



# CHOOSING WISELY

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As I mentioned in the last issue of JLGH, the Board of Internal Medicine Foundation has initiated a campaign that focuses on ways to provide safer, higher quality care to patients, while emphasizing that the overuse of healthcare resources is an issue of considerable concern. In this article I will continue to cover more of the 45 total items for which the Foundation has thus far formulated recommendations. I also have included updates in this issue on coffee and on immunization for zoster.

The routine practices used in primary care add up to megabucks when one looks at the total healthcare system in the United States. Simply by removing typical but not useful screening tests and procedures from healthcare maintenance examinations, as well as avoiding treatment of viral pharyngitis with antibiotics, huge savings can be achieved. Just prescribing less expensive but equally effective drugs for high cholesterol levels is estimated to result in saving more than \$5 billion.<sup>1</sup> The authors calculated the proportion of times each of the most common activities was performed as reported by The National Ambulatory Medical Care Survey and The National Hospital Ambulatory Care Survey. They then used this percentage to determine the additional cost to the healthcare system. The resulting costs ranked as follows for one year:

## IMAGING FOR LOW BACK PAIN

Low back pain is the 5th most common reason for all visits to physicians in the United States! One of top 5 items on the “Choosing Wisely” list of The American Academy of Family Physicians is the recommendation NOT to perform imaging for low back pain symptoms within the first 6 weeks of the complaint. Exceptions include so-called “red flag” signs, which include—but are not limited to—severe or progressive neurological deficits, or suspicion of a serious underlying condition such as osteomyelitis. Imaging of lower spine complaints before six weeks increases costs significantly but does not improve outcomes.

This item was also included in the Choosing Wisely list of The American College of Physicians, though their wording was a bit different. They stated that when a history and physical examination in a patient with back pain does not suggest a specific disease or spinal abnormality as the cause, imaging should not be done with plain radiography, CT scan, or MRI, as there is no improvement in outcomes.

## ANTIBIOTICS FOR ACUTE MILD TO MODERATE SINUSITIS

There are 16 million office visits yearly for sinusitis with an annual cost of \$5.8 billion. Though most sinusitis in the primary care setting is due to a viral infection that will resolve on its own,

Table 1. General medical examination tests or procedures

Routine CBC in adults	56% of visits	\$32.7 million
Basic Metabolic Panel in adults	16% of visits	\$10.1 million
Annual EKG	19% of visits	\$16.6 million
Urinalysis	18% of visits	\$3.4 million
Antibiotics for viral pharyngitis	41% of visits	\$116.3 million
Cough medicines for children	12% of visits	\$10.3 million
Brand name statins: atorvastatin or rosuvastatin instead of generic statins	34.6% of visits	\$5.8 billion
Pap tests for patients younger than 21 years	2.9% of visits	\$47.7 million
DEXA scans for women younger than 65 years of age	1.4% of visits	\$527.4 million

antibiotics are still prescribed in more than 80% of outpatient visits for acute sinusitis! This item on the Choosing Wisely list of the American Academy of Family Physicians advises that antibiotics should not be prescribed routinely for this presentation unless symptoms last for 7 or more days, or symptoms worsen after initial clinical improvement. Symptoms must include discolored nasal secretions (although we know from repeated studies that discolored nasal secretions do not necessarily mean bacterial infection), and facial or dental tenderness.

It's interesting that The American Academy of Allergy, Asthma and Immunology (AAAAI) also includes a corollary on this issue in their list. They clearly assert: "Don't order sinus CT or indiscriminately prescribe antibiotics for uncomplicated acute rhinosinusitis. Only 0.5% to 2% progress to bacterial infections. Most rhinosinusitis resolves without treatment in two weeks." They also state that uncomplicated acute rhinosinusitis is generally diagnosed clinically and does not require a sinus CT scan or other imaging. Though antibiotics are not recommended for uncomplicated acute rhinosinusitis, when a decision is made to treat, amoxicillin should be the first-line antibiotic for most cases.

Since the initial recommendation by the AAAAI group not to order sinus CT's for uncomplicated rhinosinusitis, there has been a new study published which brings to the fore the fact that scans of patients with CLASSIC sinusitis symptoms often did not reveal infection or even inflammation.<sup>2</sup> This study emphasizes not only the absence of standard bacterial pathogens in chronic sinusitis, but also the frequent absence of sinusitis itself in those who present with typical symptoms. They recommend that antibiotics be prescribed only if mucopurulence is seen on endoscopy and call for a moratorium on the widespread practice of long-term empirical antibiotics in these patients. Finally, they note that much of the chronic sinusitis literature includes cases identified without careful evaluation and should be viewed with "extreme skepticism."

