PSA

Patient Safety America Newsletter

November 2011 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: Responsible estimates of wasteful spending in the American healthcare industry place the amount wasted each year at: a) $700 million b) $700 billion c) $700 trillion*

Do You Trust Drugs Too Much?

My newsletters often attack the irresponsible, off-label prescribing of drugs for patients and conditions not approved by the Food and Drug Administration (FDA). Approximately 1/5 of all drugs prescribed are for off-label use, creating excess risk of harm to patients. But do you know how much to trust drugs approved by the FDA for your illness? It seems that many people place far too much trust in approved drugs.

Two MDs studied a sample of Americans to determine what they believed about drugs that had been approved by the FDA.[1] Almost 40% of their sample believed that the FDA approves only drugs that have been proven to be "extremely effective." One fourth of the surveyed people thought that the FDA approves only drugs that do not have serious side effects. In fact the FDA approves drugs for which it believes that the benefits outweigh the harms in specific instances of illness; however, the harms caused by a drug are often not apparent for several years after approval. Furthermore, the margin of benefit to harm can be slim. Once a drug is FDA approved, the manufacturer often begins an aggressive campaign of advertising that, in effect, misleads many people. Examples were given for the drugs Zetia and Vitorin.

BEWARE OF NEW DRUGS

In 2006 the Institute of Medicine recommended that any newly approved drug have a special label indicating that it is new. The FDA has failed to adopt this recommendation. You might want to know that the UK equivalent of the FDA has required a black-label warning on all new drugs for at least 2 years after their approval. The authors of the study suggest that the FDA needs to do a better job of communicating what it does and does not know about the drugs that it has approved.

An invited commentary on this study by an MD places these troubling findings in perspective.[2] He points out examples of several questionable drugs. Ezetimibe, a cholesterol-absorption-limiting drug with $4 billion sales in 2010, shows little evidence of being any better than statins alone. Approved drugs, Vioxx and Avandia, have been withdrawn or restricted in use for safety reasons.

> Many physicians have first-hand experience with situations where highly-engaged patients (or their caregivers) identified an error, potential treatment, or other opportunity to improve care that would otherwise have been missed.
> Michael A. Steinman, MD[2]

The problem is that patients struggle to make optimal decisions even when given enough information, and physicians are often not aware of the evidence supporting the basis of FDA approval of a drug. Examples are cited where concerted education of patients about a new drug or about how to talk to their physician about drugs has had some limited success. Ultimately, the commentator feels that it will take a "patient-physician partnership" to achieve high-quality prescribing of drugs.

There is a third party to the "partnership" between physicians and patients that bears careful watching – the drug company detailer (aka sales representative). Two lawyers wrote about this sort of persons in the *New England Journal of Medicine*.[3] These representatives invade physician's offices with information about the product being pushed and samples of the name-brand drug. In addition, detailers are armed with data on the prescribing habits of the specific physician. Is their customer a high-volume prescriber, or does he prescribe new drugs quickly after their approval? The detailers know the answers because they buy data from prescription drug intermediary (PDI) companies

who buy data from pharmacies and link them to information they purchase from the American Medical Association.

Critics of this process feel that this leads to overuse of branded "new drugs for which safety and efficacy data are limited." Vermont adopted a law that restricted the transfer and use of physician-identifiable data, but this law was quickly challenged by the PDIs and the association of drug manufacturers. Vermont had adopted its law based on potential harm to the public, excess costs due to overprescribing of expensive drugs, and protecting physician privacy. The challenge was based on free speech rights of the parties gathering data, but Vermont countered that it was the state's right to regulate commerce (buying and selling of data). Ultimately, the law was thrown out by the U.S. Supreme Court because it was biased against detailers. There may be another round of writing laws that circumvents the ruling by the Supreme Court.

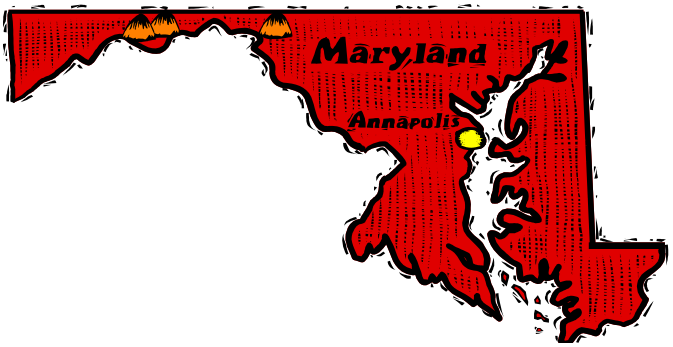
As I read this story I felt like patients have become a ping-pong ball in the game of free enterprise that poisons our American healthcare industry. If some faction in the industry can find a way to make more money, then potential harm to patients is often ignored. Furthermore, the excess costs become an economic burden to the society. Indeed, our healthcare industry costs much more per person than any other system in any other developed nation.

