Choosing Wisely XXXII

Recommendations from the American Physical Therapy Association, Society for Maternal-Fetal Medicine, and American Society of Hematology and the American Society of Pediatric Hematology/Oncology

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This is my 32nd article on Choosing Wisely from the Board of Internal Medicine Foundation. As previously noted, each specialty group is developing "Five or more Things that Physicians and Patients Should Know."

I. RECOMMENDATIONS FROM THE AMERICAN PHYSICAL THERAPY ASSOCIATION (APTA)

1. Superficial or deep heat should not be used in musculoskeletal conditions to obtain clinical long term outcomes. There is limited evidence for the use of superficial or deep heat for this purpose. A carefully designed active treatment plan has a greater impact on pain, mobility, function, and quality of life.

2. Don't prescribe under-dosed strength training programs for older adults. Instead, match the frequency, intensity, and duration of exercise to the individual's abilities and goals. Failure to establish accurate baseline levels of strength limits the benefit of training, because the proper dose and progression of strength training can't be accurately prescribed.

3. After the initiation of anti-coagulation therapy for DVT (acute deep vein thrombosis) don't recommend bed rest unless there are significant medical concerns. Given the clinical benefits of ambulation and activity, and the lack of evidence indicating they have harmful effects, both are recommended following achievement of anticoagulation goals unless there are overriding medical indications.[1]

4. Following uncomplicated total knee replacement, don't use continuous passive motion machines for postoperative management. A continuous passive motion (CPM) treatment does not lead to clinically important benefits in terms of short-or long-term knee extension, long-term knee flexion, long-term function, pain, or quality of life in patients undergoing total knee arthroplasty. As members of interprofessional teams involved in postoperative rehabilitation of patients following total knee replacement, physical therapists have a responsibility to advocate for effective alternatives to CMP for most patients.

5. Whirlpools should not be used for wound management. Utilizing whirlpools to treat wounds predisposes the patient to risks of bacterial cross-contamination, damage to fragile tissue from high turbine forces, and complications of extremity edema when arms and legs are treated in a dependent position in warm water. More selective forms of hydrotherapy should be used, such as directed wound irrigation, or a pulsed lavage with suction.[2]

II. RECOMMENDATIONS FROM THE SOCIETY FOR MATERNAL-FETAL MEDICINE (SMFM)

The Society for Maternal-Fetal Medicine now has 15 Things Physicians and Patients Should Question. We have previously covered the first 10,[3] which I will just list without comment and then add the most recent five.

1. Don't do an inherited thrombophilia evaluation for women with histories of pregnancy loss, intrauterine growth restriction (IUGR), preeclampsia, and abruption.

2. In women with short cervix who are pregnant with twins, don't place a cerclage.

3. Don't offer non-invasive prenatal testing (NIPT) to low-risk patients, nor make irreversible decisions based on the results of this screening test.

4. Don't screen for intrauterine growth restrictions (IUGR) with Doppler blood flow studies.

5. For preterm birth prevention in uncomplicated multifetal gestations, don't use progestogens.

6. For preterm birth risk assessment in asymptomatic women before 16 weeks of gestation or beyond 24 weeks of gestation, don't perform routine cervical length screening.

7. In women with the diagnosis of gestational diabetes, who are well controlled by diet alone and without other indications for testing, don't perform antenatal testing.

8. Even those at high risk should not be placed on activity restriction to prevent preterm birth.

9. After cfDNA aneuploidy screening has already been performed, don't order serum aneuploidy screening.

10. Routine prenatal laboratory studies should not include serologic studies for cytomegalovirus and toxoplasma.

11. Following sonographic identification of an isolated echogenic intracardiac focus (EIF) or choroid plexus cyst (CPC) in women with low-risk aneuploidy screening results, don't recommend diagnostic testing. The concept of using ultrasonographic soft markers for aneuploidy, such as EIF and CPC, was introduced in an era that predated screening for Down syndrome based on factors other than maternal age. Recent guidelines from the Society for Maternal-Fetal Medicine state that diagnostic testing should not be recommended solely for the indication of an isolated EIF or CPC in the setting of a negative cfDNA screening test result, or a negative first-or second-trimester screening test result.

12. After placement of a cerclage, don't perform serial cervical length measurements. Although progressive shortening after cerclage placement increases the risk of preterm birth, neither overall cervical length nor the length below the stitch correlates well with outcomes.

