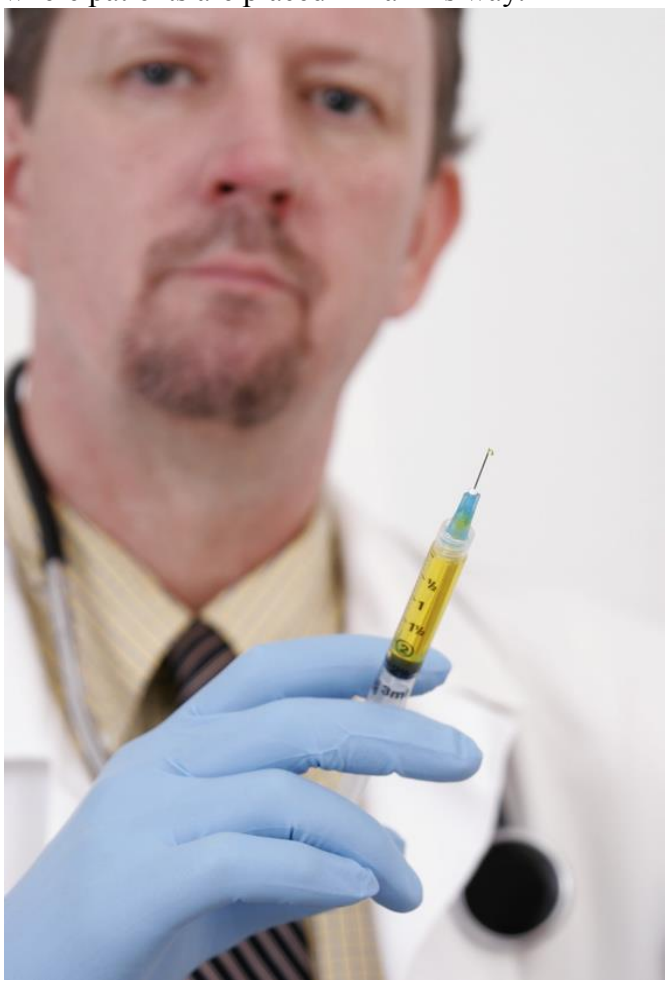
Patient Safety America Newsletter

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

***Question**: Among Medicare beneficiaries, most adverse medical events occur in hospitals. True or false?*

Old Business-Drugs and Death Certificates

I try to use only recently published analyses and expert opinions in major, peer-reviewed, medical journals to create my summaries, but this month I am going to summarize two older publications that came to my attention because my friends in the Safe Patient Project sent them to me. As you might expect, they deal with serious shortcomings of our system and describe a situation where patients are placed in harm's way.



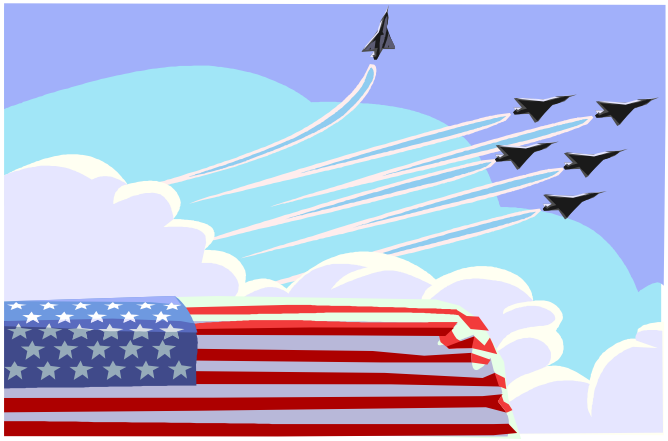
The first article comes from the journal *Pharmacoepidemiology and Drug Safety*, published five years ago. A team of four experts asked how often physicians' knowledge of FDA-approved drugs properly guides their prescribing to patients.[1] Several hundred doctors, about half primary care and half psychiatrists, responded to a mailed questionnaire containing 14 pairs of drugs and indications for prescribing each drug. For example, one pair was Neurotonin® for diabetic neuropathy.

The average physician accurately identified FDA-approval status just over half the time. In other words, in many cases the doctor did not know whether the prescription would be off label or not. About 40% of the physicians believed that one pair was FDA approved when in fact there was no supporting evidence that the drug was effective for the indication given. The authors of the study declare that a more effective means needs to be found to inform doctors about the FDA-approved indications for drugs, and the level of evidence supporting off-label use before they prescribe drugs off-label.

