PSA

Patient Safety America Newsletter

January 2010 http://PatientSafetyAmerica.com John T. James, Ph.D.

Question: According to an article in the USA Today on October 22, 2009, by what percent has Pfizer increased its lobbying expenditures from the previous year when there was no healthcare reform agenda?
a) 28% b) 52% c) 78% d) 92% e) 126% f) 144%

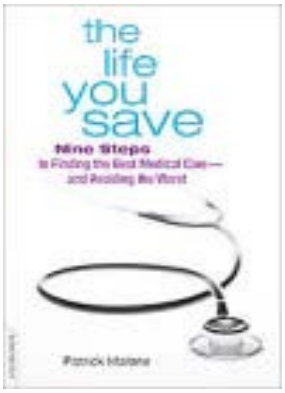
BOOK REVIEW

The Life You Save-Nine Steps to Finding the Best Medical Care-and Avoiding the Worst

By Patrick Malone

This is an exceptional book written by a Washington, D.C lawyer who has prosecuted many malpractice cases. From his decades of insight into what leads to malpractice and harm to patients, he has developed thoughtful ideas on how all Americans can avoid outcomes like those his clients have experienced. His writing flows easily from principles to examples, ending with what he calls "Lifesavers" posted in gray boxes at the end of most chapters.

Frankly, I wish I had known the steps Mr. Malone describes when my son was being treated by his careless cardiologists several years ago. Perhaps then I would be awaiting his return home for Christmas instead of taking my tears to a cemetery once again this Christmas. Do not suppose that the worst medical care will not happen to you or someone you love.



The author clearly "gets it" about the risk you face: "Medical catastrophes have been documented to so pervade the American healthcare system that a realistic risk of needless death or serious injury confronts every family in the United States at some point." The author squarely faces this reality, asserting that one must "take charge of their own health care and not merely turn their bodies over to an impersonal and broken medical industry."

The reader enjoys a journey of enlightenment and tragedy as the nine "necessary" steps emerge from this lawyer's experience: get your medical records, talk effectively to your doctor, find an excellent primary-care doctor, beware of drugs, understand the limitations of medical testing and get second opinions, carefully choose to have surgery, have an advocate with you at critical times, find a good hospital, and take responsibility for management of your chronic diseases.

Much of this is not new; however, Malone's presentation and perspective are refreshing and honest. For example, we are not given the glib statement that the quality of doctors varies. Mr. Malone dedicates a whole chapter to "steering clear of dangerous doctors." He points out what I learned the hard way: "When competence is at issue, only the most flagrant cases get a licensing board's attention." Because of lack of transparency into physician quality, the author recommends a defense that enlists an excellent primary care physician as your quality-assurance warrior.

His description of the quality of FDA-approved medications and the FDA's limited role in protecting you from bad medications should frighten even the most fearless, pill-popping patient. His bottom line: don't be a guinea pig; let someone else be the early users of any new drug unless you and your doctor agree that you have no other choice.

I'm comfortable with basic statistics, but I found the chapter on "understanding the numbers" to be a uniquely enlightening discourse. Mr. Malone explains how we (and often our doctors) misunderstand the value of screening tests. He emphasizes the risk of false positives (indication that there is disease when there is no disease) when low-risk populations are screened. He rightly asserts that to understand statistical information we must "count the people" in each category when we are

considering data. One way I do this when I give talks involves the statistics about infant mortality. For example, the one-year infant mortality in Japan is 0.3% and in the United States it is 0.7%. So what? What this means is that if the rate were as low in our country as in Japan, 16,000 more babies would live each year in America. Those are real babies with the hope of a real life, and they have been counted.

Malone's chapter on second opinions should impel you to always seek a second opinion if anything life-changing could be at stake. I trained as a PhD pathologist. Mr. Malone's comments on pathology are accurate. One day in graduate school I was discussing my research with a pathology resident while he was scoring Pap-smear slides for cervical cancer with a microscope. He quickly examined each slide and placed them in various piles, but never interrupted his technical discussions with me. To him the slides were simply work flow, but to the women from whom the smears were taken they could have been life or early death.

