

Patient Safety America Newsletter

April 2014

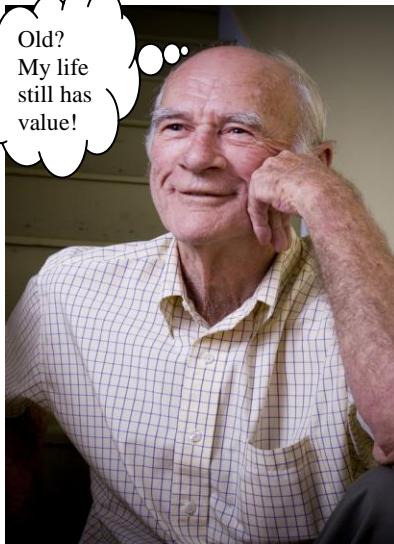
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John T. James, Ph.D.

Question: The FDA recently recommended less acetaminophen in combination prescription pain killers, but large doses are still available as over-the-counter medications (Tylenol). What bodily organ might an overdose of this medication harm? a) heart b) liver c) stomach d) eyes e) kidneys

Harm to Nursing Home Patients

Many of us have older relatives in Skilled Nursing Facilities (SNFs) and often see evidence that their care may not be optimal. The Office of Inspector General of the Department of Health and Human Services just released a report enumerating the adverse events that happen to residents of SNFs¹. A SNF is one where patients are cared for immediately following discharge from an acute-care hospital. A sample of 650 Medicare patients' medical records from the month of August 2011 was screened for adverse events and the preventability of those events was judged by physicians. The stays of the patients were all 35 days or less.



The investigators found that 33% of the residents experienced adverse events or temporary harm during their stay. Approximately 60% of those were judged to be preventable. Half of those experiencing harm while in the SNF were returned to an acute care hospital. Extrapolated from the month of August to a full year, the total cost of the adverse and harmful events in 2011 was estimated to be \$2.8 billion. The adverse and harmful events came as a result of substandard treatment, poor monitoring of SNF residents, and failure to provide care in a timely way. The authors conclude that nursing-home staff must be better educated in

recognition of adverse events and that the methods used to promote safety in hospitals be more utilized in SNFs.

This study points to a major flaw in the way the medical industry handles recovering patients once they leave an acute-care hospital. In my opinion, the most important single thing is that while in a SNF the patient must have a cognizant, assertive advocate to minimize the risk of harm. This is also true of acute care hospitals.

Meet *Clostridium difficile*

Clostridium difficile (C diff) is an opportunistic bacterium that can emerge in your GI tract when other bacteria in your body are torpedoed by antibiotics. Since C diff causes serious diarrhea in some cases, it can spread from person to person. In recent years the overuse of antibiotics has been linked to the increasing presence of C diff in hospitalized patients and in the pediatric population. A huge group of experts published a study in the journal *Pediatrics* in which they showed the



relatively high prevalence of C diff in children aged 1-3 years. Of the children that had diarrhea (about 10%), almost 3/4th had received an antibiotic in the previous 12 weeks.² Although the prevalence of C diff is low in little children, better antibiotic stewardship would reduce the number of infected kids.

Similarly, two MDs writing in the *JAMA Internal Medicine* call for improved stewardship in hospitals serving adults.³ They note that there is a

conflict between the potential need for the individual patient to receive an antibiotic and the need of society to restrain the spread of C diff by restrained use of antibiotics. When faced with the conflicting interests many doctors chose to honor the potential need of the individual patient over that of society. Thus, we are faced with increasing rates of C diff infections. The opinion-writers cite a study showing that a 30% reduction in use of broad-spectrum antibiotics would lead to a 26% reduction in C diff infections.

Before you allow your doctor to write a prescription for an antibiotic ask how certain he is that your infection is bacterial and if it is, whether a culture and sensitivity test might be used to determine which antibiotic would be best for you.

Do You Need a Transfusion?

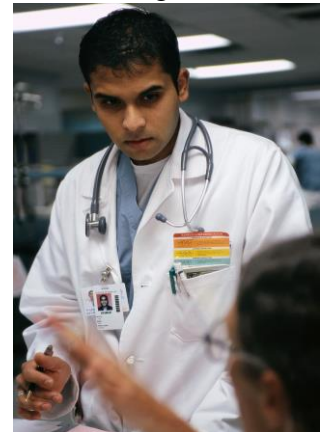
Studies involving religious persons who object to blood transfusions have shown that in some circumstances transfusions are not in the patient's best interest.⁴ A new study has just added to the body of literature suggesting that not only are transfusions unnecessary they can at times be harmful to patients. A team of medical investigators asked how well more than 2 million registry patients undergoing Stent Placement (Percutaneous Coronary Intervention, PCI) from July 2009 to March 2013 did with and without blood transfusions.⁵ Just over 2 % of the patients were given transfusions.