13. Women should not be tested for MTHFR mutations. MTHFR is responsible for the conversion of 5, 10-methylenetetrahydrofolate to 5-methyltetrahydrofolate. This can sometimes result in reduced folate levels which have been found to be a risk factor for hyperhomocysteinemia, a risk factor for cardiovascular disease and venous thrombosis. However, its cause is multifactorial and independent of the MTHFR genotype, even in homozygotic individuals. MTHFR genotyping should not be ordered as part of a workup for thrombophilia due to the lack of evidence associating genotype independently with thrombosis, recurrent pregnancy loss, or other adverse pregnancy outcomes.[4]

14. Don't screen asymptomatic pregnant women for subclinical hypothyroidism. Subclinical hypothyroidism (SCH) is defined as an elevated serum TSH level in the presence of a normal free T4 level, and is found in 2% to 5% of otherwise healthy pregnant women. SCH is unlikely to progress to overt hypothyroidism during pregnancy. Two recent large prospective randomized clinical trials of screening and treatment for SCH demonstrated no benefit to offspring IQ at age 5 years.[5]

15. The amniotic fluid index should not be used to make a diagnosis of oligohydramnios (in the 3rd trimester). Amniotic fluid volume can be measured using either the amniotic fluid index (AFI) or the deepest vertical pocket (DVP). Diagnosis of oligohydramnios based on an AFI of <5 cm has been found to lead to a greater number of obstetric interventions without a significant benefit in improving perinatal outcomes than use of a DVP of <2 cm for diagnosis.

III. RECOMMENDATIONS FROM THE AMERICAN SOCIETY OF HEMATOLOGY AND THE AMERICAN SOCIETY OF PEDIATRIC HEMATOLOGY/ONCOLOGY (ASPHO)

1. Don't perform routine pre-operative hemostatic testing (PT, aPTT) in an otherwise healthy child with no prior personal or family history of bleeding. Those tests do not effectively identify those likely to have unexpected surgical bleeding. Also, these tests may identify artifacts or disorders that do not affect bleeding risk, thus adding costs and stress.

2. Don't transfuse platelets in an asymptomatic (i.e. non-bleeding) pediatric patient with a platelet count >10,000/mcL (e.g. aplastic anemia,

leukemia, etc.), unless other signs and/or symptoms for bleeding are present, or if the patient is to undergo an invasive procedure. This practice is consistent with recommendations of clinical guidelines from multiple associations. Unnecessary transfusions put patients at risk for transfusion reactions, alloimmunization, blood borne infections, and refractoriness to future platelet transfusions.

3. Thrombophilia testing should not be ordered on children with venous access (i.e., peripheral or central) associated thrombosis in the absence of a positive family history. Thrombophilia testing has substantial financial costs, and a positive result has the potential for misinterpretation of risk assessment, leading to undue psychological distress or impact on childbearing plans, as well as possible life insurance discrimination.[6]

4. Transfusion of packed red blood cells (pRBC) for iron deficiency and anemia should not be performed in asymptomatic pediatric patients when there is no evidence of hemodynamic instability or active bleeding. Unnecessary pRBC put patients at risk for complications such as transfusion reactions, blood borne infections, and volume overload.

5. Don't routinely administer granulocyte colony stimulating factor (G-CSF) for empiric treatment of pediatric patients with asymptomatic autoimmune neutropenia in the absence of recurrent or severe bacterial and/or fungal infections. The unnecessary routine use of G-CSF could lead to intolerable side effects such as bone pain, as well as to avoidable health care costs.

Top Tips

PLANNING FOR PANDEMICS

Almost 4 billion trips were taken by air last year, and traveling passengers carry with them whatever contagious diseases they may have been exposed to. An infection anywhere in the world can find its way to a major city in less than a day. The 2014 Ebola outbreak supposedly taught us the value of strategic investments in public health infrastructure in responding to these outbreaks. Global health security requires adequate coordination led by the president of the United States, as well as ongoing long-term funding and resources.

The elimination of the Global Health Security Office by the present administration, and reassignment of the office's team members, reveals how poorly we understand our situation. Budget cuts affecting the Health Security Agenda of the National Security Council are another example of the U.S. government's poor planning.

In 2018 the CDC lost 80% of its effectiveness in preventing global disease because its allocated funds were running out. It was reduced from working in 49 countries to just 10.

The Trump administration also reduced national health care spending by $15 billion and eliminated the U.S. government's $30 million contribution to the Complex Crises Fund.

Over the past 60 years, the number of new diseases has increased fourfold; since 1980 the number of large scale outbreaks has more than tripled. There are typically three to four pandemics each century. During the 20th century, there were three serious influenza pandemics (so-called Spanish flu in 1918, Asian flu in 1957, and Hong Kong flu in 1968), and one lesser pandemic in 1977 referred to as the Russian flu.

