PSA

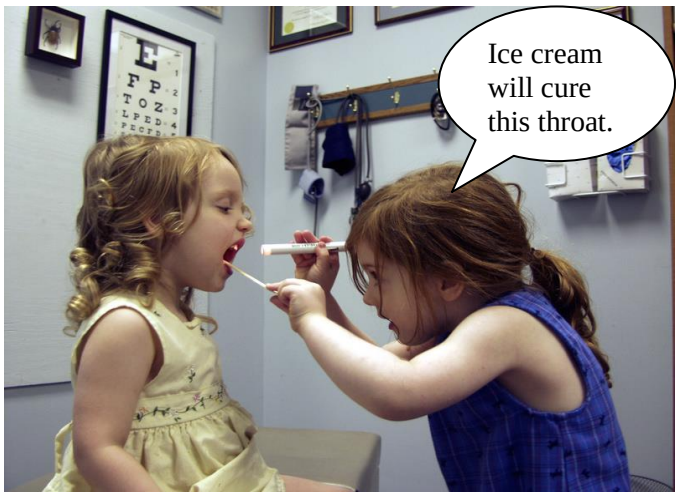
Patient Safety America Newsletter

September 2013 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: On a 4-point system, what percentage of the time did women, who were considering breast-cancer screening, rate the information they were given by their doctor as 3-4? a) 10% b) 20% c) 50% d) 70% e) 90%*

Patient Centered Care?

Plenty of lip service has been given to patient-centered care, but the reality falls far short of the talk. In a study published last month, 3 investigators ask, "How patient-centered are medical decisions?" They begin by surveying the history of how medical decisions are made, starting with a 1982 study decrying the paternalistic way physicians make decisions for their patients. Other studies up through 2008 similarly found that patients were not consistently well informed when decisions are made about their care.[1]



The investigators studied patients' feedback on whether in 2011 they were informed before making a decision in up to 10 possible kinds of encounters with providers. The subject of these encounters ranged from blood pressure medications, to screening for cancers, to joint-replacement options. The patients were all over 40 years old and responded to a survey instrument containing a few questions. Overall the investigators found that "discussions [between patient and provider]…as reported by patients do not reflect a high level of shared decision making." The least patient-centered decisions involved screening for breast and prostate cancer. Here is a link to help you understand shared decision making:
http://informedmedicaldecisions.org/what-is-shared-decision-making/

As a cautious and empowered patient you must become informed about your medical care and keep a record of what you have been told. Make sure your provider understands that you know what shared decision making is and that you want your share.

Less Care May be Better Care!

The mindset of most doctors who treat critically ill patients is that they must give intense treatment. Two experts from the Netherlands asked if this is beneficial to the critically ill patient based on recently published studies on this subject.[2] They tabulated 14 studies published since 2000 in which patients experienced increased mortality (9), no benefit (4), or increased days on a ventilator (1) from intense treatment. The intense care included liberal blood transfusions, high-dose corticosteroids, prolonged antibiotic treatment, and high caloric intake. The authors note that less care of the critically ill may benefit their health and also lead to lower medical costs for ICU patients. I might observe that there is a perverse incentive here for too much treatment, at least in the U.S.

In a viewpoint article on overuse of medical services in the U.S., the authors identify 3 types of situations where overuse can occur;[3] these are: benefit vs. harm, benefit vs. cost, and patient preference. In the first category one finds things like too frequent colorectal cancer screening, in the second category are some cancer drugs whose benefit is too small for the high cost, and in the third one might include a patient's mistaken eagerness to start dialysis. All of us, patients and providers, must become good stewards of medical care

money, but the ship of overuse will not sink easily – there is too much money keeping it afloat.

A logical question follows: How do physicians view their role in controlling healthcare costs? A team of investigators attempted to answer that question.[4] According to the 2556 responding physicians surveyed from the American Medical Association database, major responsibility for cost control lies with trial lawyers (60%), health insurance companies (59%), hospitals and health systems (56%), drug and device makers (56%), patients (52%), government (44%), and the individual practicing physicians (36%). An editorial opinion calls this finding "a denial of [physician] responsibility."[5] In a raw critique the editorialists declare, "Unless physicians want to be marginalized – unless they are willing to become just another deck hand – they must accept and affirm that they are responsible for controlling healthcare costs."