The Infectious Diseases Society of America (IDSA) published this past April its first-ever recommendations for the diagnosis and treatment of *acute bacterial rhinosinusitis* (ABRS).<sup>2</sup> Their guidelines use the new GRADE system (Grading of Recommendations Assessment, Development and Evaluation). They use the term rhinosinusitis instead of the more common "sinusitis" because the infection causes inflammation of both the sinuses and the nasal cavity. These guidelines specifically address the following:

- Changing prevalence and antimicrobial susceptibility profiles of bacterial isolates associated with ABRS;
- The effect of conjugated vaccines for *Streptococcus pneumoniae* on the emergence of nonvaccine serotypes;
- The inability of existing clinical criteria to accurately differentiate bacterial from acute viral rhinosinusitis, leading to excessive and inappropriate antibiotic therapy; and
- Gaps in knowledge and quality evidence about empiric antibiotic therapy as a result of imprecise patient selection criteria
- The guidelines suggest that the infection is probably bacterial if ANY of the following are true:
- Onset with worsening symptoms or signs characterized by new onset of fever, headache, or increase in nasal discharge FOLLOWING a typical viral upper respiratory infection that lasted 5-6 days and initially improved ("double-sickening");
- Onset with severe symptoms or signs of high fever (102°F) and purulent nasal discharge or facial pain lasting for at least 3-4 consecutive days at the beginning of an illness; or
- Onset with persistent symptoms or signs compatible with acute rhinosinusitis lasting for greater than or equal to 10 days without any evidence of clinical improvement.

These new IDSA guidelines state, however, that once a bacterial cause is "established" (as discussed above) antimicrobial therapy should be initiated immediately with amoxicillin-clavulanate, (Augmentin®) which provides better coverage than amoxicillin. NOTE: this is in conflict with the AAAAI suggestions of starting with amoxicillin.

After the AAAAI recommendations on using amoxicillin came out, a study in JAMA by Garbut suggested that amoxicillin was no better than placebo for sinusitis.<sup>3</sup> They randomized 166 adults to a 10-day course of either amoxicillin, 1,500 mg/d in 3 divided doses, or placebo. They found no difference between the 2 groups in scores on the Sinonasal Outcome Test-16. In terms of overall symptom burden, the placebo group actually had better outcomes: after 10 days, 78% of the antibiotic test group and 80% of the placebo group no longer had symptoms.

The reasons that the IDSA gives for recommending amoxicillin - clavulanate include:

- Increasing prevalence of *Haemophilus influenzae* among other respiratory tract infections in children since the introduction of the pneumococcal vaccines; and

- High prevalence of beta-lactamase-producing respiratory pathogens, particularly H influenza, among recent respiratory tract isolates in patients with ABRS.

They do suggest doxycycline as an alternate regimen in adults. They recommend against using macrolides such as clarithromycin and azithromycin; and against trimethoprim-sulfamethoxazole as well as second and third generation oral cephalosporins because of resistance. In children with non-type-1 penicillin allergy or who are from geographic regions with high endemic rates of penicillin-nonsusceptible *S Pneumoniae*, they suggest combination therapy with a third-generation oral cephalosporin plus clindamycin. Levofloxacin is recommended for children with type-1 penicillin allergy. Respiratory fluoroquinolones may be used in patients in whom the first-line therapy failed or who have risk factors for antibiotic resistance. The recommended length of therapy for uncomplicated ABRS is 5-7 days in adults, and 10-14 days in children.

Adjunctive therapy including intranasal saline irrigations with physiologic or hypertonic saline may be helpful in adults but is less likely to be tolerated in children. For persons with a history of allergic rhinitis, intranasal corticosteroids are recommended. Interestingly, topical and oral decongestants and antihistamines are specifically not recommended by these IDSA guidelines.

#### NO ANNUAL EKG'S (OR OTHER CARDIAC SCREENING)

Rounding out the list of 5 things that the Choosing Wisely initiative of the American Academy of Family Physicians advises against are routine annual EKGs or any other cardiac screening tests for asymptomatic low-risk patients. There is little evidence that detection of coronary artery stenosis in such patients improves health outcomes.

