

Patient Safety America Newsletter

June 2014

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John T. James, Ph.D.

Question: On average, what percentage of ill children is injured while receiving medical care in hospitals?

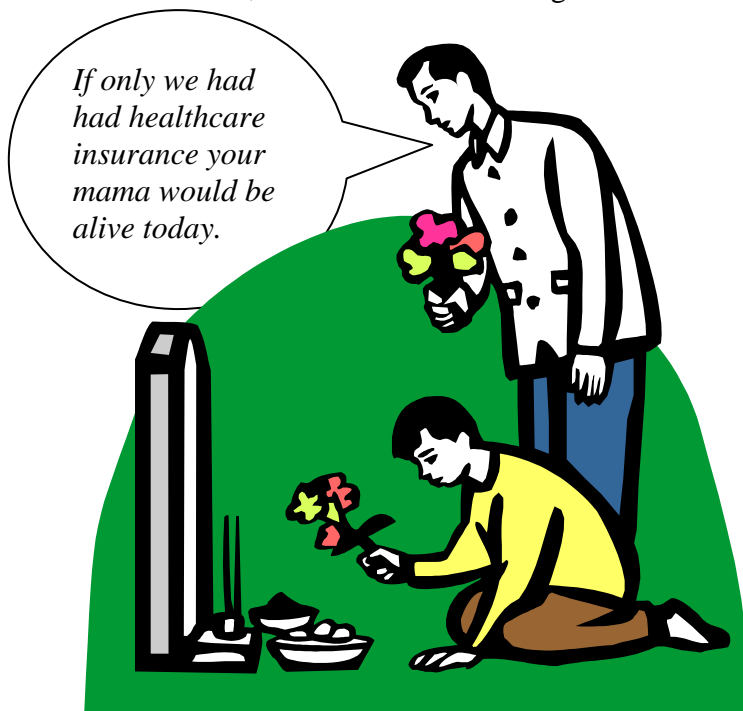
- a) 1%
- b) 3%
- c) 10%
- d) 25%
- e) 40%

Life after Healthcare Reform

The idea behind maximizing the number of people with healthcare insurance was not to make the insurance companies rich, but to make life better for those who gained that insurance. There are certainly examples of very unhappy people who bought insurance on one of the exchanges and found out it was not what they expected. The jury is out on Obama Care, but there has been a good test of the

(cancer, infections, and heart disease) decreased 4.5%. The investigators determined that about 830 adults gaining health insurance would prevent one death per year.

Let's apply this finding to Texas and assume it would apply also to children as well as adults. There were about 6 million uninsured Texans as of 2012.² The math is easy: 6,000,000/830 yields the estimate that more than 7,200 lives of Texans would be saved each year if Texas had near-universal health insurance coverage.



impact of healthcare insurance in Massachusetts, which had similar reforms go into place in 2007.

Three investigators asked what effect near-universal coverage in that state did to prolong the lives of residents.¹ They compared the pre-reform, annual death rate (2001 to 2005) with the post-reform rate (2007 to 2010) in persons aged 20 to 64, which excludes Medicare-eligible persons. Controls consisted of data from matched populations in states that did not have health insurance reform. Annual death rates for causes amenable to healthcare

Overworked Hospitalists

Hospitalists are physicians that practice exclusively within a hospital and attempt to integrate the care of a number of patients. This is in slight contrast to the traditional "attending physician" who may practice in a clinic or in a hospital. A hospitalist is typically the patient's attending physician while the patient is in the hospital. This doctor has ultimate responsibility for the care of specific patients and has completed a residency, although she may be in subspecialty residency. These doctors may also have responsibilities for training residents and medical students. The benchmark for these doctors is 10-15 patient encounters per day.

A team of investigators asked if the quality and efficiency of medical care in a hospital were affected by the workload placed on hospitalists.³ Their paper cites a previous study of hospitalists in which 40% reported exceeding a safe workload at least once per month. The unsafe conditions included: delayed care, communication lapses, unnecessary care, medication errors, and complications leading to death. The investigators did not find that in-hospital mortality or patient satisfaction was changed by hospitalist workload. They did find that the length of stay in the hospital

increased as workload increased. For example, if the occupancy level of the hospital was less than 75%, the average length of stay increased from 5.5 to 7.5 days with increasing workload.

As a prospective patient in a hospital, you might ask how the workload of their hospitalists is handled and how they assign hospitalists to specific patients. If you are going to have serious surgery on Friday, you might ask how the coverage is handled on weekends.

Making it easy for Drug-Resistant Bacteria

Over-prescribing of ordinary antibiotics promotes the risk of infection by drug-resistant bacteria. These bacteria infect approximately 2 million Americans each year, cause 23,000 deaths, and consume about \$20,000,000,000 in health care costs.⁴ The director of the Centers for Disease Control has called for stewardship programs in



hospitals to curtail this carnage. Every physician in a hospital must learn how to prescribe antibiotics. The director noted that there is a 3-fold variation in antibiotic prescribing rates in hospitals, suggesting that norms are not being followed.

