PSA

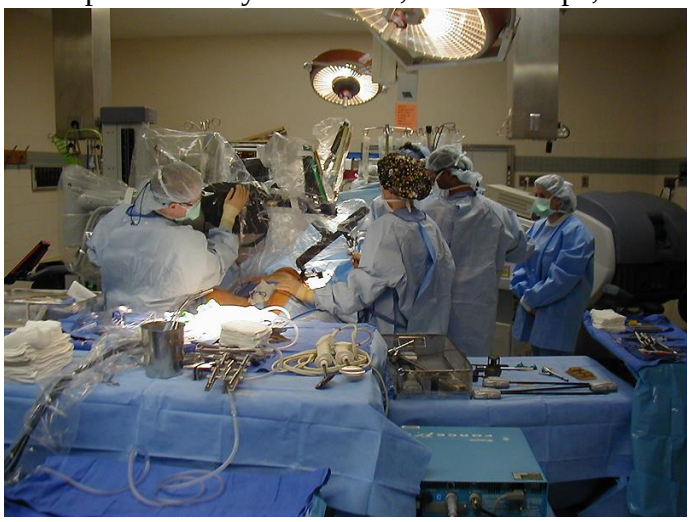
Patient Safety America Newsletter

March 2015 http://PatientSafetyAmerica.com John T. James, Ph.D.

Question: The annual per capita cost of healthcare in the U.S. is $8,900. What is the cost in Canada?
a) $3,000 b) $4,000 c) $5,000 d) $6,000 e) 7,000 f) $8,000

Surgery and Its Complications

This month the presumptive "granddaddy" of the patient safety movement, Lucian Leape, wrote



an editorial for the *JAMA* on turning complications of surgery into "treasures" for learning.[1] He summarized the findings of a study in which hospital readmissions after nearly a half million surgeries were reviewed.[2] The overall readmission rate was 6%, most often due due to surgical site infection (20% of the 6%), but bowel obstruction/inflammation came in second at 10% of the 6%. Dr. Leape points out that this sort of failure rate is far higher than rates tolerated in any other industry. He noted that changing systems within hospitals is not easy because of long-standing traditions and entrenched practices. He salutes those who refuse to accept harm to patients as inevitable.

He points out that the complication rate for patients undergoing leg-vessel bypass surgery ranges from 2% to 30%. Clearly, those hospitals with high complication rates should be learning from those with very low complication rates. The *JAMA* patient page featured a one-page summary of what patients should ask before allowing a surgeon to operate on them (before surgery). There are many other lists of questions from reputable sources. Write down your questions beforehand and then write down your surgeon's answers.

Draining Away Your Money

The healthcare industry is skilled at maintaining and expanding its bite out of your money – in case you had not noticed. In this summary, I'll show you some of the clever ways this is accomplished. Let's begin with health insurance companies. Under the Affordable Care Act everyone is supposed to be able to get insurance. But suppose you do not want to insure a high risk patient that could cost your company big money; how can you keep him out of your pool? One way is by "benefit design" or "adverse tiering." For example, to exclude a high risk person with HIV you can do this by categorizing all HIV drugs (including generics) in the high-cost sharing group, which means the patient pays a large share of the cost.[3] This tends to keep the HIV-positive person from enrolling in your plan.

The authors examined forty-eight insurance plans and found evidence of this in twelve of the plans. By comparing the adverse-tiering plans with the other plans, they found that the out-of-pocket costs for the former was about $6,000 per year, whereas for the latter it was only $2,600 per year. In the end, the authors point out that ending this practice is unlikely to end adverse tiering. Insurance companies will come up with new ways to reduce the participation of sicker patients in their insurance pool. If you think you may have been

a victim of this clever tactic or other dishonest strategies by insurers, report this at this site: report insurance fraud.

Another article speaks to how a young woman, contemplating having children, navigates the high-deductible health insurance market to minimize out-of pocket expenses.[4] It's not much different than gambling in Las Vegas. The odds are stacked against you. She may choose a cheaper bronze plan with a high deductible ($6,000), but an ordinary birth could require out-of-pocket expenses approaching this amount. The writers suggest saving money in anticipation of having a baby. The writers opine that expectant women are going to incur higher out-of-pocket expenses in the future - and that cost transparency for childbirth, like most other medical procedures is minimal. A wise, expectant mom will negotiate costs before she gives birth – and watch out for "out-of-network" ploys.

