PSA

Patient Safety America Newsletter

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

Question: The Agency for Healthcare Quality and Research has just determined that screening for obesity in children is warranted because effective treatment is now available. Which one of the following illnesses is NOT associated with adolescent obesity?
a) fatty kidney b) type 2 diabetes c) asthma d) depression e) high blood pressure

Antidepressants and Your Life: Singing the Blues

Approximately one in eight people will experience a major depressive disorder sometime in their life. Drugs meant to reduce acute depression are commonly prescribed in the United States. Three important questions involving depression and use of antidepressants were considered in the past month in major medical journals. The findings could have a direct bearing on your life or the lives of your family members.

Let's deal with the questions and findings in a stepwise fashion. First, should you be screened for depression if you are seen in a clinical setting? Second, should you be given an antidepressant if you are found to have depression? And third, are there collateral risks to your health if you do decide to take antidepressants?

A study entitled "Screening for depression in adult patients in primary care settings: A systematic evidence review" was just published in the *Annals of Internal Medicine*.[1] As a background, the standard of care recommended in 2002 was that screening adults for depression in clinical practices was effective *if* there was assurance of an accurate diagnosis and effective treatment, including follow up. The authors[1] did a search of medical databases through February 2009, distilling thousands of abstracts and hundreds of full-length articles down to a hand full of applicable studies that were ranked for quality from fair to good.

Based on trustworthy studies, the authors conclude that unless depression screening programs have non-clinician professionals to support patient care and close monitoring of patients taking antidepressant treatment, the outcomes are unlikely to improve depression. They particularly emphasize the importance of monitoring in patients younger than 30 years of age because there is an increased risk of suicide in this group of patients.

Let's examine the second question. Suppose that you have been screened and found to have some level of depression. Can the severity of your depression guide your expectations for improvement if you use antidepressants? First, let's look at how depression is ranked to understand the answer to this question. There are several ranking systems but the "gold standard" seems to be the Hamilton Depression Rating Scale (HDRS).[2] The HDRS uses 17 questions to be asked of the patient by a professional. Answers are numerically graded on each question and added to yield a total score.[3] The questions measure mood, insomnia, agitation, anxiety and weight loss.The study I am about to describe used the standard descriptions from the HDRS shown below.

HDRS Score	Degree of Depression
8-13	Mild
14-18	Moderate
19-22	Severe
More than 22	Very severe

With this background you can understand the results of a study called "Antidepressant drug effects and depression severity" published recently in the *JAMA*.[4] The investigators searched more than 2000 potentially appropriate citations and progressively distilled these down to only 6 most suitable studies, each of which had

used a placebo as control. They plotted the depression severity scores against the "improvement" when patients took either a placebo or an antidepressant. Placebo "treatment" typically elicits significant improvement in the HDRS scores.

To be clinically significant, the HDRS scores of patients using the antidepressant must improve 3 or more points more than the placebo-caused improvement. Not until the starting HDRS score was 25 or above did the antidepressant beat the placebo by 3 or more points. At a HDRS score of 25 it was estimated that the placebo gave a 9-point improvement and the antidepressant gave an improvement of 12 points. As you can see by the table above, 25 points is well into the "very severe" category of depression. Since the majority of patients receiving antidepressants are not in the very-severe category, this finding questions the value of antidepressants in mildly or moderately depressed patients. Improvements for them may be negligible.

I suspect there will be much more research on this topic since it tends to suggest that antidepressants are overused. Drug makers are not likely to leave this alone. In my opinion, one weakness of the study is that the researchers assumed that the improvements in the HDRS values for both placebo and drug would be linearly related to the initial value of the HDRS score. Beyond scores of about 27, the plotted values do not look at all linear to me.

Now, let's move on to the third and final question. If you do take antidepressants is there an associated risk to your overall health? A team of investigators looked at medical records from more than 136,000 post-menopausal women and asked if those who took antidepressants were more likely to have increased risk of coronary artery disease, stroke, or all-cause mortality.[5] The scientists looked at two classes of antidepressants, the distinction of which is beyond the scope of this newsletter. For our purposes we'll call them an older class (tricyclic) and a newer class (selective serotonin reuptake inhibitor). The table below summarizes their findings.

