PSA

Patient Safety America Newsletter

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

***Question**: Most diagnostic errors in an out-patient setting have the potential to cause moderate to severe harm. What percentage of the time do these occur? a) 1% b) 5% c) 10 % d) 15% e) 20%*

Book Review: **Bad Pharma – How Drug Companies Mislead Doctors and Harm Patients**
By Ben Goldacre, MD

This small, thick, obnoxiously orange-covered book has only 6 chapters, which are as follows: missing data, new drugs, bad regulators, bad trials, better trials, and marketing; but each chapter is packed with clever insight into the workings of the drug industry. Dr. Goldacre digs into the fundamental framework that has created a critical problem or could improve things in the interest of less harm to patients. As I read his book, I felt that there was a perverse game of chess going on between those who are determined to make as much money as possible from therapeutic drugs and those who would protect the public from unsafe drugs. We patients are the pawns, available for sacrifice as the players deem necessary to gain advantage.

Goldacre writes in a free-flowing style, almost as if he were talking to the reader. He anticipates what the reader might be wondering and pounces on that likely question. His is a sound, accessible, thorough indictment of the pharmaceutical industry and those who would regulate it.

Goldacre falls just short of proposing solutions that will change the industry's bad habits for good. In his afterward he shows how senior executives named in federal indictments of SmithKlineGlaxco, a company recently fined $3 billion for unconscionable deceptions, were quickly hired by European pharmaceutical companies after their fall from grace. At another level, Goldacre suggests that lawyers could hold liable those big-name, physician-academics that participated in accepting money for use of their name on ghost-written drug promotion articles. In my opinion, such things are late moves in the chess game.

What must happen, and I regret that Goldacre did not suggest this - when even a single patient has been seriously harmed because of the patently dishonest behavior of individuals in drug companies or in the prescribing community, they should be indicted on criminal charges. If convicted, the individuals should serve jail time. A few instances of jail time would stop the deceptive practices in no time. There would be no more rehiring of those who created harm. This is a valuable read for about $15 from Amazon. 4 stars.

Gun Violence vs. Medical Violence in Children

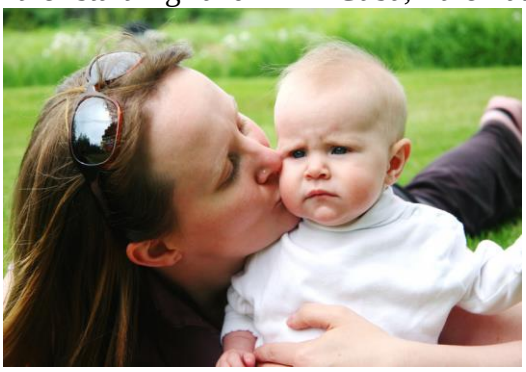
I think for most of us there is nothing we hold dearer than the children in our lives. Sometimes they frustrate us and try our patience, but children that are loved learn to give love in return. There is nothing as tragic as the unnecessary death of a child. An article in the *New England Journal of Medicine* on how we might reduce gun deaths impelled me to think about the way children die in our country.[1] By far the most common cause of death in our children is non-gun related accidents. But what cause is second?

The article shows graphically that about 6,500 persons aged 1 to 24 die each year in this country as a result of gun shots, whereas nearly 20,000 die from non-gun related accidents. Cancer comes in a distant third at about 3,000 young people per year and heart disease is fourth at about 1,500 deaths per year. Wait just a minute!

The truth is that the second leading cause of death in children 18 years old and younger is most likely unsafe medical care. In an article from almost a decade ago, two investigators looked at patient

safety indicators (PSIs) in discharge records from 5.7 million children that had been hospitalized in 2000 in 27 states.[2] They searched for patient safety events as manifested by excess length of stay in the hospital, unexpected charges for procedures, and in-hospital mortality. The authors noted that 4, 483 deaths occurred among patients that experienced a PSI event, which they assumed to be a contributor to death. If we now assume that the 27 states chosen were representative of the 50 states in the nation as a whole, then there are roughly 8,300 deaths in this pediatric group (4,483 x 50/27). The authors of the study note that "PSI algorithms can detect only a small portion of the types of the patient safety events that actually happen in hospitals." Our estimate may actually be too low.