A health economist expressed his opinion in the *JAMA* that hospital consolidation through mergers is not likely to reduce cost nor improve quality.[5] These consolidations are ongoing at an increasing rate, but the evidence he cited from a study by the Robert Wood Johnson Foundation (RWJF) showed that mergers increase costs and reduce quality.[6] So if you read a newspaper headline that hospitals in your area are merging to reduce costs and improve quality, be skeptical. They are doing it to separate more patients from their money. You might even write the entity that approves such mergers, citing the RWJF study.

Finally, the old issue of physician self-referral has come up once again as a result of a 2014 audit by the General Accountability Office (GAO).[6] A viewpoint article by two MDs points to the GAO audit from last year showing that the growth in magnetic resonance imaging (MRI) from 2004 to 2010 was seven times higher for self-referral than for non-self-referral practices. The change in CT scans was 3 ½ times higher for self vs. non-self-referrals. The GAO concluded that monetary incentives were likely behind this – note this *does not* say that patient needs had anything to do with the dramatic increases. Under the "Stark" laws (1989 and 1993) physicians are supposed to be prohibited from self-referrals, but so many exceptions have been allowed that the law is nearly meaningless. The writers declare that the GAO report is a "call for action" to Congress. Don't hold your breath for this to happen.

Medicare's physician database release has shown that physicians that receive more of your money from Medicare do so by performing more services, not by seeing more patients.[7] An analysis by three MDs revealed that for each service given to patients served by physicians in the bottom one-tenth of payments, five services were given to patients served by physicians in the top ten percent. There is no evidence on whether the many additional procedures benefited the patient. Obviously, the additional procedures benefited the income of the physician. Since Medicare dispenses *your* tax dollars, if you are a beneficiary, you must insist on knowing why your doctor recommends a procedure. Insist on shared decision making.

Shared Decision Making

One of the most abused facets of the U. S. medical care industry is the marketing of invasive

medical procedures to patients without informing them of who will actually do the procedure, what the risks and benefits of the procedure are, and what alternatives to the procedure are available, including doing nothing. In my opinion, based on recent peer-reviewed studies, cardiologists are probably the most frequent abusers of the "informed consent" process. Patients are not informed; they are often manipulated!

In the wake of this outrageously unethical situation, the language is changing. Informed consent is being replaced by "shared decision making." The idea is that the provider and patient *together* make decisions that are consistent with the patient's wishes; however, patients must acquire enough knowledge, perhaps independently of the provider, to hold their own when the "shared" decision is being framed. This requires a skeptical assertiveness on the part of the patient.

One of the major challenges to shared decisions grows out of the reality that many invasive procedures reside in what three experts call the "Gray-zone of medicine."[8] Writers in the *New England Journal of Medicine* use as an example the insertion of stents in coronary arties. Such procedures are lifesaving soon after a heart attack, but the benefits can disappear when stents are inserted long after the heart attack or in patients at low risk. Furthermore, there are well understood risks of such procedures. Using "appropriateness" criteria, medical guidelines are intended to define boundaries between, white, gray, and black procedures, but such boundaries are not always distinct. Appropriate procedures are different from "necessary" procedures. For example, imaging may be appropriate, but this can lead to inappropriate procedures. One way to reduce gray-zone procedures would be to make patients pay a larger share of the cost. Further confounding of the gray-zone appears because new technologies are constantly developed, and these may offer no better care than their predecessors. Enter evidence-based care and shared decision making – in principle.

Two writers in the *JAMA Internal Medicine* speak to the difficulties of implementing shared decision making.[9] The first issue is whether a clinical procedure requires a shared decision. The authors point out that this is especially challenging when considering screening for cancer. The best approach is to use the classifications of the US Preventive Task Force to discern when a shared decision is in order. If their classification is grade "C," then a shared decision is appropriate because this requires the physician's judgment *and* the patient's preference. For example, screening for breast cancer at age 40 has a grade "C" recommendation from the task force.