I might not have been quite so harsh. I would prefer that physicians focus more attention on safe patient care and learning from the mistakes that they and other providers commit. Cost control matters, but harmed and needlessly dead patients matter more. Frankly, cost control and patient safety should go hand-in-hand.

Let's look at another article on the cost of medical care – this time at cardiovascular procedures. A host of experts asked how much geographic variation there is in the use of cardiovascular services and how much difference there is in a fee-for-service system compared to a "capitated" system (Medicare Advantage Plan) where physicians are not paid more for doing more.[6] They evaluated records from 880,000 Medicare Advantage beneficiaries and 5,000,000 Medicare fee-for-service patients.

First let's deal with the geographic variations and just the fee-for-service patients - for simplicity. The variations were as follows (per 1000 patient years): angiography (15-44), stent placement (5-16), and coronary artery bypass graft (2 ½ to 6). Other research has shown that such large geographical variations are related to "implicit professional norms or the local practice culture." Note that this *does not* say that the variations are due to differences in the needs of patients. To me this is obvious overuse in some regions of our country.

Now let's compare utilization when physicians are paid for each cardiovascular service vs. when they are not paid for each procedure (Medicare Advantage).[6] The rates per 1000 person years were as follows: 16 vs. 26 (angiography), 7 vs. 10 (stent placement), and 3.1 vs. 3.4 (coronary artery bypass graft). *Always*, the fee-for-service rate was higher, although at least for coronary artery bypass grafts the rate differences were not significant. The authors note that the cost of cardiovascular care in the U.S. is about $273 billion per year. It seems to me that there are some obvious targets here for minimizing overuse of expensive and potentially harmful procedures. I might note that president Bush (the younger one) was recently sold a coronary artery stent, one that he probably did not need: http://www.bloomberg.com/news/2013-08-06/former-president-s-stent-surgery-reopens-debate-on-heart-care.html

Medical Bills Plague Us

Only in America do individual citizens experience bankruptcy due to medical bills. In a brief article in the JAMA from the Centers for Disease Control and Prevention, the writer notes that 20% of Americans under 65 are living in a family with trouble paying medical bills. For the first 6 months of 2012, this breaks down to rates of 36% for the uninsured, 26% for those with public coverage (Medicaid), and 14% for those with private insurance. Find more details at: http://tinyurl.com/ky27w8q.

Drug Companies Dodge Commitments

Three investigators asked how often drug companies comply with Food and Drug Administration (FDA) mandates to do post-marketing studies under the FDA

Amendments Act, which was passed by Congress in 2007.[7] Prior to this law, the FDA could only *ask* that companies voluntarily do post-marketing studies. A post-marketing study is targeted to the discovery of harmful side effects of a drug that were not apparent from the data presented for initial FDA approval of the drug. Many such side effects are discovered only after years prescribing to patients who are more-or-less the guinea pigs in the older approach.

The number of required studies has risen from 46 in 2008 to 387 in 2011. One does not have to be very bright to recognize that such studies may not be in the best interest of a drug manufacturer. What drug company wants to discover that a drug that is making big money for them has more side effects than originally supposed? The investigators found that manufacturers are often ignoring their commitment to perform mandated studies. For example, of the 154 mandated studies in 2009, 120 had not yet started (as of the end of 2011). Of the 387 mandated in 2011, only 97 were ongoing or had been submitted for FDA review by the end of that year. The investigators call for the FDA to enforce the law against companies that fail to comply with requirements. In the meantime you are still the guinea pig.

