PSA

Patient Safety America Newsletter

November 2012 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: How many Americans are estimated to die each year from diagnostic errors?*
a) 10,000 b) 20,000 c) 40,000 d) 60,000 e) 80,000

Book Review:

Unaccountable – What Hospitals Won't Tell You and How Transparency Can Revolutionize Health Care. *Marty Makary, MD*

Doctor Makary performs surgery at Johns Hopkins Hospital and is on the faculty of the Johns Hopkins School of Public Health in Baltimore. He is widely recognized for his efforts to improve patient safety. In "Unaccountable" he passionately, and with plenty of evidence, makes the point that hospitals in America and the doctors that work in them are accountable to no one for safe care of patients. In the book's pages we meet doctors you would just as soon avoid, such as Dr. HODAD, Dr. Fred Flintstone, and Dr. Shrek. He describes some remarkably famous people that have been seriously harmed by medical care gone wrong. The acculturation in many hospitals is nothing more than a "code of silence" about harm to patients.

Dr. Makary believes that transparency into the performance of hospitals is the answer to dramatic improvements in medical care, and I must agree, although it is not the whole answer. He gives convincing but isolated examples of the connection between public transparency in surgical outcomes and improvement of patient outcomes. No hospital wants a public announcement of its harming of patients. However, he does recognize the tendency of doctors to underreport complications by "orders of magnitude."

Perverse incentives centered on profits are commonplace in most hospitals, even to the point that hospital administrators have written instructions to their surgical staff to do more operations in order to improve bonuses. He speaks of outright false advertising by some hospitals to attract unwary patients who simply want to be healed from serious disease. We hear of the horrifying revelation that within a large gathering of physicians each one openly admitted knowing at least one colleague who practices unsafe medical care. The culture among physicians is to not report their colleagues. I was delighted to see that he describes how poorly most state medical boards handle impaired and aging doctors. Once a doctor, always a doctor!

You might be interested to discover what the "eat what you kill" approach to patient care means within the walls of a hospital. There are several ways hospitals foster overtreatment to improve their bottom line. Did you know that oncologists get a "commission" from the drug maker when they sell chemotherapy to patients? I didn't. He singles out certain Children's Hospitals for their ability to raise money, even from school children, and then pay their directors obscene salaries.

After his grim report of unaccountable hospitals, doctors, and medical boards, Makary highlights a few hospitals that have an endemic culture of safety and appropriate use of medical procedures. There is hope, but it will have to grow like a biblical mustard seed to elicit less harm to patients in all 4,000 American hospitals. I like this book because it gives an insider's perspective on the subtitle to the book I wrote in 2007: "Patient Rights in a Dangerous, Profit-driven Health Care System." There is still a long way to go before patients can exercise any right to safe and affordable medical care.

This is an exceptionally forthright and educational book for all parties to the health-care disaster, especially for those who would change it. Five Stars. Available on Amazon, $15.42.

Diagnostic Errors

Just this past week a man described to me the uninformed care his wife had received from the medical industry. In one case her physicians took several days to diagnose that she had a pulmonary embolism, even though her symptoms were indicative of this potentially life-threatening condition from the start. Another time his wife went to an emergency room with an injured leg, but after an X-ray, which a radiologist read as indicative of no broken bone, she was discharged. The woman's pain persisted and several days later she had another doctor's visit and that physician quickly deduced from the original X-ray images that she had a break just below the knee in her tibia.

Based on autopsy findings from some years ago, the number of deaths per year due to diagnostic error is about 60,000, give or take about 20,000 unfortunate victims. There are multiple ways that a diagnostic error can occur. Three MDs wrote an article in the *JAMA* entitled "Bringing diagnosis into the quality and safety equations." They provided a list of causes of diagnostic errors: 1) laboratory testing errors, 2) system-related errors, and 3) cognitive errors on the part of physicians.[1] In their opinion curtailing diagnostic errors has been left out of the current debate on improving medical care quality and safety.

Part of the problem seems to be that physicians are not aware of the prevalence of diagnostic errors and presume that they are not making any such mistakes. To the knowledge of the physician writers, no one is systematically collecting data on diagnostic errors and this neglect means that few physicians are giving appropriate attention to reducing the number of diagnostic errors. Something like, "If no one is keeping score, then what does it matter?"