Thus, we are left with the startling and generally unacknowledged conclusion that unsafe medical care in hospitals is at least a major contributor to children's deaths, second only to non-gun accidents. Of course, the next question is whether we as a nation are doing enough to quell the unsafe care that the children of our nation receive at the hands of the medical industry. Many of the PSIs were associated with birth trauma. With that, I cannot help but note that if our first-year infant mortality were as low as Japan's and the Scandinavian countries', 16,000 more babies would live through the first year of life in the United States. One cannot blame that all on our medical industry, but much can be placed at their doorstep because it is the free enterprise model of medical care that has locked out people who cannot pay.



Infant Mortality Close to Home

Speaking of infant mortality – might I ask you to name a third-world country very near the U.S. that has a slightly lower infant mortality rate than we do in our country. You might be surprised to learn that that country is Cuba. I am no communist; however, there are aspects of the healthcare system in Cuba that could inform the grandiose show that characterizes our healthcare industry. Two experts wrote last month about the model of medical care in Cuba.[3]

Everyone in Cuba has a primary care doctor and each doctor looks after about 1,000 people, at least in urban areas. There are no charges for medical care, not even co-pays. Each patient receives one home visit per year and emphasis is on prevention of disease. Health learning is a mandatory part of the education curriculum. There is one government healthcare system and no alternatives. Those destined to become doctors receive free education, but only receive about $20 per month in addition to housing and food subsidies once they begin practicing. The ban on American drugs has caused Cuba develop its own pharmaceutical industry to the point where it now exports therapeutic drugs.

Trying to make a point of limited resources in Cuba, the authors report that the current percentage of patients on dialysis in one region was only about 40% of that in the US. What the writer did not note is that far too many asymptomatic patients are placed on dialysis early in the US, and they subsequently die earlier than patients who waited for dialysis to begin.[4] In the U.S. dialysis is big business;[5] in Cuba it is what the patient needs when she needs it.

The authors note that the Cuban system "may inform progress in other countries." Of course the money-driven, "forget primary care and prevention" nature of the US system could learn from the Cuban system, but it won't. One physician writing in the *JAMA Internal Medicine* proposes policy changes that will restore primary care in the US.[6] He postulates that we must get primary care doctors better pay and less stress. How is that going to happen?

Dangers of Therapeutic Drugs

Although many drugs provide marked benefits to patients, there are also many ways that drugs, and the way they are marketed, can create dangers for patients. Let me begin by noting that FDA approval of a drug by no means affirms that it is safe, only that it is at least slightly more useful than dangerous , based on limited data. Patients then become guinea pigs as the drug is prescribed and its dangers gradually revealed. To avert this dangerous

reality, an MD proposed ways to quickly measure the value of what he calls "blockbuster" drugs (sales in excess of $1 billion per year) in formal studies involving 10,000 or more patients.[7] These studies would be conducted using some of the drug company profits from a blockbuster drug, but would be under the control of an independent agency – not the drug company. I like this idea.

On another front, one must wonder what mind-altering drugs our judges are taking. Since physicians are allowed to prescribe drugs off label (for unapproved purposes or patient groups) there is a perverse incentive for drug manufacturers to market drugs to physicians off label. Until recently this has been taboo; however, in December 2012 the Second Circuit of Appeals sided with a sales representative accused of off-label marketing.[8] The decision was based on the salesman's right to free speech. The sales representative had marketed the drug for unapproved disease conditions and for children and the elderly even though there was no evidence that it was safe or effective under these conditions. The judges' decision is outrageous.

Finally, even in the face of clear evidence that certain drugs are more harmful than effective, physicians continue to prescribe them. One example of this is the widespread overuse of antipsychotic drugs in nursing home patients.[9] These drugs have "marginal clinical benefits and serious side effects, including death" as noted by a team of investigators. The investigators compared the percentage of nursing home patients who were prescribed antipsychotics state-by-state. Texas was in the highest quintile (28% rate) and mountain states tended to be the lowest at 17-19%. The authors conclude that the geographic variations in prescribing rates suggest lack of an evidence-based approach to prescribing antipsychotics. In lay terms this means patients are getting drugs that are more likely to harm them than to help them.