To me this is a frightening finding. Physicians are traditionally the final gate-keeper to protect patients from potentially dangerous drugs, yet they often seem to be unaware of necessary information to do safe prescribing. **As a patient, you must break tradition and assume the role of final gate keeper of any drug put into your body. You must know if it is being prescribed to you label and you must know why that is being done. You must ask about the evidence that it may be effective and relatively safe for you to ingest. Be wary of social media advertising of drugs.**

Here are some legal constraints on drug advertising you should know about: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/UCM076768.htm.

The second 'dated' article comes from the Centers for Disease Control (CDC) and was published last year. Three MDs investigated the validity of cause-of-death reports given by medical residents working in New York City.[2] Only one



third of the 520 physician-responders said that they believed cause-of-death reporting is accurate in death certificates. About half had knowingly reported an inaccurate cause of death and about two-thirds said that cardiovascular disease was the condition most often wrongly reported. This has obvious implications because it is believed that cardiovascular events are the leading cause of death in the U.S.

Long-term Consequences of Adverse Medical Events

If you are like me, you have witnessed the decline of an elderly person after they experienced an adverse medical event. They never return to their pre-event health status and experience steadily declining health. This type of event was studied recently by four investigators. They identified adverse medical events using Medicare-claims files to include 'misadventures,' complications, and adverse drug events.[3] The team used a nationally-representative sample of Medicare claims data from 1998-2004, involving 12,500 beneficiaries. They looked for events during hospitalization and during outpatient care.

Nearly one fifth of the patients experienced at least one adverse medical event and, to my surprise, just over 60% of these were experienced as an outpatient. Patients with more chronic conditions were much more likely to experience an adverse medical event. Of those experiencing an adverse medical event, 28% died, whereas only 15% of those who did not experience an adverse medical event died. The average age of those experiencing an adverse event was 76 years, whereas the average age of those experiencing no event was 75 years.

The investigators point out that more attention is needed to discern adverse events in outpatient settings and further, that the cost to Medicare of treatment for patients in decline after an adverse medical event is substantial. **Personally, I would recommend that an elderly person treated in an outpatient setting have an advocate present to guard against adverse medical events. Such events are common, causing injury and costly care.**

Something Has Got to Give

For some time the US healthcare industry has been noted for its inordinately high costs and marginal performance (see lead story last month). Economists for some years have declared that the cost of US healthcare is not sustainable and such notables as Warren Buffett have designated it a 'tape worm.' A story reported in the *JAMA* this past month describes a speech given by a Princeton economics professor to the American Medical Association (AMA). Dr. Uwe Reinhardt (http://en.wikipedia.org/wiki/Uwe_Reinhardt) asserts that the time has come for some difficult choices to constrain US healthcare costs. He points out that states with limited budgets have already begun shifting money from education and social services to pay for medical services. We must decide how much to spend on healthcare as a nation, and then find ways to establish value-of-services. Those services with the least value will have to go. We may have to resort to something like the Quality Adjusted Life Year

(QALY) used in the UK to establish how much the government is willing to pay for medical services.

The professor apparently did not pander to his audience. He pointed out that the AMA needs to quit lobbying for increases in medical spending and wrongly suggesting that cuts in funding will compromise quality. Prevailing estimates are that $750 billion are misspent each year for needless healthcare. He warned politicians to stay away from the 'death panels' argument when the value of a QALY is debated. I would warn that we must avoid the argument that the QALY is what the 'socialized' system in the UK uses and Americans will not tolerate such socialism.

In my opinion, the one thing lacking in the US that exists in other developed countries is the worldview that I as an individual am willing to help you with your healthcare if you are unlucky enough to become seriously ill. I am willing to do this through a single payer system to which I and all others in my country contribute. In contrast, the worldview by many in the US is that I have earned enough money to buy the healthcare I want and if you, my fellow American, are unable to do that, then you get no healthcare or second-rate healthcare. Your illnesses are of no concern to me.

Decisions about how to pay for healthcare are going to be difficult, but to continue to ignore the need to constrain healthcare costs is a recipe for continuing national decay as we compromise our future through weakening education of our children, denial of humane social services, and unbridled borrowing of money that we will never repay.

Couch Potato and Diabetes Risk

Many women experience gestational diabetes while pregnant and this is associated with roughly a 50% risk for later development of type II diabetes. A study described in the *JAMA* by a correspondent reports that when the investigators followed 4550 women between 1991 and 2007 that were participating in the Nurses' Health Study, there was an inverse association between weekly, moderate exercise and risk of diabetes.[4] Specifically, women who exercised after pregnancy 2 ½ hours per week reduced their risk by nearly 50%, whereas moderate exercise for 1 ½ hours per week resulted in a 10% decreased risk. Walking is considered a moderate-level exercise, so, if you had gestational diabetes, consider partnering with a few friends and commit to walking a half hour five or more days per week. **If you need motivation to exercise to reduce your risk, then please read about the complications associated with type II diabetes:** http://www.mayoclinic.org/diseases-conditions/type-2-diabetes/basics/complications/con-20031902.