Cost Conscious Medical Care

Many thoughtful proposals continue to emerge on ways that the United States could make healthcare more affordable. An estimate from the Institute of Medicine in 2010 that was cited in an opinion letter to the *Annals of Internal Medicine* suggests that 30% of all healthcare costs could be eliminated without any diminution in the quality of care.[4] In round numbers, that means that approximately $700 billion (yes billion) dollars could be saved *each year*. A physician, in an attempt to better-engage doctors in cost control, proposed a seventh general competency for doctors: cost conscious care and stewardship of resources.

The author surveyed past attempts to make medical students and residents more cost-conscious while providing high quality care, but these have not met with much success. This is why he proposes that a new competency be formally adopted into training programs endorsed by the Accreditation Council for Graduate Medical Education and the American Board of Medical Specialties. I agree with this, but I would like to see cost-conscious care adopted as a requirement of continuing medical education for all licensed physicians. Adding this core competency to current education alone is not going to address physicians that have completed training and are now practicing. Better cost management has become a 'medical' emergency in our country.

Two physicians wrote about "Maryland's hospital cost review commission at 40: A model for the country."[6] This was of particular interest to me because I lived in Maryland for many years, my first two children were born in Maryland hospitals, and I worked at a teaching hospital while going to graduate school. Maryland is the only state that still has a hospital cost control commission. Each year this commission establishes what hospitals can charge insurers, Medicare, and Medicaid. Thus Maryland is and "all-payer" state.



The commission was chartered in 1971 because Maryland's hospitals had high rates, some hospitals were losing money, and some people were being denied care if they did not have insurance. Many other states had a similar system for a while, but these gave way in the 1980s to deregulated, market-driven schemes. The Maryland system has been phenomenal at controlling hospital costs. Between 1977 and 2009 Maryland had the lowest increases in cost per admission of any state in the nation, and for 2009 the rate increased only 2%, whereas the national average increase was 4.5%. Furthermore, Maryland now has the lowest absolute charges of any state.

According to the authors, everyone seems to favor this system. The commission is independent of governmental interference, getting its funding from hospitals, which in turn pass along these costs to payers. Patients have access to any hospital in the state and hospitals cannot shift costs from uninsured patients to those with good insurance. Payments are based on quality of care metrics that are more extensive than current Medicare quality incentives.

The authors note that Maryland is a small state and what works there might not work for the entire country. I would counter that Maryland is comprised of relatively remote western areas, eastern-shore farming and fishing areas, and the large metropolitan area of Baltimore. If hospitals in this diverse state can be managed by a cost review commission, then so can all hospitals in the U.S. This example dispels the notion that allowing free-markets to determine hospital costs is far less effective than regulation by an independent and accountable commission.

Two MDs wrote a perspective in the *New England Journal* advocating the reduction of unnecessary hospitalizations of nursing home residents.[7] They note that 1.6 million Americans live in nursing homes and roughly $4 billion may be misspent each year because residents are inappropriately sent to hospitals for conditions that are, or should be, treatable in nursing homes. Nursing homes may need to develop the infrastructure to improve the intensity of care for residents with acute conditions to avoid hospitalizations. Incentives are needed to make this happen and more appropriately trained nurse practitioners and geriatrics physicians are needed.

I would note that hospitals are dangerous places, so the decision to send a nursing home resident to the hospital has to weigh the risk of hospitalization against any inability of the nursing home to take care of the resident's illness. Regardless of cost, this is not going to be an easy decision in many cases. Furthermore, the relative costs of the two options must be considered if the physician is to be a follower of cost-conscious care as advocated by the MDs who want this to be the seventh competency in which physicians are trained.[5]

Blood to your Brain

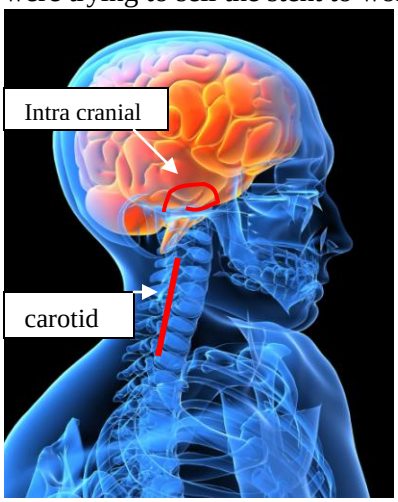
Most of us know someone who has been disabled or died as the result of a stroke, which is basically the death of brain tissue due to lack of effective blood flow through blocked arteries. Blockages can be upstream of the brain in the carotid arteries of the neck or they can be "downstream" in the cranial arteries inside the head. Two original research studies were published in September. These revealed information that patients should know about procedures designed to reduce the risk of stroke when blockages are forming in the carotid or intracranial arteries.