Risk measure	Older drug	Newer drug
Coronary artery disease	No increase	No increase
Stroke	No increase	Increased risk
All-cause mortality	Increased risk	Increased risk

A commentary on the original study reiterates the possibility that antidepressant therapy may increase the risk of stroke and total mortality in this group of women.[6] This commentary points out the difficulty of controlling for the fact that those who need antidepressants may have predisposing conditions that increase these risks. Thus, it is not perfectly clear whether the antidepressants led to higher risks, or those already at higher risk are the ones most likely to use antidepressants.

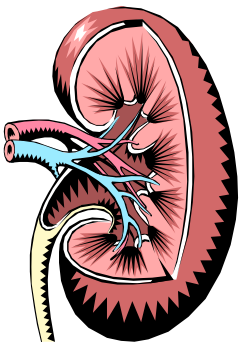
As so often occurs in medicine, there is no absolutely clear guidance on screening for illness and then use of medications. If you are diagnosed with clinical depression, then you should expect vigilant support from your doctor's professional staff if you are prescribed an antidepressant, especially if you are less than 30 years old.

Personally, I'd stay away from antidepressants unless I had severe or very severe depression. I find that vigorous exercise at least every other day goes a long way to lifting me from "the blues." Scientific studies have shown that aerobic, vigorous exercise can often deal with mild and moderate depression as defined by the HDRS.[7] Well, excuse me, it's time for my run.

Danger for Dialysis Patients

An original investigation published in *JAMA* produced data that should frighten anyone who has a family member undergoing dialysis that needs to have a stent placed into a coronary artery.[8] Certain drugs are contraindicated (not recommended) by the FDA as antithrombotic (anti-clotting) medications in patients receiving a stent because they are eliminated by the kidney, an organ that is obviously compromised in dialysis patients.

The investigating team examined the hospital records of almost 23,000 dialysis patients getting stents in more than 800 different hospitals in the U.S. from 2004 to 2008. The outcome measures were in-hospital bleeding and death. In this sample 22% of the patients received anti-clotting drugs that were contraindicated. Anti-clotting drugs that *are not* contraindicated are readily available. Use of the contraindicated drugs was associated with a 93% increased risk of bleeding and a 68% increased risk of death.



The authors, nine of whom are MDs, state that their study "illustrate[s] the problem of medication errors in the U.S. as well as the need to make patient safety a priority on the health care agenda." Regarding the prescribing of contraindicated medications, the authors state "Educational efforts targeting clinicians who prescribe these medications and quality improvement interventions, such as amending clinical pathway order sets to include consideration of [kidney] function, are urgently needed."

In my opinion this study pulls together themes that need to be emphasized. Specifically, physician continuing medical education (CME) is a broken system and the failures of the current system, because of the inadequate knowledge of some doctors, can lead directly to morbidity and mortality. Those legislators and physician leaders who continue to allow this failed system to exist must bear some responsibility for the harm caused.

At the risk of too many quotes, allow me to reinforce my point by quoting from a letter to "colleagues" like me who participated in information gathering for an Institute of Medicine Committee: "…today's professional health workforce is not consistently prepared to provide high quality health care and assure patient safety. One contributing factor to this problem is the absence of a comprehensive and well-integrated system of continuing education in the health professions."[9]

Is Your Doctor Above Average?

In my reading this month I came across an interesting editorial entitled "Measuring physicians' quality and performance – Adrift on Lake Wobegon" in the *JAMA*.[10] The writer, Dr. Donald Berwick, is an MD well known in the patient safety community. Lake Wobegon is a fictional place where "all the women are strong, all the men are good looking, and all the children are above average." It has been used to describe a real and pervasive human tendency to overestimate one's achievements and capabilities in relation to others. Berwick points out that "evidence is overwhelming that variations in practices, outcomes and costs of [health] care is unconscionably large." In other words, some of the below-average physicians are in fact *way below* average and some costs are *way above* average.

Dr. Berwick made some observations that I would like to underscore. First, if we are to identify physicians that are well below average, then we will have to obtain data from *all* payers, not just government payers such as Medicare and Medicaid. Second, patients ought to be asked about their experiences with physician care. This means that *your voice* would be heard during the assessment of physicians. However, no one expects that patient feedback will provide much insight into the *technical quality* of care. It *will* provide feedback about physician behavior when seeing patients. At least your voice can give feedback on how patient-centered your care seems to have been.