Senate Closes Barn Door after Horses Escape

Your government is supposed to protect you from industries whose activities could harm your health. For example, the US Environmental Protection Agency is supposed use laws to regulate the chemical industry so that no one has to breathe harmful air. The FDA has the responsibility to protect us from harmful drugs, but if there is no law allowing them to act, then that protection does not exist. Past laws presumed that states were regulating drug compounding companies in their states. That presumption has recently resulted in the deaths of 63 persons and about 750 persons harmed by fungal contamination of drugs from the New England Compounding Center; furthermore, Texas is not immune from such mistakes, albeit on a much less harmful scale. (http://www.cbsnews.com/8301-204_162-57598110/texas-compounding-pharmacy-recalls-drugs-after-15-infections/).

A note in the JAMA in July points out that on May 22 a Senate committee approved a law to allow the FDA to assume oversight of compounding companies. Since the tragedy generated by the New England Compounding Center, another 48 compounding companies have been found to be producing and selling drugs that are contaminated or prepared under risky conditions (http://tinyurl.com/nxog9uq). Note in the Executive Summary of this report that the risk to patients posed by compounding companies has been well known for many years.

From a patient safety perspective, the failure of Congress to act much earlier to protect the public was an abrogation of responsibility and just plain disgusting.

Bad Pictures of your Body

I'm particularly sensitive to poor quality images of bodies because a cardiac MRI was in the critical pathway of my son's care after he collapsed while running. That cardiac MRI was not properly performed because the technicians had not been fully trained. This resulted in painful and worthless invasive procedures that made plenty of money for his cardiologists and did nothing to preserve his life.

A Government Accountability Report (http://tinyurl.com/mpwus6h) cited in the JAMA declared that the Centers for Medicare and Medicaid Services (CMS) should establish minimum standards for diagnostic image service companies. Various organizations have standards, but they are inconsistent. The report concludes that without minimum national standards, the quality of images is difficult for the CMS to assess, and I would add that this places patients in harm's way. I know a physician who raised a flag about the way echocardiogram images were being misinterpreted in her hospital, and she was soon fired: (http://www.medpagetoday.com/Cardiology/Atherosclerosis/24337).

There is no reason why the quality of images and the ability to read them in a consistently accurate way should not be carefully regulated. Lives are at stake.

Nasty Cancer Drugs

Some years ago I lost a colleague to melanoma. He came into my office a few months before this aggressive cancer took his life and told me that during his initial round of chemotherapy he felt terrible. His oncologist had been unavailable for the first month of his treatment and suggested, upon his return, that maybe the initial dose prescribed to him was too high. Regardless, the melanoma soon spread to his liver and stole his life. Chemotherapy can be nasty.

A physician writing in the New England Journal asked what it looks like to develop patient-centered cancer-treatment drugs.[8] He asserts that only one cancer-treatment drug to be approved by the FDA in the past decade has had symptom (side effect) information

included on its label. He accuses the FDA and the drug industry of paying too much attention to survival times and too little attention to the patient's experience (suffering). The experience of previous patients who have used a given drug "must be regarded as essential information…without which our understanding of its risk-benefit profile is incomplete."[8]

If you are considering chemotherapy, then ask your oncologist how the treatment is going to make you feel. Ask him if there is information available on the reports of other patients about how the drug affected them. You cannot make an informed decision without this information.

Speaking of cancer drugs, an MD writing his viewpoint in the JAMA disclosed the rapid increase in prices of anticancer drugs.[9] In constant 2010 dollars, the median price of such drugs approved from 1980-1989 was just under $400/month, but drugs approved from 2000-2005 had a median cost of $4000/month. Physicians used to be reimbursed 6% of the cost of oncology drugs, but sequestration reduced Medicare payment to 4%. Lobbyists for cancer doctors have been out in force trying to influence a reversal of this limitation by Congress. Noting that the current approach is unsustainable, the author's viewpoint envisions several ways to fix this troubling situation, which I'll not go into here. Patients need to be aware that there is some incentive for oncologists to choose new and expensive drugs that may be no better than much cheaper options.

References

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6) Matlock DD, Groenveld PW, Sidney S, et al. Geographic variation in cardiovascular procedure use among Medicare fee-for-service vs. Medicare Advantage beneficiaries. JAMA 2013; 310:155-162
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Answer to question this month: b) 22.4 % were given high quality information[1]