When it comes to finding a good hospital the task can be daunting as explained in one chapter. There are websites that give us a glimpse of extreme quality outliers, but typical sites are incomplete or highly limited in scope. The author does give us several search strategies to learn more about local hospitals, but do not get your hopes up for definitive data. The expectation is that one day we will be able to learn enough about hospitals we are considering that we can choose a high-quality institution. In the mean time, use the limited tools available, many of which are provided in this book. In fact, a strong point of the entire book is that it helps us find information on the web.

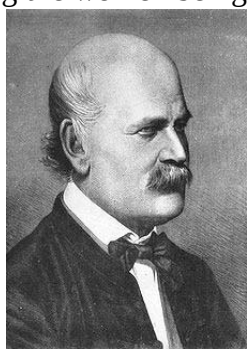
The next to last chapter "celebrates" the champions of patient safety and quality care. Several of these folks have experienced harm to a loved one and have set out to improve the broken system that harmed their loved one. Their stories are compelling. Others are professionals who recognize the problem. Here is a sobering quote: "Everyone thinks that the problem of mediocre and poor healthcare may happen to somebody else, but not to them. Their own care, many people think is pretty good. [Beth] McGlynn's work proves scientifically that we're all at high risk of poor care."

The final chapter outlines how to find a good malpractice lawyer. You need to read Mr. Malone's data if you think juries often sock innocent doctors with large awards. This is just not so. Of course, your goal must be to apply the book's nine steps so that you never need a lawyer. You may suppose that you do not need this book right now-perhaps so, but why not get a copy for a friend or family member who is struggling to manage a serious illness within our dangerous healthcare non-system**. 5/5 stars!**

Hand Washing!

A physician named Ignaz Semmelweis (1818-1865), working in Hungary 163 years ago observed that many more women died following childbirth if they had been cared for by a physician rather than a midwife.[1] He postulated that the reason for this difference was that physicians also worked in the autopsy room where they picked up something from the cadavers that put the women at risk when they were examined by a physician. He postulated, mostly based on elimination of the smell on the hands from the autopsy room, that washing hands with a chlorinated lime solution would diminish the risk to the mother. This was long before the germ theory of Louis Pasteur.

In May 1847 Dr. Semmelweis implemented his plan to reduce mortality among the women being treated in his hospital service. The mortality rate in April had been 18%, but by June this had fallen to 2%. Within a couple more months the mortality had fallen to 0%.[1] Unfortunately, the observations were not well accepted and Dr. Semmelweis was dismissed from his post and eventually sent to in an insane asylum where he died within a couple of weeks. These days Dr. Semmelweis is the name-sake for an organization of doctors very active in the patient-safety movement. These doctors are disgusted with the process of peer review that sometimes falsely punishes doctors who speak out for safe practices.[2]



Sadly, after all these years hand washing is still an issue in hospitals. Mike Mitka, writing a perspective article in the *JAMA* describes the problems associated with hand-washing compliance and the value of this practice in reducing the spread of flu virus in a hospital setting.[3] He notes that the Joint Commission estimates that roughly 1 in 140 patients in the United States become seriously ill

from hospital-acquired infection. Citing a study from 2001, Mr. Mitka noted that 80% of hospital staffers who dress wounds infected with methicillin-resistant *Staph. aureus* (MRSA) still carry the bacterium up to 3 hours later. As I noted in a summary article last month, typical hand hygiene compliance in hospitals is 30-70%. The goal of the Joint Commission is to "make available" interventions that will increase the compliance to 90%.

Barriers to implementation of hand-hygiene compliance include the time-lag between contact that delivers the infection and the clinical manifestation of an infection. Patients do not glow with contamination the instant they are contaminated. Another barrier is the inconvenience of hand washing by over-worked healthcare providers. One solution to this is widely-distributed hand-sanitizing dispensers containing an alcohol-based sanitizer.

I would add to the barriers to compliance something that was not mentioned in the article. There is essentially no individual accountability when patients become infected in hospitals. With multiple contacts with a variety of staff, there is no way to identify the person who infected a specific patient. At the hospital level, there is growing accountability, but even at this level, there are barriers to rigorous accountability for hospital-acquired infections. Many states require hospitals to report hospital-acquired infections, but few of the laws have provisions for validating the accuracy of reporting.[4]

We patients must be our own keepers. If you or a loved one is hospitalized, you have to insist that the staff always practice hand-hygiene. You cannot be shy about this. You may want to have a discussion before admission with the hospital's infection-control officer to assess their protocols for infection control. Look around the hospital for hand sanitizers – they should be everywhere. Ask staffers to sanitize their hands before they touch you.