In my opinion, assessment of physician technical competence will have to come primarily from the physician community, and that community has a track record of ignoring substandard colleagues as these individuals drift along endangering their patients' lives in a system where accountability is minimized and secrecy maximized. For now, patient beware!

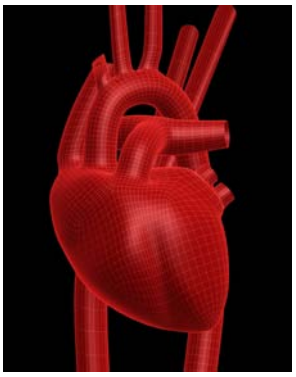
One of the broken pieces of physician knowledge-building after licensing is our failed continuing medical education (CME) system. This past month two experts emphasized the need for reducing the influence of commercial sponsors of CME in an article entitled "The agenda for continuing medical education – Limiting industry's influence."[11] The authors describe the panorama of CME providers and the controls placed on the content of CME; however, they also show how commercial sponsors can use CME in their marketing strategies, such as by overcompensating consultants who are high- prescribing doctors. One example they describe is the alleged off-label promotion by Warner-Lambert of Neurontin. The government alleged that this company gave kickbacks to physicians in the form of expensive trips to listen to presentations of off-label uses for the drug. The result was a fine of $430 million to settle criminal and civil charges.

If commercial influence of CME must end, then who will pay for it? The authors discuss three proposals: 1) physicians would pay for their own CME, 2) commercial sponsors could pay for CME but have no control of content, or 3) a respected, independent third party could create a menu of CME needs from which sponsors can select a topic and pay part of the cost. I would favor the latter approach since, in my opinion, much of current CME does not directly address the core goal of safer patient care. As a prospective patient I want all CME to make my doctor better able to treat me with evidence-based medicine founded on fresh guidelines from unbiased sources.

CT Scans and Cancer Risk

A series of editorials and scientific studies about the value and risk from CT scans was published in the *Archives of Internal Medicine* in the late December issue. As I see it, the issue breaks down into three questions: 1) Under what conditions should you have a CT scan, 2) If you need CT scans to monitor a disease risk, how often should you have a scan, and 3) what are the collateral risks generated by CT scans?

According to one editorial,[12] CT scan screening for coronary artery calcification (an indicator of blockage in an artery) has not been shown to improve outcomes of patient care. The author cites one study showing that CT scans in low-risk populations may be a tragic waste of money. Until further evidence suggests otherwise, it seems that CT scan screening is not justified unless you have risk factors for coronary artery disease. This should be discussed with your doctor.



Now, suppose your heart has been screened by CT scan and the findings suggest you need treatment. One declared purpose of CT heart scans is to determine the effectiveness of therapy, usually lifestyle changes and medication. The idea here is that if the therapy is working, the patient will show less arterial calcification when the coronary arteries are scanned. A review article[13] found that "there was no consistent or reproducible treatment effect of any therapy on this outcome measured at one year." The point being that as a patient you may not want to sign on for annual CT scans to follow the possible success of your therapy. Furthermore, CT scans are not as non-invasive as you might suppose.

An editorial that discusses two scientific articles describing the increased cancer risk from CT scans makes some points you should know.[14] One study discussed in the editorial estimated that one in 270 forty-year old women will develop cancer if they had one CT coronary angiogram (scan). The other study discussed by the editorialist estimated that the number of cancers caused by the scanning rate and dosages in 2007 will result in 29,000 cancers. The editorialist, noting the wide variability in the radiation doses received during CT scans, called for better control of the doses. In addition, all patients should be informed of the radiation risks before agreeing to a CT scan. This is especially true because "a significant number of CT scans are not appropriate…the highly profitable nature of diagnostic imaging, [and] the wide variation [in use around the country] suggest that there may be significant overuse in parts of the country."[14]

Before you agree to a CT scan ask the radiologist: 1) how will the results change my diagnosis and treatment, 2) what protocols do you use to control my radiation dose during the scan, and 3) how often will I need subsequent scans? If the radiologist does not voluntarily discuss the increased cancer risk to you, I would take this as a "red flag." You may want to seek alternative care.

