PSA

Patient Safety America Newsletter

December 2011 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question**: Approximately $200 billion is spent each year world wide on medical devices. The U.S. contains about 1/20th the world's population. What fraction of the money spent world wide on medical devices is spent in the U.S.? a) 1/50 b) 1/20 c) 1/5 d) 1/2*

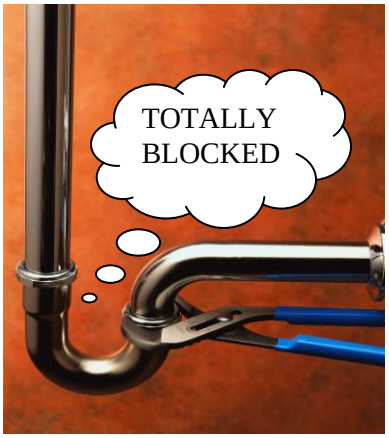
Blind and Deaf Arterial Plumbers

You have just survived your first heart attack and a couple of days later your cardiologist has told you that you have a coronary artery that is 100% blocked and he can try to unblock that artery to improve blood flow to a part of your heart that was damaged by the heart attack. That sounds reasonable doesn't it? **It isn't.**

As measured by lowering your risk of death, another heart attack, or heart failure, it is ***not*** supported by evidence or medical guidelines. Those guidelines are based on a major study paid for by the government – the National Heart, Lung and Blood Institute. That study was published in October 2006 in the *New England Journal of Medicine*,[1] and the revised guidelines were published in the *Journal of the American College of Cardiology* in November 2007.[2] The guidelines are explicit: "the procedure should not be performed."

> *The results of this study are a cause for concern on two levels. First, they imply that many stable patients with recent MI [heart attack] and persistent infarct artery occlusion continue to undergo a costly and ineffective procedure. Second, a large public, scientific, and human patient investment in the generation of robust clinical evidence has yet to broadly influence US practice.*
> Marc W. Deyell, MD et al. (in reference 3)

A team of eight experts, mostly MDs, set out to determine if publication of the study, and then later publication of the formal guideline changed the rate at which procedures were performed to open up totally blocked arteries resulting from a heart attack.[3] The study was called the "Occluded Artery Trial (OAT)." The investigators reviewed almost 28,800 records from 900 U.S. hospitals. The records pertained to patients included in a large registry of heart-attack victims undergoing this procedure from the beginning of 2005 until the end of 2008. Did publication of the OAT study in 2006 or the revised guidelines in 2007 change the rate of use of this procedure over the study period?



Heck no it didn't!

An odds ratio of 1.00 reflects no change in the rate of use of the procedure. The ratio was 0.997 after publication of the OAT study, and after the guideline was published the odds ratio was 1.007. These statistical numbers reflect no change in use of the procedure despite compelling evidence that it is of no value to the patient.

For those of us who believe that cost-effective care and patient safety go together, we might ask the following question: Why did the government sponsor a major study that showed clearly that an invasive procedure is not in the best interest of patients, yet that same government continued to pay for that procedure when done in patients? Of the 28,800 procedure documents examined in the study, 12,700 classified the "government" as the insurance payer. Almost 5% of the patients included in the study experienced complications including heart attack, cardiogenic shock, congestive heart failure, and kidney failure.

The authors of this study claim that the reason for "incomplete knowledge" transfer over the

time of the study is unclear; I disagree. I would argue that the way cardiologists undergo continuing medical education and competency assessment does not lead to most clinical cardiologists being current in their knowledge of cardiology[4] and that in our money-driven healthcare industry the patient's interests are often secondary to revenue generation. Furthermore, one must wonder what cardiologists told the patients to gain their "informed" consent. There is a serious ethical issue here beyond any issue related to cost and patient needs.

