PSA

Patient Safety America Newsletter

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

Question: Atul Gawande, MD just wrote a book showing that use of a 19-point surgical checklist reduced deaths by 47% in eight hospitals around the world. What percent of American hospitals have adopted or are planning to adopt checklists? a) 10% b) 20% c) 30% d) 40% e) 50%

Medical Guidelines and Back Pain

Few of us reach middle age without one or more bouts of lower back pain lasting several days. Some of us will "tough it out" in hopes of self recovery or will use pain killers until our backs heal; however some will seek care from their primary care doctor. Will that doctor follow medical guidelines for your care, or will you receive "unendorsed" care? A team of investigators, set out to answer that question in 3,500 Australians who went to their primary care doctor for treatment of a new episode of lower back pain.[1]

Lower back pain has been estimated to be the fifth most common reason that Americans seek care from a general practitioner, and it is seventh most common cause among Australians. Something approaching $50 billion dollars are spent in the United States each year on treatment of lower back pain. Following medical guidelines is known to produce better outcomes and reduce costs.

Guidelines have been promulgated in several developed countries and the authors[1] identified five common elements in these guidelines. I want to focus on two of these: 1) do not routinely order radiological investigations, and 2) non-prescription acetaminophen is the pain-reliever of choice. Despite these explicit guidelines, the authors report that they are often not followed. Approximately one-fourth of patients are referred for imaging, primarily diagnostic radiology.

Forty percent of the time NSAIDs (non-steroidal anti-inflammatory drugs) are prescribed for pain and 20% of the time an opioid is prescribed in combination with acetaminophen or a NSAID. Only 15% of the time is the patient told to use acetaminophen alone, and this typically in a "suboptimal" dose.

The investigators asked whether declaration of a specific guideline for management of lower-back pain in Australia would change the prescribing practices of general practitioners. They compared compliance to multi-national guidelines (similar to one adopted in Australia) for the 3 years before (2001-2004) and for the three years after (2005-2008) local guideline publication. There was no discernable change in compliance with guidelines by primary-care physicians.

The authors conclude that new strategies must be found to educate primary care physicians in the use of guidelines and how to provide guideline-based care that is in the best interest of their patients and those paying for their care. You have a role to play. Do not insist on imaging if your doctor does not recommend it. If your doctor prescribes a NSAID or an opioid ask if a less risky pain reliever would be just as effective. Look at page 3 of the March, 2009 Patient Safety America Newsletter for information on NSAID risks and see the article below for information on the risks associated with use of opioids.

Dangers of Opioids

A perspective article appearing in the *JAMA* on the increasing number of deaths from accidental misuse of opiods hit home for me.[2] Twice in the past few years I have personally seen the parental

suffering caused by the death of an adult child in their early 30s due to accidental overdose of opioid pain killers. This not only robs a young adult of his life, it dooms their parents to live out their years with broken hearts.

The number of reported deaths from accidental misuse of opioids has more than tripled from 4,000 in 1999 to 13,800 in 2006. At the behest of the FDA, manufacturers of sustained release and long-acting opioids (the most dangerous form of the drugs) initially recommended that doctors who prescribe these drugs receive special training in their use before they are licensed to prescribe them.

At a recent stakeholders meeting many expressed concern that "onerous" training requirements would dissuade physicians from receiving training and they would quit prescribing long-acting opioids. The FDA representatives argued against a voluntary plan for additional physician training. Other experts got into the fray with their opinions, so at this point we are left with no changes in prescriber training and the prospect of continuing increases in the deaths of patients due to accidental misuse of opioids. One sensible plan proposed by The American Academy of Pain Medicine seeks a national database to improve prescription monitoring so that patients cannot get repeated opioid prescriptions from different doctors. In my opinion, this is a good plan and ought to be applied to opioids and all other unusually dangerous drugs as well.

Shake Salt Out

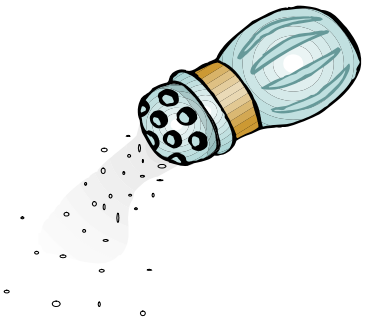
Most of my readers know that too much salt is not good for their health, but how much salt is too much? A new study published in the *New England Journal of Medicine* is not going to be reassuring to you.[3] The authors looked at how much salt we Americans consume, and then used a model to estimate the impact of that consumption on the collective health of Americans. The authors estimated that if everyone reduced salt intake by 3 g/day, the reduction in death rates would be the same as the death rate reduction due to current use of drugs to control blood pressure.