The comparison of adverse events showed **higher** risk in the transfused patients as follows: 3-fold higher risk of heart attack, 8-fold higher risk of stroke, and a 5-fold higher risk of in-hospital death. The investigators note that "thresholds for transfusion may have been driven more by local practice patterns than by clinical necessity." The authors caution that their study was retrospective (looking back) and that it points to the need for a well-conducted, randomized trial for patients undergoing PCI. I might point out that the term "local practice patterns" is a nice way to express "local need to make money from

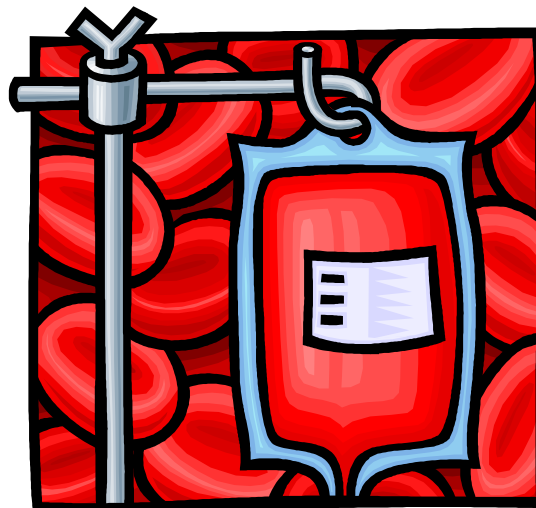
unnecessary procedures." If a transfusion has been recommended to you, ask about its necessity and the risks associated with it. You should receive this information during the consent process, but that is not a robust process in many hospital settings.

Infectious White Coats

It seems obvious to me that outer apparel, including the venerated physician's white coat, could foster transmission of infectious agents from patient to patient in many clinical settings. Based on accumulating data that white coats have been shown to carry a wide range of bacteria, including well known, drug-resistant strains, the Society for Healthcare Epidemiology of America has issued voluntary guidelines on how to mitigate the risk of patient to patient transmission on outer clothing worn by physicians.⁶ These include doffing the white coat before seeing each patient, a



bare-below-the-elbow policy, daily laundering of outer wear, and cleaning stethoscopes and anything else that touches patients between patients. As an empowered patient, you may want to ask not only about hand washing practices where you are about to be seen and treated, but also about policies on cleanliness of outerwear.



Too Much of a Good Medication

Since the FDA has had limited success in persuading drug makers to lower the dose of acetaminophen (Tylenol) in combination, prescription pain killers, it has issued an appeal to physicians to quit prescribing the medications the FDA considers too risky.⁷ Three years ago the FDA told drug manufacturers to limit the amount of acetaminophen to 325 mg/tablet, but the response has been incomplete. The reason for FDA's concern centers on liver damage so serious that it could lead

to the need for a liver transplant. In the prescription form acetaminophen is often combined with opioids.

Mixing the drug with alcohol is especially risky. There are about 20,000 visits to the emergency room each year due to unintentional overdose of acetaminophen. The FDA plans to ban the high dose medications. In the meantime, ProPublica has pointed out that some non-prescription forms of acetaminophen contain 625 mg/tablet.⁸ Yet it seems that the FDA feels little urgency to restrict the amount of drug in each over-the-counter, extra-strength Tylenol to 325 mg.

The wise user of this drug will never drink alcohol while taking it and will restrict the daily dosage total to less than 6 tablets per day. Any other risk to your liver, such as Hepatitis C, would further reduce the amount allowed. In my opinion, smaller adults – say 120 lbs. – should take much less of the stuff than larger adults – say 250 lbs. One size does not fit all when it comes to drugs.

Surgical Site Infections after Out-patient Surgery

A group of five investigators asked how often ambulatory patients that received surgery outside the acute hospital setting subsequently developed an infection at the site of surgery that impelled them to return to the surgical center or a hospital for treatment. They looked for evidence of infections that occurred within 14 or 30 days of surgery in almost 300,000 records from 8 states in the year 2010.⁹ The percentages of returns for infection was low – 0.3% within 14 days and 0.5% within 30 days. This strikes me as surprisingly good news; however, the investigating team pointed out that because such infections are serious, quality improvement is needed to mitigate the harm to unlucky patients.