For additional perspective read "Over Eager Arterial Plumbers" in the July 2011 issue of this newsletter. **It's your heart and you better protect it from the cardiologists as long as you can.**

Coffee, Depression, and Women

On a day when I have less coffee than usual, I typically get a headache and feel sluggish. Many others I know experience similar reactions to caffeine withdrawal. A new study of more than 50,000 women asked if coffee consumption has a

bearing on the occurrence of clinical depression.[5] The women were followed for 10 years (1996-2006) and during that time 2,600 cases of clinical depression were identified. The authors found that risk of depression decreases with increasing consumption of coffee. For example, when those consuming one or less cups per day were compared to those drinking 4 or more cups per day, the risk of depression dropped approximately 20%. Consumption of decaffeinated coffee was not associated with a decreased risk of depression. The authors ask if coffee consumption might help to prevent some clinically-evident depression and suggest further study to confirm their finding.

Preventing Medical Harm in Older Adults

A commentary in the *JAMA* by two MDs suggests that current indicators of quality health care for older adults are woefully inadequate.[6] The authors note that older adults tend to have medically complex needs that may not be well addressed by current quality measures. Especially lacking are quality indicators that discourage inappropriate care. An example they use is over-aggressive treatment of marginally-high blood pressure. Such treatment can lead to dizziness and fainting spells (syncope) in older adults. I personally know of an older adult who had has this experience.

The authors venture into a sensitive area when they advocate taking into account the life expectancy of patients before initiating interventions. One example they use is screening for colorectal cancer. The benefit of such screening is understood to be realized about 7 years after screening because these cancers grow slowly. Consequently, such screening in persons with a life expectancy less than 7 years does not make much sense. They assert that medical systems with electronic medical records, such as the Department of Veterans Affairs, could rather easily predict the life expectancy of individual patients and avoid the risk of unnecessary procedures in older patients. Some time ago I summarized recommendations on colorectal cancer screening, noting that one expert group recommends against this for persons over 75 years of age. I like the idea of a personalized life expectancy profile based on current wellbeing, and ***not*** one driven strictly by age of the patient.

The MDs emphasize the need to prevent unintended harms in older adults. Two people come to my mind in this regard. After a fall at home, an elderly person I know was given Flexeril, a drug listed as potentially inappropriate for use in elderly patients.[7] This caused a kind of delirium, creating a dangerous condition during which he was harmed. Andy Rooney also comes to my mind. News reports tell us that at the age of 92 he died from "serious complications following minor surgery." Those of us who advocate for safer healthcare are impelled to ask: "Was the minor procedure necessary, and what serious complication led to the death of this famous curmudgeon?"

If you are advocating for a patient over 65years of age, do not hesitate to ask if a drug

prescribed to him has a high risk of side effects in someone his age. Ask if those who write prescriptions have considered the illnesses of the patient for whom you are advocating. Consult a pharmacist if you need detailed answers to these questions and possible drug interactions.

Two MDs introduced a concept that is new to me and makes sense.[8] They suggest that as the end of life approaches, a time-limited trial may be appropriate. By this the doctors mean that the patient can be placed on treatment with the idea that it will be given for a limited period of time to determine if it is effective in improving the patient's wellbeing. There are five steps to the proposed approach.

First, define the problem and prognosis; second, make certain the patient's goals are understood; third, identify objective indicators of improvement; fourth, agree on a time for reevaluation of the patient's condition; and fifth, discuss options at the end of the time-limited trial. Obviously, clear communication between clinicians and the patient (or his advocate) is the underpinning necessary to make this approach work. This approach may be worth proposing if you are advocating for someone who is near life's end.