Overpriced American Medical Care

Here I want to summarize opinions from experts about how the exorbitant costs of medical care in our country can be lowered to move our nation from the brink of insolvency. One article by a Stanford MD notes that Warren Buffett likens our health system to a tapeworm inside the US economy that drags down our global competitiveness and steals funding from many public needs such as public education.[10] I would go on to say that we have endured this tapeworm far too long, but we seem to be unable to have it controlled or removed. It is a growing monster that will collapse our economy if we do not change directions.

The writer sees a key role for physicians in dealing with the growing monster of medical cost. He points out that the Congressional Budget Office has two trend lines, one projecting that the national debt as a proportion of our gross domestic production (GDP) will rise to 90% by 2022 and the other projecting that it will fall to about 60%. The lower percentage is driven by several factors including the expectation that Medicare's payment rate for physicians' services remains constant. The writer notes that the difference in percentages is going to depend on whether Congress can withstand the medical industry's pressure to preserve its revenue. Thus, physicians can get on board with value-based medical care, or they can be part of the lobbying efforts to preserve and grow their income. Their choice will have a strong bearing on our country's economic health.

Another team of 4 MDs asked whether overuse and misuse of ambulatory health services has changed in the decade from 1999 to 2009.[11] They looked at 9 measures of underuse; for example the underuse of beta-blockers in patients with heart failure or anti-clotting therapy for atrial fibrillation. They also looked at 11 measures of overuse; for example, electrocardiogram screening in a general medical examination or cervical cancer screening in women over 65 years of age. They also looked at two misuse measures, one of which was inappropriate medications in the elderly. During the decade of the team's assessment, 6 of 9 underuse measures improved (more useful procedures were performed), only 2 of the 11 overuse measures improved and one got worse (useless procedures continued to be performed). One of the misuse indicators, inappropriate prescribing of drugs in the elderly, did not improve. The bottom line in all this is that doctors are not changing their overuse or

misuse habits in the face of clear evidence that this can harm patients and add to medical costs.

An MD proponent of the "Less is More" concept in medicine wrote about a new report from the Institute of Medicine (IOM) that describes how our nation can achieve better healthcare at lower cost.[12] Dr. Redberg points out that in the past decade personal income has risen by 30%, whereas the cost of medical care for a typical family has risen 76%. I'd note that the 46% difference is the feasting of Buffet's tapeworm. One aspect of the IOM report I liked was called "performance transparency," which is equivalent to healthcare consumers actually knowing how capable their doctor or hospital is and at what cost.

The 3 articles I discussed herein are targeted to the physicians' role in improving the value of healthcare, but the role of patients in achieving better value is essential. As a patient you must do your homework about any disease you have or may have, ask questions about any procedure recommended to you, get second opinions, be wise about the dangers of too much screening, and report adverse outcomes (medical and financial) to those responsible as well as to organizations that monitor these things. Do not feed Buffet's tape worm any more than absolutely necessary. It needs to starve.

Post-hospital Syndrome

We have all heard of the post-traumatic syndrome from which soldiers in combat suffer long after their combat duties are finished. An MD writing in the *New England Journal of Medicine* describes what he calls "post-hospital syndrome."[13] By this syndrome he means an acquired, transient period of vulnerability to illness not necessarily associated with the reason for the original hospitalization. He summarizes data showing that the cause of readmission to a hospital after treatment for heart failure, pneumonia, chronic obstructive pulmonary disease or GI problems is usually ***not*** directly related to the cause of the first hospitalization. He suggests that the cause of readmission is often post-hospital syndrome.

Anyone who has been hospitalized for some time knows what Dr. Krumholtz is writing about. As a hospitalized patient we are often deprived of sleep, must endure a disruptive schedule, may be denied adequate nourishment, and suffer from some pain. The writer makes several recommendations on how to minimize this syndrome – including better management during hospitalization of the following: delirium prevention, strength maintenance, nutrition, sleep, and chaos minimization. Furthermore, doctors also need to look for risk factors to patient wellbeing after discharge. Failure to do this has been called a medical error of context. **If you are looking after someone in the days after they have been discharged from a hospital, be alert for post-hospital syndrome. You could keep them from being readmitted.**

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Answer to question this month: c) 10%, based on a study in two large health systems it is 11%[14]