Back from the Dead

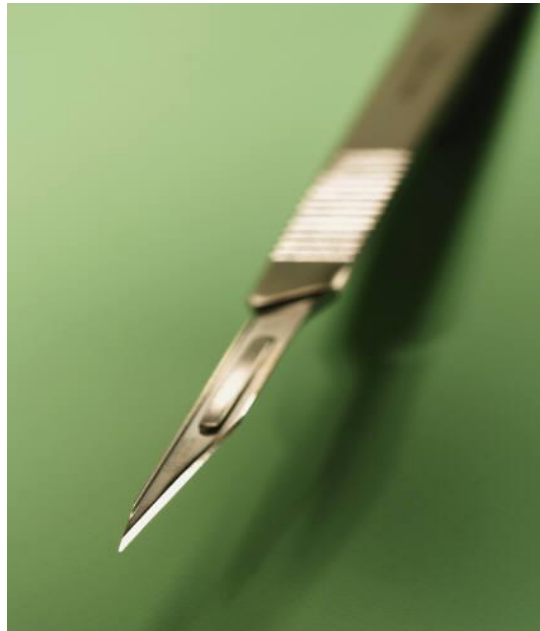
Suppose you could possess a kit that would bring back someone from the dead; would you keep it handy? Proponents of such a kit for use on people

who have ingested a lethal dose of opioid pain relievers are active in North Carolina.¹⁰ “Project Lazarus,” as their effort is called, is working to make available kits with naloxone to those looking after folks with chronic pain relieved by opioids. Naloxone is also a powerful antidote for heroin overdose. The drug, when injected or inhaled via a nose spray, blocks the cellular receptors for opioids and thereby heads off the respiratory depression that kills half as many people as automobile accidents do each year. The antidote kit is cheap by medical standards (less than \$50 for the nasal spray). Naloxone causes no important side effects, although it can cause rapid withdrawal of the beneficial effects of the opioid – that is, the relief of pain disappears.

Avoiding Hospital Dependency

Two MDs writing in the *New England Journal of Medicine* call attention to the fact that 1/5th of Medicare patients are readmitted to the hospital within 30 days of their discharge and the “system” needs to do a better job of managing what they call “hospital dependent patients.”¹¹ Many of these readmissions are caused by poor transitions from the hospital, to include: improper handling of medications, poor access to medical services after discharge, and lack of a clear line of authority as to which clinician is in charge of post-hospital care. Medicare is dealing with these shortcomings, which I would call medical errors of context, by economic punishment to hospitals when patients have to be readmitted within 30 days for a list of medical conditions.

The writers point out that this approach overlooks those patients that are best off remaining in the hospital. These are very ill people who require services that provide immediate, acute care when a new crisis appears. When not in crisis, these patients may be expected to enjoy a decent quality of life by building relationships with staff and by visits from family and friends. They are not ready to enter hospice care, although they are terminally ill. Their medical needs are also greater





than most “skilled nursing facilities” can handle. The writers call on healthcare systems to find a way to deal with such fragile folks, but the costs are not going to be small. We all know that dying in America is not easy and it is usually not cheap.

In my opinion

Medicare needs to acknowledge such patients’ existence and develop policies to help them live out their last days with dignity – in or out of a hospital.

Infection Traced to Endoscope

Nine people in northeastern Illinois were infected over a 4-month period with a resistant strain of E coli, and most of these were found to have received hospital care at a specific location. There it was discovered that the usual disinfectant protocol

for sterilization was being followed, but the hospital decided to begin sterilizing endoscopes with ethylene oxide gas. This should kill any resistant strain of bacteria, and at this point no new infections have been discovered. If you plan to have a procedure involving an endoscope, find out how the device is sterilized.



Find past newsletters:

<http://patientsafetyamerica.com/e-newsletter/>

Answer to question this month: b) liver, reference 8

¹ Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries. Report OEI-06-11-00370, February 27, 2014

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³ Flanders SA, Saint S. Why does antimicrobial overuse in hospitalized patients persist? JAMA Intern Med 2014; in <https://jamanetwork.com/collection.aspx?categoryid=5613> accessed 31 march 2014

⁴ Pattakos G, Koch CG, Brizzio ME, et al. Outcome of patients who refuse transfusion after cardiac surgery. Arch Intern med 2012; 172:1154-1160

⁵ Sherwood MW, Wang Y, Curtis J P, et al. Patterns and outcomes of red blood cell transfusion in patients undergoing percutaneous coronary intervention. JAMA 2014; 311:836-843

⁶ Kuehn BM. Time to hang up the white coat? Epidemiologists suggest ways to prevent clothing from spreading infection. JAMA 2014; 311:786-787

⁷ Mitka M. FDA asks physicians to stop prescribing high-dose acetaminophen products. JAMA 2014; 311:563

⁸ Gerth J and Miller TC. Over-the counter pills left out of FDA acetaminophen limits. ProPublica, January 16, 2014. <http://www.propublica.org/article/over-the-counter-pills-left-out-of-fda-acetaminophen-limits> Accessed 23 March 2104

⁹ Owens PL, Barrett ML, Raetzman S, et al. Surgical site infections following ambulatory surgery procedures. JAMA 2014; 311:709-716

¹⁰ Kuehn BM. Back from the brink – Groups urge wide use of opioid antidote to avert overdoses. JAMA 2014; 311:560-561

¹¹ Reuben DB, Tinetti ME. The hospital-dependent patient. N Engl J Med 2014; 370:694-696