



Patient Safety America Newsletter

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John T. James, Ph.D.

Question: *Informed consent requires that a patient understand the benefits and risks of an invasive procedure. What percent of patients about to undergo a cardiac catheterization with possible stent placement have mistaken beliefs about the benefits of the procedure?*

- a) 10%
- b) 50%
- c) 90%
- d) 100%

Book Review: A Never Event – Exposing the Largest Outbreak of Hepatitis C in American Healthcare History

By Evelyn V. McKnight and Travis T. Bennington

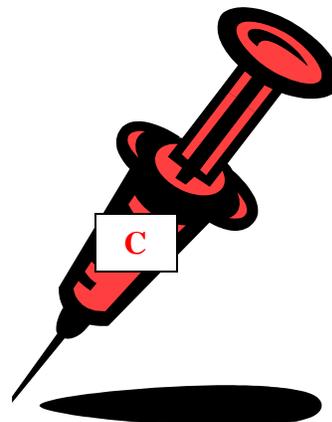
The horrifying story of harm to people who are already suffering from cancer is told by one of the victims (McKnight) and her attorney (Bennington) who represented 19 of the 99 known victims of this shocking miscarriage of healthcare and of justice. Their story unfolds in a small town in Nebraska where patients needing chemotherapy can enjoy the convenience of being treated in a local oncology clinic rather than having to commute into a larger city. The clinic is operated by an affable Pakistani doctor with good credentials from the U.S. medical community. His sidekick is a nurse with a less sunny disposition who protects her boss and his operation from accountability even in the face of overwhelming evidence that careless procedures are being practiced in the clinic.

The authors capture our attention as the mystery of a growing outbreak of hepatitis C begins to unfold in the community. At first there is disbelief that the half dozen patients initially discovered could be getting this virus from a place where people are supposed to be healed from disease. The finger of guilt begins to point unequivocally at Dr. Tahir Javed as more cases emerge and the only common factor is treatment in his oncology clinic. The reader experiences many of the elements of American healthcare that make it so poorly performing: promise of big money to a specialist, dangers of a solo practitioner, reckless care hidden behind a friendly facade,



falsification of medical records, a rigid clinic hierarchy, sexual misconduct, denial of obvious errors, obstruction by hospital administrators, an inept federal investigation, secret keeping and greed by the state of Nebraska, and finally an escape from justice for political reasons.

There is good news. Alert patients made key differences in how the reckless care was discovered and how the spread of the infection was more fully revealed. For example, the state epidemiologist, a physician, used a test to detect hepatitis C that was insufficient to detect the disease in immune-compromised people like those receiving chemotherapy. An alert patient and her lawyers were able to piece together his mistake, and then get



proper testing that revealed that many cases had been missed by the state's official investigation.

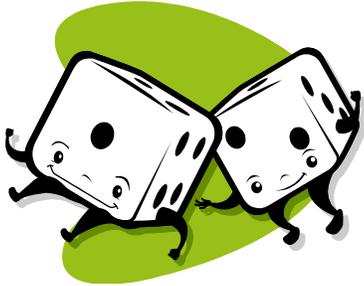
The story is well presented and reads like a mystery novel. The suffering caused by Dr. Javed's careless practices manifests itself as premature death in several patients. The reader is witness to the suffering. Death from liver failure is

ugly. The only thing uglier is lack of justice for healthcare killing. There is no lower form of human behavior than to knowingly harm a person who is already suffering from a serious disease like cancer. It is as if the Good Samaritan, instead of helping the badly injured victim of a roadside beating, walks over to him and kicks in his face. And those in power who know he has done this place a Band-Aid on the victim's broken face, turn their back, and walk away. You must read what becomes of Dr. Javed. This is a superbly told and troubling account of the darkness in American healthcare. **Read it so you'll never live it. 5 Stars.** \$16.95

<http://www.amazon.com/Never-Evelyn-McKnight-Travis-Bennington/dp/0980058287>

Adverse Events – The Dice Just Got Smaller

We are all familiar with the 6-sided dice used in many games of chance. The risk of harm while in a hospital has been reported as much lower than one in six by most agencies, perhaps about 1 in 30; however, a new study suggests that the dice by which we measure the risk of harm should only have three equal sides: no harm, no harm, and harm. Yes, you have a 1 in 3 chance of being harmed one or more times by the medical care you receive while hospitalized.