The authors propose several strategies to reduce diagnostic medical errors. Doctors need to learn to couple medical reasoning with electronic databases currently available to aid diagnosis. Competency examinations that assess a physician's knowledge must focus more on diagnostic skills pertaining to a realistic clinical scenario than rote recall of information. It may even be appropriate to allow internet access during such examinations to better simulate real-world diagnostic resources. In the end, the doctors assert, the right treatment often depends on the right diagnosis.

As a patient you need to appreciate that physicians are going to make diagnostic errors, perhaps about one in seven times, and that this is not going to change anytime soon. If you have an undiagnosed condition, you should ask your doctor how he has planned his "differential diagnosis." This is a collection of possible causes of your illness. For example, there are many possible causes of chest pain, some life-threatening and some trivial. You should understand how your doctor is ruling out diagnoses and pursuing the remaining possibilities.

Let me give you a brand new example of how a heart attack can be quickly diagnosed. A huge collection of MDs published an article in the *Archives of Internal Medicine* last month in which they describe a way to rule-in or rule-out a heart attack in a patient with chest pain within one hour.[2] It involves a high-sensitivity troponin assay on blood and how the results of that assay change over a one hour period. Troponins are released when heart muscle tissue dies, so an increasing level over one hour suggests a heart attack is in progress, whereas below a certain level of change in troponin levels a heart attack can be ruled out. Of course there is a "gray" area in between in which about a quarter of the time the change is not definitive one way or the other. My point is that there are remarkable new diagnostic procedures becoming available regularly, and your doctor may not be aware of these. If you knew the haphazard way continuing medical education for physicians is conducted, you would understand why.

Errors of Omission

Medical errors of commission (something wrong was done) are relatively easy to recognize, but errors of omission (something should have been done but was not done) are just as important, but can be more easily overlooked. In a search for errors of omission, a group of 5 MDs looked for missed opportunities to treat uncontrolled high blood pressure during office visits to physicians in the U.S.

from 2004 to 2009. They examined the National Ambulatory Medical Care Survey for patients with uncontrolled high blood pressure, identifying more than 7,000 of these individuals. High blood pressure is an important contributor to heart disease.

The investigators looked at several parameters and patient groups, but I want to focus on only one of the patient groups they studied. These are out-patients appearing for an office visit *that are taking no medications to control high blood pressure* and have a measured blood pressure above 160 mmHg (systolic) or 100 mmHg (diastolic). If the patient came in because of his high blood pressure, only 60% of the time did his physician prescribe a medication to lower his blood pressure. If the visit was for a reason other than high blood pressure, then the physician wrote a prescription only one third of the time. The authors conclude that missed opportunities to better manage high blood pressure are common in the U.S. They note that their findings are consistent with other studies from different clinical settings. In their opinion, failure to control high blood pressure when there is an obvious need is a "national problem."

I was surprised by this finding because I might have supposed that proper management of high blood pressure was something physicians had consistently mastered long ago.

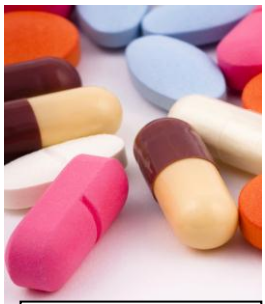
Big Pharma in Fraudulent Action

Therapeutic drugs help a great many folks enjoy a longer and healthier life than they would have enjoyed without those drugs. Unfortunately, human greed gets in the way and causes harm to people when drugs are intentionally marketed off-label, which is for a purpose not approved by the FDA. A lawyer writing in the *New England Journal of Medicine* asks "Is the GSK settlement sufficient?" The settlement he is referring to is the $3 billion settlement paid by GlaxcoSmithKline (GSK) for off label promotion of several drugs, failure to report safety data, and false and misleading promotion.[4] Since 2009 drug companies have been fined $11 billion under the False Claims Act for similar alleged misdeeds, so GSK is by no means alone. In fact the list of fines and companies in the article reads like a "Who's Who" of big Pharma.

The author describes "corporate integrity agreements," which are forced changes in the way a fined company does business. These are intended to minimize a repeat performance of potentially harmful promotion of drugs. Such agreements typically come with an independent monitor of compliance, but expire after a period of only 5 years. The author never explicitly answers his question of whether GSK was adequately punished, but it is clear to this reader that he believes they were not.