Medicare Fraud Costly

The Government Accountability Office issued a report in April calling for improved prevention and detection of fraud by the Centers for Medicare and Medicaid Services (CMS) (http://www.gao.gov/products/gao-14-560t). The estimated cost of improper payments for fiscal year 2013 was $50 billion, much of it presumed to be fraud. This occurs when CMS fails to identify and prevent clinicians, institutions, and suppliers known to be fraudulent from participating in Medicare payments. Here is a site from the Justice Department describing the conviction and sentencing of a New York doctor for his role in a $77 million fraud scheme: http://www.justice.gov/opa/pr/2013/September/13-crm-1032.html. One would think that the stiff penalty would deter this sort of thing.

Hospitals Game the System

Two experts write in the *Annals of Internal Medicine* about the track record of hospitals being able to maintain their market share despite government attempts to make them more efficient and accountable.[5] The writers call this inclination 'adaptability,' but I call it gaming. The authors observe that Medicare shifted to diagnosis-based reimbursement with the hospital Inpatient Prospective Payment System (IPPS) in 1983. This meant a shift from payment for services no matter how extensive and unneeded to one where hospitals get paid a fee for fixing a given condition. Soon hospitals began doing more cardiac and neuro-

surgery because these procedures had a high profit margin.

Hospitals also shifted to more outpatient services to avoid IPPS constraints. The authors note that outpatient services such as ambulatory surgery, imaging, and chemotherapy account for much of the cost differences between the US and other developed countries. A graph in the article shows that Medicare's 'institutional' spending from 2000 to 2010 for inpatient services was nearly constant at about $2500 per beneficiary, whereas during the same time period, the outpatient costs doubled from about $600 to $1200 per beneficiary.

The authors warn that hospitals may respond to the Affordable care Act in unexpected ways to preserve their market share. They wonder if such responses will or will not be to the benefit of patients. As for me, I am concerned about the rise in openly for-profit hospitals and the reality that many so-called non-profit hospitals are hardly that.

Limping along – Medicare's Physician Fees

One would have to be from another planet to be unaware that the current Congress is failing to deal with many important issues. That does not mean that individual members of Congress are not informed and seeking progress, only that the ideological differences, driven by those who elected them, are so large that impasse is the rule of the day. One issue that cannot be resolved is the pay scale for physicians who provide services to Medicare beneficiaries.[6] The 'Sustainable Growth Act' of 1998 stipulated that physicians fees would be adjusted according to a formula that considered the overall growth rate of the cost of physicians services compared to general economic growth.

This is not a problem when the economy is thriving, but when growth slows and physicians overall seek more payments, the formula drives a reduction in physician fees. Since 2002, the requirements of the formula have been set aside by Congress 17 times; obviously, that is no long-term solution. The law is somewhat ill-conceived in that individual physicians that practice medicine efficiently are 'punished' the same as physicians who order unnecessary and costly procedures for which they receive inordinate reimbursement. Obviously, the way to deal with this is to distinguish physicians that have controlled their reimbursements from physicians that fleece Medicare for all they can. Making that distinction is not simple, but Congress had at least attempted to legislate it with more transparency, but alas, the bipartisan agreement disintegrated because of squabbling over how to pay for repeal of the original act.

If you want to look into how much your doctor made from Medicare, try a site from the New York Times: http://www.nytimes.com/interactive/2014/04/09/health/medicare-doctor-database.html?_r=0.

References

1) Chen DT, Wynia MK, Moloney RM, Alexander GC. U.S. physician knowledge of the FDA-approved indications and evidence base for commonly prescribed drugs: results of a national study. Pharmacoepidemiology and Drug Safety 2009; 18:1094-1100
2) Wexelman BA, Eden E, Rose KM. Survey of New York City resident physicians on cause-of-death reporting, 2010. Preventing Chronic Disease (CDC) 2013. http://dx.doi.org/10.5888/pcd10.120288.
3) Carter MW, Zhu M, Xiang J, Porell FW. Investigating the long-term consequesnce of adverse medical events among older adults. Inj Prev doi:10.1136/injuryprev-2013-041043.
4) Kuehn BM. Physical activity may stave off diabetes for women at risk. JAMA 2014; 311:2263
5) Ryan AM, Mushlin AI. The Affordable Care Act's paymenr reforms and the future of hospitals. Ann Intern Med 2014;160:729-730
6) Guterman S. The "Doc Fix" – Another missed opportunity. N Engl J Med 370:2261-2263

Find past newsletters:
http://patientsafetyamerica.com/e-newsletter/

Answer to question this month: False. According to reference #3, 62% occur in outpatient settings.