A huge team of investigators asked if placing a stent in a cranial artery that was at least 70% blocked in patients that had had an ischemic (low oxygen) attack or stroke was an effective addition when trying to reduce the number of strokes within 30 days of the procedure.[8] The stent procedure was added to aggressive medical therapy or the medical therapy alone was used without any stent placement. Patients in the trial were randomized into the two test groups – those receiving stents and those not receiving stents. All received medical therapy.

The trial was stopped after 450 patients were involved because the group receiving the stent and medical treatment did much worse than the group that did not receive the stent. Specifically, the 30-day stroke or death rate in the stent group was 15%, whereas the rate in the medical-management-alone group was 6%. After 1 year, 20% of the stent group had died or had had a stroke, whereas 12% of the medical-treatment-alone group had a stroke or died.

A commentary by an MD places this study in perspective.[9] He notes that placing intracranial stents is technically more difficult than placing carotid stents (discussed below), aggressive medical therapy is an effective treatment, and the Center for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) play critical roles in defining cost-effective medical care. I want to emphasize the roles of these two government agencies because of the negative opinions of federal government in Texas.

The FDA approved the use of the stent for this investigation and the CMS refused to reimburse placement of the stent outside the context of this clinical trial. Thus the government agencies did what they should always do; they insisted that a procedure/device must be demonstrated to be effective before they pay for its use. In this case the stent placement procedure proved to be more dangerous to patients than no stent, so the trial was stopped and money was not wasted and patient lives were not needlessly risked because free market forces were trying to sell the stent to worried patients.

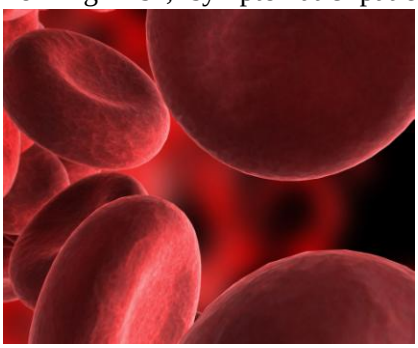


Now let's look further upstream at stent placement into larger diameter extra-cranial arteries that deliver blood to the head. A huge group of medical investigators asked whether experience was important in outcomes when stents are placed into carotid arteries.[10] They note that this procedure is technically demanding, requiring a "substantial" learning curve. They studied the outcomes of almost 25,000 stent procedures performed in Medicare patients by roughly 2,300 physicians.

They discovered two facts that were not much of a surprise: physicians that perform more frequent stent placements have better outcomes, and when inexperienced operators gain experience, their outcomes improve. The investigators looked at the 30-day mortality after stent placement. The stent procedures were grouped into four categories according to the number of procedures done by the operator each year: less than 6, 6-11, 12-23, and more than 24 per year. The number of patients in each group was roughly the same. The 30-day mortality for these four groups was 2.5%, 1.9%, 1.6%, and 1.4%, respectively. Operators early in their career

had a 2.3% death rate, whereas later in their career this dropped to 1.4%.

An MD provided editorial comments and perspective on the study above.[11] He emphasized that there must be a balance between practicing carotid artery stent placement and doing too many procedures. The stent placement procedure must compete with surgery on the involved artery, the traditional way of dealing with a partially clogged carotid artery. In 2005 Medicare approved the stent procedure using FDA-approved stents for high-risk, symptomatic patients with greater than 70% blockage. In May 2011, coverage was expanded to all patients with carotid artery disease, not just those at high surgical risk. This was based primarily on the outcomes of a clinical trial called "CREST."



The editorialist notes that clinical trials do not necessarily reflect how well the procedure will do in the real world of clinical medicine. Indeed, the results of the study above suggest that the average death rate in the real world (1.9%) is much higher than the death rate in the CREST trial (0.7%). Given the advanced age of many of the patients in the real-world study, the editorialist opines that "a substantial portion of the carotid artery angioplasty with stenting cases would probably be deemed inappropriate."

The editorialist points out that the death rate from medically-managed, asymptomatic carotid artery blockages is between 0.5 and 1%, which is significantly less than the 2% mortality experienced when either surgery or stenting is attempted. He questions whether either invasive procedure should be used in light of the success of medically managed patients. He asserts that clinical trials are needed to compare stenting, surgery, and "best" medical therapy for asymptomatic patients with carotid artery disease. **The message for you as a patient with possible blockages of your carotid or intracranial arteries is to ask your doctor about using medical therapy alone before allowing invasive surgery or stent placements. You might want to be skeptical of any answer from a carotid artery surgeon or stent operator. Get a second, independent opinion.**

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A procedure performed in a patient who would not be expected to benefit from it is inappropriate and wasteful regardless of how skilled the operator or how low the complication rate…Because many asymptomatic patients who undergo revascularization do not have a balanced understanding of the risks and benefits of all their treatment choices (surgery, stenting, or medical therapy), better educational tools are needed to foster informed, shared decision making.
Ethan A. Halm, MD in the JAMA[11]

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Answer to question this month: (b) $700 billion[4]