PSA

Patient Safety America Newsletter

December 2009 http://PatientSafetyAmerica.com John T. James, Ph.D.

December Question: The obesity rate in the U.S. is 32 %, highest of 12 developed countries studied.[15] What was the obesity rate in the second-highest country? a) 30% b) 28% c) 23% d) 18% e) 13%

Reform Continuing Medical Education

Two PhDs writing a commentary[1] in the *JAMA* have at last said openly what I reported 2 ½ years ago in my book, *A Sea of Broken Hearts*.

Physician continuing medical education (CME) must be reformed to improve patient-care outcomes. The authors begin by recalling that a century ago undergraduate medical education needed reform because of several negative factors, three of which are now relevant to CME: 1) excessive commercialization, 2) lack of a standardized curriculum, and 3) absence of patient-centered orientation.

The authors note that those who deliver CME to physicians garner a high profit margin due to commercial sponsorship and more than half of their income originates from commercial interests. This makes CME more of a marketing tool than a source of balanced and thorough education.

The authors report that physicians have a wide choice in how to pursue CME and this can lead to loss of knowledge in core competencies. Curriculum must be standardized and maintenance of certification demonstrated through proctored examinations. I would add to this that the standardization must be specialty-specific and represent all that is new in that specialty since the previous certification examination.

Finally, the authors lament the lack of focus of current CME on improving patient healthcare outcomes. This is another way of saying that the translation of knowledge from clinically-relevant findings to use in the clinical setting for the patient's benefit is not effectively addressed by current CME. If you were to look at some current CME offerings, you would understand this problem. Try a Google search for CME and luxury cruises. Call and ask if participating physicians take an examination at the end of the CME course, and if so, ask how many fail the exam.

The authors proceed to discuss CME in terms of building human capital by improved quality and efficiency – something like an investment. The authors speculate that if physicians were paid for quality and efficiency in their practices they would naturally gravitate to CME in support of that goal. They also recommend that maintenance of certification (MOC) become mandatory for licensure. One interesting suggestion called for review of the electronic medical records generated by a physician to identify areas for improvement.

They suggest that medical specialty boards should take a greater role in sponsoring CME and

enforcing MOC. Finally, they suggest that many issues would disappear if physicians purchased CME with the goal that there would be a, presumably monetary, return on their investment.

I think the authors have been far too gentle on the current CME system. A huge portion of medical specialists have been granted lifetime board certification (pre 1990), which means that any MOC they do is voluntary. Very few actually do this. In 2005 more than half of all those board certified in cardiovascular disease by the American Board of Internal Medicine had lifetime certificates and only 2% submitted to voluntary MOC.[2]

From a patient's perspective, there must be no compromise in MOC if we are to trust that our physician knows what he is doing. Medical knowledge is increasing and changing at a rapid pace, yet the physician community has been content with a haphazard approach that has caused far too many medical errors. Six states have no requirement for CME[3] and in my home state of Texas only 1 % of CME is verified each year.[4]

I believe that a model patterned according to that for commercial pilots should become mandatory for all physicians. Briefly, teaching of new material becomes comprehensive, rigorous, and specific. Where pilots must demonstrate performance in simulators under adverse conditions, physicians must demonstrate competency in use, improvement and creation of medical records in difficult cases. Either kind of learner must demonstrate mastery of core skills and new information. Those who cannot are given a second chance to demonstrate mastery.

Combining MOC and CME makes sense to me. Since medical guidelines, the hallmark of evidence-based medicine (efficient, patient-centered care), have a half-life of 3-5 years, it makes sense to me to that combined MOC and CME be conducted biannually. The states and medical specialty boards could work together to make this happen.

One way I have proposed to motivate physicians to participate in MOC is to ensure that all patients have a right to know when their physician last completed MOC and/or CME. In a national survey, almost ¾ of cardiologists admitted that they had not completed maintenance of competency in the past 3 years.[5] Many patients would think twice about seeking care from a cardiologist who had not demonstrated competency in the past 3 years. Patients have a right to know their physician's competency status, or to trust that MOC is part of the licensure of all physicians. We patients have a long way to go before we trust that our doctors know what they are doing. Even Reader's Digest seems to have finally discovered this problem.[6]

Hidden within Randomized Trials

Randomized controlled trials (RCTs) are the backbone of how medicine decides what works in healthcare. Experiments are controlled by randomly sorting a large collection of patients with the same illness into two or more groups that, because of randomization, should be on average identical. Then different treatments or interventions are given to each of the groups to determine how well the patients' disease responds to each intervention. Often one group is given a

placebo so that the "placebo effect" does not confound results.

What becomes of unexpected observations suggesting that something dangerous can happen because of one of the treatments? One might suppose that these would be evenhandedly reported along with any favorable outcomes of the treatments. In an editorial entitled "Adverse events in randomized trials – neglected, restricted, distorted, and silenced" an MD argues that this is often *not* the case.[7] He begins by noting new evidence from an investigation that there are often unreported harms.[8]

The original investigating team identified 133 reports in six high-impact medical journals, and then surveyed the completeness of reporting of adverse events. They found that most of the articles mentioned adverse events; however, half of the reports lacked any data on the withdrawal of patients from the study due to adverse events. The

authors felt that there is a need for improving the way harms are reported in trials.