A Decade after "To Err is Human"

This past month marks the 10th anniversary of the release of the landmark report "To Err is Human" from the Institute of Medicine. An invited commentary in the *Archives of Internal Medicine* points out two areas that were overlooked in the early responses to this report – disclosure of adverse events to patients and diagnostic errors.[5] The commentary discusses two new publications on these subjects that are in the same issue of the internal medicine journal and places some perspective on the hopes for improvement. There are many barriers to disclosure of adverse events, and most adverse events are not disclosed to patients. Those barriers include the fear of malpractice litigation, lack of protection for apologies, and limited physician training in disclosure techniques.

One report involved a survey of 600 patients that had been treated in hospitals in Massachusetts in 2003.[6] This survey turned up 850 adverse events, of which only 40% were disclosed to the patients involved. According to this report, when adverse events that have occurred in a hospital are disclosed to the patient, the overall quality-of-care rating of the hospital from patients is higher. One important observation from this study was that clinicians were less likely to disclose an adverse event if the impact on the patient lasted a long time. The authors note several studies that have shown the value of patient reports of adverse events.

A second scientific study gave attention to diagnostic errors. The definition of diagnostic error is a mistake that leads to a wrong diagnosis, a diagnosis that should have been made and was not made, or a delayed correct diagnosis. A team of investigators asked about 300 clinicians from 22 institutes to anonymously recall three diagnostic errors each and characterize their cause, seriousness and frequency.[7] The top three missed diagnoses were pulmonary embolism (blood clot in the lung), drug reaction or overdose, and lung cancer. Of the diagnostic errors reported, the doctors involved characterized them as 28% major, 40% moderate, and 31% mild.

> Testing for pulmonary embolism often differs from that recommended by evidence-based guidelines…A handheld decision-support system improved diagnostic decision making [20%] for patients with suspected pulmonary embolism in the emergency department.[8]

The authors note that their approach enables "tapping into a hidden cache" of errors that are not generally collected by existing reporting systems. This is an important point. My background reading took me to a report from the Office of the Inspector General of the Department of Health and Human Services published in December 2008.[9] This report surveys the hospital adverse-event reporting systems in all states. Approximately half (26) of the states have a reporting system; however, the reportable events are generally those listed by the National Quality Forum. Their list includes rather drastic errors (e.g. surgery on the wrong body part, infant discharge to the wrong person, injurious electrical shock, or sexual assault on a patient) but it does not include diagnostic errors.

Since diagnostic errors are a major contributor to the medical error problem and autopsies reveal between 10 and 15 % prevalence of diagnostic errors,[8] the reporting of adverse events needs some improvement. Why not insist that all diagnostic errors evident from autopsies be reported into the adverse event databases. Finally, the capture of this information needs to be done at the national level so that states like Texas, which had no adverse-event reporting law until 2009, are forced to take a systematic look at how healthcare is harming and killing their citizens.

Slow Death for a Dangerous Drug

A study reported in the *Archives of Internal Medicine* asked the question: How long did it take Merck to withdraw Vioxx from the drug market after convincing evidence was available showing that it increased risk of cardiovascular events (thromboembolisms) when compared to a placebo.[10] One might suppose that this should take no more than a few months, perhaps a year at the most. In fact, it was 3 ½ years after the cumulative data showed a 95% probability [the standard typically used to declare a finding statistically valid] that Vioxx was increasing cardiovascular risk.

This finding begs the question: Who is looking out for the welfare of patients? The drug maker's sales were roughly $2 billion per year, so we patients cannot expect the drug manufacturer to keep our best interests in mind. The Food and Drug Administration seems to lack the resources to follow studies of newly-introduced drugs to determine risks to patient safety. Perhaps we must heed the advice given in the book I reviewed this month: **Do not be an early user of a new drug unless you have to be.** Otherwise, you may be an unlucky guinea pig.

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Answer to Question this month: d) 92%