



CHOOSING WISELY XXVIII

*Recommendations on Benign Breast Disease,
Gastrointestinal and Endoscopic Surgery, and Occupational Therapy*

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This is my 28th article on Choosing Wisely from the Board of Internal Medicine Foundation. As previously noted, each specialty group is developing “Five, Ten, or Fifteen Things that Physicians and Patients Should Know.”

I. RECOMMENDATIONS FROM THE AMERICAN SOCIETY OF BREAST SURGEONS---BENIGN BREAST DISEASE

1. Areas of pseudoangiomatous stromal hyperplasia (PASH) of the breast should not be routinely excised if they are asymptomatic. PASH is benign and can present as either an abnormality on imaging, or a palpable mass. Unless the patient is symptomatic or the lesion is suspicious, a diagnosis of PASH made by needle biopsy does not necessitate surgical removal.

2. Biopsy-proven fibroadenomas smaller than 2 centimeters in size do not require routine surgical excision. These non-cancerous solid masses should be removed only if they are large, bothersome to the patient, or increasing in size.

3. Breast abscesses should initially have an attempt at percutaneous aspiration or drainage; they do not routinely require operations. These infections can often be drained by placing a large needle in the pocket, instead of by making an incision to remove the fluid. Needle drainage leaves less scarring, and sometimes avoids an operation.

4. Asymptomatic patients with normal exams who have less than a five-year life expectancy should not have screening mammograms.¹ There is minimal benefit from screening women with life expectancies of less than five years. There is always the risk of false positives, and the potential for procedures that do not improve outcomes.

5. Non-painful, fluid-filled breast cysts don't routinely require drainage.² If an ultrasound confirms that a breast mass is a simple fluid-filled cyst, it is harmless. It does not need to be drained unless it is bothersome to the patient, has complex characteristics, or raises concerns it could be something other than a cyst.

II. RECOMMENDATIONS FROM THE SOCIETY OF AMERICAN GASTROINTESTINAL AND ENDOSCOPIC SURGEONS (SAGES)

1. Patients presenting emergently with acute cholecystitis should not be discharged without first offering laparoscopic cholecystectomy.³ Evidence suggests that cholecystectomy during the index hospitalization is both safe and cost effective. Interval cholecystectomy may be associated with a higher chance of requiring open surgery or readmission, which increases costs. Patients discharged without undergoing surgery may also have a higher risk of presenting with complications of cholelithiasis, which can be more morbid than the initial presentation.

2. Patients with asymptomatic cholelithiasis should not undergo routine cholecystectomy.⁴ Gallstones are present in 10%-20% of the population in western countries, and 50%-70% of them are asymptomatic. Many are discovered on imaging performed for unrelated reasons. Asymptomatic patients should be managed with observation alone, unless they have a related hematologic disease. If the patient is undergoing an unrelated abdominal operation, such as gastric bypass, concomitant cholecystectomy may be considered.

3. The initial evaluation of a patient with suspected gall stone disease should not include imaging tests other than ultrasound. It is the initial modality of choice when acute cholecystitis is suspected for reasons of availability, examination time, lack of ionizing radiation, morphologic evaluation, confirmation of the presence or absence of gall stones, evaluation of bile ducts, and identification or exclusion of alternative diagnoses. When clinical features, examination, laboratory and ultrasound findings are congruent, no further imaging is required.

4. Clinical evaluation of an apparent inguinal hernia should avoid the routine use of ultrasound. The history and physical examination reliably make a diagnosis of palpable abdominal wall hernias. While the use of ultrasonography has been shown to be of

some benefit in the diagnosis of occult hernias, it should not be used routinely. It adds unnecessary cost and delays treatment, while making no useful contribution to definitive surgical care.

5. Post-operative pain control should avoid opioid-only modalities. Opioid overdose has become one of the leading causes of injury-related deaths in the United States, and can be linked to the rising rates of opioid prescriptions. Many patients report unused opioid prescriptions following surgery, and these can fall into the hands of others in the family or those visiting the family. Surgeons should utilize additional strategies such as locoregional anesthetic blocks and non-opioid medications (acetaminophen, NSAIDs, and gabapentins) for pain management where possible.

III. RECOMMENDATIONS FROM THE AMERICAN OCCUPATIONAL THERAPY ASSOCIATION INC. (AOTA)

1. Intervention activities that are non-purposeful (e.g., cones, pegs, shoulder arc, arm bike) should not be provided. Purposeful activities—tasks that are part of daily routines and hold meaning, relevance, and perceived utility such as personal care, home management, school, and work—are a core premise of occupational therapy. Research shows that using purposeful activity (occupation) in interventions is an intrinsic motivator for patients. Conversely, non-purposeful activities do not stimulate interest or motivation, resulting in reduced patient participation and suboptimal outcomes.