For example, under the corporate integrity agreement administered by the federal government, senior managers at GSK that had been paid bonuses can keep those bonuses. Requirements to publish negative safety data, which GSK had not done for Avandia, were mandated but have serious loop holes. These large fines have been described by some folks as the company's cost of doing business.

If this action by the federal government is insufficient, then what is sufficient? Legislation is needed to regulate the way drug companies operate; corporate integrity agreements are insufficient. *Individuals* must be held accountable, especially leaders who commit "egregious violations." Corporate fines may need to be increased so that no one supposes that the fines are part of the "cost of doing business." Federal law must require transparency so that negative data on a drug cannot be hidden. Finally, the whistleblower laws must be strengthened to encourage more insiders to come forward. Most of the information on drug company misdeeds comes to the federal government through whistleblowers.[4]


Just for You?

I would add one further provision. Hold physicians accountable when they prescribe a drug off label, do not tell the patient of the additional risk, and that patient is harmed by use of the drug. Physicians should know the scope of FDA approval of any drug they prescribe, and it is unethical, in my opinion, to expose patients to harm without their informed consent.

Let's have a look at another way weak oversight can expose patients to harmful effects of therapeutic drugs. A team of 5 MDs asked how the warnings of adverse effects of a drug change when it moves from a prescription-only drug to one that is available over the counter (OTC).[5] Once this change happens, the regulation of advertisement information transitions from the FDA to the Federal Trade Commission (FTC), which regulates drugs as

consumer products. The investigators looked at direct-to-consumer-advertising of 4 drugs that transitioned from prescription-only to OTC between 2004 and 2008, finding 133 discrete advertisements.

They discovered that only in print advertisements for one of the four drugs was any side effect mentioned after the OTC transition. Among the 4 drugs before the switch to OTC, potential harms were described 70% of the time in advertisements, whereas afterward potential harms were described only 11 % of the time. Did the adverse effects disappear? The generic name of the drug, which is also helpful to consumers, was mentioned about half as often in advertisements once the drug shifted to OTC availability. The investigators point out that misuse of OTC drugs is a major cause of ER visits, hospitalizations, and death. They recommend more attention be given to how OTC drugs are promoted to consumers.[5]

Ethics of Post-Marketing Drug Research

If you are a regular reader of this newsletter, then you know that the FDA typically approves drugs for clinical use with limited data on their safety and efficacy. Data from pre-marketing studies that become part of the company's submission to the FDA are generally not available to the public. In this situation, the public becomes a sort of guinea-pig community from which the FDA can learn more about the balance between harm and effectiveness of a drug. In my opinion, the post-approval monitoring of the adverse effects of drugs is not effective in protecting the public from harm. Thus, it is reasonable for the FDA to approve formal studies that seek to learn more about the risk-benefit profile of a drug sometime *after* the public has assumed its role as guinea pig.

Three experts writing in the *New England Journal of Medicine* describe the controversy over the need for a randomized control study of an approved drug that has been showing evidence of serious harm in patients.[6] The problem is the ethical dilemma between the need for robust scientific evidence on which the FDA makes its decisions and the need to protect individuals willing to participate in a post-approval study. In such a study patients are given the trial drug(s) or a placebo without knowledge of which they are receiving.

How much information constitutes "informed consent" for those participating in the study and perhaps exposing themselves to substantial risk without any distinct personal benefit? How does the FDA decide when further evidence is necessary and cannot be obtained from retrospective "observational" studies? These are studies that look back at the track record of the drug in terms of risk-benefit to patients (aka guinea pigs). Of course, without a robust adverse-event reporting system, the record can be spotty.

In the current climate of the FDA fast-tracking drug approval, patients must be wary of participation in any formal, post-marketing study. Furthermore, an empowered patient will learn all she can about any new drug prescribed to her before taking it. Drugs are an invasion of your body as certainly as surgery. If you experience side effects, report them to the FDA: https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm

What Do You Really Want from Health Care?

Often health care and medical care are used interchangeably, but to me they are generally quite different. Health care is what is done to keep one from needing medical care. For example, consuming a diet with optimal content is health care, whereas, treating the consequences of anorexia or obesity becomes medical care.

Two MDs ask an interesting question: what is the business of Health Care About?[7] They mix medical and health care together, calling this combination "health care." Then they ask: What do people really want, health or health/medical care? Of course, we want health, and we certainly want to avoid medical care. A wise business, they assert, will focus on what the consumer wants rather than on what can be produced. But that is not the way medical/health care is delivered in the US.

