nephrologists, and neurologists prescribe it with no decent evidence that the stuff works. The evidence for effectiveness comes from small studies with no placebos, conflicts of interest in the investigators, or sponsorship by the company selling the drug. Prescribing appears to be more a response to aggressive sales tactics than any scientific basis for effectiveness. My observation is that there are no effective gatekeepers. The FDA approves drugs on scanty evidence, doctors bow to sales pressure rather than scientific evidence, and Medicare blindly pays a price that cannot be negotiated because of Congressionally mandated laws.

Medication Reconciliation in Nursing Home Residents

A large team of investigators studied the effectiveness of the Multidisciplinary Multistep Medication Review (3MR) in 59 Dutch nursing homes. More than 400 patients were split into roughly equal groups, one receiving the 3MR protocol and the other receiving existing standard of care. The patients were followed for an average of 4 months after discontinuation of medications with no evidence of changes in wellbeing. One or more discontinuations were made in 91 of the intervention group and 57 in the control group. The investigators conclude that the 3MR process represents an improvement in getting nursing home patients off inappropriate drugs. My experience in caring for my father while he was in a U.S. nursing home led to our demand to take him off two antipsychotics, and this certainly improved his wellbeing. If you are looking after someone in a nursing home, make sure you understand why each drug has been prescribed and if the answers are not clear, then ask for a formal medication reconciliation.

Embarrassingly High Maternal Mortality

Two MDs wrote their perspective on why the U.S. has seen a sharp rise in maternal mortality in the past few years. Maternal mortality is defined as death due to pregnancy or within 42 days postpartum. Our death rate of 28 per 100,000 births in 2013 was nearly 3 times the rate of 11 per 100,000 births in Canada in the same year. The authors point out the huge difference in rates between white and black women, 20 and 56 per 100,000 births, respectively. Given that there are about 4 million births in the U.S. each year, if our death rate were as good as Canada's, then 40 x (28-11) = 680 more U.S. women would live each year. Given the current political trend to less care of women's health and teen pregnancy prevention, I cannot be optimistic that the U.S. will do anything about improving our shameful maternal mortality.

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Answer to question: NONE. All maternal mortalities were much better than ours.
https://www.cia.gov/library/publications/the-world-factbook/rankorder/2223rank.html