References

1) O'Connor, EA, EP Whitlock, TL Bell and BN Gaynes. Screening for depression in adult patients in primary care settings: A systematic evidence review. *Ann Intern Med*. 151:793-803, 2009
2) http://en.wikipedia.org/wiki/Hamilton_Rating_Scale_for_Depression accessed 18 January, 2010
3) Hamilton, M. A rating scale for depression. *Journal of Neurology, Neurosurgery and Psychiatry*. **23**: 56-62, 1960 PMID 14399272
4) Fournier, JC, RJ DeRubeis, SD Hollon, et al. Antidepressant drug effects and depression severity. *JAMA* 303:47-53, 2010
5) Smoller, JW, M Allison, BB Cochrane, et al. Antidepressant use and risk of incident cardiovascular morbidity and mortality among postmenopausal women in the Woman's Health Initiative Study. *Arch Intern Med* 169:2128-2139. 2009
6) O'Conner, C, and M Fiuzat. Antidepressant use, depression, and poor cardiovascular outcomes. *Arch Intern Med* 169:2140-2141, 2009
7) Dunn AL, MH Trivedi, JB Kaupert, et al. Exercise treatment for depression: efficacy and dose response. *Am J Prev Med* 28:1-8, 2005
8) Tsai, TT, TM Maddox, MT Roe, et al. Contraindicated medication use in dialysis patients undergoing percutaneous coronary intervention. *JAMA* 302:2458-2464, 2009
9) Warden, GL. letter on IOM letterhead to "Colleagues" dated December 30, 2009
10) Berwick, DM. Measuring physicians' quality and performance – Adrift on Lake Wobegon. *JAMA* 302:2485-2486, 2009
11) Morris, L and JK Taitsman. The agenda for continuing medical education – Limiting industry's influence. *N Engl J Med* 361:2478-2482, 2009
12) O'Malley, PG. A double take on serial measurement of coronary artery calcification. *Arch Intern Med* 169:2051-2051, 2009
13) McCullough, PA, and KM Chinnaiyan. Annual progression of coronary calcification in trials of preventive therapies. *Arch Intern Med* 169:2064-2070, 2009
14) Redberg, RF. Cancer risks and radiation exposure from computed tomographic scans. *Arch Intern Med* 169:2049-2050, 2009
15) Agency for Healthcare Quality and Research. *Screening for Obesity in Children and Adolescents,* January 2010 http://www.ahrq.gov/clinic/uspstf/uspschobes.htm

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Answer to Question this month:[15] a) fatty kidney is not associated with adolescent obesity

PSAN1002Links

In the spirit of hope for a new year, here's a link to an interview with President Obama from December 23 PBS where he states that medical errors harm many people and cost huge amounts of money, and that he will see that the health reform bill that he signs has provisions (unstated) to prevent them.
http://www.pbs.org/newshour/bb/white_house/july-dec09/obama_12-23.html

I just saw this during lunch and thought you might find it interesting. It seems that at some level falsifying medical records may rise to the level of a federal crime.
http://www.cnn.com/2010/CRIME/01/07/california.transplant.indictment/

NPR Story on Checklists and Patient Safety from an MD
http://www.npr.org/templates/story/story.php?storyId=122226184

Harm from radiation treatment of cancer (NYT):
http://www.nytimes.com/2010/01/24/health/24radiation.html?th&emc=th

Congressman Murtha's botched surgery (Wash Post)
http://voices.washingtonpost.com/44/2010/02/john-murtha-in-stable-conditio.html?hpid=news-col-blog

How to Protect Physician Whistleblower - Patient Advocates - from Retaliation to Benefit Patients.
a legal analysis regarding Summary Suspension, Retaliation, Peer Review and Remedies by Dr. Gil Mileikowsky, MD and Bartholomew Lee, Attorney at Law.
http://www.allianceforpatientsafety.org/protect.pdf

Fines of California Hospitals for medical errors http://www.latimes.com/news/local/la-me-hospital-fines28-2010jan28,0,4600295.story?track=rss

Limited Progress in the decade since "To Err is Human"
http://www.modernhealthcare.com/apps/pbcs.dll/article?AID=/20091207/REG/912049998/1124#