If Americans could reduce their daily salt consumption by 3 g (half a teaspoon), the number of annual deaths would be reduced by 44,000 to 92,000 persons, and the savings in healthcare costs would be in the range of $10-24 billion. One graph shown in an editorial[4] on the original paper shows that from the ages of 14 to 50 the daily salt intake of males (11.5 g) is double the recommended amount (5.8 g) for persons with no risk of salt-associated illnesses. For those with risk factors for salt-induced hypertension, the typical male consumption is three times the recommended amount (3.8 g).

The editorialists[4] point out that the United Stated has played a major role in funding research on the harmful effects of too much salt. Yet our country lags behind many others in translating findings of research into significant reductions in salt consumption. In other words *your* tax dollars are being spent on research, but our leaders have failed to act on the findings of that research to benefit *your* health.

The major sources of salt in our diets include processed food, especially processed meats (e.g. hot dogs, canned pork), canned vegetables, soups, and cereals. Other well known sources of high salt are pizza, cheese, pickles, and ketchup. One rather comprehensive list of sources is available on line.[5] As a person at risk for high blood pressure, I'm going to do all I can to reduce salt in my diet for a month to see if I can detect a reduction in my blood pressure. Please join me if you are at risk for high blood pressure.

In my opinion it is far past time to regard salt as a safe food additive – it is not safe. If someone proposed to add a substance to food that had the harmful effects of salt, the FDA would not allow it to be added. I propose that high-salt foods contain a clear and obvious warning just like alcoholic beverages and cigarettes. This warning would also extend to restaurant dishes with high salt so patrons could knowingly choose lower-salt dishes. For now, it's up to you to manage your salt intake as best you can.

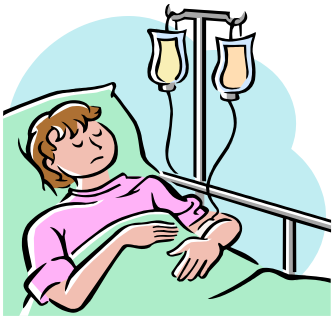


Overuse of Feeding Tubes in Patients with Advanced Dementia

A study published in the *JAMA* suggested a way to avoid potentially unnecessary medical intervention near the end of life for patients with advanced dementia.[6] The study involved a massive survey of 280,000 nursing home patients 66 years of age or older with advanced dementia that were admitted to acute-care hospitals from 2000 to 2007. Advanced dementia was defined by a Cognitive Performance Score of 4 or more. The score is complex, but to give you a feel for the degree of impairment, patients with scores of 4 or more are considered unable to be interviewed.

The investigators asked what hospital characteristics were associated with the insertion of a feeding tube into such patients. The frequency of feeding tube insertion varied widely, from a high of 39% of admissions to a low of no insertions. Of the 2,800 hospitals surveyed, 12% did not insert any feeding tubes in patients with advanced dementia.

The hospital characteristics associated with the questionable practice of feeding tube insertion were as follows: for-profit ownership, larger size, and greater use of an intensive care unit. For example, for-profit hospitals were on average 33% more likely to insert a feeding tube than government-run hospitals and larger hospitals (more than 310 beds) were 50% more likely to insert a feeding tube than smaller ones. One favorable finding was that the average percent of patients receiving a feeding tube decreased from 7.9 % in 2000 to 6.2 % in 2007.



If dementia is taking the life of someone you love, then you may want to consider an advanced directive specifying that a feeding tube should not be used to sustain that person if their dementia reaches an advanced stage. According to a study cited by the authors, most nursing home residents would rather die than live with advanced dementia and a feeding tube, yet about one-third of nursing home patients with advanced dementia have a feeding tube.

Medical Technology Should be Effective

It might surprise some of you that the Centers for Medicare and Medicaid Services (CMS) has not been rigorous in requiring evidence that a medical technology improves health outcomes before spending *your* tax dollars to pay for its use. A perspective article in the *New England Journal of Medicine* suggests that this is beginning to change.[8] It seems that by law the CMS is not supposed to pay for services unless they are reasonable and necessary. A decade ago CMS "clarified" this mandate by stating that a technology must be safe, effective, and lead to improved health outcomes. Exactly how one demonstrates improved health outcomes is debatable.

Each year the CMS releases national coverage determinations (NDCs) for about a dozen new technologies, of which a little more than half are typically approved, albeit with restrictions on how the technology is applied. The authors show that since the CMS started explaining the basis for their decisions in 1999 the flaws in the evidence submitted to CMS have been increasingly apparent.[8] One important NDC flaw is that evidence provided in support of use of the technology is not relevant to Medicare populations. This flaw has increased from 10% (2000) to 54% (2007) incidence. Another flaw that has been increasingly noted is the lack of relevant outcomes. This has increased from 36% to 58% of submissions over the same years.