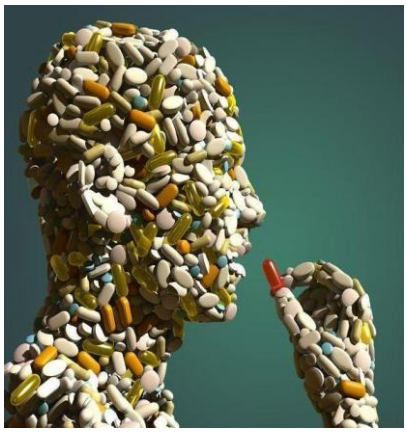
In the same journal, a 40-year old woman who writes about cancer screening described her annual physical exam.[10] Her physician handed her an order for a mammogram. When the patient questioned this and sought to discuss the pros and cons of screening, her physician slammed the door with the words "I am telling you to get a mammogram." The patient later noted that her medical record of the visit clearly suggested that the risks and benefits of mammography were discussed and that the patient will make her decision later. This outraged the journalist-patient. She writes further that after weighing the evidence, she is opting out of *any* mammography screening. She plans to watch for new information that may suggest that mammography screening has improved to the point where patients are rarely sent down the trail of overuse, but until then she is not going to be screened. I am going to assume that this patient has no risk factors for breast cancer. Risk factors for breast cancer that may make screening a wise choice can be found here: risk of breast cancer.

An article entitled "Patient perception of benefits and harms" was written by a woman MD.[11] She noted patients' tendency to overestimate the benefits of screening and to underestimate the risks of harm. She asks how doctors can "bridge the chasm" to improve patient understanding, noting that information presented directly to the public can create biased views. She also noted that individual physicians must communicate effectively with patients, and this requires that they have a balanced knowledge of risks and benefits. This often is not the case. One study she cites found that "number sense" is low among medical trainees. I would cite as one example the recent declarations by Senator Rand Paul, MD of Kentucky on vaccines in which he stated that there are "*many tragic cases of walking, talking normal children who wound up with profound mental disorders after vaccines*" This is the flip side of the coin – the mistaken view that harms outweigh the benefits for *all* vaccines.

Drug Dilemmas

Two articles on drugs came to my attention this month. The first concerned research misconduct identified during inspections by the Food and Drug Administration (FDA) at sites where clinical trials involving human subjects are underway.[12] A researcher dug out FDA inspection reports from 1998 to 2013 that identified misconduct, and then matched these with reports in peer reviewed medical literature involving the same studies. Fifty-seven

such trials were identified. The FDA inspections had revealed data falsification (22%), problems with adverse event reporting (25%), protocol violations (74%), bad record keeping (61%), and failure to protect the safety of patients or give informed consent (53%). Only 4 % of the resulting 78 open-literature, peer-reviewed publications involving the 57 trials mentioned the objectionable conditions.



Although the misconduct described above involves a small fraction of drugs, this finding should trouble the public because so many decisions about drug usage are based on findings reported in peer-reviewed literature. The FDA does exclude data from any study site that received the most severe misconduct findings during inspection. The author recommends that the editors of peer-review journals require those who submit studies to disclose any adverse findings by the FDA inspectors.

A second article suggested that too many drugs are being improperly used in end-of-life situations.[13] In the past the thinking had been that to withdraw drugs as a patient is dying would be signaling to her that she is unworthy to receive treatment. However, recent awareness of the harm caused by polypharmacy has generated a rethinking of this tradition. For example, drugs like statins, which take two years to be effective in preventing future heart attacks, or drugs to prevent the loss of bone mass are being questioned as to their benefit. Another consideration is the difficulty of administering drugs to nursing home patients with end-stage dementia. A short-term trial of drug discontinuation might be in order for those near the end of life. If you are looking after someone near the end of their life, it might be a wise idea to ask if the many drugs they are taking are of any benefit.

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Answer to question this month: d) $6,000; actual cost is $5,700 per person, reference 14