2. Individual children or youth should not be provided sensory-based interventions without documentation of difficulties processing or integrating sensory information. Many children and youth are affected by challenges in processing and integrating sensations that negatively affect their ability to participate in meaningful and valued occupations. It is important to assess and document specific sensory difficulties before providing sensory-based interventions such as Ayres Sensory Integration,[®] weighted vests, listening programs or sensory diets. Interventions that do not target documented patterns of dysfunction can produce ineffective or negative results.

3. Physical agent modalities (PAMs) should not be used without purposeful and occupation-based intervention activities. The exclusive use of PAMs (e.g., superficial thermal agents, deep thermal agents, electrotherapeutic agents, mechanical devices) as a therapeutic intervention without direct application

to occupational performance is not considered occupational therapy, whereas PAMs provided with a functional component can lead to positive health outcomes.

4. Individuals with a hemiplegic shoulder should not use pulleys. Use of an overhead pulley for individuals with a hemiplegic shoulder resulting from a stroke or other clinical condition is considered too aggressive and should be avoided. It presents the highest risk of the patient developing shoulder pain. Gentler and controlled range of motion exercises and activities are preferred.

5. Cognitive-based interventions (e.g., paper-and-pencil tasks, table-top tasks, cognitive training software) should provide direct application to occupational performance. To improve occupational performance, cognitive-based intervention should be embedded in an occupation relevant to the patient. Examples of cognitive-based interventions include awareness approaches, strategy training, task training, environmental modifications, and assistive technology.

Top Tips

GLOBAL HEALTH THREATS FOR 2019 — THE TOP 10 FROM THE WORLD HEALTH ORGANIZATION (WHO)

1. At the top of the list are air pollution and climate change. WHO estimates that 9 out of 10 people breathe polluted air every day. Air pollution kills 7 million people prematurely every year from diseases such as cancer, lung disease, stroke, and heart disease. High emissions from industry, transportation, and agriculture account for most of these deaths.

The burning of fossil fuels is the chief cause of air pollution and also a major contributor to climate change. Between 2030 and 2050, climate change is expected to cause 250,000 deaths per year from heat stress, malnutrition, malaria, and diarrhea.

2. Second are noncommunicable diseases, such as diabetes, cancer, and heart disease. WHO reports these are to blame for 41 million deaths, or more than 70% of all deaths worldwide. These include 15 million people who die prematurely between the ages of 30 and 69 years.

The key issues are air pollution, tobacco use, lack of physical activity, the harmful use of alcohol, and unhealthy diets. These factors also contribute to mental health problems.

3. Third is the likelihood of a global influenza

pandemic. Though its timing and severity are unpredictable, WHO warns that emergency preparedness and response systems need to be on the ready. WHO is monitoring potential pandemic strains in 114 countries and 153 institutions.

4. Fourth are fragile, vulnerable settings, such as regions suffering from drought or famine. Conflict or population displacement affect more than 1.6 billion people (22% of the global population), who lack access to basic care because of protracted crises and weak health services where they live.

5. Fifth is the looming threat that antimicrobial resistance could send us back to a time when we were unable to easily treat infections such as pneumonia, tuberculosis, gonorrhea, and salmonellosis. This, of course, could seriously compromise interventions such as surgery and chemotherapy.

6. Sixth is Ebola and similarly virulent pathogens. In 2018 the Democratic Republic of the Congo had two separate Ebola outbreaks, both of which spread to cities of more than 1 million people.

7. Seventh is the weakness of primary health care in many countries. WHO says that it is working with partners in many countries to revitalize and strengthen primary health care.

8. Eighth is the persistence of refusal or reluctance to vaccinate despite the availability of effective vaccines. This phenomenon threatens to reverse progress made in combating vaccine-preventable diseases. Immunizations currently prevent 2 to 3 million deaths each year, and a further 1.5 million could be avoided if vaccination coverage improved.

9. Ninth is dengue, a potentially deadly, mosquito-borne disease that has been spreading for decades. Forty percent of the world is at risk for dengue fever, which causes around 390 million infections each year. The aim is to reduce deaths by 50% by 2020. Lancaster County has mosquitoes that are able to transmit dengue.