An investigation reported in the journal *Health Affairs* used a “global trigger tool” to identify harm to patients in the medical records of 795 patients that had been treated in one of three major (tertiary)

hospitals in October 2004.¹ All three hospitals had external funding for patient safety research, they had been using internal methods for detecting harmful adverse events, and they had received external recognition for patient safety initiatives. They had been trying.

The nature of the 393 errors detected were as follows: medication related, 150; procedure related, 109; hospital-acquired infection, 72; pulmonary (including embolism), 17; and all others, 46. If you are wondering why 393 is not $1/3^{\text{rd}}$ of 795, it is because many of the patients experienced more than one adverse event. The reason I provide this list is that when you are a hospital patient you need to be acutely aware of where the greatest risks are going to come from.

As if this were not bad enough, if you have been reading my newsletters, then you know that evidence of adverse events is often missing from medical records.² Furthermore, the lead author told me that the global trigger tool cannot detect diagnostic errors, which have been estimated to kill about 60,000 Americans each year.³ The authors of this study opine that “ultimately all adverse events may be preventable.” To me this suggests that such harm is due to medical errors and not random acts of fate.

Here is a video on the intentions of the pharmaceutical industry:

http://www.youtube.com/watch?v=AazObF_pHSU

Modern medical care is incredibly complex and the vast majority of doctors and nurses have every intention of keeping you from harm while hospitalized. Unfortunately, they are human. They become exhausted, they are distracted, they are stressed, they are not up on the latest evidence-based guidelines, and they are

overworked. They make many errors even with the best of intentions. One of your most important roles as a patient is to ask a lot of questions and insist on clear, reasonable answers. Make certain that your doctors and nurses know that you are keeping a written log of your hospital care and that you are looking at your medical records. Be vigilant for medication errors. Of course, you should do your homework on hospitals in your area before selecting the one to use, but precious little information is available to guide you to the best choice. The dice only has three sides no matter how much we all would like to think otherwise.

Dialysis Too Soon

A team of investigators have just reported in the “More is Less” category of studies published in the *Archives* that physicians may be jumping the gun in starting hemodialysis.⁴ The critical issues with hemodialysis include the balancing of four factors: 1) will the patient live longer if it is started earlier, 2) will the patient’s quality of life be better with an early start, 3) how much additional risk does early-start hemodialysis pose and 4) does an early start waste money? The answer, as it is so often exists in medicine, is that it depends on the overall health of the patient. So, let’s simplify things by looking at only relatively healthy patients aged 20 to 64 to see if the first two questions can be answered. That’s what a team of investigators did.

They compiled the survival time in 81,000 non-diabetic patients whose only other illness besides renal failure was high blood pressure. They divided the patients into four groups according to their glomerular filtration rates as follows: <5, 5-10, 10-15, and >15. Early start has been traditionally applied to those in the last two groups. Current guidelines without early start suggest beginning hemodialysis when the glomerular



filtration falls below 10.5.⁵ However, the 1-year mortality rates suggest that an early start may lead to a higher death rate.⁴ The 1-year mortality in the <5 group was 7%. These were patients clearly in need of hemodialysis. The 1-year mortalities in the other groups were shocking to me: 5-10 group-9%, 10-15 group-14% and >15 group-20%. This clearly questions the value of starting hemodialysis in patients with a glomerular filtration rates above 10, and probably also above 5.

As far as the misery caused by hemodialysis the authors note that it is “an invasive, lifelong, potentially dangerous intervention.”⁴ An editorial about this study suggests that we need to rethink when to start dialysis, and that we must consider that dialysis “includes a

substantial time commitment, frequent fatigue, and infections, among other things.”⁵ This editorial suggests that the start of hemodialysis not be based on the glomerular filtration rate. It should start when the patient’s natural symptoms become severe enough that they are worse than the consequences of hemodialysis.