Helen Boucher, MD who is on the board of the Infectious Diseases Society of America and director of the stewardship program at Tufts Medical Center said that the society has called for improved antibiotic stewardship for years and that the program she has implemented at Tufts has saved millions of dollars.

As a prospective patient in a hospital you must investigate the infection rate there for your specific procedure, but if you want to be part of the

broader solution, ask the infection control officer if there is an antibiotic stewardship program at the hospital. Make it clear that you do not want to be set up for a losing battle with a resistant strain of bacteria.

Some experts have asked why it is so difficult to curtail the overuse of antibiotics in hospitals. In a somewhat philosophical discussion two experts, evoking thoughts from Locke and Rousseau, postulate how responsible antimicrobial stewardship can occur.⁵ Despite the successes of isolated stewardship programs, improvements might be made by focused training of hospitalists and implementing time-outs during team meetings to examine whether antibiotics being administered are consistent with the diagnosis. Consistent compilation of performance measures designed to display the extent to which antimicrobial guidelines are being followed would also help. How would you like to see every hospital post a sign out front saying that this hospital is __% compliant with guidelines for use of antibiotics? Dream on...

Prescribing in the Ditch

Treatment guidelines are clear when it comes to prescribing opioids for adolescents with headache: Do not do this. Yet it seems that this practice continues at a relatively high rate. A study published in the *Journal of Adolescent Health*, using pharmacy claims, found that of the 8,400 records studied 46% of those with headache received an opioid.⁶ Almost a third received 3 or more prescriptions for opioids. Adolescents that received opioid prescriptions for headache were twice as



likely to visit the emergency room afterward as those who did not receive such a prescription. From my point of view this is “prescribing in the ditch,” which means it is well off the road of evidence-

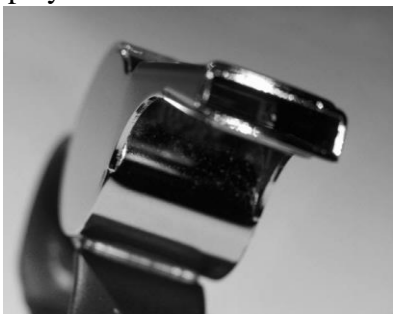
based care. It is always a good idea to ask if the care of your child is following guidelines. If your child's pediatrician looks puzzled by your question, then you may need a new pediatrician.

Two doctors call for us to "Confront the stigma of opioid-use disorder."⁷ They note that our country suffers from an epidemic of overuse of these drugs. They ask us to view opioid dependence as a medical illness rather than a moral weakness, which is commonly applied to stigmatize victims. This, they feel, will open the door for treatment of the illness rather than mounting attempts to reorient the patient's moral compass. They point out that there is no cure for this disorder, but certain medications (e.g. methadone) are supported by many expert organizations as a treatment for the disorder. Unfortunately, many in treatment facilities or programs are weaned from use of these drugs with the idea that they will get their moral compass redirected. It does not work that way, drugs like methadone may be needed for a lifetime to reduce the risk of recidivism. Furthermore, dependence on other addictive drugs must not be ignored by caregivers as opioid dependence is managed.

Physicians certainly have a role in destigmatizing opioid dependence, but, in my opinion, they need to find ways to more responsibly prescribe these addictive drugs. The study above of over-prescribing to adolescents is a prime example. Obviously, this could lead to addiction to these powerful drugs in vulnerable adolescents.

Whistleblower Rights

In most sports when the whistle blows all play must cease and often some infraction must be dealt with by penalties. Likewise, whistleblowers in large bureaucratic institutions must be protected so that when they discover what they feel to be infractions of the agency's mission, they will not be penalized by the agency that they hope to fix. Whistleblowers are