The economic consequences of the current outbreak for the United States dwarf our spending on efforts to prevent or control the next pandemic. In bringing it closer to home, Lancaster County still does not have a County Health Department. The Pennsylvania Department of Health has a few people in the county, but certainly not enough to address all the county's health problems, whether it be the safety of our well water or efforts against an infectious disease threat.

Retired pediatrician Dr. Albert Price and the Partnership for Public Health have lobbied the county commissioners for years to create a Public Health Department for the county. More than a decade ago he considered Lancaster County's lack of a Health Department -- a central agency that could

respond to crises with speed and local focus—one of the most glaring lapses of official judgment he had ever witnessed.

It is past time for us to develop and adequately fund a significant science-based effort to prevent health crises.

As Will Rogers said: "It ain't what you don't know that hurts you, it's what you know that ain't so."

COMPLIANCE WITH LEGAL REQUIREMENT TO REPORT CLINICAL TRIAL RESULTS ON ClinicalTrials.Gov: A COHORT STUDY [7]

The pervasive failure to report the results of clinical trials, particularly those with negative or inconclusive outcomes, distorts the evidence base for clinical practice, breaches researchers' ethical obligations to participants, and wastes resources for research. The Food and Drug Administration Amendments Act (FDAAA) of 2007 now requires sponsors of applicable trials to report their results directly onto ClinicalTrials.gov within one year of completion.

The first trials covered by the Final Rule of this Act were due to report results in January, 2018. Although 4,209 trials were due to report results, only 1,722 (40.9%) did so within the one-year deadline. Clearly, compliance with FDAAA 2007 has been poor, and it is not improving.

Poor compliance is likely due to lack of enforcement by regulators. Effective enforcement and action from sponsors is needed; until then, open public audit of compliance for each individual sponsor may help.

10 TOP MEDICAL INNOVATIONS FOR 2020, ACCORDING TO THE CLEVELAND CLINIC [8]

1. *Romosozumab, a dual-acting osteoporosis drug.* This drug both increases bone formation and decreases bone absorption.

2. *Expanded use of minimally invasive mitral valve surgery.* In March, the FDA broadened its approval of the MitraClip (Abbott) to include patients with secondary mitral regurgitation, providing an important new treatment option. About one in ten individuals over age 75 will suffer from mitral valve regurgitation.

3. *Inaugural treatment for Transthyretin Amyloid Cardiomyopathy.* This is a rare, progressive, and often fatal disease caused by deposition of amyloid fibrils in the myocardium. Pfizer's tafamidis meglumine (Vyndaqel) and tafamidis (Vyndamax) have been shown to prevent misfolding of the deposited protein, thus significantly reducing mortality.

4. *Therapy for peanut allergies.* The FDA has overwhelmingly recommended peanut (Arachis hypogaea) allergen powder (Palforzia, Aimmune Therapeutics) for children who are allergic to peanuts. It will be in an oral powder that is given once daily by mixing it with food.

5. *Closed-loop spinal cord stimulation.* The innovation of closed-loop stimulation allows for better communication between the device and the spinal cord. Pending approval, closed-loop stimulation could be a saving grace for chronic pain patients.

6. *Biologics in orthopedic repair.* Biologics—cells, blood components, growth factors, and other natural substances—have the power to replace or harness the body's own power to promote healing of anterior cruciate ligament (ACL) tears and to decrease inflammation. They are increasingly finding their way into orthopedic care.

7. *Antibiotic envelope for prevention of infection in cardiac implantable devices.* The recent innovation of an implantable antibiotic envelope insures delivery of two antimicrobial drugs locally in the pocket for seven days after implantation, minimizing the risk for infection. The findings, published in March 2019, show a 40% reduction in major infections.

8. *Bempedoic acid for cholesterol lowering in statin-intolerant patients.* Cholesterol-lowering statins cause muscle pain in up to 10% of patients who take them. This new product provides an alternative cholesterol-lowering approach that avoids these side effects. It can also reduce LDL-C levels by an average of about 25%. It still needs to be approved by the FDA.

9. *PARP inhibitors for maintenance therapy in ovarian cancer.* Poly-ADP ribose polymerase (PARP) inhibitors are one of the most important treatment advances in ovarian cancer.

10. *Drugs for heart failure with preserved ejection fraction.* Sodium glucose cotransporter 2 (SGLT2) inhibitors, used for type 2 diabetes, are now being explored for HFpEF in several trials. SGLT2 inhibitors showed similar results in nondiabetic individuals with heart failure and reduced ejection fraction.

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