

August 2015

<http://PatientSafetyAmerica.com>

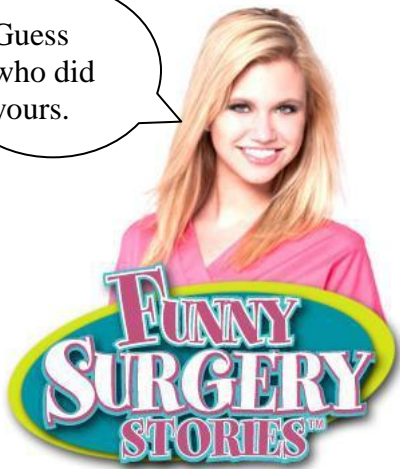
John T. James, Ph.D.

Question: The average per capita spending on healthcare in the U.S. is about 9,000. What is the per capita spending in India? a) \$50 b) \$200 c) \$1000 d) \$2000 e) \$5000

The Switch

All doctors that perform invasive procedures learned them in some sort of training program. When I was working on my PhD and relatively poor, I needed a gold crown on a molar, so I went to the dental school near my medical school and enrolled as a training subject. A dental student put in my crown, which cost \$19 for the gold, and I was delighted when the instructor called a group of dental students over to show them the excellent work my student had performed. The crown is still in place more than 40 years later. Subsequent procedures did not go quite so well, but I was awake during all of them.

Guess who did yours.



COMING SOON!
LAUNCHING MARCH 17, 2011

Now suppose you are considering treatment in a teaching hospital and need an invasive procedure involving general anesthesia. Who will do your procedure while you “sleep?” In an article entitled “Breaking the silence of the switch” written by an MD, the writer observes that patients may not be told that a trainee will be doing their surgery.¹ Generally, patients are less likely to agree to the

trainee doing the surgery if their involvement is made transparent. Patients do want to know who will do their surgery and if they are not told, then legally this constitutes battery on the part of the trainee and fraud on the part of the surgeon who elicited consent from the patient.

The writer suggests that by openly telling the patient that a trainee will be involved in their surgery and that “our” hospital is proud of its role and the patient’s role in helping young doctors learn, the patient is more likely to accept a role for the trainee. “The switch” is something patients must look out for when obtaining information to give their consent for a procedure. To my knowledge there are no studies about how often the patient is denied information about trainee involvement in surgery, but I personally know of people who have been seriously harmed when a trainee did their surgery without adequate supervision. They were never told that an untrained, unsupervised resident would be performing their surgery.

Overuse of Coronary Artery Stents

Trusted estimates place the waste associated with overuse of medical procedures in the U.S. at \$750 billion per year. In my opinion, the “poster child” for this waste is the overuse of angiography and stent-placement when the patient has stable heart disease. It has been well known for almost a decade that stenting coronary arteries in stable patients is not in the best interest of the patient.² In fact, some cardiologists have been prosecuted for doing this and many patients have died from unnecessary procedures; however, the procedure seems to go on.³ A recent study found that cardiologists do a poor job of fully informing patients about the value of angiography, which is the use of radioactive dye to visualize any obstructions in coronary arteries, and the possibility of stent

placement if an arterial narrowing is identified. You might want to look at the complications of this procedure just in case your cardiologist does not provide these ([Hopkins Medicine on Stents](#)).

A cardiologist tells the story of a 61 year old man that came to him for a second opinion after two physicians, one also a cardiologist, had recommended stent insertion to unblock coronary arteries.⁴ The man had experienced one episode of angina and came to the ER as a result. There the patient had felt “rushed, and uninformed.” He felt that all options had not been explained to him. The writer/cardiologist placed the patient on optimal medications and dietary improvements, noting that there was no scientific evidence that invasive procedures such as stents would benefit the patient. The patient’s cardiac profile, based on weight loss and blood lipids, improved greatly in 3 months. The writer observed that it is difficult to incorporate evidence-based treatments into practice.”

Painted larger, a group of experts studied completeness of information given to out-patients with stable, coronary-heart disease by their cardiologist.⁵ Completeness was assessed by the presence during the encounter of seven elements of informed-decision making. In all, 59 encounters were assessed in conversations from 23 cardiologists. Only 3 percent of the encounters included all seven elements of informed consent. Even with a less stringent definition of informed consent, only 14 % of the encounters were complete. Overall the decision to have angiography with possible stent insertion was inversely correlated with the number of elements of informed consent given by the cardiologist. Optimal medical therapy alone is known to benefit patients, yet this option was not discussed in 3/4th of encounters.

The lesson here for patients in all situations where an invasive procedure is being recommended is to know what you are getting into and ask questions until you do. Get a second or even third opinion if you do not fully trust those who would invade your body. Always frame your questioning in terms of your fears rather than in terms of your mistrust of the provider.