The editorialist digs deeper into the issue of underreporting of adverse events in RCTs. He provides a list of motives for such behavior, including failure to collect data on adverse events, restrictions on reporting adverse events, and out-right silencing of the evidence on harms. In terms of silencing, he cites the case of Vioxx in which aggressive marketing prevailed over scientific accuracy. He expresses fear that some believe that data on adverse events can wait until the drug is on the market and a huge number of patients take the drug. *Then* the harm to patients will become evident as it is slowly reported in medical literature or to the FDA. Based on this approach, we patients become the guinea pigs.

Blameless but Accountable

Two physicians, well known in the patient safety community, writing in the *New England Journal of Medicine* discuss the complex issue of balancing accountability for medical errors without over emphasis on ascribing blame.[9] They consider primarily conditions where the action or in-action of a physician places patients at known risk, but not the more complex subjects of clinical competence or disruptive behavior.

One example they mention is the 4,000 wrong-side surgeries performed each year in America, and then they note evidence that physicians often skip steps of the Universal Protocol," which is designed to prevent such mistakes through site marking and preoperative time-out.[9] As another example, the 100,000 deaths each year from healthcare-associated infections are largely preventable with rigorous infection-control practices such as hand hygiene; however, most hospitals' compliance with hand hygiene practices is between 30 and 70%. The authors call for more accountability for compliance.

They propose an evidence-based approach to determine if failure to follow a practice should result in punishment. The authors use hand hygiene as an example. Their prerequisites of evidence include consensus that the problem is important, the preventive strategy is effective, sufficient education has been provided, and there is consensus on how to fairly measure compliance. Having established this framework, the authors propose a warning for any initial infractions and then a 1-week suspension from clinical practice if repeated infractions continue.[9]

In my opinion, if a 1-week suspension does not elicit a complete change in behavior, then the physician should be suspended for 31 days. This is just over the limit required for hospitals to report a suspended physician to the National Practitioner Data Bank. The unfortunate fact is that such reports from hospitals are rare, and there is little or no punishment for hospitals that fail to comply with federal law to make such reports.[10]

The authors assert that "no blame" is not an option for "mature" patient safety practices. Indeed, the non-physician's view of physicians as professionals depends on the physician community assertively responding to such patient-safety imperatives through a system of accountability. There may be some devil in the details, however.

Suppose a physician routinely ignores hand hygiene practices. Who will report him? In most hospitals nurses are afraid to report physician infractions, especially if the physician is a big money-maker for the hospital. The patient, or his advocate, may observe what seems to be careless hand-hygiene, but they are not likely to be sufficiently familiar with the hospital's policy to recognize a violation. Perhaps one physician might "rat" on another physician, presumably after some colleague-to-colleague discussions. Unfortunately, the culture in hospitals is highly hierarchal, so lower-ranking physicians are going to be reluctant to confront or report a senior colleague.

The authors make an important proposal for professional accountability that could save many lives, but implementation, in my opinion, will require a culture change in most hospitals. I refer the reader to the book I reviewed last month called "High Performance Healthcare" to understand my point. The current hospital culture of separation of physicians from hospital team structure reduces the opportunity for accountability and patient safety.

Value and Cost

In a free society consumers purchase products based on their quality and cost. The American healthcare consumer is typically kept in the dark about both parameters, yet both are essential for making wise choices. In my opinion, this deficiency is what has allowed America to have one of the poorest-performing healthcare industries among developed countries, despite the fact that we pay far more per person than any other country for healthcare.

Two experts from the Mayo Clinic, writing a perspective in the *New England Journal of Medicine*, propose a seemingly-simple way to establish a value scale defined as "value = quality ÷ cost."[11] They propose assigning a value score to each medical institution so that patients can choose a "high-value" facility over ones that have lower value scores. One outcome would be to stem the common practice of physicians ordering unnecessary tests because of personal monetary gain. To obtain a high value rating a medical institution would have to maintain a patient-centered culture, offer coordinated care, and depend on physician leadership.

I like the simplicity of this idea, but implementation in a culture where physician leadership can be weak, where lack of transparency is the norm, and where patient feedback is seldom requested will be difficult. I am reminded of the Institute of Medicine book called "Crossing the Quality Chasm." Value-based medicine would provide a bridge across the quality chasm, but there is currently no sub-structure to support such a bridge. We have a long way to go before the quality chasm can be crossed.

The authors also make several suggestions including performance-based metrics, patient satisfaction scores, coordination of care among providers, and salary structures for physicians that discourage over-utilization driven by financial gain. I like the idea of listening to the voice of patients. I believe that quality care depends on rigorous learning structures when errors and near misses occur. Quality must also include accountability for what we can all hope is a dramatically-decreasing number of harmful medical errors.