The authors note that these national-level decisions affect a small portion of the technologies covered at the local level.[8] Given this limitation, the authors still feel that the trend is promising. It will lead to more intelligent spending of limited Medicare funds and prompt technology proponents to conduct research to demonstrate the effectiveness of their new technology if they want Medicare patients to use it.

The authors venture into troubled waters by concluding with an appeal for cost-effectiveness research to guide CMS decisions. They note that this can lead to emotional arguments that inflame thoughts of rationing and death panels. I would bet that many of those who want CMS to pay without regard to cost-effectiveness are precisely those who howl about our growing national debt.

Healthcare about You and for You

Patient-centered medical homes (PCMH) are the latest framework within which healthcare delivery hopes to improve patient care. A perspective article entitled "Lessons that patient-centered medical homes can learn from the mistakes of HMOs" was refreshing to me because it emphasized the role of the patient in her own healthcare inside the PCMH.[9]

The authors note that the failing of many HMOs was due to the perception that physicians were gatekeepers and that some physicians assumed that cost control was more important than improvement in patient care. Emphasis was on preventive care and following provider guidelines (not necessarily evidence-based medical guidelines). The PCMH vision is different.

A PCMH seeks to develop a strong patient-physician relationship, especially with primary-care physicians serving the PCMH. The primary care physician must become the *gateway* to specialized care within the PCMH, not the gatekeeper as was often the case with HMOs. PCMHs emphasize delivery of high quality care through use of information technology to keep the patient engaged and to offer multiple levels of communication. Patients pay a monthly fee plus a fee for services. One PCMH goal is to offer more transparent discussions with patients so that they are better able to make informed decisions about their healthcare. Ideally, this would reduce unnecessary interventions and save money.

The authors note that physicians must be "current in the medical literature" if they are to instill confidence in their patients who may have gotten marginal information from a variety of public sources. Early demonstration projects discovered that PCMHs require enlightened leadership to motivate the care team and to foster continuous improvement.

I like the PCMH model, but I am skeptical about its prospects for success. For example, is the PCMH going to pay each physician to keep abreast of best practice guidelines? If not, then what is going to motivate a busy physician to carve out time to remain current in medical literature? We know that the current continuing medical education structure for physicians falls far short of ensuring that physicians will deliver the best possible care to their patients.[10,11] I also envision problems when folks are traveling far from home (and their PCMH) and become acutely ill. I'd like to imagine that one day our entire country would be like a giant PCMH for all Americans. As my son would say to me, "Dad, if you are going to dream, then you should dream big. You don't have to be practical."

References

1) Williams, CM, CG Maher, MJ Hancock, et al. Low back pain and best practice care. *Arch Intern Med* 170: 271-277, 2010
2) Kuehn, BM. Safety plan for opioids meets resistance-Opioid-linked deaths continue to soar. *JAMA* 303:495-497, 2010
3) Bibbins-Domingo, K, GM Chertow, PG Coxson, et al. Projected effect of dietary salt reductions on future cardiovascular disease. *N Engl J Med* 362:590-599, 2010
4) Appel, LJ and CAM Anderson. Compelling evidence for public health action to reduce salt intake. *N Engl J Med* 362:650-652, 2010
5) http://oto2.wustl.edu/men/sodium.htm
6) Teno, JM, SL Mitchell, PO Gozalo, et al. Hospital characteristics associated with feeding tube placement in nursing home residents with advanced cognitive impairment. *JAMA* 303:544-550, 2010
7) Cognitive Performance Score (CPS) Calculator, Department of Health and Human Services, found at: www.uchsc.edu/hcpr/cmsforms/CMS-20084%20CPS%20Calc.doc
8) Neumann, PJ and SR Tunis. Medicare and medical technology – The growing demand for relevant outcomes. *N Engl J Med* 362:377-379, 2010
9) Mirabito, AM and LL Berry. Lessons that patient-centered medical homes can learn from the mistakes of HMOs. *Ann Intern Med* 152:182-185, 2010
10) Kuehn, BM. IOM: Improve clinician CME system. *JAMA* 303:716, 2010
11) Institute of Medicine. *Redesigning Continuing Education in the Health Professions*. National Academy Press, Washington, D.C., 2010
12) Rosen, D. Book Review: The Checklist Manifesto: How to Get Things Right. *JAMA* 303:671-672, 2010

Answer to question this month: a) only 10% of hospitals are using or considering using checklists[12]