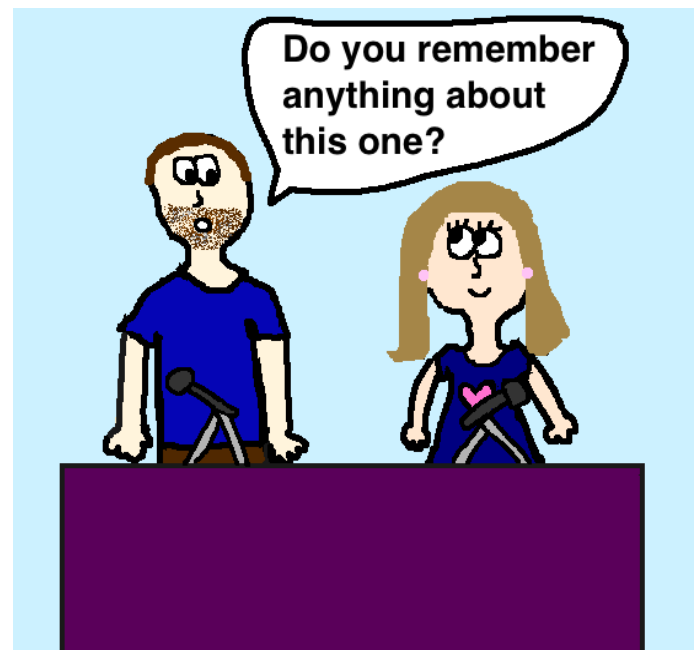
Do You Remember?

Those of us who are beginning to experience the subtle effects of cognitive deterioration might

well ask, “What can I do to slow this inevitable decline? A study published in *JAMA Internal Medicine* by a large group of researchers in Spain provides an partial answer. The team of researchers measured the cognitive changes in 334 subjects with mean age of 67 years over a period of 4 years.⁶ The subjects were recruited in Barcelona and were considered at high cardiovascular risk.

Cognition was measured before and after interventions by a large battery of tests that were ultimately distilled to three composite categories: memory, frontal cognition (attentiveness), and global. The interventions were as follows: Mediterranean diet plus extra-virgin olive oil, Mediterranean diet plus nuts, and control (advised only to reduce dietary fat). Although there were wide variations in individual responses to the interventions, the mean outcomes were interesting.

Inspection of figure 2 from the paper suggested that the control groups on average showed



a decline over 4 years in all three composite measures – memory, frontal cognition, and global. Overall the two intervention groups showed little change in composite scores over 4 years (there were no significant declines); however, the Mediterranean-plus-extra-virgin-olive-oil group showed *improvement* in frontal cognition. Due to my work at NASA, I have a passing familiarity with cognitive tests. These are tricky to administer and require careful control, such as the time of day they are administered. I did not see that degree of control in this study, but I think the findings make sense.

Kept Secrets

This spring the National Patient Safety Foundation called for greatly improved transparency into medical industry practices. One target for improved transparency is the common practice of

*Malpractice
Settlement*



imposing gag clauses on malpractice victims who settle. The primary purpose of this is to protect the provider (doctor or hospital) from public knowledge of the malpractice, and therefore maintain market share and reputation. A lawyer and two MD's performed a study of gag clauses in malpractice settlements in the University of Texas System (six campuses) before and after tort reform in that state.⁷ The authors note that the University of Texas System has a declared commitment to patient safety and transparency.

Overall, 124 settlements met the investigator's selection criteria. Of those 89% included non-disclosure provisions of some kind, although none allowed the amount of the settlement to be revealed. Perhaps most troubling to me were the findings that 46% of the settlements prohibited disclosure of the facts of the claim and 26% prohibited reporting to regulatory agencies. After tort reform (2009-2012) the non-disclosure clauses were stricter. There were more frequent restrictions on revealing the facts of the event and on reporting to regulatory bodies. In response to the study, the University of Texas System changed its policy on reporting to regulatory agencies. This can no longer be blocked.

The authors caution against generalization of their findings; however, as a Texan, I find the results deeply troubling. Writers of an invited commentary seem to see this in a different light.⁸ They admit that

“Cast in the light of buying silence about medical error, non-disclosure provisions appear unseemly.” They go on to point out that malpractice settlements seldom drive patient safety improvement compared to other drivers of improvement. Be that as it may, with tort reform, it takes a really high degree of malpractice in Texas for a provider to lose a case. In my opinion, malpractice judgments against a provider *do* provide a clue to a doctor or hospital service that should be avoided. Without public disclosure, uninformed patients can be needlessly walking into harm's way. Of course, malpractice settlements represent a tiny fraction of actual malpractice, so caution is always in order. Most recently, ProPublica has used the complication-rates of 17,000 surgeons to rate them ([surgeons rated](#)).

Decisions, Decisions...

Difficult decisions are common for patients that have a serious, chronic illness or a combination of illnesses. One “teachable moment” story in the *JAMA Internal Medicine* told of a 76 year old woman who had a carotid artery tumor discovered incidentally using CT angiography.⁹ Her doctors decided that this tumor, usually slow growing, should be CT scanned each year. The first follow up



scan surprisingly revealed a lung nodule. Since the woman had a history of tuberculosis, she was given a regimen of 4-anti TB drugs. Three days later she was admitted to the hospital because one of these drugs injured her liver; the drugs were stopped

and she recovered after 8 days in the hospital. She did not have active TB after all.