10. Although significant progress has been made against HIV by testing people for the virus and treating them with antiretrovirals (22 million are on treatment), more needs to be done to provide access to preventive measures such as pre-exposure prophylaxis. The epidemic continues with nearly 1 million people every year dying of HIV/AIDS. WHO is supporting self-testing to improve progress against this deadly virus.

The WHO's five-year strategic plan focuses on insuring that 1 billion more people benefit from access to universal health coverage, 1 billion more people are

protected from health emergencies, and 1 billion more people enjoy better health and well-being.

UPDATED BEERS CRITERIA—GUIDE TO DRUG USE IN THE ELDERLY ⁵

These criteria were first published in 1991. Since 2011, the American Geriatric Society has published the Potentially Inappropriate Medication (PIM) criteria every three years for those medications that should be avoided by older adults in most circumstances or under specific situations, such as certain diseases or conditions. These are intended for use in adults 65 and older in all acute, ambulatory, and institutionalized settings of care, except for hospice and palliative care settings.

The drugs that were deemed unsafe for older patients in these criteria are classified as potentially inappropriate, not definitely inappropriate, and advise close reading of the details. Clinicians should view the criteria as a starting point for individual prescribing.

The 2019 criteria include 30 medications or medication classes to be avoided and 40 medications or classes that should be used with caution or avoided in certain patients with certain diseases or conditions.

The following is a summary of some of the more significant changes:

Drugs that should be used with caution include:

- Dextromethorphan/quinidine. This combination has limited efficacy in alleviating behavioral symptoms of dementia in patients without pseudobulbar affect. It also potentially increases the risk of falls and drug-drug interactions.
- Rivaroxaban and dabigatran for venous thromboembolism or atrial fibrillation in patients older than 75 years, because of the risk of gastrointestinal bleeding.
- Sulfamethoxazole. It increased the risk for hyperkalemia especially in those with decreased kidney function, or those taking angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers.
- Carbamazepine, mirtazapine, oxcarbazepine, serotonin, norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors, tricyclic antidepressants, diuretics and tramadol ought to be used with caution because they may exacerbate or cause the syndrome of inappropriate antidiuretic hormone secretion. Sodium levels should be monitored very closely when using these drugs.
- Aspirin should be used with caution for

primary protection against cardiovascular disease or colorectal cancer in patients older than 70 years, not – as before – 80 years, because new data show that aspirin increases the risk of bleeding at a younger age.

- Serotonin and norepinephrine reuptake inhibitors should be prescribed with caution for patients at risk of falling or sustaining fracture.

- Ciprofloxacin in patients with decreased kidney function poses a particularly increased risk of tendon rupture and increased central nervous system effects, though one does not need decreased renal function or advanced age to have these complications from Cipro.

Select drug combinations to avoid:

- Corticosteroids and NSAIDs.
- Opioids and benzodiazepines or gabapentin/pregabalin.

Select medications to avoid in general for patients \geq age 65:

- For Parkinson’s disease, the general advice has been changed; instead of barring all antipsychotics, the following are now deemed acceptable: quetiapine, clozapine, and pimavanserin.

- For heart failure, nondihydropyridine calcium channel blockers such as verapamil and diltiazem should not be prescribed for patients with low ejection fractions; and NSAIDs, COX-2 inhibitors, thiazolidinediones, and dronedarone should be prescribed with caution in patients who have no symptoms of heart failure.

- Macrolides (except azithromycin) or ciprofloxacin should not be prescribed with warfarin owing to increased bleeding risk.

- Ciprofloxacin and theophylline should not be prescribed together owing to increased theophylline toxicity.

- Medications with strong anticholinergic properties, including first generation antihistamines, antispasmodics, and tricyclic antidepressants.

- Nitrofurantoin
- Peripheral alpha-one blockers (e.g.; doxazosin)
- Central acting alpha-agonists (e.g.; clonidine)
- Digoxin as first line treatment
- Tricyclic antidepressants
- First and second generation antipsychotics
- Barbiturates
- Benzodiazepines
- Nonbenzodiazepine-benzodiazepine receptor

agonist hypnotics (e.g.; “Z-drugs”-Eszopiclone, Zaleplon, Zolpidem)

- Testosterone
- Estrogen with or without progesterone
- Long-acting sulfonylureas
- Metoclopramide
- Non-cyclooxygenase-selective NSAIDs
- Indomethacin and ketorolac
- Skeletal muscle relaxants

TWENTY YEARS OF U.S. MEDICAL MARKETING ⁶

JAMA has printed a comprehensive analysis of consumer advertising, professional marketing, state and federal regulatory actions, peer-reviewed medical journals, business journals, and news media from 1997-2016.