Deficiencies in Drug Labeling

Two physicians wrote a disturbing perspective in the *New England Journal of Medicine* regarding information that your doctor may never see about the efficacy of drugs he prescribes to you.[12] Above I summarized an article on harms being omitted from drug testing reports. Here the authors note that the FDA reviewers often struggle to decide if benefits of a drug outweigh potential harms.[12]

They point out the example of Lunesta®, which was approved in 2004 for treatment of chronic insomnia. In the largest study of this drug the average fall-asleep time was reduced by an average of 15-minutes and the additional sleep duration was just over half an hour longer than the placebo group. Patients taking this drug still met the criteria for insomnia and were no more alert the next day than their counterparts given a placebo.

Enter marketing! You must have seen the advertisements unless you live on another planet. In 2007 the drug maker spent ¾ of a million dollars *per day* marketing Lunesta® directly to insomniacs. Nowhere on the label was there a statement of the effectiveness of this drug, only that it was superior to placebo. FDA approval means only that the drug works, not that it works well. The authors describe other examples where FDA labels fall short of communicating key information, and then conclude that "it (the FDA) needs a better way of communicating drug information to clinicians."

The message for you as a patient is to ask your doctor how effective your prescription should be, whether there are more effective alternatives, and how you can find out more about the drug's performance. You may not want to take something that is slightly better than a placebo.

Healthcare Choices in Canada Compared to the United States

You have no doubt heard the threats from those who would preserve our current expensive and inefficient healthcare industry: "You don't want a system like Canada's where you have no choice, there are huge delays in treatment, and the government tells you what treatments you can have." Let's examine the facts as described by two physicians.[14]

All Canadians are entitled to government-sponsored health insurance without cost or screening for diseases. Canadians can seek treatment from any physician in the country, although some specialists require referral from a primary-care physician. Canadians can change doctors and hospitals as they please – there is no insurer's preferred list.

For certain treatments not offered in all areas of Canada, the Canadian government will reimburse the cost of care in the United States if it is approved beforehand. Canadians do not commonly use elective health services in the United States as some suppose. Co-payments are unheard of in Canada. Some treatments (e.g. joint replacements) have been delayed in the past, but political pressure has resulted in reduced wait times for such procedures.

The bottom line seems to be that choice is alive and well in Canada, and may be thriving better than in the United States. Below I have provided some comparisons of healthcare outcomes in the two countries from a report of the American College of Physicians.[15]

Measure	**United States**	**Canada**
Infant mortality per 1000 live births	6.8	5.3
Life expectancy (years)	77.8	80.2
Obesity rate (%)	32.2	18
MRI machines per million persons	26.6	5.5
Annual prescription costs per capita	$792	$559
Annual per capita health spending	$6401	$3326

Expert advisors have recommended useful [healthcare] reforms in the past, but [the] pressure special-interest groups place on Congress usually blocks implementation.

Victor R. Fuchs in the *New England Journal of Medicine*[13]

References

1) Campbell, EG and M Rosenthal. Reform of continuing medical education. *JAMA* 302:1807-1808, 2009
2) Letter to me from the ABIM, August 18, 2005
3) AMA website
4) Letter to me from the Texas Medical Board, January 16, 2006
5) Campbell EG, S Regan, RL Gruen, et al. Professionalism in medicine: Results of a national survey of physicians. *Ann Intern Med* 147:795-802, 2007
6) Landau, MD. Is you doctor out of date? *Reader's Digest*, November, 2009, ppg 113-119
7) Ioannidis, JP. Adverse events in randomized trials. *Arch Intern Med* 169:1737-1739, 2009
8) Pitrou, I, I Boutron, N Ahmad and P Ravaud. Reporting of safety results in published reports of randomized controlled trials. *Arch Intern Med* 169:1756-1761, 2009
9) Wachter, RM and PJ Pronovost. Balancing "no Blame" with accountability in patient safety. *N Engl J Med* 361:1401-1406, 2009
10) Levine, A and S Wolf. Hospitals Drop the Ball on Physician Oversight – Failure of Hospitals to Discipline and Report Doctors Endangers Patients. Public Citizen, May 27, 2009, http://www.citizen.org/publications/release.cfm?ID=7659 (accessed 11/27/09)
11) Cortese, DA and JO Korsmo. Putting U.S. health care on the right track. *N Engl J Med* 36:1326-1327, 2009
12) Schwartz, LM and S Woloshin. Lost in transmission – FDA drug information that never reaches clinicians. *N Engl J Med* 361:1717-1720, 2009
13) Fuchs, VR. Four healthcare reforms for 2009. *N Engl J Med* 361:1720-1722, 2009
14) Ross, JS and AS Detsky. Healthcare choices and decisions in the United States and Canada. *JAMA* 302:1803-1804, 2009
15) American College of Physicians. Achieving a high-performance health care system with universal access: What the United states can learn from other countries. *Ann Intern Med* 148:55-75, 2008

Answer to December Question: The United Kingdom has the second highest rate-23%. Lowest is Japan at 3%. [15]