PSA

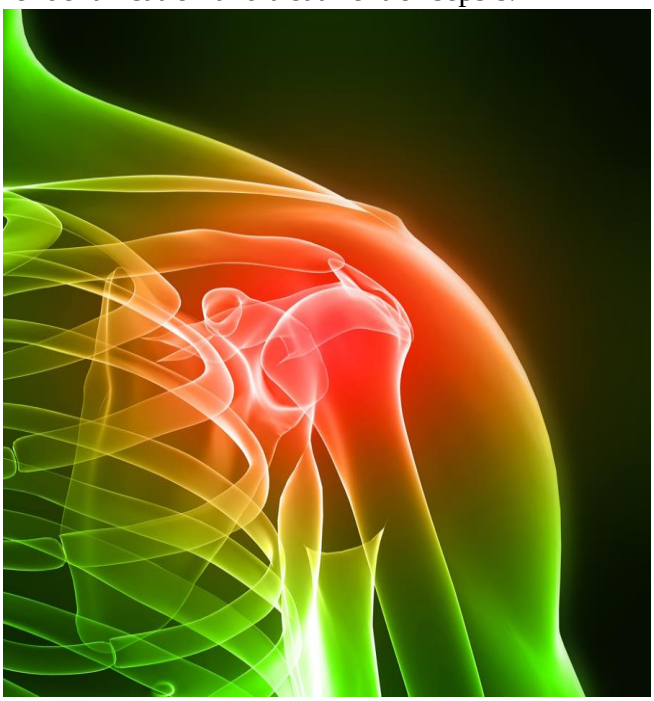
Patient Safety America Newsletter

November 2014 http://PatientSafetyAmerica.com John T. James, Ph.D.

***Question:** The most common cause of medication error in children in out-of-hospital settings is: a) wrong medication given b) medication given twice c) dispensing cup error d) took another's medication*

Is Sepsis in Your Future?

Sepsis is the inflammatory response to chemicals released in response to infection in a patient's body. It can quickly lead to multi-organ failure and death. Some have estimated that sepsis is involved in half of all hospital deaths.[1] Two MDs expressing their views in the *JAMA* call for specific mandates to improve the care of patients with sepsis.[2] You may recall some time ago that my newsletter had a story about a physician who had tried in vain to get the hospital where his mother was being treated to deal with her sepsis.[3] According to the *JAMA* article, sepsis has become the most costly and common condition that leads to in-hospital death. Yet almost two-thirds of hospitals fail to follow guidelines for the identification and treatment of sepsis.



The key factors in reducing mortality from sepsis are early recognition, proper antibiotic treatment, and fluid support. It seems that sepsis is underdiagnosed. This led the writers to call for better ways to make an early diagnosis and a learning culture to support the application of the latest findings. They called for the Centers for Medicare and Medicaid Services to get involved in pushing these changes, not with pay for performance, but with data sharing across hospitals. Innovation centers should be identified to develop research at the cutting edge of learning best practices for sepsis patients.

If you were a patient advocate, what would you look for in your patient that might suggest sepsis? The Mayo Clinic has the following approach to early diagnosis:[4]

To be diagnosed with sepsis, you must exhibit at least two of the following symptoms:

- ✓ **Body temperature above 101 or below 96.8 F**
- ✓ **Heart rate higher than 90 beats a minute**
- ✓ **Higher than 20 breaths per minute**
- ✓ **Probable or confirmed infection**

Be vigilant for any of these symptoms to appear, and if they do, accept no excuses for not giving immediate treatment, presumably with the appropriate antibiotic and fluid management.

Hyaluronic Acid Injections for your Painful, Arthritic Knee

A research letter written by three MDs in the *JAMA Internal Medicine* made the case that using hyaluronic acid injections for knee pain is a "low-value" approach to pain relief.[5] They used the Medicare data base from which they could extract the frequency of use of this procedure in various regions of the country. Overall in 2012 there were almost 1.2 million injections for which Medicare paid $287 million. Approximately 60% of the nearly

13,000 doctors performing the injections were orthopedic surgeons.

The use of hyaluronic acid injections was approved for pain in arthritic knees in 1997 by the FDA, but evidence since then suggests that this procedure has little value. In 2013 the American Academy of Orthopedic Surgeons declared this procedure should not be used because "it is not associated with clinically meaningful improvement in symptoms compared with placebo injections."