The U.S. Preventive Services Task Force states that false-positive tests are likely to lead to harm through unnecessary invasive procedures, over-treatment and misdiagnosis. Potential harms of routine annual screening exceed the potential benefit. The American College of Physicians adds a corollary: "Don't obtain screening *exercise* EKG testing in individuals who are asymptomatic and at low risk for coronary heart disease," since it does not improve patient outcomes. They define low risk as a ten-year risk under 10%.

The American College of Cardiology includes two of the five items on their list in the same general

categories. They recommend not performing stress cardiac imaging or advanced non-invasive imaging in the initial evaluation of patients without cardiac symptoms, since such patients account for up to 45% of unnecessary "screening." Testing should be performed only when high risk markers are present: diabetes in patients older than 40-years of age; peripheral arterial disease; or greater than 2% yearly risk of coronary heart disease events. Their second recommendation is against performing annual stress test cardiac imaging or advanced non-invasive imaging as part of routine follow-up in asymptomatic patients, since this rarely results in any meaningful change in patient management. It may also lead to unnecessary invasive procedures and excess radiation exposure without any proven impact on patients' outcomes. An exception to this rule is made for patients more than five years after a bypass operation.

The American Society of Nuclear Cardiology also has two of their five items much like The American College of Cardiology's. Their first recommendation is exactly the same as The American College of Cardiology's and their second one is only slightly different. It suggests not performing cardiac imaging for patients who are at low risk based on history, physical exam, EKG and cardiac biomarkers. They would not consider stress radionuclide myocardial perfusion imaging or stress echocardiography for initial testing if the patient has a normal EKG, defined as no baseline ST abnormalities, left ventricular hypertrophy, pre-excitation, bundle branch block, intra-ventricular conduction delay, paced rhythm or on digoxin therapy. They also would not perform radionuclide imaging as part of routine follow-up in asymptomatic patients. They note that unnecessary testing might again lead to unnecessary invasive procedures and excess radiation exposure without any proven impact on patients' outcomes. They also cite as an exception to this rule patients more than five years after a coronary bypass operation.

#### SUMMARY

In summary, the five "choosing wisely" items for The American Academy of Family Physicians include:

1. Don't image for low back pain within the first six weeks of symptoms unless red flags are present.
2. Don't routinely prescribe antibiotics for acute mild to moderate sinusitis unless symptoms last a week or more, or symptoms worsen after initial clinical improvement.

3. Don't use DEXA screening for osteoporosis in women younger than 65 or men younger than 70 with no risk factors. This was covered in the last issue of JLGH (Summer 2012).
4. Don't order annual EKG's or any other cardiac screening for low-risk patients without symptoms.
5. Don't perform pap smears in women younger than 21 or who have had a hysterectomy for a non-malignant disease. This also was covered in the last issue of JLGH.

#### UPDATE ON COFFEE RESEARCH

Since my article on coffee in the JLGH (Winter 2007, Vol. 2) there have been several research articles with positive outcomes that I would like to bring you up to date on. Please be aware that I am not accepting any monetary support from Juan Valdez!

The June issue of *The Journal of Alzheimer's Disease* reported that patients with mild cognitive impairment (MCI) may be able to avoid developing dementia by drinking several cups of coffee a day. This new case-control study included two cohorts of 124 participants in a Florida Alzheimer's Disease Research Center study of persons 65 years of age and older. They had baseline neurologic assessments and cognitive tests, and collection of fasting blood samples. Patients with a plasma caffeine level of 1200 ng/mL or higher at baseline had a 100% chance of avoiding progression to dementia during the 2-4 year follow-up. These patients exhibited a plasma cytokine profile that was the same as that of Alzheimer's disease (AD) transgenic mice that were given caffeinated coffee and did not progress to dementia. Half of the patients with stable MCI who had caffeine levels below 1200 ng/mL also did not progress to dementia. Clearly other factors may play a role. These could include level of cognitive and physical activity, antioxidant intake, and presence of hypertension, among other factors.

