



Patient Safety America Newsletter

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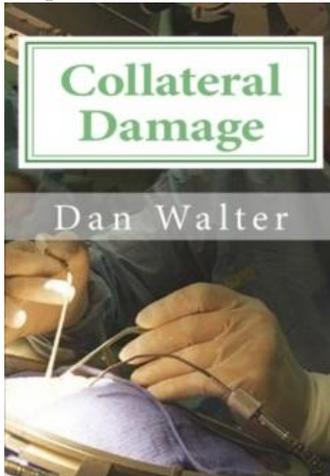
John T. James, Ph.D.

Question: The weakest level of evidence for a medical guideline is III, meaning it is based only on expert opinion. What percentage of guidelines from the Infectious Diseases Society of America is Level III?
a) 15% b) 25% c) 35% d) 45% e) 55% f) 65%

Book Review: **Collateral Damage**

By Dan Walter

This book joins others in the growing series of stories written by people who have watched a loved one suffer needlessly at the hands of the American healthcare industry. In this case, Dan Walter, a writer and political consultant, describes the dangerous treatment his wife received at a hospital regarded as one of the best *teaching hospitals* in the nation – Johns Hopkins Hospital.



Pam’s story unfolds in packets of events as the reader is carried forward and backward through her experience, starting with a botched pacemaker placement (not at Johns Hopkins) that caused years of pain to the main event, a botched catheter ablation attempt at Hopkins.

Catheter ablation is a process by which lines are inserted through a large vein into the right chambers of the heart. There are various hot tips on these things and the goal is to burn offending electrical pathways inside the heart (or major vessels) that cause atrial fibrillation (rapid heart beat in the upper chamber of the heart). The probe is guided by the cardiologist using marginal images of the heart to where he supposes the destruction should take place. And then the tissue is killed with heat.

In Pam’s case a quasi-experimental probe, which was used by an inexperienced operator who was supposedly being directed by a world class

Hopkins electrophysiologist, got entangled in muscle strands inside her heart. After several gentle attempts to remove the probe, a cardiologist decided to pull hard on the stuck probe. This shredded Pam’s mitral valve and left her in a desperately ill condition. She is faced with two choices: death with no open-heart surgery, or risky emergency surgery to replace her shredded valve.

Pam’s story is laced in with the stories of other victims of money-driven healthcare and ego driven physicians, along with pinches of humor and sarcasm. Sadly, it contains many of the elements that are hallmarks of the American medical industry: cherry-picking less-sick individuals for efficacy studies, desperate device manufacturers, two-faced promotion by doctors, off-label use of devices, callous and deceptive strategies to obtain ‘informed’ consent from patients, obtuse recording of events to obscure egregious errors, lost evidence, and blaming the equipment instead of the physician using it. Finally, the wagons are circled by cardiologists to protect their famous colleague from accountability. The Hopkins lawyers do their job in the end and get any case against the doctors pitched out.

As the Walter’s awful journey unfolds we are exposed to other known transgressions committed within this esteemed hospital: The death of Josie King, 18 months old, who died from dehydration and the death of Ellen Roche, 24 years old, from a dangerous inhalation experiment.

This book is an on-target indictment of dangerous, unethical, and money-driven factions within our healthcare industry. Many ill patients receive quality care in America, but far too many are also victims of the dark heart that poisons American healthcare. Read it. It could save your life. **5 stars.**
\$17.95 @ Amazon and \$7.98 @ Kindle

Cardiologists Ignoring Guidelines for ICD Implants

Reports of less-trained cardiologists ignoring evidence-based guidelines, and thereby placing their patients at higher risk of death, continue unabated. A team of 10 experts, mostly physicians, examined the registry records of 112,000 patients that had received an implantable cardioverter-defibrillator (ICD) in 2006 - 2009.¹ These devices employ an electrical shock to restore normal cardiac rhythm when the heart begins a useless rapid heartbeat called fibrillation. Restoration of normal rhythm saves the patient's life. I used to have a running buddy who had one of these implanted and he would never sprint because he was afraid of getting his heart rate so high that his ICD would deliver a shock. The investigators

asked if ICDs were being implanted according to published, evidence-based guidelines. Their findings did *not* shock me.

