PSA

Patient Safety America Newsletter

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

Question: How much do Americans spend on healthcare each year?
a) $500 billion b) $1 trillion c) $2.5 trillion d) $5 trillion e) $7.5 trillion

Light in the Darkness

Once in a while something happens in medicine that begins a revolutionary change in how medicine is practiced. Plenty of scattered evidence has demonstrated overuse of medical interventions. Research has shown that many interventions thought to help patients were actually more harmful in the long run. A new light on overuse of procedures appeared this month in the *Archives of Internal Medicine* in an inaugural series the editors call "Less is More." The intent of this series is to identify health situations where less treatment results in improved health outcomes for patients.

There are a number of reasons why overuse of procedures occurs. An editorial on this subject by two physicians lists the possibilities:[1] lack of recognition that almost all procedures can have adverse consequences, payment systems that reward overuse of procedures, patient expectations that doing something is better than doing nothing, time efficiency gained by ordering a procedure rather than taking time to explain why it is not needed, draw of "glamorous" new technology, and defensive medicine. Regarding this last excuse, it is my opinion that "defensive medicine" is a cover-up for the fact that clinicians may not know evidence-based procedures in a given situation, so they try to manage their knowledge deficiencies and liability risk by doing too many tests. A clinician confidently practicing evidence-based medicine has no need of too much testing, which he can otherwise rationalize as defensive medicine.

This series begins with an editorial called "Failing the Acid Test." The editorialist, a physician, summarizes the findings of studies published in the same issue of this journal.[2] He mentions the widespread use (113 million prescriptions per year) and high annual cost ($14 billion) of proton pump inhibitors (PPIs). However, he declines to target the wasted money from overuse. Instead, he targets the substantial health risk posed to patients when these drugs are inappropriately prescribed.

If you can recall your high-school chemistry you will remember that protons are hydrogen atoms and the presence of the charged form of hydrogen atoms in water results in an acidic solution. Under normal conditions, hydrogen atoms are pumped into the stomach to produce an acidic solution that aids digestion. Under some conditions too much acid causes indigestion or heart burn, so PPIs are given if the condition persists. It seems simple enough to give PPIs to relieve this discomfort, but truly helping the patient is not that simple.

Three research studies are described in which the use of PPIs to relieve symptoms poses risk to patient health. One study of 130,000 women aged 50 to 79 years found that use of PPIs was modestly associated with increased fractures of spine or forearm and wrist, but not hip.[3] The authors

estimated the increased risk of spine fractures to be about 50% and forearm and wrist fractures at about 25%. The authors recommended minimal doses of PPI for acute relief of symptoms if the drug is given over extended periods. A calcium supplement to strengthen bones may also be prescribed.

In another report, a team of investigators set out to determine if use of PPI or other gastric-acid suppressors increased risk of infection with *Clostridium difficile* (CD), a potentially lethal bacterium that can cause severe GI symptoms. They studied records from a group of 100,000 patients discharged from a tertiary hospital over a 5-year period. The patients were broken into four groups depending on the intensity of acid-suppression treatment. The risk of infection in patients not receiving acid suppressors was 0.3%, whereas in the group receiving the most intense therapy the risk was slightly more than doubled. The intermediate groups had a corresponding intermediate risk of infection. The authors note that their evidence supports the hypothesis that iatrogenic acid suppression causes many CD infections.

Now let's suppose you have cured your patient of CD infection. Can you predict whether a patient is likely to return with a recurrent CD infection based on whether they received PPI during their recovery period? A group of investigators set out to answer that question. They determined whether PPI therapy given as part of CD treatment increased the risk of *recurrence* of CD infection.[4] The experts studied outcomes in about 1200 patients treated in the VA system. They found that those patients given PPI were about 40% more likely to have a recurrence of CD infection than those not receiving PPI. Given the background of other studies involving PPI and CD infection, the authors suggest additional research and careful consideration of the risk of PPI use in patients infected with CD. The authors speculate that the mechanism of recurrence of CD infection may involve CD's "distaste" for acidic conditions, which would be suppressed with the use of PPIs.

Think twice before you accept a prescription for a PPI drug.

CT Scans, Stress Testing and Invasive Cardiology

A large team of physicians in the Netherlands looked at various ways non-invasive CT scans of coronary arteries and stress testing can be useful in deciding if invasive coronary angiography is needed.[5] They studied over 500 patients with chest symptoms and divided them into three groups. One group had a low probability of coronary artery disease, the second had an intermediate probability, and the third had a high probability of the disease.

The investigators concluded that in the low-probability group a non-invasive stress test is sufficient evidence for or against invasive coronary angiography without any CT scan, especially since CT scans use ionizing radiation – thought to slightly increase cancer risk. For the intermediate-probability group the CT scan alone seemed useful as a first-line test in identifying those patients that ought to have invasive coronary angiography. For the high-probability group there was no need for a CT scan because it was clear from other factors that invasive coronary angiography was needed.