A discussion with the patient's family revealed that she would not have agreed to surgery to remove the carotid artery tumor. This means that the surveillance of the tumor using CT angiography was pointless, because there was not going to be any surgery regardless of the behavior of the tumor. Much harm to the patient could have been avoided if only she had been asked whether she would decide to undergo surgery if the tumor grew. The authors

point out that incidental findings using CT scans of the chest are common in older patients, and when these are investigated, less than 10 percent of the time does the patient receive a clear benefit. **There is a role for the patient’s advocate in this story. Make sure you know the purpose of testing. If it is to determine if surgery is needed and your patient will not agree to surgery, then there is no point in the additional testing.**

The story above was meant to kick off a broader discussion of decision tools – specifically decision aids. Last year the highly respected Cochrane Review published a review of decision aids.¹⁰ Last month a team of investigators published a study on decision aids for those with serious illness.¹¹ They found seventeen good-quality, randomized trials of aids and reported that most improved the patient’s awareness of the treatment choices. The patient’s illness ratings were from moderate to severe, but many of the aids studied are not presently available. The aids dealt with advanced planning, palliative care, feeding options in dementia, lung transplantation in cystic fibrosis, and truth telling in terminal cancer.

The authors noted that research in this area is still in its infancy, which explains why many of the results were “no impact” on patient-centered outcomes. **Anyone advocating for a seriously ill patient should ask if a decision aid is available, and must also do their homework using unbiased medical literature.** I have heard far too many stories of patient’s unnecessary suffering near the end of their life at the altar of medical interventions.

References

- 1) McAlister C. Breaking the silence of the switch – Increasing transparency about trainee participation in surgery. *N Engl J Med* 2015; 372: 2477-9. <http://www.ncbi.nlm.nih.gov/pubmed/26107052>.
- 2) Boden WE, O’Rourke RA, Teo KK, et al. Optimal medical therapy with or without PCI for stable coronary disease. *N Engl J Med* 2007; 356:1503-1574. <http://www.nejm.org/doi/full/10.1056/NEJMoa070829>.
- 3) Waldman P, Armstrong D, Freedberg S. Deaths linked to cardiac stents rise as overuse continues. *Bloomberg Business*, September 25, 2013.

- 4) Brown DL. The Recommendation for Stenting in Stable Coronary Artery Disease—Ignoring the Evidence, Excluding the Patient: A Teachable Moment. *JAMA Intern Med* 2015; 175: 1090-1. <http://archinte.jamanetwork.com/article.aspx?articleid=2294239>.
- 5) Rothberg MB, Sivalingam SK, Kleppel R, et al. Informed Decision Making for Percutaneous Coronary Intervention for Stable Coronary Disease. *JAMA Intern Med* 2015; 175:1199-206. <http://www.ncbi.nlm.nih.gov/pubmed/25984988>.
- 6) Valls-Pedret C, Sala-Vila A, Serra-Mir M, et al. Mediterranean diet and age-related cognitive decline – A random clinical trial. *JAMA Intern Med* 2015; 175:1094-1103. <http://www.ncbi.nlm.nih.gov/pubmed/25961184>.
- 7) Sage WM, Jablonski JS, Thomas EJ. Use of nondisclosure agreements in medical malpractice settlements by a large academic health care system. *JAMA Intern med* 2105; 175:1130-35. <http://www.ncbi.nlm.nih.gov/pubmed/25961829>.
- 8) Mello MM, Catalano JN. Should malpractice settlements be secret? *JAMA Intern Med* 2015; 175:1135-7. <http://archinte.jamanetwork.com/article.aspx?articleid=2293075>.
- 9) Nguyen LT, Sullivan CT, Makam AN. The diagnostic cascade of incidental findings – A teachable moment. *JAMA Intern Med* 2015; 175: 1089-90. <http://archinte.jamanetwork.com/article.aspx?articleid=2289128>.
- 10) Cochrane Review: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001431.pub4/abstract;jsessionid=BCA9377F5F0DA0F77E8DA28FD809907C.f04t01>
- 11) Austin CA, Mohottige D, Sudore RL, et al. Tools to promote shared decision making in serious illness- A systematic review. *JAMA Intern Med* 2015; 175:1213-21. <http://archinte.jamanetwork.com/article.aspx?articleid=2294238>.
- 12) Reddy KS. India’s aspirations for universal health coverage. *N Engl J Med* 2105; 373:1-5. <http://www.nejm.org/doi/full/10.1056/NEJMp1414214>.

Find past newsletters: <http://patientsafetyamerica.com/e-newsletter/>

Answer to question this month: a) actual is \$61. Life expectancy in India is only 66 years (reference 12)