More than 25,000 of the ICD implants were performed out of compliance with well-known, evidence-based guidelines. The death rate in those given non-evidence implants was 3-fold higher than in those

who received implants according to guidelines. The range of percentages of non-evidence based implants in the hospitals studied was from 0 to 60%. Furthermore, the rate of performance of non-evidence based implants did not decrease during the 3 ½ years of the study. The authors noted that "These findings highlight the importance of continuing to enhance practitioners' knowledge of practice guidelines."

A commentary by two physicians calls for action based on the results of this ICD study.² Why was there deviation from guidelines? Does public policy need to mandate formal training in an approved fellowship program by those who would implant ICDs? They conclude that there is an opportunity here to improve patient outcomes and save money at the same time. To my knowledge there is no incentive to save costs by reducing the number of unneeded ICD implants because this

would be viewed as lost revenue by hospitals and doctors. **If someone wants to stick an ICD in you or someone you love, then ask what guideline is being followed and what training he has received to do the implant.**

Heart Attacks after Stent Insertion

A review article called "Myocardial Infarction Due to Percutaneous Coronary Intervention" written by two physicians disclosed the surprisingly high rate of heart attacks associated with insertion of stents into coronary arteries.³ These sleeve-like tubes, when used appropriately, can save many lives by restoring adequate blood flow to heart muscles. Stents are placed in about 1 ½ million Americans each year, and between 5 and 30% of the recipients show evidence that they have had a heart attack in association with the procedure. The thing we non-physicians call a "heart attack" is the death of some amount of heart muscle tissue because blood was not carrying oxygen there. Obviously, the amount of dead tissue depends on the amount of tissue that is denied blood by the blocked artery.

A "heart attack" can occur when placing a stent into a major coronary artery by several processes. The stent could block blood from entering a side branch off the 'stented' main artery, the stent procedure could dislodge plaque from the area and this could block downstream arteries, or the area of dislodged plaque could release chemicals that stimulate vessels to contract. The best way to determine if a patient has had a heart attack while receiving a stent is to measure cardiac troponin in the patient's blood. Troponin is a complex of three control proteins involved in regulating the contraction of muscle cells, in this case heart muscle cells. When cells die as a result of insufficient blood supply, cardiac troponin levels increase in the blood.

Many patients have elevated cardiac troponin levels before stent placement and these patients seem to be at higher risk for small heart attacks in association with the placement of a stent. Such patients should be given precautionary therapies (e.g. anticoagulants) before the stent procedure begins. The authors note that the patient should be informed of the risks of a large heart attack. If one does occur during the procedure the patient should be told afterward. Patients that experience a heart attack during the procedure are at higher risk for



adverse outcomes, so they will require more medical attention after the procedure.

So what does all this mean to you as a patient? First of all it means that having a stent stuck in a coronary artery is not without considerable risk. Ask if guidelines are being followed for placement of a stent into your heart. Very often cardiac stents are put into people who, according to guidelines, do not need them. Before the procedure ask your cardiologist to quantify the risk of the procedure for you. Ask, "How often does the stent placement cause a heart attack?" Ask if your cardiac troponin has been measured and whether it is normal or elevated. After the procedure is completed ask whether your cardiac troponin has changed. **You only get one heart (barring a transplant) so you need to look after it intelligently.**

One of the key tools to discern how your heart is doing is the electrocardiogram (ECG). This tool has been available for more than a century; however, there are still plenty of challenges in how the results are interpreted. For example, if a patient is not doing well after a stent placement, then an ECG can provide valuable information for the clinician.³ This month a new series has been introduced in the *Archives of Internal Medicine* that is intended to improve the ability of clinicians to interpret ECGs.⁴ The authors (two physicians) note that *misinterpretations* of ECG are not uncommon and that this can result in a "substantive impact on clinical care." They indicate that they are targeting improved education of early-career physicians as well as seasoned career physicians to improve their ability to properly interpret an ECG.