This study has important implications for your treatment and associated costs if you experience chest symptoms that could be caused by blockages in your coronary arteries. Invasive coronary angiography has a significant risk of inducing a heart attack and one in roughly 800 patients die as a result of the procedure.[6] You do not want to have a CT scan unless it is clinically useful to you. Furthermore, you or your insurance carrier should not have to pay for such a test if it is not going to benefit you. **Always ask your physician how a test he has proposed will affect the care you receive and what risks are associated with the testing**.

Transformers in Healthcare

An invited commentary related to healthcare reform examined the problem of transforming discovery of new and effective drugs into benefits for the patient.[7] Citing another source, the author makes the point that too often genuine advances in therapy are not widely or quickly adopted, whereas some marginal medications are placed into clinical practice more because of aggressive advertising than clinical efficacy. Often such therapies pose a risk to the patients that would not exist if older medications were used. It is the job of translational research to discover ways to quickly bring the effective and safer medications into widespread clinical use.

The author addresses the final step in translation, which is taking findings of well-performed clinical studies and ensuring that such results are applied to clinical practice. The author describes the situation when older hypertension medications were compared to newer and more expensive medications for the same condition. The results clearly indicated that the older medications were just as good or better than more expensive medications, but this finding had little effect on clinical practice. The author attributes this to interactive, one-on-one presentation of information to physicians by sales personnel on behalf of the expensive medications.

The author concludes with a plea for understanding of the importance of end-stage translational research. Obviously, no matter what new discovery occurs, it is of no value until patients gain safer, less-expensive treatment because of the discovery.

In my opinion there are two reasons why clinicians do not apply the benefit of new research to patient treatment. In the first place their continuing education system is broken because it does not effectively disseminate new findings to the practicing doctor. Secondly, there is no accountability when doctors prescribe highly-marketed, dangerous, and less effective medications to treat patients. Pharmaceutical companies get the blame and punishment for unethical marketing, but no accountability is accorded the doctors who allow themselves to be misled into risking patients' wellbeing.

Hidden in Hospitals

A recent report from the Office of the Inspector General of the Department of Health and Human Services should frighten us all.[8] The title is "Adverse Events in Hospitals: Methods for Identifying Adverse Events." The part of the report that should matter to you as a prospective patient is not the various ways the investigators used to identify adverse events, but the frequency of adverse events and the hospitals' approach to dealing with adverse events.

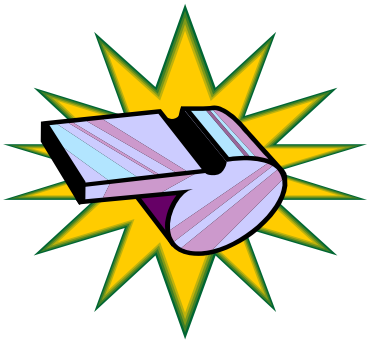
The investigators defined "adverse event" as harm to a patient as a result of medical care or harm that occurs in a healthcare setting. The expert team looked at 278 randomly selected records from hospitalizations of Medicare patients in a defined population. Using the various methods of identifying medical errors, including physician reviews, they found 120 adverse events. Thus the frequency of adverse events was 120 events in only 278 patients. Many patients experienced more than one adverse event, so the percentage that experienced any adverse event was 30%. This is bad news if you are a Medicare patient and need care in a hospital.

You might suppose that the hospitals from which the records were obtained would be making an effort through internal investigations to learn from the adverse events and take corrective actions. However, of the 120 adverse events identified, only eight were the subject of internal investigations by the hospitals. There were no incident reports for 93% of the adverse events, including ones involving death and permanent disability. In a surprisingly detached way the investigators note that hospitals may fail to track and report adverse events as required by regulation, and the data on adverse events assembled from hospital reports may be unreliable.

Assuming the sample of records, which is small and limited in scope, is representative of Medicare hospitalizations in this country, the results suggest a woefully troubled industry incapable of

dealing with and learning from the harm it causes to patients. **The frequency of adverse events should be a sobering reminder to patients that our country has a long way to go before patients have reasonable assurance of safe care while hospitalized.**

Whistleblower's Experiences



A special report in the *New England Journal of Medicine* examined the experiences of whistleblowers that led to successful federal-government prosecutions for fraud in the pharmaceutical industry from 2001 to 2009.[9] The total of settlements for the 17 examples listed came to $6.3 billion. The improper conduct by drug companies included off-label marketing, kickbacks to prescribers, and suppression or falsification of data.

The whistle blowers were motivated to report the fraud by self preservation, justice, integrity, and altruism. The payouts to whistleblowers ranged from $100,000 to $42 million. Sadly, because of the hassle associated with the investigational phase, most felt that the payoff had not been worth the personal cost. The investigators suggested that the government should take measures to reduce the hardships associated with whistleblowers' experiences. They note that this is an important means to limit healthcare fraud. I would add that this is an important mechanism to limit your risk of being prescribed a dangerous drug

References

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Answer to question this month: c) $2.4 trillion or about $8,000 per person