An accompanying editorial says that the analysis is “a unique contribution and represents a comprehensive, rigorous, and insightful report on the ubiquitous, multifaceted, multitargeted, and well-financed phenomena of medical marketing.” Another commentary about the investigation concluded: “patients’ trust in physicians puts them at a position to help mitigate the harms of direct-to-consumer (DTC) advertising. However, trust in physicians and health care institutions may be at stake if medical marketing by practitioners, health care organizations, and manufacturers of health care products continues to increase unchecked.”

Findings of the primary article include:

- The Joint Commission, which accredits health care organizations, does not consider advertising during its review processes.

- Many hospitals market “executive physicals” that involve 1 to 2-day examinations with unproven advanced imaging.

- People have been found to falsely believe in drug benefits based on information from disease awareness campaigns.

- Drug, device, and technology companies have made substantial donations to patient advocacy groups and work with television scriptwriters to create disease-related stories without disclosing the collaboration.

- From 1997 to 2016, spending on medical marketing of drugs, disease awareness, health services, and laboratory testing nearly doubled, increasing from \$17.7 billion to \$29.9 billion.

- Marketing to physicians and other health care professionals by pharmaceutical companies accounted for most promotional spending, and increased from \$15.6 billion in 1997 to \$20.3 billion in 2016. The 2016 figure included \$5.6 billion for prescriber detailing

and \$979 million of direct physician payments (e.g., speaking fees, meals).

- The most rapid increase in medical marketing was in DTC advertising: from \$2.1 billion (11.9%) of total spending in 1997 to \$9.6 billion (32.0%) of total spending in 2016.

- DTC prescription drug advertising increased from \$1.3 billion for 79,000 advertisements in 1997 to \$6 billion for 4.6 million advertisements in 2016, with a shift toward advertising high-cost biologics and cancer immunotherapies.

- DTC advertising for health services increased from \$542 million to \$2.9 billion.

- One hundred three financial settlements between drug companies and federal and state governments totaled more than \$11 billion in fines for off-label or deceptive marketing practices.

- Advertising in journals declined substantially, from approximately \$744 million to \$119 million.

- Regulation by the FDA Office of Prescription Promotion remained quite limited. Despite an increase in submissions to review, from 34,182 to 97,252, the number of violation letters declined from 156 to 11.

- The FTC has never acted against a misleading promotion for a laboratory test.

A related article in JAMA Network⁷ quantified excessive pricing of cancer drugs. It found that between 1989 and 2017, drug companies earned an average of \$14.50 (range \$3.30 – \$55.10) for every dollar they spent on research and development for 99 cancer drugs that were approved. The researchers concluded: “Cancer drugs, through high prices, have generated incomes for the companies far in excess of research and development costs. Lowering prices of cancer drugs, and facilitating greater competition, are essential for improving patient access, the health system’s financial sustainability, and future innovation.”

The problem of drug pricing, and its relationship

to the vast sums spent on marketing compared with the strikingly smaller sums spent on R&D, was discussed at some length in the Editor’s column in the previous (Spring 2019) issue of JLGH.⁸

GOING “NUTS” ABOUT NUTS⁹

A recent article reports on a study showing higher consumption of nuts, especially tree nuts, is associated with a lower incidence of cardiovascular disease (CVD) and lower mortality among participants with diabetes.

This was a prospective analysis of 16,217 people with diabetes and the Nurses’ Health Study/Health Professionals Follow-up Study. Their nut intake was by a questionnaire. It was observational, so no causation was established.

Their findings include the following incidences of various events compared with controls:

- CVD incidence: 0.83 (0.71-0.98; P trend = .01).
- Coronary heart disease incidence: 0.80 (0.67-0.96; P trend = .005).
- CVD mortality: 0.66 (0.52-0.84; P trend < .001).
- All-cause mortality: 0.69 (0.61-0.77; P trend < .001).

Tree nut intake was linked to reduced risks across the board, but peanut consumption was linked only to reduced all-cause mortality. There were no effects on stroke incidence or cancer mortality. Nut consumption before the diabetes diagnosis was also linked to risk reduction.

These authors call the findings “novel evidence” supporting adding nuts to the diet, although a previous study had linked nut intake to reduced CVD risk in the general population.

The takeaway is that eating more nuts might help more people with diabetes reduce their CVD and mortality risk. I have written previously in JLGH about the health benefits of nuts,¹⁰ and we should continue to emphasize them.

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