If this treatment is recommended to you, make certain that you have knowledge of all alternatives, including physical therapy and pain medications, before accepting such an injection. Ask your doctor to be specific about his rate of success in patients like you. Also ask about the risk of complications such as an infection. The authors of the study disclosed that they were unable to look for this sort of complication from such injections.

Varicose Vein Treatments

Varicose veins can be unsightly and eventually may become painful and cause risk of more serious medical problems; however, there are home treatments that can forestall the need for medical treatment.[6,7] The number of treatments for varicose veins in the US must be enormous, but I could not find a specific estimate.

A team of 19 British investigators asked how successful each of three types of medical treatment for varicose veins had been in a group of 800 patients treated at 11 medical centers in the United Kingdom.[8] They compared foam sclerotherapy, laser therapy, and surgery. The primary outcome measures were disease-specific and general quality of life 6 weeks and 6 months after the treatment.

The only outcome that was identified as worse for any of the procedures was a slightly lower disease-specific quality of life for patients receiving foam treatment. Procedural complications were much lower in the laser-treated group (1%) compared to the other groups (6-7%). Serious adverse events occurred with about the same frequency (3%) in all three groups. There are other ways to augment treatments and other studies have not necessarily been fully consistent with the results of this one. The message to patients is to ask many questions before you agree to treatment of your varicose veins. With some effort at home, you may be able to avoid the need for medical treatment.

How to Get Satisfaction

A team of investigators, most associated with the Johns Hopkins medical community, asked what the relationship was between patients' perception of shared understanding of their hospitalization and their degree of satisfaction with their care.[9] Questions to assess the knowledge of patients hospitalized at the Johns Hopkins Hospital in Baltimore measured how satisfied patients were with their care. Their overall understanding of their hospitalization was assessed by comparing their answers about their diagnosis, medications, and procedures with the documentation of their care, which the authors called "shared understanding." The investigators hypothesized that shared understanding and satisfaction would be correlated.

In fact, they found that only 40% of patients with the lowest perceived shared understanding were "extremely satisfied" with their care. At the other extreme, more than 90% of patients with the highest measure of perceived shared understanding were extremely satisfied with their care. The authors note that their findings suggest that patients value the information needed to have understanding of their care. In my opinion this study links two important facets of hospital care. Shared-understanding is a surrogate for informed consent, which is an often-neglected part of care. Furthermore, patient-satisfaction is related to patient-perceived quality of care, about which the hospital should care deeply. These are both at the heart of patient-centered care.

Tell it to Me Again

The most fundamental aspect of all science is that the findings of an experiment must be repeatable. Many years ago when I was performing cancer research, I did a complex and prolonged experiment using scores of mice each given 20 weekly doses of a radioactive carcinogen. The findings were stunning the first time around. I knew, however, that

I had to perform the entire experiment again to establish that my findings were repeatable. I did that over a period of many months and was relieved when the second experiment gave results identical, within the margin of expected error, to the first. I'm not sure what I would have done if the second experiment did not confirm the first.

Two MDs wrote an editorial in the *JAMA* expressing their opinion that the data obtained in a clinical trial of drugs on humans should be readily available.[10] This is because the cost of clinical trials is so enormous that such trials are not likely to be repeated. By making the data available, others can inspect the data and reanalyze it to determine if they reach the same conclusions as the original investigators. The writers lament the fact that this rarely happens in clinical trials. According to a companion article, 35% of the time reanalyses of the data leads to different conclusions than those of the original article regarding the types and number of patients that should be treated.[11] Reanalysis does happen in other sciences and it is time for clinical trials to be given the same transparency as other scientific studies. Until this happens on a sustained basis, be cautious about using newly approved drugs; there may be some secrets that have yet to be told.

Medication Errors in Children

From 2002 through 2012 almost 700,000 medication errors in children less than 6 years old were reported to the National Poison Database System. A team of investigators extracted the properties of the medication mistakes.[12] The reported medication errors dropped with increasing age of the child from about 180,000 in children less than a year old to about 70,000 in children aged 5 years. Almost all errors occurred at home or in another residence and were caused by a liquid formulation or a solid, such as pills. About 40,000 children were taken to a healthcare facility, almost 350 experienced a major adverse effect, and 25 of the children died from the medication error over a 10-year period. Half of the medication errors involved either a pain reliever or a cough-and-cold medication.