The authors suggest that by soliciting their colleagues to report misinterpretations of ECGs in journal articles, they hope to contribute to the new series in the Archives called "Less is More." A properly interpreted ECG can avoid expensive and invasive testing, such as a cardiac catheterization. To quote the authors: "By improving the accuracy of our diagnoses, we can save our patients, as well as ourselves, from further testing, inappropriate procedures, hospitalization, and emotional and financial stresses." **When you have an ECG make certain that the clinician interpreting it has experience. If there are any questions about its meaning, then get a second opinion. You only get one heart.**

Aspirin Cuts Risk of Cancer Death

Have you been taking a baby aspirin to cut your risk of heart attack or stroke? I used to do that until my internist advised that my risk was so low that the aspirin was doing me no good. In light of a new finding, I'm reconsidering that decision, not to protect my heart, but to reduce my risk of cancer. The new data come from a review of eight trials of aspirin use in more than 25,000 patients lasting at least 4 years.⁵ Let's look at selected results from the study.

In the seven trials that included individual patient data, the benefit after 5 years was estimated to be a 34% reduction in total cancer deaths. For gastrointestinal cancers the reduction was 54%. After 20 years the reduction in all deaths from solid tumors was 20% and for gastrointestinal cancers was 35%. To me these are impressive reductions.

Aspirin can cause gastrointestinal bleeding, but enteric coated aspirin should protect against this risk. You should read the literature to weigh the risk of taking aspirin vs. the risk of not taking aspirin. It does seem that the "baby dose" of 81 mg is sufficient to reduce cancer risk.

Methicillin-Resistant Staphylococcus aureus (MRSA) Hospital Infections

Not too long ago the Centers for Disease Control estimated that about 99,000 Americans die each year as a result of infections resulting from hospital care.⁶ To put this in perspective, this death rate is about 3 times the number dying from automobile accidents. This is a serious concern if you or a loved one is in a hospital, nursing home, or uses outpatient services. Several studies have shown that thoughtful management of patients can cut infection rates to near zero. Now we can add another study describing how to reduce MRSA infections by more than 90% in patients undergoing cardiothoracic surgery.⁷

The investigators (two MDs and an RN) describe their 5-step intervention program on approximately 2,500 patients as follows: 1) screen and decolonize all cardiothoracic staff, 2) screen surgical patients for MRSA and give appropriate antibiotics, 3) apply mupirocin ointment inside nose, 4) screen patients for MRSA before discharge, and

5) when removing chest tubes cover the exit wound with a large pad containing mupirocin.

The outcome was dramatic over the 3-year study period. The percentage of MRSA infections decreased from 1.16 % to 0.08%. A commentary on this study by another MD suggests that one cannot be certain which combination of the 5 interventions resulted in this favorable outcome.⁸ What is clear is that there are effective procedures to control MRSA infections after surgery. Implementation of these across the board in all hospitals will probably require a monetary carrot-stick approach. Pay hospitals a premium if they are successful in reducing MRSA infections. Refuse to pay hospitals for follow-up treatment of MRSA-infected patients when the hospital has given that infection to them. **If you or a loved one is having surgery, ask the hospital what their procedures are for control of MRSA and other infectious agents.**

Influenza-Like Illness (ILI)

We all have our strategies for escaping the flu during epidemics. Some folks get a flu shot in anticipation of an epidemic, hoping that these are effective against the actual strain of flu going around. Others vow to stay away from anyone who might be infected with the flu virus. That may not be easy if you are hospitalized during an epidemic.

A host of MDs just published a study designed to determine how much ILI increased in hospital patients according to their exposure to other patients or healthcare workers with ILI.⁹ The study covered three flu seasons (generally late fall through early spring) of 2004-2005, 2005-2006, and 2006-2007. There were 22,000 patients and 2,200 healthcare workers involved. The findings are given in the table below:

Exposure to 1 or more persons with ILI such as a:	Relative risk of infection compared to no ILI exposure
Contagious hospital worker	5.5%
Contagious patient	18%
Contagious patient and a contagious worker	35%

Given the suffering and death caused by flu, especially in older adults, this finding is important.

The authors call for more attention to limiting the spread of ILI in the hospital setting. This would include improved hand hygiene, use of masks and gloves, isolation of infected patients, and better vaccination of health care workers. If I were running a hospital I'd insist that no one show up for work with ILI as long as they want to keep their job. If I were ill during a flu epidemic I'd think twice about staying in a hospital. Of course, there are times when one has no choice.



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Answer to question this month: e) 55% (Lee, DH and O Vilemeyer, *Arch Intern Med* 171:18-22, 2011)