My opinion is that the healthcare industry does not make money waiting for a patient to reach a glomerular filtration rate that is low enough to clearly warrant initiation of dialysis. The industry makes money by “early start” of dialysis. And, as you might expect, the average filtration rate for starting dialysis has increased to the point where it was 11 in 2007. The message here for patients is to recognize that dialysis can have serious adverse effects. **If dialysis is recommended to you by your nephrologist (kidney doctor), ask about side effects and if you are feeling OK, then tell him you would like to wait until you really must go on dialysis. Ask him what the risk of not going on dialysis might be and tell him you have read that patient survival can be shorter when placed on dialysis too early.**

Incidentalomas

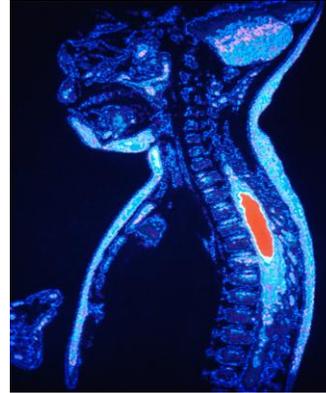
I can hear your outcry now - please not another big medical word! Let’s have some fun with this word, although the subject is quite serious. Three physicians writing in *Archives* coined this word to describe those findings in a CT scan that were incidental to the purpose of the scan and led to further testing.⁶ These findings are far more often than not false alarms causing the patient anxiety, physicians visits, testing, surgery, and loss of a small part of an organ from biopsy.

[This] reflects a problem at the core of American medicine: there is a self-reinforcing cycle that says health depends on testing more, finding more, and treating more...Our intense pursuit of diagnosis...is a defining characteristic of the American health care system. In fact it is why many people say we have the best medical care in the world. But to be brutally honest, we may simply be the most over-tested-and over diagnosed-people in the world.
Lisa M. Schwartz, et al.⁶

The authors note a story by a New York Times (NYT) columnist who experienced an incidentaloma. A ‘mass’ was seen on his kidney during a CT scan for lower back pain. He undergoes 4 days of hospitalization and a partial nephrectomy, only to discover that the mass was not cancer; it was mistaken identity. The NYT columnist is relieved at his “brush with death,” but the three doctors say no – this was not a brush with death, it was a brush with over diagnosis. Somehow the NYT

columnist and many of us would interpret the harm of over diagnosis as benefit.

The doctors give advice to patients in the face of



a possible incidentaloma. First, find out from the ordering physician if the ‘tumor’ has anything to do with why the scan was performed. Second, get a second opinion about the presence of the incidentaloma if you think that’s what it could be. Interpretation of images of organs can vary widely and

can often be wrong.⁷ Third, know that you do not need to act immediately. Perhaps, another imaging test a few months later will show if the incidentaloma is growing and requires invasive evaluation. Invasive diagnostic procedures can be harmful. Finally, reduce your risk of developing an incidentaloma by not having so many tests performed. If you suspect that your doctor is uncritically ordering a test, ask how the results of that test will affect your treatment.

Tainted Guidelines

If you have been reading my newsletters, then you know that I am a proponent of clinical practice guidelines to optimize patient care and safety. However, there are two major reasons to be cautious with such guidelines. Guidelines more than a few years old could be dangerously out of date and many guidelines have not been developed using satisfactory approaches to ensure an unbiased guideline. Some time ago I summarized an article that ranked some popular guidelines very low.⁸ A team of experts recently published a study asking how often experts writing guidelines have conflicts of interest. Their focus was on 17 guidelines from the American College of Cardiology/American Heart Association.⁹

An expert was deemed to have a conflict of interest if he received research funding, was listed on a speaker’s bureau, owned stock, or was a consultant to an advisory board of a company with an interest in the cardiology guidelines. Of the 498 experts surveyed, 56% had a conflict of interest. The total number of companies involved was 478, and the number involved in each guideline, through the experts with conflicts of interest, ranged from 2 to 242.

The authors point out that conflicts of interest are extremely important when guidelines are being developed because these are supposed to guide clinical practice across the nation and recent guidelines depend more on expert opinion rather than clinical trial data (real evidence). The next obvious question is whether there are experts available without a conflict of interest. The

investigators assert that there are sufficient experts without conflicts of interest to form panels for guideline development. One limitation that the authors mention is that their study did not address the fact that professional societies produce the guidelines and these societies typically receive substantial money from companies.