To put this harm in perspective, about 65 kids under 5 years of age are killed each year in the US in back-over accidents.[13] In 2013 about 44 kids (almost all under 5 years of age) were killed by heatstroke after being left in a vehicle.[14] In the year after Sandy Hook, about 35 children under the age of 5 were killed by gun accidents.[15] Although medication errors kill far fewer children than back-over accidents, left-behind children or firearms, parents have the responsibility to control access to medications and know what they are doing when administering them. Presumably, few if any medication errors in hospitals are reported to the National Poison Database System. We know these do harm to hospitalized kids, at least in Australia.[16]

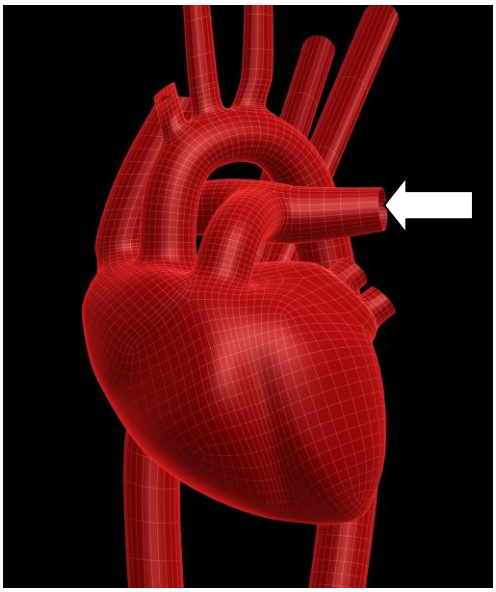
Information on Stents in Stable Angina

One of my favorite points of attack is the overuse of stents (called percutaneous coronary intervention [PCI] by cardiologists) for opening coronary arteries when the patient is stable. Another point I find easy to attack is the lack of information provided to patients so they can make an *informed* decision about their treatment. A couple of articles in the *JAMA Internal Medicine* gave me a chance to have a go at both deficiencies in medical care.

The first one analyzed forty encounters between cardiologists and their patients who were considering PCI in the years 2008-2012.[17] Their goal was to determine the quality and quantity of information imparted to the patient during the discussion. It seems that patients get the idea that PCI will decrease their risk of a heart attack and death, but substantial data show that this is not the case. How do patients get this mistaken understanding? Here are some of the insights. In only 2/40 cases did cardiologists explicitly tell the patient that PCI would not reduce the risk of heart attack or death. The main rational for the test (24/40) was an abnormal stress test. In 5 encounters there was explicit overstatement of benefits and in 14 there was implicit over-suggestion of benefits. One cardiologist described the "widow maker" type of heart attack and then asked the patient if he was married. Risks of the procedure were generally downplayed and quantitative information was rare.

In 30 of the 40 encounters the cardiologist's communication style was such that it discouraged patient participation, and in 14 of 40 encounters there were styles that encouraged participation. I asked the lead author if the known risks of subclinical heart attack were ever expressed by the cardiologist. She said that presumably this was not yet known during the survey period. In fact, studies have for many years found that PCI often causes an increase in troponin, a clear indicator of tissue damage to the heart.[18] The bottom line here is that cardiologists are not being consistently honest with their patients.

In a companion study a group of investigators read prepared statements to more than 1200 subjects considering PCI.[19] One statement said nothing about PCI's effect on risk of heart attack, one said that it does not reduce the risk of heart attack, and one explained why the risk is not reduced by using PCI. Seventy percent of the first group believed that PCI would prevent heart attacks, only 39% of the second group believed this, and just 31 % of the third group believed this. Across all groups the decision to undergo a PCI was strongly correlated with the belief that it would prevent heart attacks. The authors call for studies of optimal interventions to reduce the misconceptions that patients have about the value of PCIs. In my opinion, this is not going to be easy when PCIs are a major income producing procedure for cardiologists and hospitals.



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Answer to question this month: b) medication given twice, reference 12