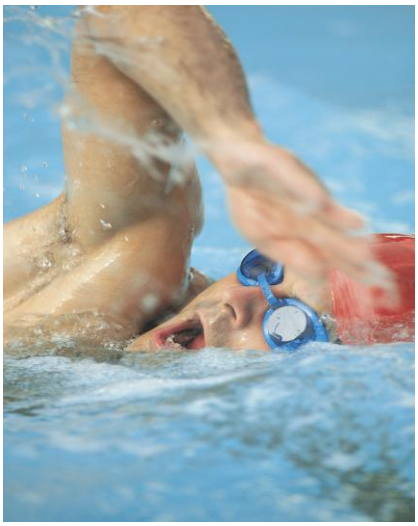
Quality Measures of Asthma Care in Children

Your child has just experienced an asthma attack so serious that hospitalization was necessary. What should you look for in the way of care as your child recovers in the hospital? The Joint Commission, a hospital regulatory body controlled by hospitals, has designated three major factors that define quality of care for children hospitalized because of an asthma attack. These are as follows: 1) drugs to relieve the acute exacerbation, 2) systemic corticosteroids to reduce inflammation, and 3) a complete home management plan.

A team of medical investigators used administrative records of more than 37,000 children treated in one of 30 children's hospitals to determine the level of compliance with these measures and whether compliance reduced post-discharge readmission to the hospitals or visits to the emergency room.[9] The good news was that the first two measures had a high rate of compliance, with the minimum rate during the study period of 97% for the first measure and 90% for the second measure. In fact the compliance was so high that the investigators could not determine if either rate had a bearing on the rates of readmission.

The "bad news" was that the average compliance with the third measure, a home management plan, averaged only 41%. However, failure to comply with this measure had no effect on the rates of readmission or visits to the emergency room 7, 30, or 90 days after discharge from the hospital. Compliance with this measure did increase over the time in which measurements were compiled, which was from early 2008 through the third quarter of 2010. Since the Joint Commission considers this a measure of quality care, it is important to discover that readmissions were not associated with failure to comply with this measure.

There are several possible reasons for the lack of association. For example, there is no indication how well the plan was implemented at home, nor could the investigators determine whether admission to another hospital other than the initial hospital had occurred. Patients, or their parents, may not have understood the plan and how to implement it. A commentary on this study notes that there is a "gulf" between patient centered plans involving coaching and timely follow up with parents and the mere existence of a written plan.[10] Finally, it may be that the readmission measure is insensitive to the quality of care a child with asthma receives at home. Perhaps it is time to search for other quality measures of care received by hospitalized children with asthma.



If you are the parent of a child with asthma that could become life-threatening, you should identify a nearby children's hospital that is more likely to follow quality measures than a general hospital. You should ensure that you understand the care plan given to you when your child is discharged. You do not want your child in a hospital any more often than absolutely necessary.

Discovering Dangerous Drugs

The chemotherapy drug Avastin has just been un-approved by the FDA for use in treating metastatic breast cancer. The drug works by inhibiting growth of blood vessels, which are essential for tumor growth. It received fast-track approval in 2008 by the FDA, but additional study impelled an expert panel to recommend that approval be removed for treatment of metastatic breast cancer, and last week the FDA followed this recommendation to remove Avastin's approval. Interestingly, this does not mean that you will not be able to get the drug prescribed to you if you have metastatic breast cancer only that it is unlikely that insurers will pay for it. Costs tend to be in the $100,000 per year range. Avastin remains approved for use in treatment of several other cancers. Why has it taken so long after the introduction and marketing of Avastin to remove its approval for breast cancer? A commentary in the *JAMA* addresses the general problem of post-marketing safety of drugs.[11]

In 2007 Congress gave the FDA more power to monitor the safety of drugs after initial approval. The FDA responded with a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of a drug outweigh the risks. REMS for a drug can include an FDA-approved medication guide to be given by professionals to patients if there is a significant public health concern, a communication plan to professional societies that targets risks of specific uses, and a plan that includes certification of physicians who would prescribe the drug. The commentators argue that there is concern about this process for the following reasons: 1) almost half of the REMS have included only a medication guide, 2) pharmaceutical manufacturers design the effectiveness program, and 3) there is little data on the effectiveness of the REMS program even though it is more than 3 years old.

The authors call on the FDA to provide more transparency into the success of the REMS program and strengthen its surveillance of post-market drug safety. It seems to me that the Avastin story reinforces their point.

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Answer to December question: d) 1/2[12] the U.S. spends about $95 billion each year on medical devices