I have included this story to remind you that medicine is an imperfect enterprise littered with elements designed more to produce revenue than to heal patients. Guidelines are subject to biased influences. In my opinion, the scoring tool used to identify the highest quality guidelines should be used to rank the quality of all guidelines.⁸ This would help physicians and their patients identify the best possible care. Right now it's a bit of a crap shoot.

Our finding that most episodes of guidelines participation involve conflicts of interest, and that most individuals involved in producing guidelines report conflicts of interest, is a cause for concern.

Todd Mendelson et. al.⁹

Single-Payer Healthcare

I try to keep this newsletter out of political debates because the environment there is hostile. Here I want to describe what is going on in Vermont that may prove successful in guiding the nation's healthcare industry.¹⁰ It will be an experiment. Vermont wanted healthcare for their citizens that provided universal coverage, controlled the rate of cost increases, focused on primary care, and integrated delivery to patients. A team of experts at the Harvard School of Public Health was asked by the Vermont legislature to identify the best option for doing this. The constraints by stakeholders were severe and beyond the scope to characterize here. Basically, no one wanted to give up anything.

The Harvard group concluded that the best approach was a single-payer system that gives everyone a standard benefit package with uniform payment to all providers through a single payment mechanism. The immediate savings would be about 13% through administrative simplification and reducing fraud. Cost increases would be controlled by an independent board deciding coverage changes, paying providers for the number of people they cover (capitation) rather than per procedure, integrating the care systems, and having no-

fault malpractice. The experts estimated a savings of about 25% once all this goes into place.

The author of the perspective article points out that the system proposed in Vermont will never be as efficient as the ones already enjoyed by Taiwanese and Canadians. Federal laws and porous state borders ensure that limitation. One can only hope that, as this 'experiment' unfolds other states, perhaps this entire highly-polarized nation, can find the wisdom to follow the evidence to a functional, national healthcare system for all Americans. That is my dream, but sadly, I'd never bet on that happening.

References

- 1) Classen, DC, R Resar, F Griffin, et. al. 'Global trigger tool' shows that adverse events in hospitals may be 10 times greater than previously measured. *Health Affairs* 30:581-589, 2011
- 2) Weisman, JS, EC Schneider, SN Weingart, et. al. Comparing patient-reported hospital adverse events with medical record reviews: Do patients know something that hospitals do not? *Ann Intern Med* 149:100-108, 2008
- 3) Newman-Toker, DE and PJ Pronovost. Diagnostic errors-The next frontier for patient safety. *JAMA* 301:1060-1062, 2009
- 4) Rosansky, SJ, P Eggers, K Jackson, et. al. Early start hemodialysis may be harmful. *Arch Intern Med* 171:396-403, 2011
- 5) Johansen, KL. Time to rethink the timing of dialysis initiation. *Arch Intern Med* 171:382-383, 2011
- 6) Schwartz, LM, S Woloshin, and HG Welch. Not so silver lining. *Arch Intern Med* 171:489-490, 2011
- 7) PSA Newsletter, February 2011, p 4 (misinterpretation of heart echocardiographs)
- 8) Ferket, BS, EB Colkesen, JJ Visser, et al. Systematic review of guidelines on cardiovascular risk assessment. *Arch Intern Med* 170:27-40, 2010
- 9) Mendelson, TB, M. Meltzer, EG Campbell, et al. Conflicts of interest in cardiovascular clinical practice guidelines. *Arch Intern Med* 171:577-585, 2011
- 10) Hsiao, WC. State-based single payer health care – A solution for the United States? *N Engl J Med* 1188-1190, 2011
- 11) Schenker, Y and A Meisel. Informed consent in clinical care – Practical considerations in the effort to achieve ethical goals. *JAMA* 305:1130-1131, 2011

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Answer to question this month: c) A recent study found that 88% of patients have mistaken beliefs about the benefit of cardiac catheterization and possible stent placement.¹¹