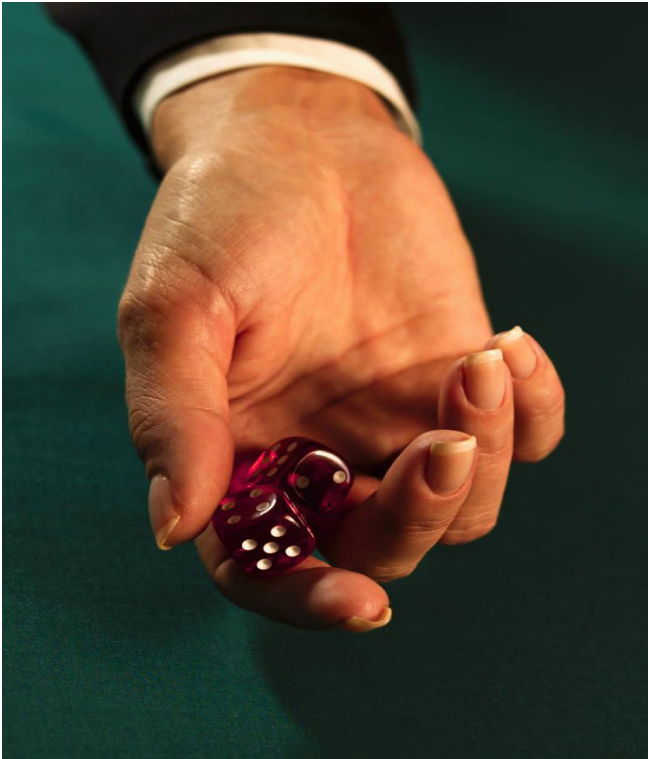


essential in any bureaucracy. Two Congress-persons have released a report suggesting that the Food and Drug Administration (FDA) violated the rights of whistleblowers in that agency by monitoring their computers, including email messages between them and their attorneys, Congress, and the Office of Special Counsel.⁸

The whistleblowers had come forth in 2009, accusing the agency of approving unsafe and risky medical devices. The agency claimed its computer monitoring was about protecting confidential information between device makers and the agency. The whistleblowers thought that the agency was giving in to device manufacturer's wishes for approval. It will be interesting to see how this plays out. In my opinion, there is compelling evidence, aside from any whistleblower accusations, that the FDA approves medical devices that are unsafe – metal-on-metal hip replacements are one prime example.

How Drug Companies Game the System

Two gaming schemes that I was unaware of were described in an April issue of the *New England Journal of Medicine*. The first described how companies use a safety-tool to prevent competition.⁹ It works like this. A law in 2007 required that makers of high-risk drugs maintain a database to learn more about risk-benefit profiles. When one of these drugs loses its market exclusivity, makers of generic drugs try to bring their products to market. But to do that they must demonstrate bioequivalence to the original drug. Using arguments involving maintenance of the safety database, makers of the brand-name product argued that they did not have to provide their drug to the makers of generic drugs to demonstrate bioequivalence. Generic competition results in lower drug prices and less profits for the brand-name drug maker. If the risk database is patented by the brand-name drug maker, then this can preclude the generic manufacturer from participation in further development of any shared database. The writers offer solutions to these issues. Would you care to wager on whether drug companies could game those solutions?



In a second article, experts discuss how high prices for cancer drugs block comparative-effectiveness studies.¹⁰ The authors describe 2 drugs available to treat difficult cases of prostate cancer – one costing about \$600 per month and the other about \$7000 per month. No study has conclusively demonstrated that the more expensive drug is any better than the cheaper drug and they are biologically similar. Is Johnson & Johnson (J&J), maker of the more expensive drug, going to test it head-to-head with the cheaper drug? Unlikely! If a third party (say the government with your tax dollars) wanted to do the proper comparative research J&J would sell them a suitable number of doses at a cost of almost \$70 million. The authors give 4 other examples similar to this and assert that “high prices protect a drug’s market share, precluding challenges from cheaper alternatives.” It really is a game and the losers are the patient and the healthcare cost payers, but the private payers also have their games to play. Government payees seem to sit back and function like a mindless ATM machine - freely paying out your money.

References

- 1) Sommers BD, Long SK, Baicker K. Changes in mortality after Massachusetts health care reform. *Ann Intern Med* 2014; 160:585-593
- 2) <http://www.politifact.com/texas/statements/2013/dec/19/kathleen-sebelius/texas-has-highest-uninsured-rate-and-most-uninsure/>
- 3) Elliott DJ, Young RS, Brice J. Effect of hospitalist workload on the quality and efficiency of care. *JAMA Intern med* 2014; 174:786-793
- 4) Kuehn BM. CDC: Hospital antibiotic use promotes resistance – Checklist can improve practices. *JAMA* 2014; 311:1485-1486
- 5) Flanders SA and Saint S. Why does antimicrobial overuse in hospitalized patients persist? *JAMA Intern Med* 2014; 174: 661-662
- 6) Devries A, Koch T, Wall, E, et al. Opioid use among adolescent patients treated for headache, accessed May 20, 2014, <http://www.ncbi.nlm.nih.gov/pubmed/24581795>
- 7) Olsen Y and Shasfstein JM. Confronting the stigma of opioid use disorder – and its treatment. *JAMA* 2104; 311: 1393-1394
- 8) Mitka M. Sen. Grassley: FDA may lack whistleblower protections. *JAMA* 2104; 311:1389
- 9) Sarpatwari A, Avorn J, Kesselheim AS. Using a drug-safety tool to prevent competition. *N Engl J Med* 2014; 370: 1476-1478
- 10) Mailankody S and Prasad V. Comparative effectiveness questions in oncology. *N Engl J Med* 2014; 370: 1478-1481
- 11) Walsh KE, Bundy DG, Landrigan CP. Preventing health care-associated harm in children. *JAMA* 2014; 311: 1731-1732

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Answer to question this month: best answer is d) 15-35% from reference 11