Health/medical care delivers only a small portion of what enables people to live long, productive lives, i.e. experience good health; the more important factors are social factors (especially poverty), environmental influences, and personal choices. They speculate that the future will be one in which successful doctors, hospitals, and health systems focus on health and wellness rather than delivering health/medical services. The authors lament the lack of an infrastructure for delivering

health, thus it will be difficult to move from product orientation to consumer orientation.

In a subsequent article, two MDs write about how we might "reengineer" prevention into our system, thus moving it from "sick care" to "health care."[8] That's parallel to the distinction I made between medical care and health care. They designate obesity and smoking as the most prevalent preventable causes of chronic disease. Generally, preventive strategies cannot be patented, so they are not as profitable as a new medical device or procedure. They opine that reimbursement schemes should reward application of effective, non-patentable strategies for disease prevention.

Working against prevention, drug marketing conveys the idea that one can have most any condition quickly fixed or at least the symptoms relieved by taking the right pill. Who needs preventive care? Furthermore, persons with subclinical "disease" are often over diagnosed to impel use of some drug or procedure.

The authors seem to think that the solution lies in better training in medical school to foster physician health promotion to patients. Furthermore, primary care physicians should see themselves as "health coaches" to their patients and be valued and reimbursed accordingly.[8]

The authors recognize that this will require fundamental restructuring of health care, a task not readily achieved in my opinion. As I was once told by an official at the Institute of Medicine – you are not going to fundamentally change the current system because too much money is being made for the system to allow that to happen.

In my opinion, the change to prevention is going to come from the consumer. As the system becomes more transparent, as it seems that it must, and ordinary folks become aware of the profound risks associated with drugs and medical care, fear might impel them to take better care of themselves.

High Hospital Prices!

Most of us know someone who has been shocked by a hospital bill, or we ourselves have been shocked. According to the viewpoint of two MDs, part of the reason for high hospital bills is that many hospitals have the power to capture regional market share to the point where they can increase prices to private payers almost as they please.[9]

The authors note that hospitals are increasing prices as demand *decreases* and many hospitals are experiencing low bed occupancy. The current trend of consolidation of hospitals into local systems has resulted in higher, not lower, prices. Academic medical centers typically have political clout to keep price-control regulators off their back. The looser in all this is the medical-care consumer.

The authors offer three possible steps to better control of hospital costs: 1) incentivize (i.e. bribe) physicians to be sensitive to hospital prices in ways that avoid the fee-for-service trap, 2) improve price cost transparency for patients especially when costs are laundered through greedy (my word) insurance companies, and 3) restructure local markets to give patients more choices. The authors assert, rightly I believe, that without some improved competition, hospitals are going to continue to wield inordinate pricing power.

References

1) Graber MI, Wachter RM, Cassel CK. Bringing diagnosis into the quality and safety equations. JAMA 2012;308:1211-1212
2) Reichlin T, Schindler C, Drexler B, et al. One-hour rule-out and rule-in of acute myocardial infarction using high-sensitivity cardiac troponin T. Arch Intern Med. 2012;172:1211-1218
3) Khanna RR, Victor RG, Bibbins-Domingo K, et al. Missed opportunities for treatment of uncontrolled hypertension at physician office visits in the United States, 2005 through 2009. Arch Intern Med. 2012;172:1344-1345
4) Outterson K. Punishing health care fraud – is the GSK settlement sufficient? N Engl J Med. 2012;367:1082-1085
5) Greene JA, Choudhry NK, Kesselheim AS, et al. Changes in direct-to-consumer pharmaceutical advertising following shifts from prescription-only to over-the-counter status. JAMA 2012;308:973-975
6) Mello MM, Goodman SN, Faden RR. Ethical considerations in studying drug safety – The Institute of Medicine report. N Engl J Med. 2012;367:959-964
7) Asch DA, Volpp KG. What business are we in? The emergence of health as the business of health care. N Engl J Med. 2012;367:888-889
8) Marvasti FF, Stafford RS. From sick care to health care – Reengineering prevention into the U.S. system. N Engl J Med 2012;367:889-891
9) Kocher B, Emanuel EJ. Overcoming the pricing power of hospitals. JAMA 2012;308:1213-1214

Answer to question this month: best answer is d) 60,000 (reference 1)