This study was a retrospective analysis, so a definitive relationship will have to be determined in a clinical trial of participants who consume either caffeinated coffee, other caffeinated products, or decaffeinated coffee, over a period of several years. One weak point in the study is that unlike epidemiologic studies, alternative explanations were not taken into account. It's possible that a person who is drinking less coffee may also have more hypertension, more depression, more heart disease, less social activity than those with higher levels, and those factors are themselves related to the onset of dementia. The issue of whether some people

are protected against dementia because they drink coffee or because they do something else that non-coffee drinkers don't do, remains to be elucidated.<sup>4</sup>

Another study that looked at nearly 35,000 Swedish women who were free of cardiovascular disease at entry showed that drinking little or no coffee was associated with a higher stroke risk. It is postulated that phenolic compounds in coffee might have antioxidant properties that improve endothelial function. Intake was stratified into the number of cups ingested daily, but because decaffeinated coffee is uncommon in Sweden, coffee type was not addressed. In a follow-up period that averaged 10.4 years, there were 1680 stroke events. After controlling for cardiovascular risk factors including smoking, alcohol or aspirin use, body-mass index, physical activity, socioeconomic status, diabetes, and hypertension, it emerged that daily consumption of a cup or more of coffee daily, compared with less than a cup of coffee daily, was associated with a 25% reduction in risk for total stroke, cerebral infarction, and subdural hemorrhage, but not for intracerebral hemorrhage (adjusted RR for total stroke: 0.76; 95% confidence interval [CI] 0.66-0.88).

The study is limited by potential unmeasured confounders associated with caffeine dose. The editors warned that further prospective studies of coffee consumption in relation to stroke and other cardiovascular outcomes are warranted.<sup>5</sup>

Finally, follow-up on 47,911 men in the Health Professionals Follow-up Study was reported in *The Journal of the National Cancer Institute*. Participants recorded the intake of regular and decaffeinated coffee in 1986 and every 4 years thereafter. Men who consumed 6 or more cups per day had a lower overall risk for prostate cancer than non-drinkers (RR=.082; 95% CI =0.68 - 0.98,  $P_{\text{trend}} = .10$ ). This reduction in risk was due almost entirely to a reduced risk of lethal prostate cancer. Consumers of more than 6 cups of coffee daily had a relative risk (RR) of 0.40 (95% CI = 0.22 to 0.75,  $P_{\text{trend}} = 0.03$ )!

The strong inverse association between coffee consumption and risk of lethal prostate cancer was similar for both regular and decaffeinated coffee, so they concluded that the association appeared to be related to non-caffeine components of coffee.<sup>6</sup>

Coffee consumption did not appear to be associated with the risk of non-advanced or low-grade cancers, and was only weakly inversely associated with high grade cancer.

### ZOSTER VACCINE CONFERS NO BENEFIT AFTER AN EPISODE OF SHINGLES

An article published online in the *Journal of Infectious Disease* on June 4, 2012 changes some of our thoughts on the need for immediate vaccination after an episode of shingles, although the authors remind us again that these findings need to be replicated in larger population studies.<sup>7</sup> In 6,216 immuno-competent Kaiser members aged 60 years and older, there were fewer than 30 confirmed cases of *recurrent* shingles during a mean follow-up of 2 years. Vaccination appeared to have little effect on the likelihood of developing a second case of shingles. In 1,036 vaccinated individuals, there were 19 cases per 10,000 adults, and among the 5,180 unvaccinated individuals there were 24 cases per 10,000 adults (adjusted hazard ratio [HR], 0.73; 95% confidence interval [CI], 0.25-2.09; P=.55).

The findings are important because the study revealed that the risk of having a recurrent episode of shingles was not as high as previous research had indicated, and immediate vaccination may not be necessary after an episode of shingles.

Dr. Michael Oxman, Professor of Medicine and Pathology at the University of California, San

Diego, said that a case of shingles boosts cell-mediated immunity to the varicella virus. "If I knew for certain that a patient had a real case of shingles with plenty of blisters indicating plenty of virus and virus antigen, I would tell them to wait 2 or 3 years [before receiving the vaccine]." The CDC presently recommends vaccination of all individuals age 60 and older, including those who have experienced an episode of shingles. Alternatively, the FDA has approved prophylactic vaccination starting at age 50, but views shingles *recurrence* as "unlikely" and recommends against immunizing individuals with a "diagnosis or verification by a healthcare provider of a history of chickenpox or shingles." Dr. Oxman sees no conflict between the positions adopted by the 2 agencies. "The reason for this is that the diagnosis and memory of having shingles are not reliable: you wouldn't want to tell someone not to bother with the vaccine because they've had shingles, and then develop a case associated with long-term pain." Further studies are needed to determine the vaccine's efficacy for preventing recurrence in patients with a confirmed history of shingles, as well as the duration of that effect.

### REFERENCES

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